PRIN PNRR 2022 Research Project

Unscrambling Global and European Union Health Security

A Brief Scientific Treatise on the Legal and Institutional Foundations of Global and EU Health Security

Edited by

Sabrina Tranquilli and Giordana Strazza

Editoriale Scientifica

Prin Pnrr Project "Unscrambling Global and European Union Health SECurity", ("GlEUHSec" - Project Code P20222RER9), Funded by the European Union, Next Generation EU, Mission 4, Component 1, CUP I53D23007240001 (P.I. Sabrina Tranquilli) 300401PRIN22PNRR_STRAZZA and CUP D53D23022170001 (Vice P.I. Giordana Strazza)

Unscrambling Global and European Union Health Security

A Brief Scientific Treatise on the Legal and Institutional Foundations of Global and EU Health Security

Edited by

Sabrina Tranquilli and Giordana Strazza

Editoriale Scientifica
Napoli

The volume has been funded under the PRIN PNRR Project "Unscrambling Global and European Union Health Security" ("GlEUHSec" – Project Code P20222RER9), funded by the European Union – Next Generation EU, Mission 4, Component 1, CUP I53D23007240001 (Principal Investigator: Sabrina Tranquilli) and CUP D53D23022170001 (Vice Principal Investigator: Giordana Strazza), Project Code 300401PRIN22PNRR_STRAZZA.

via San Biagio dei Librai, 39 - 80138 Napoli
www.editorialescientifica.com info@editorialescientifica.com
ISBN 979-12-235-0592-2

INDEX

EDITORS' INTRODUCTION: FRAMING GLOBAL AND EU HEALTH SECURITY

This volume collects the scientific contributions developed within the framework of the PRIN Project *Unscrambling Global and European Union Health SECurity (GlEUHSec)*. The Project officially began in November 2023 and concluded in February 2026, following an articulated research trajectory structured through conferences, seminars and workshops hosted by the partner universities in Southern Italy: the University of Naples "Parthenope", the University of Salerno, the University of Calabria, the University of Naples "Federico II", and the University of Catania.

From its inception, GlEUHSec was conceived as an interdisciplinary and inter-university endeavour. It brought together scholars of administrative law, international law, constitutional and public law, and private law, alongside medical experts in hygiene and public health. This structured dialogue between legal scholarship and medical expertise constituted one of the defining methodological features of the Project. Health security was therefore addressed not merely as a normative and institutional phenomenon, but as a concrete public health challenge requiring epidemiological knowledge, preventive strategies and systemic risk assessment. The confrontation between disciplines enabled the development of a genuinely integrated and multilevel perspective on contemporary health governance.

The opening contribution by Sabrina Tranquilli, *The GlEUHSec Research Project: Challenges, Boundaries and Emerging Perspectives*, provides the conceptual and methodological framework of the Project. Health security is interpreted not as the emergence of a new fundamental right, but as a structural parameter for evaluating the adequacy of public powers in the face of systemic risks. The essay identifies the principal challenges generated by fragmented competences and emergency governance, delineates the legal and institutional boundaries of Union and international action, and outlines emerging perspectives for a more integrated and accountable model of multilevel governance.

The European institutional dimension is examined by Giordana Strazza, in *The challenges facing European agencies in health security*.

The strengthening of the mandates of EMA and ECDC, the establishment of HERA and the proliferation of digital platforms are analysed through the lens of agencyfication. The contribution highlights coordination problems, overlaps of competences and the persistent issue of democratic legitimacy within an increasingly technocratic governance architecture, emphasising the need for rationalisation, transparency and reinforced parliamentary oversight.

The global projection of the European Union is addressed by Stefania Negri, in *The European Union's role in global health: building a European Health Union with a global vision*. The essay reconstructs the Union's trajectory from initial hesitation during the COVID-19 pandemic to a more assertive and structured role in global health governance. The construction of the European Health Union and the adoption of the EU Global Health Strategy are presented as complementary pillars of a broader ambition: strengthening internal resilience while consolidating the Union's capacity to shape international health law and multilateral cooperation.

A systematic reconstruction of the European legal framework for health security is offered by Enza Romano, in *The European legal framework for health safety and the enhancement of the role of the European Medicines Agency (EMA)*. The contribution analyses the evolution from Decision 1082/2013 to the 2022 regulatory package, focusing on preparedness planning, the Health Security Committee, joint procurement mechanisms and the enhanced crisis-management role of the EMA, as well as ongoing pharmaceutical reform.

A comparative regional perspective is introduced by Elisa Tino, in *ASEAN's commitment in the field of health security*. The ASEAN model illustrates a form of predominantly consensual and non-supranational cooperation in the management of cross-border health threats. While demonstrating progressive institutional consolidation, it also reveals the structural limits of "soft" regionalism in contexts characterised by significant economic and infrastructural asymmetries.

The digital and technological dimension of health security is explored by Franco Trubiani, in *Health data governance: towards the creation of an international and European digital sharing ecosystem*. The essay analyses the governance of health data at both international and European levels, with particular attention to the Pathogen Access and

Benefit-Sharing system and to the European Health Data Space (Regulation (EU) 2025/327). It examines the transition from a consent-centred paradigm to a public-interest-oriented framework for secondary use, as well as the emerging regime of civil liability. The One Health paradigm is examined by Ida Santalucia, Michele Sorrentino, Paolo Montuori, Maria Fiore, Margherita Ferrante and Maria Triassi, in *The 'One Health' principle: applications in the International Health Regulations*. The authors demonstrate how multisectoral integration between human, animal and environmental health is progressively embedded within the IHR Monitoring and Evaluation Framework, while identifying critical gaps revealed by the pandemic and the need for stronger normative consolidation.

The national dimension is analysed by Federico Francesco Guzzi, in *Care and prevention in the national context*. The essay links the right to health with issues of public finance, prevention policies and administrative organisation in Italy, highlighting structural weaknesses such as underinvestment in prevention, territorial asymmetries and governance fragmentation that affect the effective implementation of health security.

Finally, Luca Albino, in *The protection of the right to health between State and regional competences*, reconstructs the constitutional dialectic between State and Regions, focusing on Essential Levels of Assistance, fiscal constraints and the tension between autonomy and equality within the Italian multilevel system.

Conceived in the aftermath of the COVID-19 pandemic, the GlEUHSec Project was initially structured around the lessons learned from that global emergency. However, as the research progressed, it encountered unexpected and highly significant developments in international and European law. The approval of the WHO Pandemic Agreement and the adoption of the amendments to the International Health Regulations have profoundly reshaped the normative landscape of global health governance, with direct repercussions on national legal systems. More recently, the European Commission's Communication of 28 November 2025 — *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Introducing the Union Prevention, Preparedness and Response Plan for Health Crises* —

has further consolidated the trajectory towards a structurally integrated European framework for prevention and crisis management. These developments confirm that health security is not a temporary policy response, but a dynamic and evolving field of law, continuously influenced by global regulatory shifts and by the redefinition of institutional competences at both Union and national levels.

Taken together, the contributions collected in this volume—developed within the PRIN GlEUHSec Project between November 2023 and February 2026—demonstrate that health security has become a structural category capable of reshaping institutional balances, redefining competences and integrating global, European and national dimensions of governance. Through sustained interdisciplinary dialogue and successive stages of collective reflection across the partner universities, the Project has sought to "unscramble" the complex legal and institutional web of global and European Union health security, offering a coherent and multilevel interpretative framework for understanding its ongoing transformation.

We sincerely thank the entire research team for the outstanding work carried out over these years, as well as our consultant, Leandra Abbruzzo, whose contribution has been invaluable throughout the Project.

It is our hope that the results achieved represent not a conclusion, but the beginning of a broader and still evolving research trajectory—one that continues to explore, with the same rigor and collaborative openness, the many legal, institutional and scientific dimensions of global and European Union health security that remain to be assessed and further developed.

Naples–Salerno
February 2026

The Editors
Sabrina Tranquilli and Giordana Strazza

SABRINA TRANQUILLI

UNSCRAMBLING GLOBAL AND EUROPEAN UNION HEALTH SECURITY RESEARCH PROJECT: *AN INTRODUCTION*

The PNRR research project *Unscrambling Global and European Union Health Security* was conceived not as a contingent reflection on a pandemic emergency, but as a structural inquiry into the transformation of administrative authority in a context defined by transnational risk, digital interdependence and multilevel governance. From the outset, the project deliberately brought administrative law, international law and medical sciences—particularly hygiene and preventive medicine—into systematic dialogue. As the analysis progressed, it became increasingly evident that a comprehensive understanding of health security governance also required the integration of public constitutional theory and private law perspectives, given the centrality of issues such as competence allocation, supranational coordination, procurement regimes, liability structures, data protection and the circulation of medical countermeasures. Health security thus emerged as a paradigmatic field in which the classical boundaries between legal orders are progressively destabilised.

The research trajectory unfolded during a period marked by profound geopolitical instability, renewed armed conflicts, fragmentation of multilateral cooperation and the reassertion of sovereign claims in global governance. The negotiation process of the Pandemic Agreement was repeatedly slowed down by political tensions, strategic rivalries and diverging conceptions of sovereignty and equity in access to vaccines and medical countermeasures. These setbacks did not merely reflect diplomatic contingencies; they revealed structural fractures within the contemporary international order. The hesitations surrounding stronger binding obligations in matters of pathogen sharing, surveillance and equitable distribution underscored the extent to which global health security remains deeply entangled with geopolitical balances and economic asymmetries.

Against this background, the European Union progressively reinforced its role, both from a regulatory and an administrative standpoint. The strengthening of the European Health Union, the expansion of the mandates of the European Centre for Disease Prevention and Control and the European Medicines Agency, the consolidation of the Health Emergency Preparedness and Response Authority and the adoption of the Union Prevention, Preparedness and Response Plan for Health Crises illustrate a trajectory of functional centralisation. While global cooperation experienced phases of stagnation, the European legal order deepened its capacity to structure preparedness through binding instruments, composite administrative procedures and interoperable digital infrastructures. Risk assessment became increasingly centralised at supranational level, and risk management, although formally national, was substantively framed by European coordination mechanisms.

It is precisely at this juncture that the doctrinal tradition of international administrative law regains analytical relevance. Long before contemporary debates on global governance and regulatory networks, early twentieth-century scholarship had already identified the existence of administrative phenomena operating beyond the territorial State. In his 1912 essay on the character and object of international administrative law, Umberto Borsi recognised that certain forms of cooperation among States were structured not merely through diplomatic negotiation but through procedural, organisational and regulatory techniques characteristic of administrative activity[1]. In Borsi's conception, the international sphere increasingly displayed administrative traits—continuity, technicality, regulation of shared interests—while remaining embedded within a State-centred international legal order. The emphasis was placed on the functional character of certain international legal phenomena rather than on the emergence of an autonomous supranational administrative regime.

[1] U. BORSI, *Carattere ed oggetto del diritto amministrativo internazionale*, in *Riv. dir. int.*, 1912, 384; S. BATTINI, *Amministrazioni senza Stato. Profili di diritto amministrativo internazionale*, Milano, 2003; B. G. MATTARELLA, *Umberto Borsi e il diritto amministrativo internazionale*, in *Riv. It. Dir. pubb. Com.*, 3-4, 933-94.

Andrea Rapisardi Mirabelli's[2] notion of "International Administrative Law" marked a further conceptual development. His analysis moved beyond the identification of administrative techniques within international law and pointed toward the structural consolidation of administrative frameworks operating in a relatively stable and organised manner at the international level. In this perspective, administrative authority was not simply a functional aspect of international cooperation but a constitutive element of emerging transnational regimes capable of shaping State behaviour through procedural continuity, regulatory coordination and supervisory mechanisms. The distinction is not merely terminological. Borsi highlighted the administrative dimension within international law; Rapisardi Mirabelli anticipated the formation of international administrative regimes that contribute to the reconfiguration of sovereignty itself.

Contemporary health security governance confirms the convergence and maturation of these doctrinal intuitions. The adoption of the WHO Pandemic Agreement and the amendments to the International Health Regulations establish obligations of surveillance, notification and data sharing that operate through permanent administrative infrastructures rather than episodic diplomatic commitments. The Pathogen Access and Benefit-Sharing mechanism institutionalises a continuous regulatory relationship mediated by reporting duties, interoperability standards and monitoring procedures. These instruments do not simply coordinate sovereign decisions; they shape the very conditions under which such decisions can be effectively taken. At the European level, composite administrative procedures link supranational agencies and national authorities within shared decision-making frameworks. Risk assessment is centralised within expert bodies whose authority derives from epistemic competence, while risk management remains formally national yet substantively embedded within supranational planning cycles and shared standards.

In this perspective, contemporary health security governance exemplifies the emergence of a planetary legal order structured through regulatory interdependence. The reflection developed by Aldo Schiavone, Pasquale De Sena and Cesare Salvi on the "order of the world"

[2] A. Rapisardi Mirabelli, *International Administrative Law*, Padova, 1939.

captures the transformation of legal rules within a global society that transcends the traditional State-centred paradigm. Health security constitutes a particularly illuminating case of this evolution. Administrative techniques—surveillance, interoperability standards, digital infrastructures and coordinated procurement—organise collective responses to global risks within a framework that is neither purely international nor purely domestic. Sovereignty is not formally displaced, but functionally redefined. Its effectiveness increasingly depends on participation in shared administrative and digital ecosystems.

Surveillance systems, interoperable health data infrastructures and coordinated procurement frameworks thus constitute the backbone of a transnational administrative regime that transcends the classical dichotomy between domestic administrative law and international law. In this sense, contemporary health security provides concrete evidence that international administrative law is not an antiquated doctrinal curiosity but an indispensable interpretative category for understanding the reconfiguration of authority in a planetary society structured by transnational risk, digital interdependence and regulatory interconnection.

At the same time, this transformation raises enduring constitutional questions. The centralisation of epistemic authority within supranational agencies intensifies the tension between expertise and democratic legitimacy. While technical competence is indispensable in contexts of scientific uncertainty and geopolitical volatility, the delegation of significant decision-making functions to bodies operating beyond direct electoral accountability requires renewed attention to transparency, parliamentary oversight and participatory mechanisms. Moreover, digitalisation introduces structural inequalities. Divergences in technological capacity and administrative infrastructure among States risk producing asymmetries in effective participation in preparedness systems, thereby affecting substantive equality in access to health protection.

The research undertaken within this project does not claim to provide definitive answers to these tensions. Rather, it consciously situates itself as an initial contribution to a broader and still evolving scientific debate. The transformations analysed here—spanning international treaty-making, European regulatory consolidation and digital adminis-

trative integration—signal the emergence of a governance paradigm that demands sustained theoretical reflection. By integrating administrative law, international law, constitutional theory, private law and medical sciences, the project seeks to offer a structured analytical framework within which future research may further explore the constitutional implications of preparedness, the evolution of international administrative law and the reconfiguration of sovereignty within an increasingly planetary legal order. Far from representing a conclusive assessment, this work is intended as the beginning of a longer intellectual trajectory, inviting continued scholarly engagement with the profound legal transformations that health security governance has set in motion.

GIORDANA STRAZZA

THE CHALLENGES FACING EUROPEAN AGENCIES IN HEALTH SECURITY

1. *Introduction*

In the field of health, the European Union, which has a purely supporting role vis-à-vis Member States (Article 168 TFEU)[1], has now embarked on a process of gradually developing its policies, thereby triggering a transformation of a sector that has historically been under national sovereignty[2]. Over time, the inadequacy of the existing legal basis in the EU Treaties has clashed with the urgent need for intervention by (among others) European institutions to deal with various health crises (above all, that caused by the spread of COVID-19), making it necessary to implement the tools available, also in view of future cross-border health threats.

The recent pandemic has therefore further accelerated the process of transformation to achieve (or attempt to achieve) a new European

[1] T. HERVEY, J. MCHALE, *Health law and the European Union*, Cambridge, 2004.

[2] G. ROSEN, *A History of Public Health,* Baltimora, I ed., 1958, updated in 1993.

governance of health security, which effectively deals with the set of measures and actions to protect the health of European citizens from threats that may have a transnational impact[3]. In the case of COVID-19, the structures and mechanisms[4] in place until then proved to be not entirely adequate to provide, coordinate and communicate a timely and common response to the risk faced and to ensure solidarity between Member States.

Therefore, with the treaties unchanged[5], over the last three years the EU has adopted three new Regulations with a "cross-cutting" scope[6], namely Regulation 2022/2371 on serious cross-border threats to health[7], Regulation 2022/2372 introducing a framework of measures to ensure the supply of crisis-relevant medical countermeasures in the event of a public health emergency at EU level, and Regulation 2025/327 on the European Health Data Space (EHDS), thus opting for the most effective instrument in terms of EU integration. Added to this is the European Commission's recent proposal to revise the Regulation on the Union Civil Protection Mechanism (UCPM) by integrating funding for preparedness and response to health emergencies to ensure a comprehensive and integrated EU response to crises[8]. Furthermore, after approximately two years of negotiations, in recent months, EU Member States have also agreed on a proposal to revise

[3] Such as pandemics, epidemics, infectious diseases, or accidents that can cause harm to public health. See also S. TRANQUILLI, *Nobody saves himself alone: who decides on health security in the European Union?*, in *Federalismi.it*, 12, 2023, 270 ss.

[4] Established by Decision No 1082/2013/EU, which bases (was) EU coordination mostly on the Early Warning and Reaction System - SARR, as well as on the exchange of information and cooperation within the Health Safety Committee – CSS.

[5] It is understood that already the year after the outbreak of the pandemic, the EU adopted Regulation 2021/522, establishing the EU4Health programme for the period 2021-2027, to strengthen preparedness for major cross-border health threats and strengthen health systems to be able to address epidemics and long-term challenges.

[6] The clarification is necessary, because the EU has also intervened, again with the Regulation, for interventions aimed at expanding the mandates of two relevant agencies in the sector already operational, albeit with "systemic" repercussions, as will be highlighted below, in this par.

[7] Repeal of Decision 1082/2013.

[8] *https://health.ec.europa.eu/latest-updates/boosting-health-resilience-enhancing-union-civil-protection-mechanism-strategic-health-funding-2025-07-17_en*.

pharmaceutical legislation in Europe. The issue of health security, indeed, is now placed in a context of growing and increasingly complex crises, to the point that on 26 March 2025 the European Commission published a EU Preparedness Union Strategy, proposing actions to ensure that the EU and its citizens are prepared for events of this magnitude, including any future pandemics[9].

Moreover, the oft-stated goal is to create a "European Health Union"[10] and thus improve protection, prevention, preparedness and response to risks to human health in Europe, with a comprehensive and systematic regulatory framework.

Indeed, the transformations taking place and in the making in the field of health security are also institutional in nature.

Strengthening the European Union's role in health security now revolves around the gradual enhancement of European agencies that deal with the issue in various ways and increasingly represent, also (if not above all) in this context, "An Important Part of the EU's Institutional Machinery"[11].

Of the thirty-six European agencies, at least four have direct and specific competences in the field of health (the European Medicines Agency - EMA, the European Centre for Disease Prevention and Control - ECDC, the European Food Safety Authority - EFSA, the European Health and Digital Executive Agency - HaDEA) and at least three have competences that affect health protection (the European Chemicals Agency - ECHA, the European Environment Agency - EEA, the European Agency for Safety and Health at Work - EU-

[9] On the European Preparedness Union Strategy, Brussels, 26 March 2025, JOIN(2025) 130 final.

[10] A follow-up to what was announced at the 2020 State of the European Union address by European Commission President von der Leyen, a State of the Year communication set the objective of "Building a European Health Union: strengthening the EU's resilience to cross-border health mines" (COM(2020)724). See also, *https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_it*.

[11] E. CHITI, *An Important Part of the EU's Institutional Machinery: Features, Problems and Perspectives of European Agencies*, in *Common Market Law Review*, Vol. 46, 5, 2009, 1395 ss., doi.org/10.54648/cola2009059, that replicates the words of EU Commissione COM(2008) 135 final, *The European Agencies-The Way Forward*.

OSHA). Among these, we can distinguish between the "first generation" European agencies, established in the 1990s, such as EU-OSHA and EEA (1994), the EMA (1995), the "second generation" agencies, established from 2000 onwards, such as the ECDC (2005) and the EFSA (2002), and, finally, the "third generation" agencies, such as the HaDEA (2021). Even the "first generation" agencies have recently undergone a restyling.

As a result of the entry into force of Regulation 2022/123, the EMA[12] has a strengthened role in crisis preparedness and management in relation to medicines and medical devices, through the provision of new tasks and the stabilisation of the structures and processes established during the COVID-19 pandemic, which have now been made permanent. Similarly, Regulation 2022/2370 has updated and strengthened the ECDC's mandate with the establishment of an EU health task force to assist local responses to disease outbreaks and provide expertise to Member States and the European Commission, for example in the development, review and updating of preparedness plans[13].

In addition to these agencies, there is also the European Health Emergency Preparedness and Response Authority (HERA) (2021), which was initially modelled on the US Biomedical Advanced Research and Development Authority (BARDA)[14] and operates as an "in-

[12] For further information, please refer to the contribution by E. ROMANO, below.

[13] See T. DERUELLE, *The Paradox of Communicabile Diseases Governance in the EU. The European Centre for Disease Prevention & Control Discreet Empowerment*, Oxford, 2025. Regarding an extension of the mandate of the ECDC, see D. EERENS, R. HRZIC, T. CLEMENS, *The architecture of the European Union's pandemic preparedness and response policy framework*, in *European Journal of Public Health*, Vol. 33, Issue 1, February 2023, 42 ss., doi.org/10.1093/eurpub/ckac154.

[14] *https://www.medicalcountermeasures.gov/barda*. BARDA is a department of the United States government, created in 2006 to prepare and operate an integrated medical control system in the event of a public health emergency. As stated in the European Parliament's Legislative Train Schedule, a Council regulation on a framework of measures to ensure the provision of relevant medical countermeasures in the event of a crisis in the event of a public health emergency at Union level. In "Promoting our European way of life", in "*On 11 November 2020, the European Commission published the communication 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'. The Commission emphasised the fact that the EU lacks*

ternal department" of the European Commission[15]. The Authority was established during the COVID-19 pandemic, on an "emergency" basis, quickly, without using the ordinary legislative procedure and without an impact assessment, to improve preparedness and response to serious cross-border threats in the field of medical countermeasures, while recognising the need for a short-term review of its functioning[16].

The creation of these new bodies and/or the strengthening of existing ones demonstrates the EU's willingness[17] to address and manage new threats in the field of health security, benefiting also, and indeed above all, from technical expertise.

Having rebuilt the legal basis for European governance on health risk assessment and management, the aim of the research is to identify

access to relevant medical countermeasure stockpiles. It also hinted to the vulnerability of EU supply chains for these critical medical countermeasures. Two weeks later, in the European Commission's Communication Pharmaceutical Strategy for Europe, however, the name Biomedical Advanced Research and Development Authority (BARDA), was replaced by European Health Emergency Response Authority (HERA)".

[15] Art. 1, Decision 16 September 2021. M. ANDERSON & AL., *Navigating the role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and beyond*, in *The Lancet Regional Health – Europe*, Vol. 9, 100203, October 2021; O.J. WOUTERS E A., *The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness?*, in *Health Policy*, Vol.133, 104844, July 2023, doi.org/10.1016/j.healthpol.2023.104844; A. RENDA, C. DEL GIOVANE, H. VU & N. JACOB, *Improving the mission, governance and operations of the EU HERA*, CEPS, 1 January 2023, in *https://www.ceps.eu/ceps-publications/improving-the-mission-governance-and-operations-of-the-eu-hera/*. L. VÄLIKANGAS, M. LUISTRO-JONSSON & S.L. JARVENPAA, *Health crisis and the EU's HERA: amplifying partial organizing with resourcing for stability, agility, and evolvability*, in *J Org Design*, Vol. 11, 2022, 169 ss., doi.org/10.1007/s41469-022-00125-7; M. Anderson & a., *Navigating the role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and beyond*, in *The Lancet Regional Health – Europe*, Volume 9, 100203; P. DELSAUX, *Preparing Europe for future health threats and crises – the European Health Emergency and Preparedness Authority; improving EU preparedness and response in the area of medical countermeasures*, in *Euro Surveill.*, 24 November 2022; 27(47):2200893, doi: 10.2807/1560-7917.ES.2022.27.47.2200893.

[16] Review which, as we will see, took place in March 2025. See *infra*.

[17] Among other things confirmed by the adoption of Regulation (EU) 2022/2371 on serious cross-border threats to health and Council Regulation 2022/2372 on the supply of products relevant to medical countermeasures in the event of a crisis.

the main "challenges" of "agencyfication"[18] in the field of health security. We should first ask ourselves whether the many different EU authorities that share powers for health risk assessment and containment pose coordination problems and, if so, how these can be resolved (also considering the many new digital platforms and emerging working methods, such as task forces). Then, we should assess whether and how the need for coordination between EU agencies and bodies based on expertise in health security should also be projected onto an international (or rather, global) dimension. Finally, we should consider what corrective measures should be taken about the democratic legitimacy deficit resulting from the "delegation" of decision-making to experts.

2. *The "magmatic" legal basis*

In the European Union's system of competences, the protection and improvement of human health fall within the scope of (only) supporting, coordinating and supplementing national policies, for which the possibility of harmonising the laws and regulations of Member States is generally excluded, pursuant to Articles 6 and 2(5) TFEU.

In the framework outlined by the Treaties, pursuant to Article 168 TFEU (formerly Article 152 TEC), health is not subject to the exclusive competence of the EU, but is nevertheless subject, albeit only in

[18] E. CHITI, *The Agencification Process and the Evolution of the EU Administrative System*, in P. CRAIG, G. DE BÚRCA (ed. by), *The Evolution of EU Law*, III ed., Oxford, 2021, 123 ss., doi.org/10.1093/oso/9780192846556.003.0005; K. VERHOEST, S. VAN THIEL, S. DE VADDER, *Agencification in Public Administration*, in *Oxford Research Encyclopedia of Politics*, 25 March 2021, in *https://oxfordre.com/politics/view/10.1093/acrefore/9780190228637.001.0001/acrefore-9780190228637-e-1466*; M. CHAMON, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration*, Oxford, 2016, 3 ss., doi.org/10.1093/acprof:oso/9780198784487.003.0002; M. SCHOLTEN, M. VAN RIJSBERGEN, *The Limits of Agencification in the European Union*, in *German Law Journal*, 2014; 15(7):1223-1255, doi:10.1017/S2071832200019350; D. GERADIN, R. MUNOZ, N. PETIT (ed. by), *Regulation through agencies in the EU*, Cheltenham, 2005. See also J. ALBERTI, *Le Agenzie dell'Unione europea*, Milan, 2018; C. TOVO, *Le agenzie decentrate dell'Unione europea*, Napoli, 2016.

paragraph 4, to shared competence with the Member States when it comes to addressing "common safety concerns in public health matters", pursuant to Article 4(2)(k). (k). Concurrent competence exists for measures "laying down high standards of quality and safety of organs and substances of human origin, blood and blood derivatives", as well as "medicinal products and medical devices" and, finally, for measures "in the veterinary and phytosanitary fields, the primary objective of which is the protection of public health". It is no coincidence that Article 168(4) TFEU was introduced in the context of the bovine spongiform encephalopathy (BSE) crisis, commonly known as "mad cow disease", which affected Europe in the 1980s and 1990s.

Further confirmation of the EU's complementary role regarding Member States' actions in the field of public health is provided in Article 168(5) TFEU, which provides, among other things, for the possibility of adopting measures relating to monitoring, early warning and combating serious cross-border threats to health.

A significant contribution to EU harmonisation in the field of health security has been made through an additional legal basis, identified in Article 114 TFEU (formerly Article 95 TEC), on the establishment and functioning of the single market, a matter of shared competence between the EU and Member States[19]. For some time now, the Court of Justice has affirmed the legitimacy of harmonising measures based on Article 114 TFEU that affect the protection of human health, if they are useful for the completion of the internal market[20].

The EU has then gradually extended its sphere of influence in this area in relation to the internal market, on the basis of the Health In All

[19] See the study conducted for JEF Europe by J. JÄRVINIEMI, R. SCHOLZ, K. HOFFMEISTER, *From COVID-19 to a European Health Union Proposals for Reform of the Health Treaty*, Brussels, May 2022, defines "catch-call" the juridical basis based on art. 114 TFEU.

[20] CJEU, 5 October 2000, C-376/98, Germany c. Parliament and Council, pp. 76-78, 84 and 88, with commentary by T. K. HERVEY, *Community and national competence in health after tobacco advertising*, in 38 C. Mkt. L. Rev., 6, 2001, 1442. CJEU, 14 December 2004, C-210/03, Swedish match, page 31. Consider, for example, that art. 114 TFEU is the legal basis of Directive 2001/83, on the so-called farm code for human use.

Policies (HIAP)[21] principle, which requires a high (*rectius*, the highest) level of health protection to be ensured in all Union policies (and actions)[22] (as is the case for the environment), linked, with specific reference to human health, to Articles 9 and 152(1) TFEU, the wording of which has been reproduced verbatim in Article 35 of the Charter of Fundamental Rights of the EU.

The provision is even more significant when read in conjunction with Article 169 (formerly Article 153 TEC) on consumer protection or Article 153 TFEU (formerly Article 137 TEC) on social policies to ensure the improvement of the working environment.

However, regarding external relations, the expansion of the EU's sphere of influence in health security is based on the principle of consistency referred to in Article 21 TEU[23].

Finally, the COVID-19 pandemic has marked the "rediscovery" of Article 122 TFEU[24] as a clause for dealing with emergency situations, which can be activated on the initiative of the Commission and by a

[21] For an in-depth analysis, it is against ML FLEAR, *Governing Public Health. EU Law, Health and Biopolitics*, Oxford, 2015, 54 ff.

[22] CJEU, 4 May 2016, Philip Morris Brands and Others, C-547/14.

[23] Consider, for example, "Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuing, verification and acceptance of interoperable COVID-19 vaccination, testing and recovery certificates (EU digital COVID certificate) to facilitate free movement during the COVID-19 pandemic". On the extension of the EU's internal and external health policy (with reference to health security), see, among others, G. DI FEDERICO, S. NEGRI, *European Union and greeting. Principles, Actions, Rights, and Quality Standards*, Padua, 2020; E. RUIZ CAIRÓ, *Public Health Promotion in EU External Relations*, Zurich, 2021.

[24] In these terms, the shareable considerations of P. DERMINE, *Article 122 TFEU and the future of the Union's emergency powers*, in *EU Law live*, 25 January 2024. According to M. DE GREGORIO MERINO, *The EU Treaties as a Living Constitution of the Union in Times of Crisis*, in *AJIL Unbound*, Vol. 118, 2024, 162 ff., doi.org/10.1017/aju.2024.25, is a provision ""sleeping beauty"". For further information, see v. B. DE WITTE, "*The European Union's Recovery Plan from COVID-19: The Legal Engineering of an Economic Policy Change*," in *Common Market Law Review*, Vol. 58, 3, 2021, 635 ff., doi.org/10.54648/cola2021046; M. DE GREGORIO MERINO, "*The Recovery Plan: Solidarity and the Living Constitution*", in D. UTRILLA, A. SHABBIR (ed. by), *EU Law in Times of Pandemic – The EU Legal Response to Covid-19*, 2021, 33 ff.; M. CHAMON, *The Rise of Article 122 TFEU*, in *VerfBlog*, 2023, doi: 10.17176/20230203-113329-0.

qualified majority decision of the Council, with the role of the Parliament being marginalised, used to trigger the Emergency Support Instrument, which has facilitated, among other things, the collective purchase of vaccines. This is (in theory) an exceptional mechanism, but one that risks losing this characteristic if the crises to be addressed become progressively more frequent.

Given this "magmatic" scenario, which is also due to the numerous cross-cutting implications of health security, the European agencies dealing with this issue have a legal basis that is, in some respects, equally complex.

By way of example, consider the EU bodies that played a leading role during the recent pandemic[25].

The EMA was initially established under the flexibility clause, pursuant to Article 352 TEC (which allows the EU to act in areas not expressly provided for in the Treaties, if necessary to achieve Union objectives)[26], a procedure that excludes the participation of the Parliament as co-legislator[27]. Since 2004, however, the agency has based its legal basis on Articles 95 and 152(4)(b) TEC, subsequently confirmed by the new regulation of 2022, which refers to Articles 114 and 168(4)(c) TFEU.

In contrast, the Regulation establishing the ECDC refers only to Article 152(4) TEC and, similarly, the amending (and power-extending) Regulation refers to Article 168(5) TFEU.

[25] It is understood that these are considerations that can also be replicated for the additional agencies that, in various capacities, deal with health security. For example, EFSA has a juridical basis in Articles 37, 95,133 and 152 (4)b TEC.

[26] Under the orders of agencyfication, consider the juridical basis more appropriate for the purposes of establishing agencies. On this point, reference is made to R. H. LAUWAARS, *Auxiliary bodies and agencies in the EEC*, in *Common Market Law Review*, 1979, 376.

[27] In the opinion of AG Jääskinen, 12 September 2013, Case C-270/12, United Kingdom c. European Parliament and Council (short selling), p. 65, this is a mechanism that favors democratic legitimacy for the municipality, because, under Article 352(2), the Commission must be rich in activating national parliaments on the proposal. In a critically understandable sense, E. MACIARIELLO, *EU agencies and the question of conferring delegations, implicit powers and the state of exception*, in *European documents*, vol. 4, 3, 730.

HADEA, as an executive agency (not decentralised) of the European Commission, pursuant to Regulation 58/2003[28], is delegated certain tasks relating to the management of Union programmes; HERA, established on the basis of the aforementioned Article 122 TFEU, as a new directorate-general of the Commission, benefits from "the full range of financial, regulatory, technical and organisational powers and instruments available"[29] to the Commission.

The picture is even more complex when one considers that, to respond to cross-border health crises, Regulation 2022/2731 requires horizontal coordination between the Commission and the agencies (as well as vertical coordination with the Member States). Once notification of the cross-border threat has been received, Article 20 of the Regulation entrusts the agencies[30] with risk assessment based on their respective areas of competence. At the request of the agency carrying out the risk assessment, the others must provide it without delay with all relevant information and data at their disposal[31] and then entrust the adoption of risk management measures to the Member States.

3. *Internal coordination between European agencies and HERA*

As already evident from the mechanism described above[32], outlined in the Regulation on cross-border health threats, the proliferation of health security agencies and the strengthening of their mandates also creates a need for coordination between them and with the work of other EU institutions, notably HERA.

First and foremost, coordination requires a clear framework of competences, which is essential to prevent the usurpation of activities

[28] See Art. 3.

[29] Decision EC 2021/929.

[30] ECDC, EFSA, ECHA, EEA EMCDDA.

[31] The Commission shall promptly follow up the risk assessment to the competent national authorities, through the' European Union Early Warning and Response System (EWRS) and the Health Safety Committee (HSC), to which reference is made below, and, where appropriate, through linked warning systems.

[32] Please refer above, previous para.

entrusted to other bodies and to promote collaboration and cooperation between the various authorities.

The coordinating body between the EMA, ECDC, HADEA and HERA is the Health Security Committee (HSC), hosted (along with other independent scientific committees) by the Directorate-General for Health and Food Safety (DG-SANTE), the Commission department responsible for EU health policy. The HSC, which deals with "prevention, preparedness and response planning for serious cross-border threats to health", is tasked with "reinforce the coordination and sharing of best practice and information on national preparedness activities"[33].

The HSC, which has been in existence since 2013, is now reinforced by the Health Crisis Board (HCB), which is activated whenever the former declares an emergency, as per Regulation 2022/2372, with its legal basis in Article 122 TFEU[34].

It is the same Regulation, moreover, which repeatedly emphasises the need for coordination and, to this end, on the one hand, requires the Commission, in collaboration with Member States and competent agencies/bodies, to establish an EU preparedness, prevention and response plan, precisely for their timely cooperation with the Council and the HSC; on the other hand, it specifies that the HCB must coordinate with the HERA Board. Moreover, the latter authority switches to emergency mode under the coordination of the HCB and supports its activities by providing preparedness and response and management plans and monitoring joint procurement.

3.1. *Persistent critical issues: the existence of overlaps and the need for (further) rationalisation*

Regulation 2022/2372 highlights that the HSC and the HCB should coordinate, but the division of their work (and responsibilities) still seems to be definition by the Commission, even though it is ex-

[33] *https://ec.europa.eu/health/health-security-and-infectiousdiseases/preparedness-and-response/health-security-committee-hsc_sv*.

[34] See *supra*, para. 2.

tremely important for Member States to have a single predefined point of reference in the event of an emergency[35].

Similarly, the relationship between the HERA Board and the new role of the HSC does not seem entirely clear, with the risk of at least partial overlap between the two bodies. There also appears to be confusion in the division of responsibilities between HERA, the Commission itself and other health security agencies, particularly the EMA, about vaccine supply.

However, it is significant that in 2024, when providing recommendations to help agencies be better prepared for future health emergencies, the European Court of Auditors (ECA) itself noted a partial overlap of competences between HERA, the ECDC and the EMA, to the extent that it urged the Commission to clarify the division of competences and strengthen coordination[36].

This is even more significant when one considers that, in the previous year, HERA signed agreements with the ECDC and the EMA to strengthen cooperation on preparedness and response to health emergencies, to avoid unnecessary duplication and ensure more efficient use of resources[37].

[35] A. RENDA & A., *Revamping the EU's health security framework to manage future health crises*, in *Eurohealth*, Vol. 29, No. 3, 2023, 50.

[36] European Court of Auditors (ECA), *Special report 12/2024: The EU's response to the COVID-19 pandemic – The EU medical agencies generally managed well in unprecedented circumstances*, in *https://www.eca.europa.eu/en/publications/SR-2024-12*. For a comparative comparison of previous roles and functions for HERA, ECDC and EMA during the preparedness and crisis phase, see. COM (2021) 576 final, *ANNEX to the Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Brussels, 16 September 2021.*

[37] *https://health.ec.europa.eu/latest-updates/hera-signs-agreement-ecdc-and-ema-strengthen-cooperation-health-emergency-preparedness-and-response-2023-03-14_en*. The update published on the Commission's website states that *"The agreed working arrangements will help ensure that there are no unnecessary overlaps and that resources are used more efficiently. HERA and ECDC identified the following areas of collaboration:*

- *Intelligence gathering and assessment of health threats relevant to medical countermeasures*
- *Modelling, forecasts and foresight activities relevant to medical countermeasures*

It is also noteworthy that, in its response to the aforementioned report, the Commission itself (as the formal addressee of the recommendation) recognised "in particular" the need to address the critical issue highlighted by the ECA, but also that, among the key recommendations of the report reviewing HERA's activities, it reiterated the need to strengthen synergies between HERA, the ECDC, the EMA, the HSC and the new Advisory Committee on Public Health Emergencies (ACPHE)[38], established on the legal basis of Article 168(5) TFEU to support and advise the Commission and Member States before, during and after a health emergency, through the involvement of experts from different fields[39].

- *Promoting advanced research and development of medical countermeasures and related technologies*
- *Strengthening knowledge in preparedness and response related to medical countermeasures*
- *Contribution to reinforcing the global health emergency preparedness and response architecture.*

HERA and EMA identified the following areas of collaboration:

- *Assessment of serious cross-border threats to health relevant to medical countermeasures*
- *Identification of medical countermeasures and priority research areas*
- *Identification of vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures*
- *Coordination, in relation to medical countermeasures, in the event of recognition of a public health emergency*
- *Contribution to reinforcing the global health emergency preparedness and response architecture*

DG SANTE, as the partner DG for ECDC and for EMA, and co-signatory of the Working arrangements, will be kept informed of all relevant activities carried out under these working arrangements that fall under DG SANTE mandate".

[38] EC Decision C(2023)6017, *setting up the group of experts 'Advisory Committee on public health emergencies'*.

[39] See the EC Report *Review of the implementation of the operations of the Health Emergency Preparedness and Response Authority (HERA)*, Brussels, 26 March 2025, COM(2025) 147 final: "*Both in the external and internal consultations, concerns were raised about the risk of duplication and a lack of clarity in the role of HERA in public health, civil protection and research funding, including in the interaction with the ECDC, with the Health Security Committee and the newly established Advisory Committee on Public Health Emergencies, as well as with the EMA (both on medical coun-*

Indeed, a few years earlier, when HERA had not yet been established, in its special report on the future of EU agencies[40], the European Court of Auditors had recommended, among other things, the need to avoid duplication of work and to rationalise joint activities, While the vast majority of respondents to the report generally felt that cooperation between agencies and their partners (at national, EU and international level) worked well, some also suggested that significant improvements were needed, for example, in our case, in relations between the EMA and the Commission.

Similarly, Parliament also called for greater coordination between the EMA, HERA, ECDC (as well as the competent national authorities), in cooperation with the relevant industry, to boost production during health emergencies[41].

3.2. *The proliferation of actors and methods of inter-agency cooperation*

The awareness of the indispensability of "internal" coordination seems, moreover, to be further confirmed by the "Cross-agency One

termeasures and critical medicines). The profile and branding of HERA has been seen to create some confusion amongst outside stakeholders as to who is speaking for the Commission. Tangible efforts have already been made to streamline the collaboration within the Commission and with agencies, for instance through working arrangements. A good example came with the Commission proposal for a Critical Medicines Act where HERA's expertise in joint procurement and extensive contacts with the pharmaceutical industry were drawn upon. The Commission set out that HERA will also organise collaborative procurements for critical medicines and other medicinal products of common interest and will continue to provide secretariat services to the Critical Medicines Alliance, an essential consultative and cooperation mechanism aiming to reinforce the EU pharmaceutical supply chain. But more can be done to increase effective interaction and bring synergies. President Niinistö's report underlines that effective preparedness requires a comprehensive and integrated approach".

[40] European Court of Auditors (ECA), *Special Report 22/2020, Future of EU agencies – Potential for more flexibility and cooperation*, in *https://www.eca.europa.eu/Lists/ECADocuments/SR20_22/SR_Future_of_EU_Agencies_EN.pdf*.

[41] European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)).

Health task force framework for action 2024-2026", shared by the ECDC, ECHA, EEA, EFSA and EMA[42], incentivised and politically guided by the Commission. The document, adopted based on the commitment made at the ONE Conference in 2022, outlined the strategic objectives, lines of action and expected results of the "inter-agency" task force[43], which became operational in 2023, to facilitate the implementation of the One Health approach[44], which is also essential for averting health risks[45], until 2026.

Consider, for example, the cooperative activity carried out by the ECDC, EMA and EFSA, which led to the drafting of a joint scientific opinion on a list of outcome indicators for the surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals[46] and the publication of joint inter-agency reports on the integrated analysis of data on antibiotic consumption and the development of antimicrobial resistance in Europe (2019-2021). on the integrated analysis of data on antibiotic consumption and the development of antimicrobial resistance in Europe (2019-2021)[47].

[42] S. BRONZWAER, W. DE COEN, O. HEUER, I. MARNANE & A. VIDAL, *The framework for action of the Cross-agency One Health Task Force*, in *One Health*, Vol. 19, 2024, doi.org/10.1016/j.onehlt.2024.100925.

[43] *Cross-agency knowledge for One Health action – Joint Statement by European Union Agencies*, 13 November 2023.

[44] Lastly, v. K. WOOLASTON, J. KOTZMANN (ed. by), *The Cambridge Handbook of One Health and the Law. Existing Frameworks, Intersections, and Future Paths*, Cambridge, 2025, doi.org/10.1017/9780109653732. The Jean Monnet module "One health: global and EU perspectives" (1HEALTH), led by Prof. S. NEGRI. AL. PHELAN, S. NEGRI, M. HESSELMEN, *Environmental Health: Toward Synthesis in Global Law and Governance*, in *Journal of Law, Medicine & Ethics* (2025), 53, S1, 41 ff., doi:10.1017/jme.2025.10.

[45] Consider zoonotic diseases and mines of environmental origin, including those due to climatic conditions.

[46] ECDC, EFSA Panel on Biological Hazards (BIOHAZ); EMA Committee for Medicinal Products for Veterinary Use (CVMP). ECDC, EFSA and EMA Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals. EFSA J. 2017 Oct 26;15(10):e05017. doi: 10.2903/j.efsa.2017.5017. PMID: 32625307; PMCID: PMC7009961.

[47] In February 2024, the agencies just mentioned published their fourth report on the topic.

Given the EU's growing role in health security and the proliferation of actors involved, it is realistic to expect that we will soon see an increase in synergies and cooperation between European agencies (and between them and other EU bodies) that deal with this issue in various ways.

The establishment of a coordinated administrative network between agencies and/or other EU institutions will most likely require, first and foremost, further regulatory clarification on the division of activities, as well as task forces, working groups, control rooms, or, more generally, mechanisms (such as agreements or work plans/documents) that provide effective opportunities for sharing and convergence, capable of overcoming institutional fragmentation, with regular meetings, a constant flow of information, stress tests, reports and monitoring of the progress of activities carried out and the objectives set.

In any case, there is still a need not to further increase the already highly fragmented framework of authorities responsible for health risk assessment and management within the EU.

The institutional landscape of European health security is already very complex and fragmented, so it seems more appropriate to limit rather than increase the number of "players" in the system.

3.2.1. *One Health, many agencies, many risk assessment models*

The agencies (and HERA) that deal with health safety in various capacities are characterised not only by different mandates, but also by different approaches to scientific evidence for preventing threats in this area[48].

In other words, risk assessment approaches, although based in all cases on technical expertise, follow different models: for example, the environmental scientific community is "traditionally" less accustomed to expressing itself about immediate risk (within 48 hours).

The "sectoral" diversification of risk assessment in terms of food, environmental or animal safety, although related and linked – in a "holistic" view – to (purely) health risks, seems likely to have repercus-

[48] Art. 20 of Regulation (EU) 2022/2371.

sions at the administrative level and to lead to possible problems of collaboration between agencies in the One Health approach.

Starting with the Regulation on serious cross-border threats to health, the attempt is to formalise the involvement and cooperation (especially, but not only, at information level without undue delay, data useful to the lead agency carrying out the risk assessment) of the different EU agencies, to obviate evaluation fragmentation[49].

3.3. *The problem of data interoperability and the proliferation of platforms*

The need for coordination must also be translated into the responsible use of health data, avoiding duplication, so that the creation of the European Health Data Space (EHDS) leads to effective interoperability between the EU institutions that deal with this issue in various ways.

Meanwhile, we are witnessing a proliferation of data platforms related to health security. First of all, it should be noted that Article 14 of Regulation 2022/2371 provided for the establishment of a digital surveillance platform to support the prevention and control of communicable diseases, entrusted to the ECDC, in cooperation with Member States and in accordance with the specifications issued by the Commission, in order to address one of the main critical issues that emerged during the pandemic, namely the lack of interoperable data[50].

[49] See also *infra* following para.

[50] 1. The ECDC shall ensure the continued development of the digital platform for surveillance, after conducting data protection impact assessments and having mitigated any risks to the rights and freedoms of the data subjects, as appropriate, through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control. The ECDC shall ensure that the operation of the digital platform for surveillance is subject to human oversight and shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as establish robust procedures for data quality review. The ECDC, in close cooperation with Member States, shall also ensure the interoperability of the digital platform for surveillance with national systems. 2. The digital platform for surveillance shall: (a) enable the automated collection of surveillance and laboratory data, make use of relevant

Consideration should also be given to the vaccine monitoring platform, established in May 2022 as a collaboration between the EMA and the ECDC, to generate real-world evidence through EU-funded post-authorisation studies on the use, safety and efficacy of vaccines. This is not the only example of a health safety platform. Another example is the European Shortages Monitoring Platform (ESMP),

non-personal health data from a previously defined and authorised list from electronic health records and health databases, and of media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting, including statistical reporting; and (b) allow for the computerised handling and exchange of information, data and documents. 3. Member States shall be responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete and accurate information, data and documents transmitted and exchanged through the digital platform. Member States may promote the automation of this process between the national and the Union surveillance systems. 4. The ECDC shall monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission. 5. For epidemiological surveillance purposes, the ECDC shall also have access to relevant health data accessed or made available through digital infrastructure enabling the use of health data for research, policy-making advice and regulatory purposes. 6. The Commission shall adopt implementing acts for the functioning of the digital platform for surveillance which lay down: (a) the technical specifications of the digital platform for surveillance, including the electronic data exchange mechanism for exchanges with existing international and national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures; (b) the specific rules for the functioning of the digital platform for surveillance, including for the protection of personal data and security of exchange of information; (c) contingency arrangements including secure data backups to be applied in the event of unavailability of any of the functionalities of the digital platform for surveillance; and (d) arrangements for promoting standardisation of the infrastructure for storage, processing and analysis of data. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2). 7. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation concerning: (a) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the digital platform for surveillance and the practical arrangements for such access; (b) the cases where, and the conditions under which, the data, information and documents referred to in Article 13 are to be transmitted using the digital platform for surveillance and the list of such data, information and documents; and (c) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructure referred to in paragraph 5".

launched by the EMA to collect information on the availability, supply and demand of medicines to prevent, detect and manage shortages of medicines for human use in the EU and the European Economic Area (EEA). The platform collects data from national competent authorities (NCAs) and marketing authorisation holders (MAHs)[51] and offers different levels of access depending on the user.

More recently, the European Commission released the central open-source platform HealthData@EU[52], containing metadata from Member States, European institutions, third countries and research infrastructures, to meet the requirements of the European Health Data Space Regulation, with features constantly being updated and implemented[53]. The aim is to create a common information pool and unlock the potential of secondary use of such data, for example, for research and scientific development, while complying with the General Data Protection Regulation (GDPR), so as to complement the MyHealth@EU[54] platform, an infrastructure dedicated to cross-border electronic health services, where data provided by Member States converge[55].

The increase in digital platforms under the control of the European authorities therefore raises the need to preserve the IT security of centralised hubs containing large amounts of health data from across Europe.

[51] For further details, please refer to *https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-informational-brief_en.pdf*. It should also be noted that the EMA and the Heads of Medicines Agencies (HMA) have published a common work plan called "Data and AI in medicines regulation to 2028", which illustrates how the European Drugs Regulatory Network intends to exploit large volumes of regulatory and health data, as well as new tools to encourage research, innovation and support regulatory decision-making to achieve better drugs that reach patients more quickly.

[52] https://code.europa.eu/healthdataeu. It is built using the HealthDCAT-AP metadata standard, to ensure data reusability.

[53] *https://acceptance.data.health.europa.eu/healthdata-central-platform?locale=en*.

[54] *https://health.ec.europa.eu/publications/myhealtheu-qa_en?prefLang=it*.

[55] See F. TRUBIANI, *Health data governance: towards the creation of an international and european digital sharing ecosystem*, in this book.

About the EU4Health programme[56], HADEA's implementation role also involved the creation of ATHINA[57], a new health intelligence and IT systems platform designed to prevent and develop countermeasures in the event of a health emergency, with a call for tenders published on behalf of HERA[58]. This is symptomatic not only of HADEA's crucial collaborative role with both HERA and other European agencies in carrying out the wide range of planned actions requiring the use of data, but also of the existence of an additional platform on health security, meaning that their number is beginning to become significant.

Indeed, there is a risk that the problems of overlap and duplication, already highlighted in terms of the competences of European health security authorities, will also be transferred to their respective data platforms.

For example, the latter platform sets the following objectives ("*Providing a secure way of information sharing, through the Intelligence Gathering Function. Facilitating the analysis, identification, and prioritisation of possible health threats, through the Threat Assessment Function. Facilitating the identification of vulnerabilities in the supply chain of critical Medical Countermeasures, through the Mapping, Modelling and Analytics Function. Facilitating the assessment for response options concerning Medical Countermeasures, through the Emergency Response Function*"[59]) which, at least in part, overlap with those of the EMA platform described previously.

[56] *https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en*.

[57] *https://athina.ec.europa.eu/*.

[58] See also *supra*.

[59] As noted by A. LUPONE, *Il coordinamento tra HERA e HaDEA: la via obbligata nella risposta efficace agli effetti traumatici delle emergenze transfrontaliere sulla salute mentale?*, in *Eurojus*, 5 Septemper 2022, already "Nella comunicazione del 12 luglio HaDEA non è citata ma nella premessa del Direttore al Programma di lavoro 2022 di HaDEA, reso noto due settimane dopo, vi è un espresso riferimento al proposito di costruire una stretta relazione, fra gli altri, con HERA attraverso un meccanismo di interazione sui programmi («policy feedback framework») che garantisca un «efficient and effective feedback loop»".

4. *External coordination between European agencies and HERA*

It now seems short-sighted to limit the coordination of agencies and HERA to the European dimension alone, and therefore to the "internal" dimension.

The mantra "No one is safe until everyone is safe"[60] emphasises the need for institutional cooperation to be conceived on an international, or rather global, scale in the face of a health risk that can spread internationally, or rather globally[61]. Consequently, to be effective, the work of European agencies and HERA cannot ignore "external" coordination. If we consider only the level of interinstitutional relations, it is therefore necessary to take into account the necessary collaboration with other agencies (such as the UK Health Security Agency, BARDA, Africa Centres for Disease Control and Prevention-CDC, Japanese Infectious Disease Surveillance Centre and Korea Disease Control and Prevention Agency-KDCA) and international organisations (such as the World Health Organisation - WHO, Food and Agriculture Organisation of the United Nations - FAO, World Organisation for Animal Health) or other global partners (such as the G7 and G20). Moreover,

[60] See for example https://www.un.org/en/desa/%E2%80%9Cno-one-safe-until-everyone-%E2%80%9D or https://assembly.coe.int/LifeRay/SOC/Pdf/DocsAndDecs/2021/AS-SOC-2021-54-EN.pdf

[61] Moreover, the Commission, in *Preparing the EU for the next health crisis: a strategy for medical countermeasures*, COM (2025) 529 final, Brussels, 9 July 2025, also stressed that "Joint, coordinated and concerted actions at EU level and enhanced global cooperation are essential to ensure the availability of and access to medical countermeasures. (…) The Commission services and the European External Action Service will enhance coordination with Member States, EU agencies, and global partners to ensure prompt detection of any emerging health threats to the EU and the world, facilitate quick and equitable access to medical countermeasures. This reflects also the findings of the HERA review noting that activities in the area of medical countermeasures contribute to building a robust global health security framework. Effective worldwide warning systems for new threats requiring medical countermeasures are essential to promptly develop and distribute appropriate medical countermeasures, while medical research, pharmaceutical production, and supply chains are inherently global. (…) Global coordination is critical to stop any new outbreak locally before it crosses borders or turns into pandemic".

Article 30 of Regulation 2022/2371 provides for "the establishment of a framework for enhanced cooperation with the WHO, in particular about communication and review activities"[62].

The ECDC EU Health Task Force (ETF) needs to work with other relevant "actors", including not only the Commission services, but also WHO.

The EMA Pandemic Task Force (ETF) needs to coordinate not only with DG HERA and ECDC, but also with WHO.

Among the key mandates of HERA is to support EU leadership on global health security[63]. The international dimension of HERA covers six crucial areas, namely intelligence gathering and threat assessment, research and development, productive capacity, resource donations, cooperation agreements, and an international health instrument.

For example, HERA collaborates with the WHO Hub for Pandemic and Epidemic Intelligence and the WHO Regional Office for Africa (AFRO) to support intelligence gathering and health threat assessment functions, as well as initiatives to increase the transparency of critical supply chains and expand laboratory capabilities for clinical and environmental surveillance[64]. oppure, più in generale, le collaborazioni tra le agenzie europee e OMS Europa.

Also consider the launch of the Partnership to Accelerate Mpox Testing and Sequencing in Africa (PAMTA), an initiative of the European Commission and the CDC, based on donations of vaccines for the so-called "monkeypox" or "monkeypox" (approximately 600,000

[62] E. RUIZ CAIRÓ, *The promotion of public health in EU external relations*, Geneve, 2021, 50 ss.

[63] H. VU, M. DELL'AQUILA, *Scoping paper on HERA's engagement with low- and middleincome countries*, Bruxelles, 2024.

[64] *https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/international-cooperation_en*. The information page also includes HERA's collaborations with WHO, supporting the SECURE initiative to expand sustainable access to essential antibiotics, while monitoring an activity launched in 2022 on priority reporting on resistant bacteria and fungi, pipeline analysis for antibacterial and antifungal agents, and diagnostics and vaccines against resistant pathogens. However, the link to which the page refers is inactive.

doses, by mid-2025) by HERA and Team Europe[65] to major African countries[66].

More generally, consider collaborations between European agencies and WHO Europe on topics of impact[67].

Another example is the collaboration between the Commission, ECDC, EMA, EFSA and the Governments and relevant specialized agencies of the United States, Canada, Norway and the United Kingdom under the Transatlantic Antimicrobial Resistance[68] Task Force (TATFAR).

Indeed, further upstream, the "external" coordination of European agencies and HERA presupposes a precise vision of the EU's role in the context of global health security.

In awareness of the emergence of a new global health order, in 2022 the Commission adopted the EU Global Health Strategy to improve global health security and ensure better health for all[69]. As a key component of Global Gateway[70], which promotes peer alliances based on shared responsibility, the strategy aims to incentivize solid global governance and international partnerships, as well as the Team Eu-

[65] It is a mechanism based on joint external action to intervene in the primary factors limiting development in a country or region. For further information, see *https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives_it#what-is-team-europe.*

[66] *https://health.ec.europa.eu/latest-updates/strengthening-health-resilience-new-initiative-mpox-testing-and-sequencing-africa-launched-2025-07-30_en.*

[67] For example, through the collaboration between WHO Europe and the ECDC (as well as numerous other institutions) in consideration of the' WHO European Centre for Humanitarian and Health Emergency Preparedness.

[68] Antimicrobial resistance (AMR) "is a major global public health concern and a food safety issue. When pathogens become resistant to antimicrobial agents they can pose a greater human health risk as a result of potential treatment failure, loss of treatment options and increased likelihood and severity of disease". Thus the Code of Conduct of the Codex Task Force on Antimicrobial Resistance (TFAMR), in *https://openknowledge.fao.org/server/api/core/bitstreams/ebcf2f59-ce5e-4974-ba2d-cb8ae65aa8af/content.*

[69] *https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en.*

[70] *https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_it.*

rope[71] approach and more effective forms of financing (e.g., innovative financing, co-investments) in the healthcare field.

However, since 2022, the landscape has changed significantly: in May 2025, the WHO adopted the Pandemics Agreement, in whose negotiations the EU actively participated (indeed, as the instrument's main driver), and the US will officially leave the WHO on January 22, 2026.

In this new phase for global health, the EU has the chance to rethink and redefine its role in governance on health security worldwide.

Renewed collaboration with WHO to achieve universal health coverage with the launch of Phase V (2025-2028) of the Partnership for Universal Health Coverage (UHC), with new EU financial support of €40 million and an additional contribution expected in 2027, depending on the largest WHO platform, for the strengthening of health systems and the advancement of primary health care (concerning over one hundred and fifteen countries and guaranteeing quality care to over three billion people in the world) constitutes, meanwhile, a "first step".

4.1. *The ongoing critical issues: ambitions not always adequately supported and the absence of a "single voice"*

The first monitoring report on the EU's global health strategy to improve global health security and ensure better health for all, published in July 2025[72], describes its implementation status, highlighting both its progress and the critical issues arising from ambitions that are not always adequately supported in terms of resources and structures.

It is particularly interesting that the report identifies both "internal governance and coordination within the EU" and "external and multilateral governance" as priorities (on which improvements are needed).

Similarly, strengthening global cooperation and cross-sectoral collaboration (in addition to expanding the HERA Invest programme[73])

[71] *https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives_en*.

[72] COM(2025)392.

[73] *https://health.ec.europa.eu/health-emergency-preparedness-and-response-*

is one of the key actions of the new EU strategies on stockpiling and medical countermeasures to strengthen crisis preparedness and health security[74].

In this context, the need for a "single voice" for the EU at international level, if necessary, through a special representative for global health[75], should not be underestimated. This would help to achieve political leadership and exert "external" diplomatic influence to translate strategies into concrete action.

5. *The democratic legitimacy deficit due to the "delegation" of decision-making to experts*

Precisely because of the "agencyfication" of health security shifts and centralises decision-making responsibility to European expertise, there is also the problem (of the deficit) of democratic legitimacy[76] of

hera/funding-and-opportunities_en.

[74] Launched by the Commission as part of the Preparedness Union agenda on 9 July 2025. See *https://health.ec.europa.eu/latest-updates/eu-sets-out-new-plan-boost-health-crisis-readiness-2025-07-09_en*.

[75] L. Bengtsson, H. Holmer, *Why the EU needs a Special Representative for Global Health*, 4 July 2025, in *https://www.ceps.eu/why-the-eu-needs-a-special-representative-for-global-health/*: "*Reporting to the EU's High Representative, an EU Special Representative (EUSR) has both the political weight and institutional mandate to represent the EU in high-level diplomacy, coordinate cross-sector policy and ensure continuity across Commission cycles. (…) Creating an EUSR doesn't require legislation or treaty change. The Council appoints EUSRs by qualified majority vote, typically following a proposal from the High Representative. The most recent appointment was in 2021, for the Horn of Africa. These roles are time-bound, targeted and designed to reflect strategic priorities. With a new Commission and Parliament now in place, and political space for fresh initiatives, now's the moment to act and ensure clear responsibility for implementing the EU's global health strategy and beyond*".

[76] *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Ademocratic_deficit*: '*Democratic deficit' is a term used to denote a situation where institutions and their decision-making procedures may suffer from a lack of democracy and accountability. In the case of the European Union (EU), it refers to a perceived lack of accessibility or lack of representation of the ordinary citizen with respect to the EU institutions – a sense of there being a gap between the powers of those institutions and a perceived inability of citizens to influence those institutions' decisions*. See J.H. WEILER,

the power affecting the fundamental rights and freedoms of European citizens entrusted to the agencies operating in this area. The latter are, in fact, an expression of technical-scientific governance, created to assist EU institutions in implementing policies, with indirect democratic legitimacy, since they are not directly elected by citizens.

The response to COVID-19 has marked the rise of "science-based"[77] technocratic governance, entrusted precisely to these agencies, and has emphasised the "technocracy/democracy"[78] dyad (or, if you prefer, dualism) on issues of extreme political importance, with a high degree of uncertainty and subject to divergent technical assessments[79], as well as having a significant impact on the lives of European citizens.

There is no doubt, in fact, that European agencies, established to improve, thanks to their specialisation, the efficiency of EU action (including) in the field of health security, can be examples of legitimacy by results (complementary, at least according to part of the doctrine,

Living in a Glass House. Democracy and the Rule of Law, in *EUI Working Papers*, 2014, 25, 25; ID., *La Costituzione dell'Europa*, Bologna, 2003, 137; J.H. WEILER, U.R. HALTERN & F.C. MAYER, *European Democracy and its Critique*, in *West European Politics*, 18, 3, 1995, 4 ss.; C. JOERGES, C. GLINSKI (ed. by), *The European Crisis and the Transformation of Transnational Governance. Authoritarian Managerialism versus Democratic Governance*, Oxford, 2014; V. BOGDANOR, *Legitimacy, Accountability and Democracy in the EU, A Federal Trust Report*, 2007. Ancor prima si v. N. RONZITTI, *Elezione a suffragio universale e controllo democratico del processo di integrazione europea*, in G. ZAGREBELSKY, N. RONZITTI, A. TIZZANO, A. GIARDINA, E. VINCI (ed. by), *Parlamento europeo, forze politiche e diritti dei cittadini,* Milano, 1979, 72 ss.; A. PLIAKOS, *L'Union européenne et le Parlement européen: y a-t-il un déficit démocratique?*, in *Revue du Droit Public et de la science politique en France et a l'étranger*, 1991, 393 ss.; U. VILLANI, *Il deficit democratico nella formazione del diritto comunitario*, in DCSI, 1992, 310 ss. Regarding agencies, VON DOROTHEE FISCHER-APPELT, *Agenturen der Europäischen Gemeinschaft*, Berlin, 1999, 184 ss.

[77] V. DELHOMME, T. HERVEY, *The European Union's response to the Covid-19 crisis and (the legitimacy of) the Union's legal order*, in *Yearbook of European Law*, 41, 2022, 81, https://doi.org/10.1093/yel/yeac01.

[78] *Ivi*, 49. C. RADAELLI, *Technocracy in the European Union*, London, 1999, *https://doi.org/10.4324/9781315840932*. On technocratic politics within democratic systems, E. BERTSOU (ed. by), *The Technocratic Challenge to Democracy*, 2020.

[79] H.H. TRUTE, *Ungewissheit in der Pandemie*, in *Zeitschrift für das Gesamte Sicherheitsrecht* (GSZ), 2020, 93 ss.

to that by input from participation and representation)[80] and that, even today, the concept of democracy and, by osmosis, that of democratic deficit are far from peaceful[81].

In any case, without prejudice to the "classical" conception, according to which Parliament is, if not the sole, at least the main repository of legitimacy and democracy[82], there is now a "dissatisfaction with one-dimensional definitions of democracy"[83], which must be considered. Therefore, the possible remedies for the democratic legitimacy

[80] F. SCHARPF, *Governing in Europe. Effective and Democratic?*, OUP, Oxford, 1999; V. SCHMIDT, *Democracy and Legitimacy in the EU Rivisited: Input, Output and "Throughput"*, in *Political Studies*, 2013, 61, 2; M. CHITI, *La legittimazione per risultati dell'Unione europea quale "comunità di diritto amministrativo"*, Report at the XVII Italian-German Colloquium on Public Law, Universität Augsburg, March 2016, in *Astrid*. In a critical sense, see. J.H.H. WEILER, *In the Face of the Crisis: Input Legitimacy, Output Legitimacy and the Political Messianism of European Integration*, in *Journal of European Integration*, 2012, 34, 7, 825. About the different kinds of legitimacy in EU, see J. MENDES, *La legittimazione dell'amministrazione dell'UE tra istanze istituzionali e democratiche*, in L. DE LUCIA, B. MARCHETTI (ed. by), *L'amministrazione europea e le sue regole*, Bologna, 2021, 89 ss.

[81] L. VESNIC-ALUJEVIC, R. C. NACARINO, *The Eu and Its Democratic Deficit: Problems and (Possible) Solutions*, in *European View*, 2012, 11, 1, 63 ss., doi.org/10.1007/S12290-012-0213-7: "*The concept of democratic deficit is not univocal. In fact, the democratic deficit debate has been present in EU politics for the last 30 years*". In addition to the bibliographical references indicated in the previous notes, on the debate relating to the concept of democracy see R. DAHL, *A preface to Democratic Theory*, Chicago, 1956; P.C. SCHMITTER, T. LYNN KARL, *What democracy is... and is not*, in *Journal of democracy*, 2.3, 1991, 75; A. VON BOGDANDY, *The European Lesson for International Democracy: The Significance of Articles 9–12 EU Treaty for International Organizations*, in *EJIL*, 23, 2012, specie 322 ss.; P. SCARLATTI, *Democrazia e teoria della legittimazione nell'esperienza dell'Unione europea. Contributo a una critica del costituzionalismo multilivello*, Roma, 2010; L.M. DIEZ PICAZO, *I problemi della democrazia nei livelli non statali di governo*, in *La sostenibilità della democrazia nel XXI secolo*, M. CARTABIA, A. SIMONCINI (ed. by), Bologna, 2009, 157. On the debate related to the absence of a European *demos* see D. GRIMM, *Una costituzione per l'Europa?*, J. HABERMAS, *Una costituzione per l'Europa? Osservazioni su Dieter Grimm*, in G. ZAGREBELSKY, P.P. PORTINARO & J. LUTHER (ed. by), *Il futuro della costituzione*, Turin, 1996, 339-375. *Contra*, A. VON BOGDANDY, *The emergence of European society through public law: a Hegelian and anti-Schmittian approach*, Oxford, 2024.

[82] J.H. WEILER, *La Costituzione dell'Europa*, cit., 137.

[83] M. CHITI, *op. cit.*., 8.

deficit caused by the "delegation" of decision-making on health security to European expertise, proposed below, consider the ambiguities just mentioned.

One underlying fact remains, resulting from the recent pandemic experience: technocracy itself (as the alter ego of democracy tout court) is more vulnerable in the event of technical uncertainty. In these circumstances, in fact, technical assessments can be divergent[84], so that the risk underlying decisions increases and makes them less "legitimate", with an impact also on public (dis)confidence, unless strategies for better uncertainty management are adopted.

5.1. *A first corrective measure: strengthening the role of the European Parliament*

To correct the democratic legitimacy deficit resulting from the "agencyfication" of health security, a first corrective measure could be to strengthen the role of the European Parliament in political and institutional dynamics with European agencies operating in the sector, as well as with HERA.

Without distorting the nature of the agencies, the European Parliament could play a more incisive role in monitoring their activities by strengthening hearings (to ask for accountability for the work carried out) through committees of inquiry (on specific issues to investigate possible abuses, inefficiencies or irregularities) or in any case by involving them in mechanisms for reporting critical situations, so as to ensure more effective supervision by the Commission[85], which exercises legislative powers and is committed to pursuing the interests of the EU, pursuant to Article 17 TEU.

As regards relations with HERA, the marginalisation of Parliament when it was set up, without recourse to the ordinary legislative procedure[86], has already attracted criticism both from the institution[87] and

[84] H.H. TRUTE, *op. cit.*

[85] See J. ALBERTI, *Le agenzie dell'Unione europea*, Milan, 2018.

[86] See *supra*, para. 1.

[87] European Parliament resolution of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP)), p.

from individual MEPs belonging to different political groups[88], not least because its status as a Commission service does not allow the same level of parliamentary scrutiny (impact assessments, annual reports, audits, *ex-post* evaluations) that agencies enjoy[89]. It is therefore not surprising, and indeed should be taken seriously, that a suggestion has been made to establish parliamentary powers of control over HERA and to ensure that Members of Parliament are represented on the HERA board[90], to move beyond their current role as mere observers. In 2003, Parliament itself called for HERA to be transformed into "an independent EU agency with sufficient funding"[91] and a greater level of parliamentary control and reiterated this in 2024 when it formulated its position on pharmaceutical reform, proposing to make HERA a separate entity within the ECDC[92].

11: "*Criticises the Commission's decision to refrain from using the ordinary legislative procedure through Article 168 TFEU in setting up the new European Health Emergency Preparedness and Response Authority (HERA), thereby failing to establish it as a fully-fledged independent agency that has a mandate to protect the public interest and is subject to the same rigorous scrutiny as other EU agencies; regrets the fact that the Commission's approach, which has led to Parliament being excluded from overseeing the work of HERA, can be regarded as yet another shortcoming that has undermined transparency and accountability for public spending and decision-making in the area of public health* (…)".

[88] See the considerations of Jytte Guteland of the Social Democrats (S&D), Michel Rivasi, of the Greens, Vincenzo Sofo, of the Brothers of Italy in the ECR (Conservatives and Reformists) group reported by F. LUCA, *HERA, l'Europarlamento vuole un ruolo rafforzato nell'unità europea anticrisi. "Escluderci è antidemocratico"*, in *Eunews*, 5 October 2021.

[89] European Commission: Health Emergency Preparedness and Response Authority, Open Evidence and PwC, *Study supporting the review of the Health Preparedness and Emergency Response Authority (HERA) with regard to its operations, structure, and governance – Final report*, Publications Office of the European Union, 2025, *https://data.europa.eu/doi/10.2929/322979*, 97 and the bibliographical references indicated therein.

[90] Ivi, 93 and 98. Representatives of the ECDC, the EMA and the Emergency Response Coordination Centre and a representative of the European Parliament may, in fact, participate as observers in HERA board meetings.

[91] European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)).

[92] See also the European Commission's report to Parliament and the Council, Re-

However, the possibility of a new "guise" seems to have been ruled out by the Commission's recent review of HERA's activities[93], which does not appear to consider the possibility of additional parliamentary control powers, an aspect on which a compromise more favourable to parliamentary oversight would seem neither unjustified nor unfeasible.

5.2. *A second corrective measure: strengthening the transparency and accountability of agencies and HERA*

The European Parliament itself and some stakeholders have highlighted the need for greater transparency in the activities and governance of HERA[94], which is subject to the same transparency and accountability[95] mechanisms applicable to other Commission services, whose logic and political guidelines it follows. However, subjecting HERA to the same rules as those applicable to the Commission in terms of transparency and accountability (such as compliance with ethical standards, stakeholder involvement, internal audits and evaluation, access to documents, communication obligations, etc.) does not resolve all the critical issues.

This is demonstrated by the so-called Pfizergate scandal[96], when the EU Court annulled the European Commission's decision to deny a New York Times journalist access to text messages concerning negotiations[97] for the agreement to purchase Pfizer's COVID-19 vaccine,

view of the implementation of the operations of the Health Emergency Preparedness and Response Authority (HERA), cit.

[93] *Ibidem*.

[94] *Ibidem*.

[95] Parliament can raise issues or ensure accountability in the same way as other areas of Commission activity, as happened in the case of closed meetings with MEPs on COVID-19 vaccine negotiations.

[96] Trib. UE, Grande Chambre, 14 May 2025, C-T-36/23, Matina Stevi e The New York Times Company c. Commissione. See Z. NOWIKA, *"Von der Leyen's lost Phone: a Case for greater EU Transparency (T-36/23)"*, in *Eu Law Live*, 23 May 2025; P. Ollikainen, *Inconsistent and Imprecise Explanations: NYT v Commission, Transparency, and the Search for Lost Documents*, in *European Papers*, 10, 2025, 2, 451 ss., doi: 10.15166/2499-8249/840.

[97] For 1.8 billion doses, according to M STEVIS-GRIDNEFF, "*How Europe Sealed a Pfizer Vaccine Deal With Texts and Calls*", in *The New York Times*, April 28, 2021.

exchanged between President Ursula von der Leyen[98] and the CEO of the pharmaceutical company. The Commission had claimed that it did not have the requested documents because they had not been archived, as they lacked substantive content or were of short-lived nature. According to the Commission's internal rules[99], documents are only recorded if they contain important information that is not of short-lived nature or if they involve actions or follow-up. Indeed, as early as the beginning of 2022, the then EU Ombudsman had found evidence of "maladministration" in the Commission's actions and had unsuccessfully attempted to obtain the text messages in question, considering that they fell within the category of accessible documents[100]. The lack of an adequate response from the Commission led, as mentioned, to a dispute that attracted considerable media attention[101].

According to the EU Court, as a rule, all documents of the EU institutions should be accessible to the public, provided that, if the latter declare that they do not exist, such a statement is presumed to be true, even if it can be overturned by sufficiently credible and consistent evidence, as was the case in this instance[102]. Considering the plausible existence of the messages covered by the request for access, the Court annulled the Commission's refusal because it lacked a 'credible explanation as to why those documents could not be found' (para. 68) and the justification for their absence from the management system (para. 83) and, therefore, adopted in violation of the right to good admin-

[98] Against which, for this case, a motion of no confidence was raised –and then rejected –, proposed by the right-wing Romanian MEP Gheorghe Piperea.

[99] Commission Decision 2021/2121 on the management of documents and archives.

[100] Case 1316/2021/MIG, https://www.ombudsman.europa.eu/en/decision/it/158295.

[101] V. MALINGRE, *«Pfizergate»: la justice européenne inflige un revers à Ursula von der Leyen*, in *Le Monde*, 14 May2025; L. DUBOIS, *EU court rules against Ursula von der Leyen over missing Pfizer texts*, in *Financial Times*, 14 May 2025; P. VALENTINO, *Pfizergate, von der Leyen bocciata dal Tribunale Ue: il Nyt potrà chiedere accesso agli sms sul Covid*, in *Il Corriere della Sera*, 14 May 2025.

[102] The complainants mentioned press articles and public statements proving the existence of the documents that were the subject of the access request.

istration, provided for in Article 41 of the Charter of Fundamental Rights of the EU (CFREU).

The Commission did not appeal the judgment but merely provided a more detailed explanation for the refusal, acknowledging for the first time that a senior official had examined the messages[103], thereby admitting their existence, but then adding that they were no longer in its possession, as it considered that it was not required to keep them[104].

Meanwhile, the dispute over the issue has not been completely resolved. Belgian lobbyist Frédéric Baldan reported the case to the Liege public prosecutor's office for 'usurpation of functions and titles', 'destruction of public documents' and 'misappropriation of interests and corruption'[105]. Several associations, political parties, European citizens and some countries, such as Hungary and Poland, have joined the complaint, which has been declared inadmissible due to lack of standing to sue (as, by extension, have those who joined it)[106]. According to media reports, however, not only have Baldan and Hungary appealed to the Court of Cassation, but the European Public Prosecutor's Office (EPPO) is also conducting an investigation into the matter for "interference in public functions, destruction of text messages, corruption and conflict of interest"[107], and, furthermore, the Belgian lobbyist has even filed an additional complaint against the EPPO itself for "alleged delaying tactics"[108].

[103] The Chief of Staff of the President of the Commission.

[104] EC, Brussels, 28 luglio 2025 C(2025) 5429 final. See J. SMIALEK, *E.U. Did Not Retain Texts Sought by Journalists on Covid Vaccine Deal*, in *The New York Times*, 1° August 2025.

[105] A.S. GAYET, C. BAUER BABEF, *«Pfizergate»: audience devant un Tribunal belge sur fond de conflit de compétence avec le Parquet européen*, in *Euractiv*, 26 aprile 2024; A.S. GAYET, *Contrats Pfizer: un lobbyiste belge poursuit Ursula von der Leyen en justice*, *ivi*, 17 April 2023.

[106] P. LAWSON, *Ursulagate à l'origine de la plainte initiale contre Ursula von der Leyen. Frédéric Baldani n'exclut pas une citatio directe*, in *L-post*, 20 January 2025; ID., *Ursulagate la plainte au penal contre Ursula von der Leyen jugee irrecevable à Liege*, *ivi*, 21 January 2025.

[107] *Nuovi guai per von der Leyen: la procura europea indaga sulle sue trattative con Pfizer per i vaccini Covid*, in *La Repubblica*, 2 April 2024.

[108] The Brussels Times Newsroom, *Belgian who filed complaint against VDL files another against European Prosecutor*, 6 January 2025.

Indeed, in two previous disputes, the EU Court[109] had already overturned the European Commission's refusal to grant access to certain MEPs and private individuals to elements of vaccine purchase contracts and the contracting procedure[110], which had been published online with redactions[111].

In one of the two cases, this time, the Commission challenged the Tribunal's ruling and obtained the (rare) suspension *ex* Art. 278 TFEU of the enforcement of part of the judgment[112].

The long trail of litigation concerning transparency in health safety, which involved the Commission, certainly serves as a warning to HERA, which provides a service in this area, but also to all European agencies operating in this sector. Moreover, even the latter have not

[109] EU Court 17 July 2024, Case T-689/21, Auken & a. v Commissione e T-761/21, Courtois & a. v Commission. See A. BAEYENS, *Auken and Others v Commission, 17 July 2024 (case t-689/21) and Courtois and Others v Commission, 17 July 2024 (case t-761/21)*, in *European Journal of Health Law*, 31, 5, 557 ss., doi.org/10.1163/15718093-12423567. See E. BROSSET, *Contrats d'achats anticipés de vaccins contre la Covid-19: quelle transparence en droit de l'Union européenne?*, in *Revue des affaires européennes*, 3, 2024, 611 ss.; F. D'ORAZIO, *L'accesso alle informazioni commerciali riservate detenute dalle Istituzioni ed Agenzie europee. Una riflessione a partire dal caso dei contratti di approvvigionamento dei vaccini per il Covid-19*, in *Diritto dell'Informazione e dell'Informatica*, 2024, 6, 816 ss.

[110] Formulated pursuant to Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 on public access to European Parliament, Council and Commission documents.

[111] In the Court's view, in fact, the Commission did not demonstrate that broader access to clauses limiting or excluding liability would actually prejudice the commercial interests of pharmaceutical companies and, equally, did not sufficiently explain how access to the definitions of "dol" or "best reasonable effort" and to the contents of agreements on vaccine donations and resales could actually and specifically prejudice their commercial interests. As regards the protection of people's private lives, invoked by the Commission to deny, in part, access to the declarations of conflict of interest of the members of the team that negotiated the purchase of the vaccines, the Court of First Instance held that the applicants had demonstrated the specific purpose of the public interest in disclosing the personal data requested, to assess any conflict of interest, with the addition that only by knowing the names, the surnames and details of the professional or institutional role of the members, it would have been possible to ascertain their existence.

[112] CJEU, Order of the Vice-President, 4 February 2025, Case C-632/24 P(R), Commission v Courtois.

been immune with respect to the demand for transparency conveyed before the EU judges. The very filing of an appeal to overturn an EMA decision, which partially denied access to BioNTech's responses to a specific obligation (SO1(a)) linked to the conditional marketing authorisation for the COVID-19 vaccine, triggered a rectifying decision by the Agency[113].

[113] The EMA had disclosed the omitted documents, pursuant to Article 4(2), first para., of Regulation 1049/2001, citing the need to protect BioNTech's commercial interests and, after filing the appeal, admitted that there was no reason to omit them, because the information had already been made public in a previous communication, and then published it. On this point, then, the EU Court, IV Sec. enlarged, 19 Novembre 2025, SD v EMA, Case T-623/22, declared the matter of dispute to have ceased and in declaring the other grounds of appeal unfounded, specified that "Therefore, it is only where the particular circumstances of the case substantiate a finding that the principle of transparency is especially pressing that that principle can constitute an overriding public interest capable of prevailing over the need for protection of the commercial interests of the undertakings and, accordingly, capable of justifying the disclosure of the redacted data in the present case in accordance with the last line of Article 4(2) of Regulation No 1049/2001 (judgment of 25 March 2015, Sea Handling v Commission, T-456/13, not published, EU:T:2015:185, paragraph 101). In the case of medicinal products such as the Comirnaty vaccine, which was developed in the exceptional context of the COVID-19 pandemic, the public has a clear interest in being informed of the essential elements of the EMA's action regarding the grant of a conditional MA. However, the existence of that public interest does not oblige the EMA to grant generalised access, on the basis of Regulation No 1049/2001, to any detailed information obtained from the holder of the conditional MA in the context of such a procedure. (…) In addition, as the EMA and the interveners have argued, in the particular context of the COVID-19 pandemic, a large amount of information has been published by the EMA concerning the Comirnaty vaccine, including regular interim assessments and safety updates, which the applicant does not dispute. Measures to ensure a high degree of transparency with regard to that vaccine, including its quality, have therefore already been adopted, precisely in view of the exceptional context in which that conditional MA had been granted for that vaccine". On the subject of transparency and related exceptions, it should also be noted that, on 8 September 2025, Mylan Healthcare BV acted to annul, in whole or in part, the decision of the European Medicines Agency of 27 June 2025 (EMA/208014/2025), granting partial access to a periodic safety update report on the medicinal product Dymista (azelastine/fluticasone) to third parties, pursuant to Regulation (EC) No 1049/2001 (Case T-610/25).

By the way, notwithstanding its limited impact[114], the CJEU's "Pfizergate" ruling (preceded by the contribution of the European Ombudsman)[115] should help to strengthen civil society's call for the creation of a record-keeping system for this type of new digital 'document' (such as messaging exchanges, if made known to another public official) and the opportunity to re-examine in a contemporary light, or (even better) to update, Regulation 1041/2001 on public access to documents of the EU institutions, which is now around 25 years old, taking into account modern forms of communication[116].

In other words, there is scope for reviewing and reorganising internal working methods[117], not only of the Commission, but also of the European institutions and, even more so, of the EU agencies, given both their crucial role in health security management and the need to compensate, including through the principle of transparency, for their lack of democratic legitimacy.

Nor is this a dispute exclusively linked to the COVID-19 pandemic. After all, for example, back in 2022, the EU Court[118] had already overturned the EMA's refusal to grant a drug manufacturer access to data on the collection and fractionation system in Italy of plasma delivered by Italian suppliers, because it was based on a generic "confidentiality" of the information requested[119], without considering that the disclosure had been requested only for certain data, other than those considered subject to protection.

[114] R. ALEMANNO, *Text Messages, Transparency, and the Rule of Law Pfizergate and the Fight for Institutional Accountability*, in *Verfassungsblog,* 21 May 2025.

[115] See also the recommendations arising from the European Ombudsman's strategic initiative on recording text and instant messages (SI/4/2021/MIG).

[116] T. MANGIN, *Pfizergate: le Parlement européen se réjouit de la décision de la CJUE*, in *Euractiv*, 14 maggio 2025, "*La députée européenne libérale García Hermida-van der Walle (Renew, Pays-Bas), qui participera aux négociations sur la révision du texte, voit dans le jugement de la CJUE un levier politique. «Cette décision renforce énormément notre position dans les négociations», a-t-elle déclaré, qualifiant la décision d'«absolument juste».*".

[117] R. ALEMANNO, *op. cit*.

[118] EU Court, Sec. IV, 26 January 2022, Case T-570/20, Kedrion SpA v EMA.

[119] Data on the active ingredients of drugs and personal data obtainable from the information contained in the file and relating to inspections of supply centres.

Since COVID-19, however, the dispute on this issue seems to have changed, at least in part, in terms of its media implications and potential repercussions on civil society, if only because the cases just mentioned were not brought by commercial operators.

Moreover, the transparency of European agencies on health safety issues is not only appropriate but also necessary, considering that, in the (rejected) appeal against the rejection of the request for access submitted by some health professionals to obtain data on COVID-19 vaccines, the Italian Medicines Agency (AIFA) stated that the documents covered by the request are part of the authorisation dossier filed with the EMA, which the Italian authority does not hold[120].

When national agencies themselves state that the corresponding EU agencies are the sole holders of documents of public interest that are unavailable to them, it is inevitable that the need for transparency, as well as accountability, ends up being concentrated at EU level and requires adequate implementation (at least) there.

There is no doubt that HERA[121], like the health safety agencies, especially the EMA[122], has taken steps to increase proactive communi-

[120] Lazio Regional Administrative Court, Rome, Sec. III-*quater*, 3 August 2023, n. 13094 (not appealed).

[121] Since February 2024, for example, HERA has been publishing bimonthly newsletters and fact sheets illustrating its work. It then devised information days in all Member States and launched the HERA stakeholder hub.

[122] Consider, for example, the constant updating of the EMA website during the pandemic period and the awareness campaign on the safety and efficacy of medicines in the EU, via Twitter and LinkedIn (https://www.ema.europa.eu/en/news/working-together-safe-medicines-eu) or the social campaign #HealthNotHype, in collaboration with content creators from 7 EU countries, to promote the correct use of antidiabetic drugs, misused for weight loss. "To raise awareness about AMR, the European Centre for Disease Prevention and Control (ECDC) founded the European Antibiotic Awareness Day (EAAD) which aims to raise awareness about the threat to public health of antibiotic resistance and the importance of prudent antibiotic use. Over the years, European Antibiotic Awareness Day - marked annually on 18 November together with the World AMR Awareness Week - has developed into a platform of global reach, partnering up with many countries outside the EU as well as relevant stakeholders, in line with the Commission's "One Health" approach to AMR.

Furthermore, the Commission launched a campaign in September 2024 to promote greater awareness of AMR amongst young people and tackle AMR through a whole of society approach. The EU is also a vocal advocate of a stronger One Health

cation with external stakeholders and to raise awareness among the public through its institutional websites and social media.

However, these forms of communication do not address the issue of transparency and accountability of the work of EU agencies and HERA through access to documents as a mechanism for understanding and evaluating technocratic decision-making.

The governance structure of HERA then deserves final consideration for its innovativeness. The Board of Directors of the Authority, composed of representatives of Member States and relevant agencies, and the Consultative Forum, supported by the Civil Society Forum and the Joint Forum for Industrial Cooperation, respectively contribute to strategic planning and to ensuring the involvement of a diverse group of stakeholders in its mission.

In this way, at least on a form level, the consultative configuration thus developed shows that it does not underestimate the importance of democratic legitimacy.

However, the participatory governance underlying such a designed structure risk being more symbolic than real, if not adequately supported in terms of communication and information accessibility and/or in the absence of demonstrating concrete consideration of the input provided "from below" in the decision-making process[123].

6. *Conclusions*

The "agencyfication" of health security in Europe poses numerous challenges.

First of all, the many different "technical" authorities in the EU, which, with different legal bases, share powers for the assessment and containment of health risks, pose problems of administrative coordination.

response to the threat of AMR globally" (https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en#raising-awareness).

[123] It seems evident from the report by A. OLANDINI, T. YEUNG, *How to make HERA stakeholder engagement count*, in *CEPS*, November 13, 2025.

The persistent and harmful overlaps (especially, but not only, between HERA, the Commission itself and other agencies involved in health security, particularly with regard to vaccine supply, as well as between the HSC and the HSB in the event of an emergency) have even been highlighted by the European Court of Auditors and the European Parliament and seem to be resolvable only through careful rationalisation of the competences of HERA and other agencies.

Therefore, while until recently there were shortcomings in the competences of European agencies in the field of health security, the creation of new authorities, such as HERA, or agencies, such as HADEA, the strengthening of the mandates of existing ones and the proliferation of bodies within them, without a clear delimitation of their respective roles, is causing possible administrative interference and undermining full cooperation in this area. Indeed, the feeling is that there are too many bodies and that their rationalisation may be appropriate soon.

The very need for coordination between the numerous agencies, which would require, first and foremost, a clear framework of competences, is leading to the emergence of new working methods, such as the task force model – in particular, the "Cross-agency One Health task force framework for action 2024-2026" – there will probably be an institutionalization of this flexible mechanism and we are likely to see an increase in working groups/round tables and control rooms.

These operational and collaborative methods are necessary to overcome administrative fragmentation on the issue and to tackle some fundamental critical issues, due, for example, the different approaches to risk that, at least until now, have characterised the technical expertise of the agencies involved in assessing scientific evidence on environmental, animal and food safety, compared to those dealing with health safety "tout court", without (at least in theory) considering the "holistic" dimension of health.

The administration of health security by expertise entrusted to European agencies has also required the need to overcome one of the main critical issues that emerged during the pandemic, namely the lack of interoperable data. After all, if, as expected, the future of health safety will increasingly depend on the timely availability of standardised data, it is not difficult to imagine that their coordinated sharing –

and, therefore, "information cooperation"[124] between agencies/authorities – will prove indispensable for research, innovation, policy-making and regulation in the field of health risk prevention and management.

The need for ready availability of large data sets has also led/is leading to the emergence of numerous new digital platforms, each under the aegis of a European agency (or more than one, in collaboration).

The progressive digitisation and datafication of the healthcare sector, as well as the automation of decision-making processes, seems to have led to a new way of administering via or on platforms. The proliferation of these digital infrastructures, in addition to requiring specific attention in terms of the security of the data collected therein, seems to suffer from the same critical issues already reported, which characterise the relationships (and boundaries) between agencies/authorities in the sector, due to the lack of a completely clear framework of their respective competences. In other words, the overlapping competences between health security agencies and authorities also have an impact on the platforms available to them, leading to harmful overlaps/duplications between the digital infrastructures provided.

It should also be emphasised that coordination between EU agencies and bodies on health security cannot be reduced to an "internal" dimension alone but should also extend to the international (or rather, global) level (including WHO and WHO Europe). Yet, among the priorities for improvement, both "internal governance and coordination within the EU" and "external and multilateral governance" of health security remain, for example by strengthening international partnerships.

Following the announcement of the US withdrawal from the WHO, the global health security landscape has entered a new phase, which may redefine the EU's role at supranational level, even if, at

[124] Although referring to relationships between different territorial entities, the expression is used by A. SIMONATI, *La leale cooperazione "informativa": un principio "seminuovo" nei rapporti fra legislatore statale e regionale?*, in *Le Regioni*, 2010, 1330 ss. and by R. FUSCO, *La giustiziabilità del principio di leale cooperazione informativa tra pubbliche amministrazioni*, in *Ceridap*, 29 October 2025.

present, ambitions that are not always adequately supported in terms of resources and structures and the absence of a "single voice" for the EU on the international stage seem to constitute a significant limitation.

Finally, the challenge facing European agencies concerns the need to adjust to bridge the democratic legitimacy gap resulting from the "delegation" of decision-making to experts, given the particular interest that health security holds for European citizens.

To this end, a first corrective measure could be to strengthen the role of the European Parliament in the political and institutional dynamics with the European agencies operating in the sector, as well as with HERA. This could be achieved, first and foremost, by strengthening parliamentary oversight of the agencies through enhanced hearings, committees of inquiry or mechanisms for reporting and alerting to critical situations, as well as by establishing powers of control over HERA and allowing Members of Parliament to be represented on the HERA board, thereby moving beyond their current role as mere observers.

A second corrective measure could consist of strengthening the transparency and accountability of the agencies and HERA. There is no doubt that the latter have taken steps to improve proactive communication with external stakeholders and to raise awareness among the public through campaigns on their institutional websites and social media. However, with regard to access to documents, the litigation brought before the CJEU (particularly, but not only, in the "Pfizergate" case, which received considerable media coverage) and the contribution of the European Ombudsman reveal the need to overcome any reluctance on the part of agencies/authorities on this issue, so as to eliminate any opacity in their work. Therefore, considering technological evolution, the legislative review and reorganization of internal working methods, which guarantees transparency to a "functionalized" concept of documents, cannot be ruled out due to the institutional relevance of the content, especially if disclosed to a high-ranking public official.

Moreover, the "inclusive" structure of HERA governance (although it needs improvement, so as not to be reduced to a mere symbolic contribution or stylistic exercise), through the consultative in-

volvement of a heterogeneous group of stakeholders, shows the need not to ignore the importance of democratic legitimacy even of authority characterised by a high rate of technicality, especially if they have decision-making powers that have a significant impact on European citizenship.

The (now) formal empowerment of health security agencies and HERA, which came about with the strengthening or confirmation of their respective mandates, cannot ignore the specific issue of reputation. The role of the bureaucratic reputation of these bodies also requires transparency, which (at least in part) compensates for the deficit of democratic legitimacy, to safeguard public confidence in these institutions and ensure their credibility, including in terms of public accountability, in an area with a high collective impact, such as health security.

NOTE

While the publication of the volume was in press, on 28 November last the Commission adopted a new act relating to the construction of a "European Health Union", namely the Union's plan for the prevention, preparedness and response to health crises. The Plan reinforces the belief that agencies –in particular, ECDC and EMA– and HERA (in particular, for EU storage strategies and medical countermeasures) have a key function in health crisis governance. In implementation of the EU Regulation 2022/2371 on serious cross-border health threats, EU planning, which is in addition to state plans to be updated every three years, promotes a coordinated, data-driven, evidence-based and expert advice response to health crises, based on the "One health" approach and international collaborations.

The adoption of the plan confirms the extreme topicality of the issue and the need to pay full attention to the major health security challenges facing European agencies in their attempt to resolve them, also considering (hopefully entirely remote and hypothetical) any further pandemic events.

STEFANIA NEGRI

THE EUROPEAN UNION'S ROLE IN GLOBAL HEALTH: BUILDING A EUROPEAN HEALTH UNION WITH A GLOBAL VISION[*]

1. *The European Union and the COVID-19 pandemic response: from hesitation to protagonism*

The COVID-19 pandemic posed unprecedented challenges to the European Union (EU) and its Member States. Despite initial hesitation and criticism about the slowness of a coordinated reaction and the prevalence of autonomous decision-making at national level, a more comprehensive European response emerged within a few months, with decisions taken at EU institutional level and in intergovernmental settings. The European Union soon turned into a key player in the response to COVID-19 and its institutions became primary actors, combining short-term crisis management with mid-term policy- and law-making and long-term reforms. In the wake of the pandemic the Union also reached an unparalleled level of commitment in the field of global health law and governance, with a view to asserting its role as a leading global actor.

In order to step up the fight against the COVID-19 pandemic and

[*] This chapter builds on a previous article published in the Global Health Law Column of *The Journal of Law, Medicine and Ethics*: S. NEGRI, *The European Union as Global Health Actor: Challenges and Opportunities*, 52 JLME (2024) 755-758, available at https://www.cambridge.org/core/journals/journal-of-law-medicine-and-ethics/ article/european-union-as-a-global-health-actor-challenges-and-opportunities/9A54C89 B291EAFDCF054588D12C2897A.

future health emergencies, the EU moved along two parallel and complementary pathways, focussing on strengthening internal health resilience while simultaneously acting as a proactive, collaborative, and values-driven leader in global health security.

To strengthen the EU's health security framework, the European Commission started a wave of internal reforms and took steps to build a European Health Union "to protect the health of all European citizens", to ensure better coordination within the Union and to reinforce the crisis preparedness and response role of key EU agencies.

At the international level, the EU acted as a strong supporter of rules-based multilateralism and a key defender of the World Health Organization's central role in global health governance. Its action laid the foundations for prospective improvement of its leadership in global health at a time of profound changes in global health governance, of new geopolitical scenarios and of increasing relevance of multilateral cooperation. Beyond the diplomatic and political dimensions of EU health activism, the Union also took a proactive and engaged stance to advance global health law, both contributing to the revision of the International Health Regulations (IHR)[1], and promoting and supporting the negotiation of a Pandemic Agreement at the World Health Assembly[2].

This chapter provides an overview of the political process that has substantially changed the EU approach to emergency prevention, preparedness and response to public health emergencies, as well as the structural reforms that have supported this paradigm shift, leading to

[1] Submission of proposed amendments to the International Health Regulations (IHR) (2005), pursuant to decision WHA75(9) of the World Health Assembly, by the Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the IHR and in coordination with the European Union, and on behalf of the Member States of the European Union, A/WGIHR/2/6, 6 February 2023, at 26, available at https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_6-en.pdf.

[2] The proposal for an international treaty on pandemics was first announced by the President of the European Council, Charles Michel, in November 2020 and the EU's latest draft proposal (EU drafting suggestions, as introduced during INB 9, version of 28 March 2024, A/INB/9/3, 13 March 2024) is available at https://www.eeas.europa.eu/sites/default/files/documents/2024/INB%209_DRAFT%20revised%20negotiating%20text%20WHO%20PA%20-%20EU%20drafting%20suggestions.pdf.

the creation of the European Health Union and to the development of a new EU Global Health Strategy. It describes the building blocks of this strengthened and comprehensive European health policy and the strategic priorities of its external dimension, offering a concise picture of the EU role in global health and its contribution to global health security.

2. *Building a European Health Union with a global vision*

During the early days of the COVID-19 pandemic, Member States took unilateral measures to protect their own populations. However, those uncoordinated measures resulted in disruption of essential supply chains across the EU internal market and some of them became largely ineffective. The need for strengthened coordination in addressing public health emergencies within Europe and globally led the EU institutions to take significant steps towards more synergic collective action.

Early examples of closer collaboration at EU level were the EU Vaccines Strategy[3] and the EU COVID-19 digital certificate[4]. The Vaccines Strategy presented in June 2020 was a European success story that helped the EU to deliver vaccines saving at least 1.4 million lives in Europe. Beyond Europe, the EU and its member States became the world's largest vaccine supplier when the availability of vaccines was a question of top necessity, with over 530 million doses donated to low- and middle-income countries. The subsequent creation of the EU Digital COVID Certificate helped to reopen Europe's societies, restore business, and allowed people to resume travel safely, mov-

[3] European Commission. EU Strategy for COVID-19 vaccines, COM (2020) 245 final, 17.6. 2020, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0245.

[4] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953.

ing the EU closer to normal life. This Certificate became the global standard for mobility at international level and supported the re-opening of economic activity also at global level.

In November 2020, the European Commission elaborated the concept of a "European Health Union" (EHU)[5] based on the idea put forward by President Ursula von der Leyen in her State of the Union address[6]. Building on the lessons learnt from the first stage of the pandemic, the Commission's Communication setting out the agenda for the development of the EHU advocated the strengthening of existing structures and mechanisms for better EU level protection, prevention, preparedness and response against human health hazards. It recommended a reinforced framework for cross-border cooperation against all health threats in order to better protect lives and the internal market as well as to maintain the highest standards in the protection of human rights and civil liberties. It also aimed to strengthen the EU role in international coordination and cooperation to prevent and control cross-border health threats and improve global health security.

In accordance with the Commission's vision, building the EHU would meet the need for a stronger health security framework to pursue the triple objective of better protecting the health of European citizens, addressing future pandemics more effectively, and improving the resilience of health systems. To translate this vision into practice, the Commission took steps to start a wave of reforms which revamped the EU legal, policy and institutional framework.

In 2021, the Commission set up the Health Emergency Preparedness and Response Authority (HERA), a new Directorate-General established within the structure of the European Commission, whose core mission is to strengthen the development, manufacturing, procurement, and equitable distribution of critical medical countermeas-

[5] European Commission. Building a European Health Union: Reinforcing the EU's Resilience for Cross-Border Health Threats, COM (2020) 724 final, 11.11. 2020, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0724. See S. GALLINA, *Preparing Europe for Future Health Threats and Crises: The European Health Union*, Euro Surveillance, (2023) 28(5):2300066, 1-3; V.P. ANDRIUKAITIS, G.A. CERNIAUSKAS, eds., *European Health Union: A Blueprint for Generations* (Vilnius: Foundation for Progressive European Studies, 2023).

[6] Available at https://state-of-the-union.ec.europa.eu/state-union-2020_en.

ures in order to address vulnerabilities in times of PHEs[7]. HERA thus plays a critical role in anticipating risks, securing medical countermeasures and coordinating pandemic preparedness and response actions internally as well as with international partners. Amid ongoing geopolitical shifts and reductions in global health financing, its mandate is increasingly important[8].

In 2022 and 2023, the adoption of a set of legislative proposals added other complementary pillars to the EHU building process.

In order to further contribute to guaranteeing prompt and equitable access to medical countermeasures, the Commission launched a revised Pharmaceutical Strategy[9] through the adoption of a proposed new directive and regulation, both meant to replace and revise the existing general pharmaceutical legislation. To make medicines more available, affordable, and innovative within the Union by promoting a high level of quality, efficacy and safety standards, the new strategy aims to support the competitiveness and leadership of the European pharmaceutical industry in the world. It builds on four key pillars: ad-

[7] Commission Decision establishing the Health Emergency Preparedness and Response Authority, C (2021) 6712 final, 16.9.2021, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021D0929(02); see also Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, C (2021) 576 final, 16.9.2021, available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021DC0576.

[8] M. ANDERSON, R. FORMAN, E. MASSIALOS, *Navigating the role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and beyond*, 9 The Lancet Regional Health Europe, October 2021, 100203; O.J. WOUTERS, R. FORMAN, M. ANDERSON, E. MASSIALOS, M. MCKEE, *The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness?*, *133 Health Policy*, July 2023, 104844.

[9] European Commission. Pharmaceutical Strategy for Europe, COM (2020) 761 final, 25.11.2020, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761. On 26 April 2023 the Commission adopted a proposal for a new Directive and a new Regulation which revise and replace the existing general pharmaceutical legislation. See at https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en.

dress unmet medical needs and ensure access to affordable medicines to patients throughout Europe; support competitiveness, innovation and sustainability; ensure diversified and secure supply chains to cope with medicine shortages; make the EU voice in the world even stronger.

This Strategy is complemented by the proposed Critical Medicines Act[10], which aligns with its objectives of increasing access to medicines, improving security of supply, and addressing shortages, whilst giving due consideration to the affordability of medicinal products. It complements the main provisions on the availability and security of supply of medicinal products as proposed in the new pharmaceutical legislation. While the revised EU pharmaceutical framework strengthens obligations for marketing authorisation holders to prevent shortages and introduces EU coordinated actions to mitigate critical shortages, this proposed Regulation creates the necessary conditions – investments, procurement coordination – to proactively reduce dependencies and strengthen EU production capacity. It also builds on the extended mandate of the European Medicines Agency (EMA), the launch of the European Shortages Monitoring Platform – which requires national authorities and companies that market their medicines in the EU to directly report information on supply, demand and availability of authorised medicines – and the Union List of Critical Medicines – which helps to identify critical medicines and vulnerabilities in their supply chains, so that Member States are better prepared. Considered as a whole, the EU pharmaceutical reform aims to strengthen coordination at EU level to monitor, report and manage medicine shortages, providing an updated regulatory approach which combines stronger obligations with new incentives and assistance for companies to make the EU more attractive for the pharma industry and to encourage it to invest and innovate.

As mentioned above, EMA's mandate was strengthened in parallel

[10] European Commission. Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, COM (2025) 102 final, 11.3. 2025, available at https://health.ec.europa.eu/publications/proposal-critical-medicines-act_en.

with the mandate of the European Centre for Disease Prevention and Control (ECDC) in order to enable key EU Agencies to reinforce their role in crisis preparedness and response. On the one hand, Regulation 2022/213[11] broadened EMA's functions to improve prevention, preparedness for, coordination and management of the impact of PHEs on medicinal products and medical devices, including precisely the monitoring of medicine shortages. In the same wake, Regulation 2022/2072[12] set out a framework of measures to be activated in the event of a PHE – including setting up a Health Crisis Board, deploying emergency funding and implementing emergency research and innovation plans – so as to enable the EU to take the necessary measures for a sufficient and timely availability and supply of crisis-relevant medical countermeasures. On the other hand, Regulation 2022/2370[13] strengthened the mandate of the ECDC granting it expanded powers to better detect, assess, and respond to cross-border health threats, to provide stronger evidence-based recommendations to guide public health measures, and to reinforce cooperation and coordination with Member States and international bodies. Most interestingly, Regulation 2022/2370 expanded the ECDC's international role, establishing clear procedures for cooperation with the public health actors in third countries and international organisations, first and foremost the WHO, thus contributing to the Union's commitment to reinforcing

[11] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123. *See* E. COOKE, 'Preparing Europe for Future Health Threats and Crises — The European Medicines Agency; Ensuring Safe and Effective Medicines and Medical Devices', Euro Surveillance, (2022) 27(42):2200798, 1-4.

[12] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, OJ L 314, 6.12.2022, available at https://eur-lex.europa.eu/eli/reg/2022/2372/oj/eng.

[13] Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control, OJ L 314, 6.12.2022, available at https://eur-lex.europa.eu/eli/reg/2022/2370/oj/eng.

partners' preparedness and response capacities, including third countries' capacities under the International Health Regulations. As a result of this reform, ECDC is now a key player in public health outside of EU borders and building on its reinforced mandate it will contribute even more actively to EU's international cooperation and global health security preparedness.

The key role of ECDC is also reflected in Regulation 2022/2371 reforming the legal framework related to serious cross-border health threats[14]. Repealing Decision 2013/1082, this Regulation introduced new and strengthened rules based on a robust preparedness planning, a more integrated surveillance system and a better capacity for risk assessment and targeted response. The Centre's functions under this Regulation include monitoring and evaluating epidemiological surveillance; providing rapid risk assessments and non-binding science-based recommendations on management and control measures for communicable diseases; triggering alerts in the Early Warning and Response System; supporting the Health Security Committee in coordinating responses at EU level; assessment of the state of implementation of national prevention, preparedness and response plans and their consistency with the Union's plan[15] (an additional novelty introduced by the Regulation); responsibility for conducting Public Health Emergency Preparedness Assessments within States.

Especially noteworthy is also the new power that Regulation 2022/2371 confers on the Commission to recognise a PHE at Union level – after considering the expert opinion of the ECDC or of any other relevant agency and after informing the WHO. Such a declaration triggers increased coordination and activate the emergency framework for ensuring the supply of crisis-relevant medical counter-

[14] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, OJ L 314, 6.12.2022, available at https://eur-lex.europa.eu/eli/reg/2022/2371/oj/eng.

[15] *See* Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Introducing the Union prevention, preparedness and response plan for health crises, COM (2025) 745 final, 28.11.2025, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0745.

measures[16]. It may however raise concerns about the coherence of the global health governance framework and the necessary coordination between global and regional systems notwithstanding the EU's substantial independence from WHO action. In fact, the close collaboration between the Commission and EU relevant agencies with the WHO Regional Office for Europe (WHO Europe) is reassuring[17]. In particular, the long-standing partnership between the Commission and WHO Europe bears witness to their joint commitment to align global and regional policies on health emergencies, particularly within the EU Global Health Strategy. Strategic collaboration between the ECDC and WHO Europe provides further evidence of coordination in prevention, preparedness and response to public health emergencies. This vital partnership is progressively advanced and upgraded by new bilateral agreements aimed to fulfil the common mission of strengthening health security across Europe[18].

[16] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, OJ L 314, 6.12.2022, available at https://eur-lex.europa.eu/eli/reg/2022/2372/oj.

[17] See, inter alia, *Joint Statement of the European Commission and the WHO Regional Office for Europe*, November 2020, available at https://health.ec.europa.eu/system/files/2020-11/2020_who_euro_cooperation_en_0.pdf; *Partners for health in the WHO European Region*, at https://www.who.int/europe/about-us/partnerships/the-eu-and-who-partners-for-global-health/partners-for-health-in-the-who-european-region; *WHO/Europe and the European Commission to bolster cooperation*, Press Release, 6 February 2024, at https://www.who.int/europe/news/item/06-02-2024-who-europe-and-the-european-commission-to-bolster-cooperation.

[18] See for example the renewed Memorandum of Understanding signed between ECDC and WHO Europe on 29 January 2026, reinforcing cooperation on joint missions, scientific advice, surveillance and data exchange. See Press Release at https://www.ecdc.europa.eu/en/news-events/ecdc-and-whoeurope-renew-joint-commitment-strengthen-european-health-security-and.

3. *The new EU Global Health Strategy: bridging EU internal and external health policies for better global health security*

The new EU Global Health Strategy emerged in the wake of the COVID-19 pandemic to add a global dimension to efforts towards improving public health within the EU. With the European Health Union's internal capacities substantially boosted by the first round of reforms, in May 2022 the EU institutions started reflecting on how to leverage the Union's contribution to global health security and to strengthen its external action accordingly[19].

Heralded at the G7 Health Ministerial meeting in Berlin by Commissioners Kyriakides and Urpilainen, a new EU Global Health Strategy (GHS)[20] was adopted on 30 November 2022 to encapsulate the Commission's new vision of the EU role in global health and to design a robust external dimension of the EHU "rooted in the universal values of human rights, equity, solidarity and cooperation"[21]. The GHS relaunched the EU's global health agenda and positioned health as an essential pillar of EU external policy, with a view to shaping a "new global health order" while promoting and sharing EU values and guiding principles.

A cornerstone of the Global Gateway strategy[22], the GHS serves as a roadmap to guide the Union's action in the field of global health until 2030. The Strategy sets three major priorities: deliver better health throughout life, strengthen health systems and advance towards universal health coverage, and prevent and combat health threats applying a One Health approach. To successfully achieve them, it outlines

[19] L. BENGTSSON, *The New EU Global Health Strategy: Reflections on Context and Content*, European Policy Analysis, August 2022, 1-18, at 2, available at https://www.sieps.se/globalassets/publikationer/2022/2022_15epa.pdf.

[20] European Commission. EU Global Health Strategy – Better Health for All in a Changing World, 30.11.2022, available at https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en.

[21] Statement by Commissioners Stella Kyriakides and Jutta Urpilainen, 'Towards a new EU Global Health Strategy', Brussels, 19 May 2022, at https://ec.europa.eu/commission/presscorner/detail/en/statement_22_3128.

[22] See at https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en.

twenty guiding principles and defines concrete lines of action related to each of them. It also creates a new permanent monitoring mechanism to assess progress and ensure the accountability of the EU's global health action.

The Strategy highlights the importance of stronger international rules and cooperation mechanisms, with the reinforced role of the WHO at its core and the alignment of EU and WHO priorities as a primary concern. The GHS calls for ensuring a stronger EU role in international organizations – first and foremost the WHO – and for strengthening engagement with key global health stakeholders[23]. It positions the EU as a global health leader that is capable of driving international cooperation in health through equal-footing partnerships guided by shared values and common policy priorities. In sum, the Strategy requires the EU to fill existing gaps in global governance, avoid duplication of efforts and ensure complementarity and coherence of action in the multilateral health system, expanding equitable and mutually-beneficial bilateral, regional, trans-regional and global partnerships. In fact, the Strategy should ensure coherence between domestic and international EU action on health, overcoming the division between internal and external policies, and it does so to some extent by recognising that health developments in the EU affect partners across the world and vice versa.

The Global Health Strategy has been widely welcomed, albeit tempered by caution and some criticism. *The Lancet* published an expert assessment that considers the Strategy a step forward on which to build a shared vision of global health, its governance and challenges within and outside the EU, despite certain shortcomings and criticalities[24]. According to these experts, to make the Global Health Strategy a truly transformative tool, funding and implementation will be key to

[23] Beyond WHO and the WHO Regional Office for Europe, the EU works closely with the G7, G20, the Global Health Security Initiative and other global, regional and bilateral partners. However, it is not a member of the Global Health Security Agenda.

[24] M. Mckee Et Al., *The EU has a global health strategy: the challenge will be in the implementation*, The Lancet, Volume 402, Issue 10407, September 23, 2023, available at https://www.thelancet.com/journals/lancet/issue/vol402no10407/PIIS0140-6736(23)X0038-5.

translating its ambitious commitments into concrete actions. The ambitions of the EU's new strategy must be accompanied by a scale-up of its global health funding, through both bilateral funding and support to global health multilateral initiatives, as well as an increase of global health-related R&I investments under Horizon Europe and the EU4Health programme 2021-2027. Accountability will also play a key role but a robust monitoring and evaluation framework needs measurable, relevant indicators that allow for regular reporting on progress.

Indeed, as Kickbuch and Pérez-Canado observe, "[e]arly achievements demonstrate the [EU Global Health] strategy's potential, but important challenges lie ahead in fulfilling it"[25]. As emphasized by the Council of the European Union in its conclusions on the GHS, the EU and its Member States should "seize the opportunity to strengthen their impact as a global and regional actor to contribute concretely and measurably to a healthier and safer world" [26].

4. *Concluding remarks*

The COVID-19 pandemic was a trigger event for a change in approach and trajectory in pandemic prevention, preparedness and response worldwide. In Europe, it set off profound structural changes to the European Union's health architecture, with a wave of reforms to EU health legislation gaining increasing momentum. The EU's internal and external response to the pandemic describes how the EU engaged in coordinated joined-up actions at home and on the global stage. Building a stronger European Health Union to protect the health of Europeans and developing a new EU Global Health Strategy to contribute to global health security were the pillars of the new vision put forward by the European Commission.

In the wake of the pandemic the Union has progressively rein-

[25] I. KICKBUSCH I., F. PÉREZ-CAÑADO, *The EU Global Health Strategy, One Year On. Early Achievements and Challenges Ahead*, Think Global Health, 12 December 2023, at https://www.thinkglobalhealth.org/article/eu-global-health-strategy-one-year.

[26] Council of the European Union. EU Global Health Strategy – Better health for all in a changing world - Council conclusions, 29.1.2024, available at https://data.consilium.europa.eu/doc/document/ST-5908-2024-INIT/en/pdf.

forced its leadership in global health security by adopting a more proactive and cooperative approach to preparedness and response. However, the successful implementation of this new paradigm requires an innovative, integrated, coordinated and evidence-based approach, as well as new and different ways of thinking and working. Most of all, it necessitates coherence in domestic and international EU actions, coherence and consistency (along with defragmentation) between global and EU legal/regulatory frameworks, convergence of EU and global goals and priorities, coherent behaviour in global affairs and in global health diplomacy, a fair balance between protection of European domestic interests and the EU ambition to be perceived as a multilateral reliable partner. Last but not least, it demands synergic collective action to overcome confrontation/collision between universal and regional systems, especially in case of a declared PHEs of both international and regional concern (something that is currently being put to the test in another geographical context, following the WHO declaration of monkeypox as a "public health emergency of international concern" under the IHR and the declaration of "public health emergency of continental security" issued by the Africa Centers for Disease Control and Prevention).

Overall, the European response to the pandemic offered the opportunity to reflect on the EU role in the global legal order and within the current political scenario. Recent events pushing towards international disorder prompt fresh discussion over the Union's positioning within the new global health architecture, its capacity and willingness to fill the leadership gap left by the United States' withdrawal from the WHO, and the success of its strategic partnerships with other emerging global health actors.

ENZA ROMANO

THE EUROPEAN LEGAL FRAMEWORK FOR HEALTH SAFETY AND THE ENHANCEMENT OF THE ROLE OF THE EUROPEAN MEDICINES AGENCY (EMA)

1. *Introduction*

This paper aims to reconstruct the European Union's regulatory framework on health security[1].

The paper is divided into two parts. The first examines European health security regulations with a view to preventing and combating health crises. The second focuses on developments in pharmaceutical legislation to meet the demand for new drugs or vaccines, with a particular focus on strengthening the role of the EMA in coordinating activities at the level of the European Union.

[1] S. TRANQUILLI, *Nobody saves himself alone: who decides on health security in the European Union?*, in *Federalismi.it*, 12, 2023, 270 ss.

The paper also analyses proposals for legislative reform and the prospects for the evolution of legislation in this field [2].

Efforts to protect and prevent health and safety issues, and the challenges of protecting public health, are in the collective public interest and have an international dimension[3]. However, while the European Union's intervention in this area complies with international law and practice, it can also rely on more decisive intervention powers[4].

2. *The European Union's competence in health safety*

The EU exercises complementary competence in public health,

[2] M. GNES, A. MAGLIARI, *Rassegne - cronache europee 2021-2022*, in *Riv. trim. dir. pubb.*, 2023, 1367, according to which "*Per quanto riguarda l'assetto istituzionale dell'Unione, è da segnalare lo sviluppo di una politica europea in materia di salute, annunciata dalla presidente della Commissione von der Leyen nel suo discorso sullo stato dell'Unione 2021 con lo scopo di garantire un livello elevato di protezione della salute umana, quale definito nella Carta dei diritti fondamentali dell'Unione europea. Due sono i pilastri su cui poggia: il primo è la preparazione alle crisi sanitarie e il secondo la terapia e la fase post-cure per malattie come il cancro. La strategia europea segue i principi One Health, basato sul riconoscimento della stretta interconnessione tra salute umana, animale e ambientale.*".

[3] See S. NEGRI, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale*, Turin, 2018, 19, according to which "*Garantire la sicurezza sanitaria e la tutela della salute pubblica a livello globale rappresenta oggi una delle sfide più impegnative che la comunità internazionale debba affrontare. Di fronte alla gravità delle emergenze sanitarie che hanno segnato l'inizio del nuovo secolo – SARS, influenza aviaria, pandemia influenzale A/H1N1, epidemie di Ebola e Zika, sindrome respiratoria mediorientale – alla progressiva diffusione delle malattie croniche e non trasmissibili, ed al problema emergente della resistenza antimicrobica 2, non si pu non riconoscere nella tutela della salute pubblica un interesse collettivo prioritario".* And "*sembra invece indiscutibile il fatto che uno degli effetti più evidenti della globalizzazione sia sicuramente il pericolo di accelerazione del contagio. Com'è noto, infatti, l'elevato ritmo di circolazione delle persone e delle merci, indotto dalla globalizzazione, ha favorito una moltiplicazione esponenziale del rischio sanitario e reso sempre più difficile prevenire e controllare la diffusione delle malattie infettive, soprattutto di quelle patologie che presentano un potenziale epidemico tale da mettere in serio pericolo la salute pubblica mondiale*".

[4] See G. DI FEDERICO, S. NEGRI, *Unione europea e salute. Principi, azioni, diritti e sicurezza*, Padua, 2019, 17.

meaning it supplements national policies. The EU supports, coordinates and complements the legislative actions of Member States[5].

The most relevant provisions are Article 168 TFEU and Article 114 TFEU[6].

According to Article 168 TFEU, "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their caus-*

[5] On health protection in the European Union legal system and the division of powers between Member States and the EU, see G. DI FEDERICO, S. NEGRI, *Unione europea e salute. Principi, azioni, diritti e sicurezza*, cit., 17 ss. See also P. DE PASQUALE, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19*, in *DPCE online*, 2, 2020, 2295, which highlights that "poco chiaro è il riparto di competenze tra i due livelli, soprattutto a causa delle forti resistenze degli Stati a cedere sovranità in tale settore". Cfr. F. BESTAGNO, *La tutela della salute tra competenze dell'Unione europea e degli Stati membri*, in *Studi sull'integrazione europea*, 2, 2017, 317 ss.; B. DE WITTE, *Les competénces exclusives des Ètats members existentelles?*, in AA. VV*, Liber Amicorum Antonio Tizzano. De la Cour CECA à la Cour de l'Union: le long parcours de la justice européenne*, Torino, 2018, 306.

[6] D.G. RINOLDI, '*In deroga… e in conformità': prospettive dell'Unione europea della salute muovendo dall'art. 168 TFUE*, in *Corti supreme e salute*, 1, 2022, 276, points out that "*Il TFUE si occupa di sanità pubblica specificatamente ed estesamente nel sopra considerato art. 168 (cui è collegata l'annessa Dichiarazione n. 32, sugli standard elevati di qualità e sicurezza circa i quali dispone proprio il par. 4 dell'art. 168 da cui il nostro ragionamento è partito), mentre tracce diffuse su tale contesto organizzativo sono presenti nello stesso Trattato – oltre che nell'art. 4.2, lett. k) (già visto) – anche negli artt. 45.3 (limitazione alla circolazione dei lavoratori giustificabile fra l'altro per ragioni di sanità pubblica); 52.1 (regime particolare per cittadini di Paesi terzi giustificabile pure da motivi di sanità pubblica); 114.3 e 114.8 (ravvicinamento delle legislazioni statuali per necessità del mercato interno da fondare tra l'altro su un livello elevato di protezione in materia di sanità); 202 (rapporto fra regole sulla pubblica sanità e circolazione dei lavoratori); 207.4 lett. b) (azione esterna dell'UE e accordi in materia, fra le altre, nel settore della sanità)".*

Other relevant provisions are Article 196 TFEU and the Union's civil protection system, as well as Article 222 TFEU, for which reference should be made to the discussion by P. DE PASQUALE, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19*, cit., 2300.

es, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention" [7].

The European Union's shared competence[8] can only and exclusively be referred to in relation to paragraph 4 of Article 168 TFEU, which refers to Article 4 TFEU, paragraph 2, letter K,[9] according to which "*By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures; (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; (c) measures setting high standards of quality and safety for medicinal products and devices for medical use*". Furthermore, "*The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the*

[7] For further information, please refer to the essay by G. STRAZZA, *The challenges facing European agencies in health security,* in this book.

[8] Article 4 TFEU, which in paragraph 2(k) mentions "*common safety concerns in the field of public health*" among the areas of shared competence, although limited to the aspects expressly defined in the Treaty.

[9] D.G. RINOLDI, '*In deroga… e in conformità': prospettive dell'Unione europea della salute muovendo dall'art. 168 TFUE*, cit., 274.

abuse of alcohol, excluding any harmonization of the laws and regulations of the Member States".

Therefore, in general, in the field of public health, the European Union exercises supporting competence with respect to that of the Member States[10]. However, specifically in the field of health security, the European Union exercises shared competence, which allows it to take action to prevent and combat major health threats with a cross-border or international impact, such as pandemics or bioterrorism[11].

3. *The European legal framework for health security*

The pandemic period marked an important change in the European Union's regulatory framework for health security[12].

The health protection sector has undergone a process of evolution in relation to preparedness and response to cross-border health crises,

[10] D.G. RINOLDI, *'In deroga… e in conformità': prospettive dell'Unione europea della salute muovendo dall'art. 168 TFUE*, cit., 276: "*l'art. 168 TFUE in materia di sanità pubblica potrebbe essere oggetto di un'iniziativa di cooperazione rafforzata – magari promossa proprio dall'Italia – per portare sotto competenza concorrente fra UE e Stati membri l'intero ambito di intervento regolato dal Titolo XIV TFUE, che ora applica le modalità di tale competenza limitatamente ai settori – sopraddetti –. di cui al par. 4 della norma*".

[11] P. DE PASQUALE, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19*, cit., 2296.

[12] L. TORCHIA, *Le crisi fanno bene all'Unione europea: il caso dei piani nazionali di ripresa e resilienza*, in *Riv. trim. dir. pubbl.*, 2023, 577 ss.; S. FABBRINI, *Sdoppiamento. Una prospettiva nuova per l'Europa*, Roma-Bari, 2017, 52 ss. L. PARONA, *Il rafforzamento e la centralizzazione della committenza pubblica europea: il ruolo della commissione*, in Riv. trim. dir. pubbl., 2024, 1076, note 1 for bibliographical references. The European Union's response to the Covid-19 pandemic lacked generalized coordination measures on the most critical health issues, both because the Member States '*expressed, at least initially, a clear desire to manage the health crisis autonomously*' and because the tools available to the Union were limited. See P. DE PASQUALE, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19*, cit., 2306. It is no coincidence that the regulatory measures taken after the pandemic were aimed at coordinating the actions of the various Member States and creating new entities capable of ensuring this coordination at a central level.

characterized initially by emergency measures and subsequently by more comprehensive and systematic legislative responses.

Coordination at European Union level on health security is not only aimed at protecting competition and the market but also serves to ensure a high level of human health protection[13].

In the field of health security, Decision No 2119/98/EC[14] of the European Parliament and of the Council established a network for the epidemiological surveillance and control of communicable diseases. Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council[15] to strengthen and provide a more coordinated and comprehensive approach to health security at Union level.

The implementation of that Decision has confirmed that coordinated Union action on monitoring, early warning and combating such threats contributes to the protection and improvement of human health.

The COVID-19 pandemic has highlighted the need to further strengthen the European Union's competences in the field of planning for the prevention, preparedness and response to cross-border health crises and threats.

Experience gained during the pandemic has demonstrated the need for the Union to take further and more decisive action to support cooperation and coordination between Member States.

A health crisis can have a significant impact on a country's healthcare system and consumes most of its care capacity. Therefore, it

[13] G. DI FEDERICO, S. NEGRI, *Unione europea e salute. Principi, azioni, diritti e sicurezza*, cit., 27, argues that "*poiché la tutela della salute costituisce un obiettivo che permea tutte le politiche dell'Unione, l'azione delle istituzioni non riguarda solo l'esercizio delle libertà economiche. Invero, se la prevenzione e l'accesso a cure mediche di qualità costituiscono un diritto fondamentale dei singoli, pare legittimo prendere in considerazione anche le basi giuridiche in materia di non discriminazione, cittadinanza e di immigrazione.*".

[14] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

[15] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

is crucial to implement tools for the prevention and management of health crises that ensure the continuity of care and an adequate medical and pharmacological response to the event.

Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/ 2013/EU[16], which plays a crucial role in the EU's health security framework and helps countries to collaborate, prepare and respond effectively to health threats.

The requirements of the Regulation are based on the 'One Health' approach: a multi-sectoral approach that recognizes that human health is linked to animal health and the environment and that actions to address health threats must take these three dimensions into account.

The scope of the Regulation extends to public health measures addressing health threats arising mainly from communicable diseases, antimicrobial resistance, biotoxins, chemical and environmental threats and, in general, events that can be defined as "public health emergencies". The aim of the Regulation is to establish a coordinated response between Member States to deal with "serious" cross-border health threats, i.e. those that go beyond national borders.

In summary, the Regulation lays down rules concerning: the Health Security Committee (HSC); prevention, preparedness and re-

[16] The strengthened Union health framework for responding to serious cross-border health threats must work in synergy with and complement other Union policies and funds, such as actions implemented under the 'EU4Health' programme (EU4Health) programme, established by Regulation (EU) 2021/522 of the European Parliament and of the Council; the European Structural and Investment Funds (ESI Funds), namely the European Regional Development Fund and the Cohesion Fund, established by Regulation (EU) 2021/1058 of the European Parliament and of the Council; the European Social Fund Plus, established by Regulation EU; the Emergency Support Instrument (ESI), referred to in Regulation (EU) 2016/369 of the Council; and the Single Market Programme, established by Regulation (EU) 2021/690 of the European Parliament and of the Council. (EU) 2021/1057 of the European Parliament and of the Council, the European Agricultural Fund for Rural Development, established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council, and the European Maritime, Fisheries and Aquaculture Fund, established by Regulation (EU) 2021/1139 of the European Parliament and of the Council; the Horizon Europe programme, established by Regulation (EU) 2021/695 of the European Parliament and of the Council.

sponse planning, including preparedness plans at Union and national level as well as reports and assessments of preparedness at national level; joint procurement of medical countermeasures; emergency research and innovation; epidemiological surveillance and monitoring; the epidemiological surveillance network; the rapid alert and response system (RARS); risk assessment; response coordination; and the recognition of a public health emergency at Union level (Article 1 – Subject matter).

"*Anticipate*", "*respond*" and "*recover*" are the key steps that the Union intends to coordinate in relation to a health emergency so that each Member State involved could prepare an appropriate response to the crisis.

4. *The Health Security Committee (HSC)*

In the architecture outlined by the Regulation, the Health Security Committee (HSC), formally established by Decision No 1082/2013/EU, is the main player, which must be able to ensure central coordination of actions and implementation of the measures provided for.

The HSC is composed of representatives of the Member States divided into two working levels[17]: (a) a high-level working group responsible for holding regular discussions on serious cross-border health threats and adopting opinions and guidance as referred to in paragraph 3(d); (b) various technical working groups responsible for discussing specific issues as necessary.

The senior level group shall create a general working group to discuss general technical and operational issues linked to serious cross-border threats to health. The terms of reference of the general working group shall be defined by the senior level group.

The Working Groups are: General Working Group; Technical Working Group on Preparedness (TWG PREP); Technical Working Group on Threat Detection and Early Warning and Response System

[17] See "*Rules of procedure for the Health Security Committee*".

(TWG EWRS); Technical Working Group on Civil-Military Cooperation on Health Security Preparedness (TWG CIV/MIL).

The question remains as to the powers of the HSC in the context of European health security and, above all, its actual usefulness, especially given the number of entities (agencies, task forces, the Commission, the ECDC) that could also have been entrusted with the same tasks.

The reason for its establishment probably lies in the desire to create a body with a high level of technical expertise and specialization in the field, capable of coordinating with other bodies involved in the prevention and response to health crises. In fact, the HSC is required to coordinate the actions of the various bodies.

However, the CSS sometimes also includes the health ministers of the Member States (as in the case of Italy), which are political bodies, for which there is no guarantee of specialization in the sector in the strict sense.

In any case, the idea of strengthening the role of a body with specific expertise in the sector is a legislative solution that can have favorable repercussions in practical and applicative terms.

The Health Security Committee, which brings together national authorities, focuses, for example, on the importance of sharing data and methods to increase the uptake of vaccines.

The HSC carries out its tasks "in agreement" and "in liaison" with the Commission.

The European Parliament appoints a technical representative to participate in the HSC as an observer.

The HSC has adopted several acts since its establishment, for example: Opinion of the Health Security Committee on rapidly increasing incidence of carbapenem-resistant Enterobacterales (CRE) in healthcare settings (13 May 2025); Opinion of the Health Security Committee on Sexually Transmitted Infections (29 November 2024); Opinion of the Health Security Committee on zoonotic avian influenza (19 December 2023).

5. *The Union prevention, preparedness and response plan for health crises*

Strategic planning for the prevention of and response to cross-border health crises is organized at two levels: central and national.

The Regulation provides for the development of a new European Union plan for the preparation of health crises and pandemics, including recommendations and provisions for the exchange of information between the European Union and its Member States.

EU countries are also encouraged to develop national plans with the support of the European Centre for Disease Prevention and Control (ECDC) and other European agencies.

The European plan aims to coordinate the various Member States' efforts in preventing and managing crises. The objective is to improve preparedness and strengthen capacity for coordinated responses to health crises across the EU.

The European Union's strategy in this area draws on the governance, capabilities, and resources of each Member State, which are to be monitored and coordinated.

The Regulation provides for the Commission, in collaboration with Member States and, where appropriate, relevant Union agencies, bodies or international organizations, to organize stress tests, simulation exercises and reviews with Member States during and after actions, and to update the plan as necessary.

Furthermore, at the request of Member States, the Commission shall provide support for the development of personnel plans to address specific healthcare needs and facilitate the exchange of personnel between Member States in the event of a serious cross-border health threat (Article 5(6)).

The ECDC carries out a triennial assessment of prevention, preparedness and response planning, evaluating the implementation of national plans in relation to the Union plan.

In accordance with Article 5 of the EU Regulation on serious cross-border threats to health, on 28 November 2025 the Union plan for the prevention, preparedness and response to health crises was drawn up.

As stated in Commission staff working document of 28.11.2025[18] "*The Union plan is structured around the different phases of the health crisis management cycle, a comprehensive framework that guides preparation for, management of and recovery from health crises in the EU (see Figure 3). The cycle consists of four interconnected phases: Prevention & Preparedness; Detection & Assessment; Response; and Recovery. Each phase builds on the previous one, creating a continuous process that strengthens the EU's ability to protect public health and respond effectively to emerging threats*"[19] (…)

[18] Accompanying the document communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions introducing the union prevention, preparedness and response plan for health crises.

[19] "*The Prevention and Preparedness phase focuses on reducing the risk of health crises before they occur. This involves building response capacities and resources to strengthen the resilience of the health systems by ensuring a skilled health workforce, investing in health infrastructure, ensuring continuous access and availability of medicines and other MCMs, and in developing national prevention, preparedness, and response plans. The Commission and EU agencies and bodies work closely with Member States to assess their readiness, identify gaps, and support improvements in their capacity to manage cross-border health threats. Moreover, the EU joint arrangements provide additional support for the prevention of health threats such as EUHTF support for planning and EU training for the health workforce. The Detection & Assessment phase involves identifying potential health threats early, assessing their risks and determining the appropriate level of response. This phase relies on public health intelligence on health threats performed by the Member States, the Commission and the EU agencies and bodies according to their mandates. Member States and the Commission are responsible for alerting events through early warning systems to trigger a response. Risk assessments and intelligence gathering conducted at national or EU level help us understand the type, likelihood and severity of the threat. This allows the EU and Member States to take informed, necessary and proportionate action. The Response phase is vital to prevent an escalation of an event and to mitigate the impacts of a health crisis by coordinating actions across the EU, mobilising capacities and resources, and supporting affected countries. The Member States, relevant EU agencies and bodies and the Commission coordinate their actions, among others, in the Health Security Committee, in the HERA Board and under the Union Civil Protection Mechanism, if activated. In major or complex crises, the Council is responsible for the overall cross-sectoral coordination of responses with the activation of the Integrated Political Crisis Response arrangements. These joint arrangements for governance enable information exchange, consultation, coordination and adoption of advice, guidance and recommendations based on which the stakeholders im-*

6. *Different actors and efforts to coordinate Member States' actions*

The Commission, the relevant Union agencies and the Member States shall consult each other within the HSC to coordinate their efforts to develop, strengthen and maintain their capacity for monitoring, early warning, assessment and response in relation to serious cross-border threats to health (Article 10).

An important aspect that must certainly be implemented and on which efforts should be focused is coordination between the various actors and agencies[20], optimizing the resources available and avoiding duplication of efforts[21].

Coordination between different agencies can be decisive in setting up a system that is effective in preventing communicable diseases, such as vaccine-preventable diseases, and other health problems, such as antimicrobial resistance, while avoiding duplication of efforts.

plement response measures in accordance with their respective mandates. EU joint arrangements for capacities and resources ensure situational awareness, risk and crisis communication, emergency research and innovation, availability and supply of related MCMs and emergency funding. Moreover, these joint arrangements facilitate continuity of care across borders, including contact tracing and medical evacuation. If a situation becomes serious enough, the Commission can formally recognise a public health emergency at Union level. This allows the Council to decide on the activation of measures for ensuring the supply of crisis-relevant MCMs and establishing the Health Crisis Board. The Recovery phase focuses on restoring people's health and well-being, rebuilding the health systems' resilience and supporting broader social and economic recovery. As the immediate emergency subsides, efforts turn to helping affected communities recover and restoring essential services. This phase also involves strengthening systems to better withstand future crises, by reviewing the response, identifying lessons learned during and after the health crisis, and using these insights to drive concrete improvements that enhance the health and stability of all. Simulation exercises help to identify areas of improvement in the joint arrangements for governance, capacities and resources outside real-life events".

[20] See B. MARCHETTI, *Sviluppi recenti nell'amministrazione dell'Unione europea: integrazione, disintegrazione o rigenerazione?,* in *Riv. trim. dir. pubbl.*, 2018, 509 ss.; C. FRANCHINI, *Le fasi e i caratteri del processo evolutivo dell'organizzazione amministrativa europea*, in *Riv. it. dir. pubbl. com.*, 2017, 375 ss.

[21] For further information, please refer to the essay by G. STRAZZA, *The challenges facing European agencies in health security*, cit.

7. *Epidemiological surveillance, EU reference laboratories and ad hoc monitoring. Early warning and response system (EWRS)*

Epidemiological surveillance, EU reference laboratories and ad hoc monitoring are key elements of public health for the prevention and management of health threats, coordinated at European level by the ECDC, which supports national laboratories in improving detection and rapid response to emergencies through tools such as the EWRS (Early Warning and Response System), integrating data collection, scientific analysis and policy coordination to protect European public health[22].

The aim is to systematically monitor the spread of communicable diseases, making relevant data available to the Union so that centralized observation and evaluation of data can improve the response to cross-border health crises.

A key role is played by the Early Warning and Response System, whereby in the event of health risk, national authorities send a notification to the System; the Commission manages the dissemination of the notification to other States, which can prepare countermeasures and preventive measures and are required to report any actions taken to the Commission. The purpose of the system is to provide a coordinated and, therefore, more effective response.

8. *Recognition of a public health emergency at Union level and advisory committee (art. 24)*

Regulation (EU) 2022/2371 has established a procedure whereby a health crisis can be classified as an emergency that could harm public health at Union level.

[22] Decision No 2119/98/EC of the European Parliament and of the Council established a network for the epidemiological surveillance and control of communicable diseases in the EU. The network was also confirmed by Decision No 1082/ 2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and Regulation (EU) 2022/2371 on serious cross-border threats to health, which strengthens the European epidemiological surveillance network.

In this context, Article 24 of the Regulation establishes that the Commission shall set up an advisory committee for public health emergencies ("advisory committee") which, at the request of the Commission or the HSC, shall advise the Commission or the HSC by issuing opinions on the matter.

The advisory committee is composed of independent experts and has a multidisciplinary composition so that it can provide advice on public health, biomedical, behavioral, social, economic, cultural and international aspects. It is a technical body with specific tasks in the procedure for recognizing a public health emergency.

It is worth asking whether the tasks entrusted to the advisory committee could have been carried out by the Commission or the HSC.

9. *The Joint Procurement Agreement (JPA) to procure medical countermeasures*

In accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046[23], the Commission and any Member State may initiate a joint procurement procedure for the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable timeframe (art. 12 Regulation (EU) 2022/2371).

The previous rule was Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision 2119/98/EC, article 5(3).

[23] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012.

The Joint Procurement Agreement to procure medical countermeasures[24] was approved based on the above provision[25]. This agreement was approved pursuant to Decision 1082/2013/EU[26].

Strengthened purchasing power and equitable access to medical countermeasures against serious cross-border threats to health are to be expected from joint procurement by the Contracting Parties.

The Agreement provides a general framework for acquisitions relating to the medical case and specific requirements.

This is a voluntary mechanism that does not require the harmonisation of regulations across different Member States.

The Agreement was a tool used in the management of the Covid-19 health crisis[27], highlighting critical issues[28], between the need for speed and the protection of the market[29].

[24] https://health.ec.europa.eu/publications/commission-decision-c2014-2258-final _en.

[25] F.S. MENNINI, N. DIMITRI, L. GITTO, F. LICHERE, G. PIGA, *Joint Procurement and the EU perspective*, in G. PIGA, T. TATRAI (eds.), *Law and economics of Public Procurements Reforms*, Abingdon, 2017, 119 ss.

[26] G.M. RACCA, S. PONZIO, *Nuovi modelli organizzativi per il joint procurement e l'innovazione dei contratti pubblici in Europa*, in R.F. ACEVEDO, P. VALCARCEL FERNANDEZ (eds.) *Compra Pública Agregada*, 2016, 373-406; N. AZZOPARDI-MUSCAT, P. SCHRODER-BÄCK, H. BRAND, *The European Union Joint Procurement Agreement for cross-border health threats: What is the potential for this new mechanism of health system collaboration?*, in *Health Economics, Policy and Law*, 2017, 12(1), 43-59; R. CAVALLO PERIN, G.M. RACCA, *European Joint Cross-border Procurement and Innovation*, in *Joint Public Procurement and Innovation. Lessons Across Borders*, G.M. RACCA, R. YUKINS (eds.), Bruxelles, Bruylant, 2019, 93-131.

[27] E. MCEVOY, D. FERRI, *The Role of the Joint Procurement Agreement during the COVID-19 Pandemic: Assessing Its Usefulness and Discussing Its Potential to Support a European Health Union*, in *European Journal of Risk Regulation*, 11(4), 2020; 851-863; A. GEORGOPOULOS, *The EU's Joint Procurement Agreement in the Light of COVID-19: Learning the Correct Lessons from the Pandemic and Identifying Action for Improvement*, in S. ARROWSMITH, L.R.A. BUTLER, A. LA CHIMIA, C. YUKINS (a cura di), *Public Procurement Regulation in (a) Crisis? Global Lessons from the COVID-19 Pandemic*, Oxford, Hart, 2021, 175 ss.

[28] G. SDANGANELLI, *Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica: The European joint procurement agreement (JPA) for coordinating responses to serious cross-border health threats*, in *DPCE Online*, 2020, 43(2). Retrieved from https://www.dpceonline.it/index.php/dpceonline/article /view/1005.

[29] G.M. RACCA, C. R. YUKINS (eds.), *Integrity and Efficiency in Sustainable Public Contracts. Balancing Corruption Concerns in Public Procurement Internationally*, Bruylant, Bruxelles, 2014.

10. *The European Solidarity Fund and the Solidarity Reserve for emergency aid to address major public health crises*

The European Union Solidarity Fund (EUSF) is an additional instrument designed to support Member States facing emergencies caused by major natural disasters. It was established by Regulation 2012/2002 and amended by Regulation 2020/4618 to include health emergencies within its scope.

11. *The role of the EMA in authorising and supervising medicinal products for human and veterinary use within the framework of the European Health Union*

The European Medicines Agency (EMA) plays an important role within the European Union's regulatory framework for public health safety, both in regulating the authorisation and circulation of medicines, and in monitoring their safety[30].

Regarding EU pharmaceutical legislation, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 introduced Community procedures for the authorization, supervision and pharmacovigilance of medicinal products for human and veterinary use and established the European Medicines Agency[31].

The Regulation provides for a "centralized" marketing authorization procedure at European level, which is sometimes mandatory (e.g.

[30] See M. FILICE, *The accountability of the European Medicines Agency*, in *riv. Riv. it. dir. pubb. com*. 2018, 1013; R. ROLLI, M. MAGGIOLINI, *Authorities e gestione dei farmaci. La rete amministrativa del farmaco tra AIFA e EMA*, in *DPCE Online*, 47(2), 2021; M. GRANIELLO, *The role of supranation authorities in the regulation of the European pharmaceutical market*, in G. FARES, P. GARGIULO, *La regolazione europea del mercato farmaceutico. Tendenze, bilanci, prospettive*, Napoli, 2025, 125.

[31] The European Medicines Agency (EMA) is a European agency that has been operating since 1995 in the field of pharmaceutical product evaluation. Its mission is to combine the needs of market openness and free movement of medicines with the protection of public health.

See P. GARGIULO, *Le competenze dell'Unione Europea nella regolazi*one del mercato farmaceutico (*The EU jurisdiction in regulating the pharmaceutical market*), in G. FARES, P. GARGIULO, *La regolazione europea del mercato farmaceutico*, cit., 24 ss.

for all medicinal products for human use containing a completely new active substance) and in other cases optional (but recommended).

The rationale is not only to harmonize the internal market for medicinal products.

It is a measure aimed at ensuring innovation and competitiveness with a view to protecting public health. Indeed, one of the cases in which centralized authorization is possible is where "(b) the applicant demonstrates that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of an authorization under this Regulation is in the interest of patients or animal health at Community level".

The rules governing the procedure in question are complex.

The EMA plays a decisive role in the authorization procedure.

In fact, the Committee for Medicinal Products for Human Use, which is part of the Agency (Article 5 of Regulation 726/2004), submits its opinion to the Commission, which in turn takes the final decision; The Commission then takes the final decision, but may only deviate from the findings of the opinion in exceptional cases and must give adequate reasons for doing so.

In other words, once it has been established that the medicinal product is safe, effective, and meets all the technical requirements for marketing, the Commission is required to grant authorisation once the EMA committee's opinion has been obtained. The Commission does not have the power to choose the most appropriate measure for the applicant by balancing different interests.[32].

Marketing authorisation is granted only and exclusively if the applicant has adequately or sufficiently demonstrated the quality, safety or efficacy of the medicinal product.

Several issues arise in relation to the authorisation procedure: the "opacity" of the procedure, the division of responsibilities between the EMA and the Commission, the instruments of *legal accountability* and guarantees in authorisation procedures[33], the appropriateness of "*conditional*" marketing authorisation for medicinal products (and there-

[32] M. FILICE, *L'accountability della European Medicines Agency*, in *Riv. it. dir. pubbl. com.*, 2018, 1013.

[33] M. FILICE, *L'accountability della European Medicines Agency*, cit., 1013.

fore the balancing of interests that is carried out, insofar as the marketing authorisation of a medicinal product is granted despite limited clinical trial data).

The EMA exercises – at least in substance – significant authorisation powers that transcend national borders and take precedence over national laws when conditions so require and permit.

Marketing authorisations issued under the Regulation are valid throughout the Union.

The EMA also works with national agencies that regulate the pharmaceutical market by promoting effective forms of administrative cooperation and harmonisation of procedures and regulations in the sector[34].

12. *The EMA's role in European health security: Regulation (EU) 2022/123*

The experience of the pandemic has highlighted the need for medicines and medical devices to be available, as well as the need to develop new ones.

It has raised the issue of further and more decisive action by the Union[35].

In the pharmaceutical sector in particular, the emergency is driving a strategic push for reform of the system. The need to ensure cross-border health security is driving changes in the pharmaceutical sector.

Health security and emergency response (epidemiological) are the focus of new legislation or, in any case, of reform proposals.

The exception is becoming the rule in public health management, especially in the pharmaceutical sector. In what sense? In the prepara-

[34] R. ROLLI, M. MAGGIOLINI, *Authorities e gestione dei farmaci. La rete amministrativa del farmaco tra AIFA e EMA*, cit. See also S. CASSESE, *Le reti come figura organizzativa della collaborazione*, in S. CASSESE, *Lo spazio giuridico globale*, Bari, 2003.

[35] EU Commission Communication (October 2020) stated that "*coordination at EU level is necessary to align our efforts, to ensure and demonstrate solidarity, and to best guarantee the full functioning of the internal market, the sound management of public health for issues related to COVID-19 and beyond, and the protection of all EU citizens regardless of where they live*".

tion of crisis management tools that can ensure a safe and effective response to serious events (such as a pandemic).

This is the context for Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a strengthened role for the European Medicines Agency in crisis preparedness and management in relation to medicinal products and medical devices.

The role of the EMA has been significantly strengthened because of Regulation 2022/123.

With a view to harmonising national legislation, the Regulation aims to ensure consistency between the various national rules on procedures for the authorisation of medicinal products for human use in accordance with current quality and safety standards[36].

An executive steering group on medicine shortages and safety has been set up within the Agency (Article 3).

Article 4 of the Regulation highlights the renewed and strengthened relationship between the EMA and the AIFA, which includes reporting and monitoring obligations for any event that could lead to a public health emergency or a shortage of a medicinal product in each Member State.

An Emergency Task Force has also been set up within the Agency to provide scientific advice and support in crisis management.

In any case, Regulation 2022/123 marked a further step forward in the management of public health emergencies and contributed to 'refining' the crisis management system, although some issues remain.

For example, shortages of certain active substances remain a significant concern.

While these measures have accelerated the authorisation of innovative and promising therapies, these medicines do not always reach patients who continue to have varying levels of access to medicines within the Union.

This has led to a new pharmaceutical package, which is currently being negotiated.

[36] P. GARGIULO, *Le competenze dell'Unione Europea nella regolazi*one *del mercato farmaceutico* (*The EU jurisdiction in regulating the pharmaceutical market*), cit., 24 ss.

13. *Proposals for pharmaceutical reform*

The European Commission package of reforms includes a directive and a regulation to authorise and supervise medicines in the EU. The proposals aim to respond to patients' needs, promote competitiveness and support innovation. Together, the proposals aim to increase the availability of innovative medicines across the EU, while stimulating the competitiveness of the EU pharmaceutical industry, promoting environmental standards and reducing administrative burdens.[37].

In April 2023, the European Commission published its pharmaceutical package. On 4 June 2025, the Council agreed on its negotiating position (agreed mandate). The Council and the European Parliament must now reach an agreement on the final wording of the new rules.

The new rules have several objectives: ensuring that patients across the EU have equal access to safe, effective and affordable medicines, regardless of where they live; strengthening the competitiveness of the EU pharmaceutical industry by reducing regulatory burdens and simplifying the regulatory framework; addressing security of supply issues by monitoring and preventing shortages; and mitigating the environmental impact of medicines by better enforcing environmental rules. The new legislative proposals reduce the current standard period of regulatory data protection from eight to six years, while encouraging companies to make new medicines available in all EU countries by providing an additional two years of regulatory data protection. The proposals also encourage research into rare diseases by providing an extended period of market exclusivity (nine years in the original proposal, and ten years in the Council's proposal), which can be increased by one year if the medicinal product meets high unmet medical needs or is introduced in all Member States (Article 72: Extension of Market Exclusivity). A new "transferable data exclusivity voucher" should be

[37] However, for negative comments on the proposed reform of pharmaceutical legislation, see M. CATTANI, *The role of innovation for the competition in the European Drugs market*, in G. FARES, P. GARGIULO, *La regolazione europea del mercato farmaceutico*, cit., 95: "*le misure previste dalla proposta della Commissione Europea scoraggiano gli investimenti, penalizzano competitività e innovazione e mettono a rischio accesso a terapie, occupazione e crescita*".

introduced. This would provide an additional 12 months of data protection. It would be available to companies developing "breakthrough" antimicrobials. This is set out in Article 40 of the proposed Regulation.

Additionally, there is a proposal to strengthen the Medicines Agency's inspection powers to enhance the supervision of medicine manufacturing worldwide in the interests of the Union.

This proposal to regulate the environmental impact of medicines is significant because it is inspired by the integrated 'One Health' approach.

14. *Health security, EMA and environmental risk*

The Regulation, as proposed, includes several provisions that would adjust the procedure. The aim of these adjustments would be to strike a balance between the interests of health protection and the environment, ensuring that both are adequately protected[38].

The application for authorisation to market a medicinal product containing or consisting of genetically modified organisms (as defined in Article 2(2) of Directive 2001/18/EC) must be accompanied by an environmental risk assessment (Article 7).

According to Article 20, it is possible to carry out a post-authorisation environmental risk assessment study; and risk to the environment may constitute grounds for suspension of authorization (art. 24).

Conditions may be laid down for the safe and effective use of the medicinal product or to minimise its impact on the environment. Deadlines shall be set for the submission of such studies (art. 33).

[38] On the interconnection between the environment and health protection, see S. NEGRI (edit by), *Environmental Health in internation and Eu law. Current chiallenges and legal responses*, Routledge-Giappichelli, 2019.

ELISA TINO

ASEAN'S COMMITMENT IN THE FIELD OF HEALTH SECURITY

1. *Introduction*

South-East Asia is a region particularly exposed to emerging zoonotic diseases due to a combination of factors, such as intensive livestock production systems, high diversity of wildlife, rapid changes in land use, and impacts of climate change[1]. As some scholars observed, «[t]hese dynamics foster high rates of contact among humans and animals – including livestock and wildlife – amplifying the risk of disease spillover»[2]. The pandemic-potential outbreak of avian influenza in the 2000s and the more recent occurrence of COVID-19 corroborate these considerations. Moreover, Southeast Asian States range from advanced economies to least-developed countries, resulting in stark disparities in healthcare access[3]. Thus, for instance, in countries like Cambodia, Laos and Myanmar, fragile health infrastructure and lim-

[1] All ASEAN Member States consider health as part of the sectors most impacted by climate change. In this sense see ASEAN State of Climate Change Report (ASCCR), Jakarta, ASEAN Secretariat, October 202, 43-47.

[2] See S. LÂM ET AL., *Operationalizing regional One Health initiatives in Southeast Asia: Ways forward,* in *One Health*, 2025, vol. 20, 101034, 1.

[3] In this regard, legal scholars have referred to «a 'two-speed' health challenge for the region» (R. TUNDANG, *Sub-regional coordination is the cure for ASEAN's health divide,* in *East Asian Forum*, 2025, https://eastasiaforum.org/2025/11/05/sub-regional-coordination-is-the-cure-for-aseans-health-divide/).

ited purchasing power mean life-saving drugs and vaccines often arrive late or at prohibitive cost.

On the premise that, in a globalized and interconnected world, the health emergency in a State can possibly amount to a risk to global security[4], the vulnerability of Southeast region to public health emergencies and the vast differences in healthcare realities of Southeast Asian States, call for robust health security systems and, for this purpose, make it essential to focus on heightening resilience and agility through the adoption of effective integrated disease control and prevention strategies[5]. In other words, multi-level governance is needed in the field of health security. In this scenario, it seems legitimate to ask what contribution ASEAN can provide to the construction of such multi-level governance.

ASEAN is an intergovernmental organization whose members are currently eleven Southeast Asian States, namely Brunei Darussalam, Cambogia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam and, lastly, Timor Est[6]. It was originally es-

[4] Actually, as WHO emphasized, pandemics, health emergencies, and weak health systems pose risks to global security, so building health system resilience is a prerequisite to addressing public health emergencies.

[5] The expression «health system resilience» refers to the ability to prepare for, manage (absorb, adapt, and transform), and learn from sudden and extreme health system changes. See S. THOMAS ET AL., *Strengthening health systems resilience. Key concepts and strategies*, in *Policy Brief*, 36, 2020, 5.

[6] About ASEAN see, *ex multis*, H. DAVID, *Die ASEAN zwischen Konflikt, Kooperation und Integration*, Hamburg, 2003; C. B. ROBERTS, *ASEAN Regionalism. Cooperation, Values and Institutionalisation.* London, 2003; P. C. SINHA (ed.), *Handbook of ASEAN and Regional Cooperation. 12th Summit and Beyond*, New Delhi, 2007; E. L. FROST, *Asia's New Regionalism*, London, 2008; A. AMIRANTE, *La nuova Carta dell'ASEAN: un trattato per la transizione dalla cooperazione alla integrazione del Sud-est asiatico*, Napoli, 2010; S. TIWARI (ed.), *ASEAN. Life after the Charter,* Singapore, 2010; O. VON FEIGENBLATT, *The Association of Southeast Asian Nations (ASEAN). Conflict and Development,* New Delhi, 2012; D. DESIERTO, D. COHEN (eds.), *ASEAN law and regional integration: governance and the rule of law in Southeast Asia's single market, A*bingdon/New York, 2021; L. JONES, *ASEAN, Sovereignty and Intervention in Southeast Asia,* New York, 2012; A. W. ZIETEK, G. GIL (eds.), *ASEAN in a Changing World*, Berlin, 2021; E. Y. JOONG LEE (ed.), *ASEAN international law*, Singapore, 2022; S. CHO, J. KURTZ, *Investing the ASEAN Way: Theories and Practices of Economic*

tablished by the Bangkok Declaration in 1967 in order to facilitate interstate cooperation in economic, social, cultural and technical fields, and to promote regional peace and stability through abiding respect for justice and the rule of law and adherence to the principles of the United Nations Charter[7]. So, from legal point of view, it originally amounted to a *soft organization*[8], that is to say, it developed a cooperation model characterized by a strong flexibility already expressed by the non-legally binding nature of its founding act. However, a significant change in this respect took place in the 2000s. Indeed, in 2003, the Heads of State of ASEAN Members agreed to establish an «ASEAN Community» by 2020[9], which should have been based on three pillars: 1. the ASEAN Political-Security Community; 2. the ASEAN Economic Community; and 3. the ASEAN Socio-Cultural Community[10]. According to ASEAN Member States, it should have been a *Community of Nations* that was outward looking, living in peace, stability and prosperity, bonded together in partnership in dynamic development and in a community of caring societies. In other words, such «ASEAN Community» envisioned as a community with

Integration in Southeast Asia, Cambridge, 2023; J. DOSCH, F. KLIEM (eds.), *The Elgar Companion to ASEAN,* Cheltenham, 2023.

[7] See *ASEAN Declaration*, Bangkok, 8 August 1967 (hereafter, *Bangkok Declaration*). The Bangkok Declaration was originally signed by Indonesia, Malaysia, Philippines, Singapore and Thailand in 1967, launching the start of ASEAN. Brunei joined in 1984, Vietnam in 1995, Laos and Myanmar in 1997, and Cambodia in 1999.

[8] The expression *soft organization* usually refers to a form of association which is established and regulated by State manifestations of will expressed in political and diplomatic acts (that are not legally binding) and designed in such a way to favour fewer constraining options for the freedom of their Member States. In legal literature see, among others, J. KLABBERS, *Institutional Ambivalence by Design. Soft Organization in International Law*, in *Nordic Journal of International Law*, 2001, 403 ss.; A. DI STASI, *About Soft International Organizations: An Open Question*, in R. Virzo, I. Ingravallo (eds.), *Evolution in the Law of International Organizations,* Leiden, 2015, 44 ss..

[9] See Declaration of ASEAN Concord II (Bali Concord II), Bali, 7 October 2003; Cebu Declaration on the Acceleration of the Establishment of an ASEAN Community by 2015, Cebu, 13 January 2007.

[10] About the ASEAN Community and its articulation in three pillars see R. SUKMA, *Building the ASEAN Community*, in *The Indonesian Quarterly*, 3/4, 2008, 258-277: V. CHHEANG, *Track-two diplomacy and ASEAN community building*, in J. Dosch, F. Kliem (eds.), *op. cit.,* 136-150.

enhanced capacity and capabilities to both respond effectively to challenges and to seize opportunities. It was evident that its realization required a firm foundation. To this purpose, in 2007 ASEAN Member States concluded the so-called *ASEAN Charter*, namely an international treaty formalizing the interstate institutionalized cooperation among ASEAN Member States and governing it[11]. In essence, following its entry into force, the existing interstate cooperation among the Southeast Asian States changed from a *soft organization* to a *treaty-based* one[12].

2. *ASEAN's Road to Health Security*

The 1967 Bangkok Declaration lacked any expressed reference to health security. Indeed, due to the complicated geo-political situation[13], the priority of ASEAN Founding Members was the maintenance and strengthening of security and stability in the region[14]. Like-

[11] See *Charter of the Association of the Southeast Asian Nations*, Singapore, 20 November 2007, which entered into force on 15 December 2008.

[12] About this change of legal status see S. TIWARI (ed.), *op. cit.*

[13] It is to be borne in mind that ASEAN was established during a period of continuing political unrest and armed conflict in various parts of the region. About the situation in Southeast Asia in the 1960s see J. GRAHAM PARSONS, *Southeast Asia, 1950-1960*, in *World Affairs*, 1, 1960, 3-5; R. BUTWELL, *Growing Involvement in Asia: 1960-1968,* in *Current History,* 336, 1969, 88-92.

[14] This can be easily inferred from the Preamble of the Bangkok Declaration reading «[d]esiring to establish a firm foundation for common action to promote regional cooperation in South-East Asia in the spirit of equality and partnership and thereby contribute towards peace, progress and prosperity in the region; Conscious that in an increasingly interdependent world, the cherished ideals of peace, freedom, social justice and economic well-being are best attained by fostering good understanding good neighbourliness and meaningful cooperation among the countries of the region already bound together by ties of history and culture; Considering that the countries of South-East Asia share a primary responsibility for strengthening the economic and social stability of the region and ensuring their peaceful and progressive national development, and that they are determined to ensure their stability and security from external interference in any form or manifestation in order to preserve their national identities in accordance with the ideals and aspirations of their peoples (…)». About ASEAN's commitment in security field see J. VALUCH, O. HAMUĽÁK, *Association of*

wise, the ASEAN Charter fails in conferring an explicit competence to the Organization in this field. However, this omission does not have to be interpreted as indicating that Member States wish to exclude the health sector from ASEAN's areas of competence. Indeed, it is worth bearing in mind that neither the Bangkok Declaration nor the ASEAN Charter define precisely which were/are the matters falling under ASEAN's jurisdiction. Therefore, these must be deduced through a systematic interpretation of the two legal documents, starting with their provisions governing the Organization's objectives. Such interpretation reveals that interstate cooperation in the field of health security had (in the past) and has (now) its legal basis in the Bangkok Declaration and in the ASEAN Charter respectively.

Firstly, on the premise that health issues fall into social as well as technical/scientific fields, it can be argued that, in stating «the aims and purposes of the Association shall be (…) to promote active collaboration and mutual assistance on matters of common interest in the economic, social, cultural, technical, scientific and administrative fields», Article II, para. 3 of the Bangkok Declaration left the door open to the possibility that the Organization could also deal with health issues.

Given that there is a close link between health security and environmental protection, and that diseases represent a cross-border threat, the legal basis for ASEAN's competence in health matters can be inferred even more clearly from the wording of Article 1 of the ASEAN Charter. Indeed, pursuant to this provision, ASEAN aims «to respond effectively, in accordance with the principle of comprehensive security, to all forms of threats, transnational crimes and transboundary challenges» (para. 8), «to enhance the well-being and livelihood of the peoples of ASEAN providing them with equitable access to opportunities for human development, social welfare and justice» (para. 11) and «to strengthen cooperation in building in a safe, secure and drug-free environment for the peoples of ASEAN» (para. 12).

Concretely, regional cooperation in public health only emerged high on the ASEAN agenda in 1980, when for the first time Health

Ministers of ASEAN Member States decided to meet regularly and «to strengthen and coordinate regional collaboration in health among ASEAN countries»[15]. Since then, and even more so after the severe acute respiratory syndrome (SARS) epidemic in the early 2000s, health security became a significant issue and was the subject of many legal documents adopted by ASEAN intergovernmental bodies over the years. These were, in particular, Declarations adopted at the conclusion of ASEAN Summits[16], as well as Statements issued at the ASEAN Health Ministers Meetings[17] and *ad hoc* strategic plans they approved to outline the main health action lines[18]. Conversely, health-related is-

[15] See Declaration of the ASEAN Health Ministers on Collaboration on Health, Manila, 24 July 1980.

[16] See, for example, ASEAN Declaration of Commitment: Getting to Zero New HIV, Infection, Zero Discrimination, Zero AIDS-Related Deaths (Bali, 17 November 2011); Bandar Seri Begawan Declaration on Noncommunicable Diseases in ASEAN (Bandar Seri Begawan, 9 October 2013); ASEAN Declaration on Commitment on HIV and AIDS (Vientiane, 6 September 2016); ASEAN Leaders' Declaration on Ending All Forms of Malnutrition (Manila, 13 November 2017); ASEAN Declaration on Culture Prevention for a Peaceful, Inclusive, Resilient, Health and Harmonious Society (Manila, 13 November 2017); ASEAN Leaders' Declaration on Antimicrobial Resistance: Combating AMR through One Health Approach (Manila, 13 November 2017); Declaration of the Special ASEAN Summit on the Coronavirus Disease 2019 (14 April 2020); ASEAN Leaders' Declaration on One Health Initiative (Labuan Bajo, 11 May 2023); ASEAN Declaration on the Right to a Safe, Clean, Healthy and Sustainable Environment (Kuala Lumpur, 28 October 2025).

[17] See particularly Declaration of the 6th ASEAN Health Ministers' Meeting on Healthy ASEAN Lifestyles (Vientiane, 15 March 2002); Declaration «ASEAN Unity in Health Emergencies» issued at the 8th ASEAN Health Ministers Meeting (Yangon, 21 June 2006); Joint Statement of the 11th ASEAN Health Ministers Meeting (Phuket, 5 July 2012); Joint Statement at the 12th ASEAN Health Ministers Meeting (Ha Noi, 18 September 2014); Joint Statement of the 13th ASEAN Health Ministers Meeting (Bandar Seri Begawan, 6 September 2017); Joint Statement of the 14th ASEAN Health Ministers Meeting (Siem Reap, 29 August 2019); Joint Statement of the 15th ASEAN Health Ministers Meeting (Bali, 15 May 2022); Joint Statement of the 16th ASEAN Health Ministers Meeting (Vientiane, 9 August 2024).

[18] See, for instance, the Healthy ASEAN 2020 Plan referring to the overarching ASEAN Vision 2020 goals and the immediate Hanoi Plan of Action (HPA) 1999-2004, which included health and human development components alongside economic ones. See also the Hanoi Plan of Action on Strengthening ASEAN Economic Cooperation and Supply Chain Connectivity in Response to the COVID-19 Pandemic (19

sues have been rarely regulated in international agreements concluded by ASEAN Member States under the auspices of ASEAN[19].

3. *ASEAN Institutional Framework on Health Security*

Health issues, which fall primarily under the ASEAN Socio-Cultural Community pillar, are primarily discussed by Health Ministers of ASEAN Member States who usually meet every year. Their Annual Meetings are the highest decision-making process for issues in health sector. They are usually preceded by those of Senior Officials who play decisive preparatory and supporting role in the activities of Health Ministers. Clearly, the strategic direction for ASEAN action in this area are defined by the Summit gathering the Leaders of ASEAN Member States, who are also responsible for endorsing any decisions on this matter taken by any other ASEAN intergovernmental body. In this regard, it is worth noting that, due to the cross-cutting nature of health issues, sometimes they are also discussed by ASEAN Member States' Ministers responsible for other matters (e.g. finance, economic development, etc.) and dealt with in documents approved at the conclusion of their meetings[20].

Over the years, ASEAN institutional framework in health field has been enriched by a series of structures with technical composition and operational responsibilities in order to respond to the urgent need for coordination and collaboration among ASEAN Member States. Thus, in 2016 ASEAN Leaders agreed the establishment of the Coordinating Centre for Animal Health and Zoonoses (ACCAHZ) aimed to provide

June 2020), which implemented the Declaration of the Special ASEAN Summit on the Coronavirus Disease 2019 adopted on 14 April 2020.

[19] The most significant example is the ASEAN Sectoral Integration Protocol on Healthcare (Vientiane, 29 November 2004).

[20] See, lastly, the ASEAN Economic Ministers' Statement on Strengthening ASEAN's Economic Resilience in Response to the Outbreak of COVID (20 March 2020); the Joint Statement of the 1st ASEAN Finance and Health Ministers Meeting (Jakarta, 24 August 2023); the Joint Statement of the 2nd ASEAN Finance and Health Ministers Meeting "ASEAN's Path to Health and Finance Collaboration for Sustainable Health System Resilience" (Vientiane, 8 August 2024).

a framework of cooperation and coordination to prevent, control and eradicate transboundary animal diseases and zoonoses and to contribute towards food security and safety, animal and human health, poverty alleviation, and the well-being and livelihood of ASEAN people[21]. Then, in response to the outbreak of COVID-19 pandemic and to the renewed need for a coordinated and cross-sectoral ASEAN management of health-related issues, the Coordinating Council Working Group on Public Health Emergencies (ACCWG-PHE) was set up[22]. It is composed of Senior Officials from all three ASEAN Community Pillars, with the mission to facilitate coordination and collaboration among relevant ASEAN sectors as the region responds to public health emergencies. To this purpose, during the pandemic, its meetings offered ASEAN Member States the opportunity to exchange ideas on measures to prevent, contain, and manage the disease and their national efforts to "flatten the curve" of COVID-19 spread[23].

The creation of the Coordinating Council Working Group on Public Health Emergencies was then followed by the establishment of the ASEAN Centre for Public Health Emergencies and Emerging Diseases (ACPHEED), which consists of three pillars: surveillance or detection, response, and risk management. Each of them is under the responsibility of an *ad hoc* Centre located in a specified country, namely Vietnam (Prevention and Preparedness), Indonesia (Detection and

[21] See Agreement on the Establishment of the ASEAN Coordinating Centre for Animal Health and Zoonoses, Singapore, 17 October 2016, in force since 8 September 2021. The Centre, which was established with the support from the FAO Emergency Centre for Transboundary Animal Diseases (ECTAD) in Asia and the Pacific and the Australian, became operational in 2024.

[22] Its establishment was proposed by Vietnam, the ASEAN Chair 2020, to promote a coordinated response across the ASEAN Community. The ACCWG-PHE held its first meeting on 31 March 2020.

[23] Thus, for instance, in occasion of the meetings of the ACCWG-PHE held during the pandemic, measures centred on quarantines, tightening border controls, safety nets especially for the most vulnerable, capacity building and training, and the next steps in a post-COVID-19 scenario were discussed and shared. A tabletop exercise in June 2020 was planned in collaboration with the ASEAN Centre of Military Medicine in Bangkok.

Risk Assessment), and Thailand (Response)[24]. It serves as a centre of excellence and regional hub to strengthen ASEAN's regional capabilities to prepare for, prevent, detect and respond to all health-related hazards including biological, chemical, radiological-nuclear and emerging threats. Its establishment is in line with the goals defined in the ASEAN Post-2015 Health Development Agenda for 2021–2025 and in the ASEAN Sociocultural Community Blueprint 2025 and contributes to their realization.

4. *ASEAN Legal Framework on Health Security*

As mentioned above, over the years ASEAN bodies have adopted a huge number of legal documents dealing with health security and healthcare[25]; in particular, the strategic directions and actions to be taken to realize the identified goals have been mainly defined by *soft law* acts, namely acts that did not impose legal obligations to ASEAN Member States, but through which the latter merely made political

[24] The establishment of the ACPHEED was announced by the ASEAN Leaders during their 37th Summit on 12 November 2020. The proposal of its creation resulted from the *Feasibility Study on the Establishment of the ASEAN Centre for Public Health Emergencies and Emerging Diseases* that was supported by the Government of Japan through Japan-ASEAN Integration Fund (JAIF). The working principles of the ACPHEED are similar to those of the Centres for Disease Control and Prevention in the US. The launch of its Secretariat Office took place in 2022 in Bangkok.

[25] It is worth noting that health-related issues have long been also in the agenda of ASEAN's external relations, as it is proved by discussions within the ASEAN Regional Forum (see, for instance, Chairman's Statement of the 12th Meeting of the ASEAN Regional Forum, Vientiane, 29 July 2005, para. 31; ASEAN Regional Forum Statement on Disaster Management and Emergency Response, Kuala Lumpur, 28 July 2006; Chairman's Statement of the 27th ASEAN Regional Forum, Hanoi, 12 September 2020; Chairman's Statement of the 29th ASEAN Regional Forum, Phnom Penh, 5 August 2022; Chairman's Statement of the 30th ASEAN Regional Forum, Jakarta, 14 July 2023; Chairman's Statement of the 31st ASEAN Regional Forum, Vientiane, 27 July 2024) and the ASEAN Plus Three cooperation process with China, Japan and the Republic of Korea. Moreover, over the years, ASEAN has enhanced its cooperation in health field with global partners, such as the United States and the EU (in this regard, in literature see V. ROLLETT, *Influence of EU-ASEAN Health Interregionalism on Regional Health Governance*, in *Asia Europe Journal*, 2017, 243-259).

commitments in health field. However, there have also been (rare) cases in which, being intertwined with the pursuit of other objectives, health-related issues have been regulated by treaty-norms[26].

On the premise that – as mentioned above – health issues fall under ASEAN Socio-Cultural pillar, interstate cooperation in this field has been firstly guided by the ASEAN Socio-Cultural Community (ASCC) Blueprints which have been periodically adopted by ASEAN Leaders to define/update the strategic objectives of the Organization and related key actions to realize and consolidate ASEAN as a people-oriented and socially responsible Community[27]. Thus, over the years, they have established a strategic framework on health and development to guide action in health governance, mainly focusing on access to adequate and affordable healthcare, medical services and medicines, and promotion of healthy lifestyles. Moreover, they have sought to improve the capability to control communicable diseases and to pay a new attention to food quality control. In particular, in order to realize a sustainable community that promotes social development and environmental protection, as well as a resilient community with enhanced capacity and capability to adapt and respond to social and economic vulnerabilities, disasters, climate change as well as emerging threats, and challenges, the ASCC Blueprint 2025 identified the following strategic measures: (i) strengthening of health systems to be resilient in preparedness for effective response to health-related hazards, including biological, chemical, radiological-nuclear hazards and emerging threats; (ii) promoting regional standards to enhance interoperability, ensure unity of action and strengthen collective resilience; and (iii) enhancing institutional and human capacities and approaches to support the effective implementation of policies, strategies and programmes in preparing and responding to all health-related hazards and emerging threats[28].

[26] See *supra*, note 19.

[27] See the ASEAN Socio-Cultural Community Blueprint 2009-2015 adopted by the ASEAN Leaders at the 14th ASEAN Summit in 2009; the ASEAN Socio-Cultural Community Blueprint 2016-2025 adopted by ASEAN Leaders at the 27th ASEAN Summit in November 2015.

[28] See ASEAN Socio-Cultural Community Blueprint 2016-2025, cit., 20.

In order to translate the strategic directions contained in the ASCC Blueprints, as well as in *ad hoc* Leaders' joint Declarations[29], into more detailed and concrete actions, over the years some *ad hoc* soft law acts have been adopted. The reference is particularly to the Healthy ASEAN 2020 Plan, referring to the overarching ASEAN Vision 2020 goals and the immediate Hanoi Plan of Action (HPA) 1999-2004, which included health and human development components alongside economic ones. These documents were followed by the adoption of the ASEAN Strategic Framework on Health Development (2010-2015), endorsed at the 10th ASEAN Health Ministers Meeting. It aimed to create a healthy, caring and sustainable ASEAN Community, so it focused on four main areas: food safety, access to healthcare services (including pharmaceuticals, traditional medicines, and maternal/child/migrant health), promoting healthy lifestyles to prevent non-communicable diseases, and communicable disease prevention and pandemic preparedness.

The aforementioned ASCC Blueprint 2025 and the ASEAN Vision 2025 guided the ASEAN Post-2015 Health Development Agenda, namely a strategic plan covering the period 2016-2025 and aiming – once again - to build a «healthy, caring, and sustainable ASEAN Community»[30]. Its mission included: 1. promoting healthy lifestyles; 2. ensuring universal access to quality healthcare and financial protection; 3. ensuring food safety; and 4. building resilient health systems to address all hazards and emerging threats. This Agenda, which incorporated principles like a «whole-of-society and whole-of-government approach», being «people-centred» and embracing «innovation», focused on twenty health priorities across four clusters[31].

[29] See documents quoted *supra*, in note 16.

[30] See ASEAN Secretariat, ASEAN Post-2015 Health Development Agenda, Jakarta, October 2018.

[31] The four health clusters concerned: a) promotion of healthy life and focused on prevention of non-communicable diseases (NCDs), reducing tobacco and alcohol consumption, promoting good nutrition, and supporting healthy and active aging; b) responding to all hazards and emerging threats and addressed on preparedness and response to public health emergencies; c) strengthening of health systems and access to care; d) ensuring food safety.

4.1. ASEAN's Response to the COVID-19 Pandemic

A renewed impetus to ASEAN's commitment to promote health security was given by the outbreak of COVID-19 pandemic[32]. Indeed, starting from March 2020 many legal documents have been adopted by ASEAN intergovernmental bodies in order to help Member States in addressing the pandemic. See, for instance, the Declaration of the Special ASEAN Summit on COVID-19 indicating seven measures as ASEAN's collective response in addressing the pandemic[33]. Then, in order to enhance ASEAN's preparedness, detection, response and resilience to public health emergencies the ASEAN Strategic Framework for Public Health Emergencies (hereafter, ASEAN Strategic Framework for PHE) was launched in November 2020. It is a comprehensive plan identifying financial and resource mechanisms to increase

[32] In literature see F. KIMURA et al., *Pandemic (COVID-19) Policy, Regional Cooperation and the Emerging Global Production Network,* in *Asian Economic Journal*, 2020, 3-27; F. KLIEM, *ASEAN and the EU amidst COVID-19: Overcoming the Self-Fulfilling Prophecy of Realism*, in *Asia Europe Journal*, 2021, 371–89; R. DJALANTE et al., *COVID-19 and ASEAN Responses: Comparative Policy Analysis*, in *Progress in Disaster Science*, 8, 2020, 1-12; K. SPANDLER et al., *Sovereignty scripts and regional governance: ASEAN's response to the Covid-19 pandemic,* in *The Pacific Review,* 2024, 604-633.

[33] See Declaration of the Special ASEAN Summit on Coronavirus, cit. In particular, ASEAN Leaders agreed on: (i) strengthening public health cooperation measures to contain the pandemic and protect the people; (ii) prioritizing the well-being of peoples and provide appropriate assistance and support to the nationals of ASEAN Member States affected by the pandemic in each other's country or in third countries; (iii) enhancing effective and transparent public communication involving multiple forms of media; (iv) reaffirming the commitment to take collective action and coordinate policies in mitigating the economic and social impact from the pandemic, safeguarding the people's well-being and maintaining socio-economic stability: (v) stressing the importance of a multi-stakeholder, multi-sectoral, and comprehensive approach by ASEAN to effectively respond to COVID-19 and future public health emergencies.; vi) tasking Economic Ministers and Senior Economic Officials to explore an arrangement to preserve supply chain connectivity, particularly among ASEAN Member States; (vii) supporting reallocating existing available funds and encourage technical and financial support from ASEAN's partners to facilitate cooperation against COVID-19, including the proposed establishment of the COVID-19 ASEAN Response Fund.

support and investments in public health emergency preparedness at all levels, and to effectively mobilize resources in scaling-up response as necessary. It also aims to initiate the establishment both of mechanisms to sustain laboratory and medical surge capacity in the event of public health emergencies and disasters, and of coordination mechanisms, like the ASEAN Public Health Emergency Coordination System (APHECS)[34]. The Strategic Framework for PHE is based on mutual respect for independence and sovereignty of each ASEAN Member State by accommodating flexibility for the continued implementation of domestic laws and regulations, while ensuring effective regional cooperation. At the same time, given that all ASEAN Member States are also members of the WHO, it also aligns with the International Health Regulations 2005 and uses a multi-sectoral One Health approach to manage threats, like those posed by the COVID-19 pandemic and other emerging infectious diseases. It is worth noting that – in order to respond effectively to emergency-related needs – it is provided that the ASEAN Strategic Framework for PHE will be reviewed every two years or as needed. Alongside the Strategic Framework for PHE, the Leaders of ASEAN Member States adopted the ASEAN Comprehensive Recovery Framework and Implementation Plan serving as the region's consolidated exit strategy from the COVID-19 crisis and charting a path to recover and build back better[35]. To this purpose, the Comprehensive Recovery Framework focuses on key sectors and vulnerable groups that are most affected by the pandemic and

[34] The APHECS is a formal, multi-country mechanism to better prepare for, and respond to, public health emergencies. The system aims to integrate existing but disparate coordination mechanisms in the region under a single, cohesive institutional platform, enabling ASEAN Member States to coordinate across relevant stakeholders and mount swift and collective responses. Its establishment, which is articulated into three phases, is supported by the U.S. Agency for International Development (USAID)-funded Partnership for Regional Optimization within the Political-Security and Socio-Cultural Communities (PROSPECT) project. See Framework Agreement on the ASEAN Public Health Emergency Coordination Systems, November 2024, https://asean.org/wp-content/uploads/2024/11/ASEAN-Public-Health-Emergency-Coordination-System-APHECS-Framework.pdf .

[35] The Comprehensive Recovery Framework and its Implementation Plan were adopted at the 37th ASEAN Summit on 12 November 2020. See https://asean.org/asean-strategic-framework-for-public-health-emergencies/

identifies measures for a comprehensive recovery in line with sectoral and regional priorities. In particular, it covers a range of broad strategies, including: enhancing health systems, strengthening human security, maximising the potential of intra-ASEAN market and broader economic integration, accelerating inclusive digital transformation, advancing towards a more sustainable and resilient future. The factors identified in enabling recovery are: policy responses and reforms, financing and resource mobilisation, institutions and governance mechanisms, stakeholder engagement and partnership and effective monitoring. The Comprehensive Recovery Strategy is complemented by an Implementation Plan which is an integral accompanying document (Annex) to it. Developed with inputs from ASEAN sectoral bodies across the three Community pillars, the Implementation Plan details the specific initiatives and programmes that contribute to the five broad strategies of the ASEAN Comprehensive Recovery Framework, their respective outputs, phase of implementation, as well as the responsible lead sectoral bodies and other supporting or collaborating sectoral bodies. The Implementation Plan is a living document inasmuch as it is regularly updated and monitored in order to remain agile, sustainable, adaptable, and flexible.

Developing Health Protocol in Public Places is one of the key priorities and deliverables that ASEAN articulates under the Comprehensive Recovery Strategy; it was concretely launched in 2022 after the endorsement of ASEAN Health Ministers Meeting[36]. The ASEAN Health Protocol for Pandemic Preventive Measures in Public Places provides guidance and measurements in preventing and controlling transmission of COVID-19 in the ASEAN community, specifically in public settings stated in this document. Embedded to the Health Protocol is the Operationalising Guidelines that serves as a supporting document to the Health Protocol; indeed, they provide explanatory material to detail the Health Protocol to assist stakeholders in applying

[36] See ASEAN Health Protocol for Pandemic Preventive Measures in Public Places, November 2022, https://asean.org/book/asean-health-protocol-for-pandemic-preventive-measures-in-public-places/ The Protocol were developed under the leadership of the ASEAN Senior Officials Meeting on Health Development (SOMHD) chair, the Ministry of Health, Indonesia, and was endorsed by the ASEAN Health Ministers at their 15th Meeting on 14 May 2022.

it[37]. The Health Protocol and the Operationalising Guidelines should be used on a voluntary basis in accordance with the context and regulation in each ASEAN Member State due to the notable difference in pandemic status across ASEAN Member States, among others.

At their 15th Meeting, alongside the Health Protocol for Pandemic Preventive Measures, ASEAN Health Ministers also endorsed the Protocol for Cross-Border Contact Tracing and Rapid Outbreak Investigation aiming to provide an effective communication mechanism among relevant border authorities in ASEAN Member States with quality information to prevent and mitigate transmission of COVID-19 and other similar infectious diseases in the future.

The COVID-19 pandemic also made clear the existence of a strong connection between health security and zoonotic diseases. For this reason, ASEAN decided to develop the Strategy for Exotic, Emerging, Re-Emerging Diseases and Animal Health Emergencies aiming to strengthen the effective management of animal health emergency preparedness AHEP and response capacity by improving core public health systems, increasing regional connectivity and coordination, and investing in ongoing performance improvement[38]. This Strategy was followed by the adoption of another document concerning zoonotic diseases, namely the ASEAN Strategy for Preventing Transmission of Zoonotic Diseases from Wildlife Trade[39]. The latter aims to prevent transmission of zoonotic diseases from wildlife to humans and reduce demand for illegal wildlife products. To this purpose, it recommends measures consisting in regulating and closing high-risk commercial wildlife markets, strengthening law enforcement and legal

[37] The material in the Operationalising Guidelines should be viewed as a supplement to the health protocol.

[38] ASEAN Strategy for Exotic, Emerging, Re-emerging Diseases and Animal Health Emergencies, May 2021, https://asean.org/wp-content/uploads/2021/12/FAFD-35.-ASEAN-Strategy-Exotic-Emerging-Diseases-and-Animal-Health-Emergencies.pdf .

[39] ASEAN Strategy for Preventing Transmission of Zoonotic Diseases from Wildlife Trade, October 2022, https://asean.org/wp-content/uploads/2023/01/15.-ASEAN-Strategy-for-Preventing-Zoonotic-Diseases-Transmission-from-Wildlife-Adopted.pdf .

frameworks against illegal trade, and promoting public health measures, like hygiene and responsible consumerism.

As far as future outlooks are concerned, health issues will keep on being at the centre of ASEAN Agenda. Indeed, ASEAN Community Vision 2045[40] aims for a healthy, resilient, and people-centred Community by focusing on holistic health and well-being. This includes achieving universal health coverage, increasing life expectancy, and ensuring access to resilient healthcare architecture. Moreover, it emphasizes proactive responses to non-communicable and communicable diseases and strengthening of connection between health goals and ASEAN broader objectives, such as creating a «caring, inclusive community», thus promoting sustainable development. Consistently, in the 2026-2030 Strategic Plan for the ASEAN Socio-Cultural Community, ASEAN includes the promotion of healthier populations and higher quality of peoples' life among twelve goals it outlines[41]. To reach them it envisions several concrete measures, including: the development of policies and programs to support the health and well-being of an aging population; the strengthening of the region's healthcare architecture to be more resilient and prepared for future challenges; the fostering of deeper collaborations between public and private sectors, and the people to implement health initiatives; the adoption of policies that respond to the health impacts of the climate crisis and the enforcement of programs protecting for vulnerable groups (e.g. older adults, children, and migrant workers), and ensuring their access to healthcare.

5. *ASEAN's Approach to Health-Related Issues*

A careful reading of the large number of acts adopted by ASEAN bodies reveals that, as regards health sector, ASEAN made use of a multi-dimensional and cross-cutting approach; its Member States

[40] See ASEAN Community Vision 2045: Resilient, Innovative, Dynamic and People-Centred and the Kuala Lumpur Declaration on ASEAN 2045: Our Shared Future adopted by the 46th ASEAN Summit (Kuala Lumpur, 26 May 2025).

[41] The ASEAN Socio-Cultural Strategic Plan, adopted by the 46th ASEAN Summit, 26 May 2025, https://asean.org/wp-content/uploads/2025/05/08.-ASCC-Strategic-Plan_adopted.pdf .

committed to advocate «Health in All Policies (HiAP)» in order to tackle social injustice and health inequity that cause ill health. The choice of such approach stems from the awareness that health development is a shared responsibility and that close collaboration with non-health sector and participation of the people, communities and institutions are prerequisites to achieve healthy ASEAN[42].

Such multi-dimensional and cross-cutting approach is articulated into three main fronts: human rights, development and security.

The human rights argument, which was originally introduced in the aforementioned Healthy ASEAN 2020 Plan, was then confirmed in the ASEAN Human Rights Declaration[43]. Indeed, its Article 29(1) states that «every person has the right to the enjoyment of the highest attainable standard of physical, mental and reproductive health, to basic and affordable health-care services and to have access to medical facilities». It is worth noting that the connotation of health in terms of a right and its recognition to every person, which are uncontroversial in Western culture, are much less obvious in the Asian one which is based on the so-called "ASEAN Values"[44]. Therefore, they are particularly noteworthy.

Analysis of the aforementioned acts also shows that health is considered as an integrated part of the overall socioeconomic development; in particular, it is regarded as an engine for social development and, consequently, the prerequisite for the wellbeing of every ASEAN citizen. Such a link between 'health' and 'social development' is espe-

[42] In this regard see Joint Statement at the 12th ASEAN Health Ministers Meeting, cit., para. 12.

[43] See ASEAN Human Rights Declaration, Phnom Penh, 19 November 2013.

[44] The so-called "Asian Values" provide the background for a different perception of human rights based on the assumption that they are not universal and cannot be globalized. The values commonly proposed as the essence of Asian culture and identity are pragmatism, consensus, harmony, unity, and community. Additionally, unlike Western societies, Asian ones are centred not on the individual but on the family and the Nation. Consequently, according to Asian understanding, their combined interests of family and Nation go before the interests of each individual and, therefore, Asian societies rank social and economic rights over an individual's political rights. In this regard in literature, see M. JACOBSEN, O BRUUN, *Human Rights and Asian Values: Contesting National Identities and Cultural Representation in Asia*, London, 2003. In a political perspective see A. SEN, *Human Rights and Asian Values*, New York, 1997.

cially visible in the ASCC Blueprint 2009-2015 which placed health under the heading of «social welfare and protection». It equally suggests that access to adequate and affordable health care and promotion of healthy lifestyle be ensured in order to enhance the wellbeing and the livelihood of the peoples of the ASEAN. In this context, collaboration among the ASEAN Member States on health promotion, lifestyle and risk factors of non-communicable diseases as well as sharing of best practices on primary health care infrastructure development are highly encouraged by the ASEAN Secretariat.

The 2003 SARS epidemic prompted ASEAN to prioritise another approach when dealing with communicable diseases: a security approach. On the premise that health is a major factor for regional stability and security, ASEAN has, on many occasions, presented challenges, such as HIV/AIDS and avian influenza, as significant security threats to Member States which consistently decided to strengthen their cooperation in this domain and to develop regional policies to face potential pandemics. Such 'security' framing of a health issue-was recognised by the global community as an example of effective international cooperation against a common disease threat[45] and also led to formal agreements between ASEAN and the WHO[46].

The devastating impact of disease outbreaks first-hand, including highly pathogenic avian influenza and African swine fever experienced over the years, has made ASEAN Member States to realize also that zoonotic and transboundary animal diseases can pose significant risks to human and animal health, food safety, economic development and livelihoods. So, on the premise that health of people, animals and ecosystems are strictly connected, ASEAN has decided to answer the need

[45] WHO 's position is relevant in this regard. See https://www.who.int/news/item/29-04-2003-who-welcomes-asean-unity-against-sars

[46] See Memorandum of Understanding of the collaborative framework between the Secretariat of the World Health Organization and the Secretariat of the Association of South-East Asian Nations 2009–2013, and Memorandum of Understanding of the collaborative framework between the Secretariat of the World Health Organization and the Secretariat of the Association of South-East Asian Nations 2014-2017. It is worth noting that all aforementioned Memoranda were concluded within a consolidated partnership between ASEAN and WHO which was formalized in an *ad hoc* Memorandum of Understanding adopted on 26 February 1997.

for comprehensive preparedness and coordinated responses between its Members by embracing the so-called One-Health Approach[47]. In line with it, the ASEAN Coordinating Centre for Animal Health and Zoonoses (ACCAHZ) was established in 2016[48]; it provides a framework of cooperation and coordination among ASEAN Member States to prevent, control and eradicate transboundary animal diseases and zoonoses and to contribute towards food security and safety, animal and human health, poverty alleviation, and the well-being and livelihood of ASEAN people.

Then, still driven by the conviction that animal health and zoonoses are crosscutting concerns that affect regional public health and food safety, ASEAN concluded a Memorandum of Understanding with the World Organization for Animal Health in order to strengthen cooperation to control, prevent, and eradicate animal diseases in the region through actions like developing joint roadmaps and strategies, providing vaccines, and implementing campaigns. Moreover, in 2023, recognising the need for a multi-sectoral and collaborative approach towards health risks, ASEAN Member States committed to establishing a «One-Health Network» and to developing an «ASEAN One-Health Joint Plan of Action»[49]. These initiatives, which were formally launched one year later, aim «to improve regional and national capacity and capabilities with targets that are tangible, measurable, and time-bound, that calls for a stronger cross-sectoral collaboration between the relevant sectors involved in human, animal, plant, and environmental health, as well as food safety among the ASEAN Member

[47] The expression "One-Health Approach" usually refers to an integrated, unifying approach in managing health issues that aims to sustainably balance and optimize the health of people, animals and ecosystems. It moves from the belief that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. About the One-Health Approach followed by ASEAN, see D. L. GOH, *ASEAN One Health Efforts: Tackling the Intersections of Climate Change and Health,* in *RSIS Commentary,* 89, 2024, 1-3; C. LAJAUNIE et al., *Southeast Asia at the heart of the implementation of the One Health Approach*, in *Discover Public Health*, 2025, 335-336; S. LÂM et al., *op. cit.*,

[48] See *supra,* note 21.

[49] See ASEAN's Leaders Declaration on One Health Initiative, Labuan Bajo,10 May 2023.

States»[50]. Now, the ASEAN One-Health Network» and the related One-Health Joint Plan of Action are guiding ASEAN Member States in shifting towards preventive action rather than reactive efforts to boost their health resilience.

6. *Concluding Remarks*

The overview of ASEAN's actions in the field of health security and healthcare reveals that the Organization has mainly served as a forum for exchanging information and sharing best practices. Indeed, rather than imposing legally binding obligations, it has assisted its Member States in harmonising their national standards with reference to international standards, practices and guides[51]. In essence, ASEAN has provided guidance for its Member States by identifying the main directions of their national policies and by suggesting them relevant homogeneous measures, strategies and approaches to be taken. In doing so, it has opted for a flexible approach through the adoption of documents that, although variously named, all share the same legal nature. The blueprints and visions they presented, the declarations and joint statements that have followed, and the various action plans, strategies, etc. that have been approved over the years, can all be classified as *soft law acts,* since they all are not legally binding. In essence, ASEAN has addressed health security and healthcare issues opting for an approach based on strict adherence to the concepts of sovereignty

[50] *Ibid.*

[51] It is worth noting that the ASEAN Member States, being WHO Member States, are obligated to conform to the provisions of the International Health Regulation (2005) as amended. Indeed, they all accepted the 2024 amendments which were adopted by consensus at the World Health Assembly in September 2024 and are formally bound by them since 19 September 2025. However, it should be noted that, although the Philippines welcomed the aforementioned amendments, it had to formally register its rejection of them because, in accordance with domestic legal requirements, international instruments and changes thereto may not enter into force before such requirements are met. However, the Philippines has committed to withdrawing this rejection upon completion of domestic requirements in accordance with Article 63 of the International Health Regulations (2005).

and non-interference with domestic policy of individual ASEAN Member States, as well as to the tradition of solving problems by negotiation and consensus decision-making. That is to say, it has acted in compliance with the so-called «Asian way», namely in compliance with a markedly voluntaristic view of interstate cooperation based on constant mutual benefit[52]. Thus, in line with this approach, which is typical of Asian States' culture[53], on the one hand ASEAN included health into its Agenda only when it became apparent to its Members the actual benefit that would accrue to all of them *uti universi* and each of them *uti singuli* from its collective and concerted handling. On the other hand, it has neither imposed nor recommended solutions that could go against the interests of even just one of its Member States. The choice to address health security and healthcare issues mainly adopting a wide range of non-legally binding instruments allowed ASEAN to strike a delicate but vital balance between the need to act collectively to address common and national regional challenges, on the one hand, and the need to maintain the principle of non-interference with respect to sovereignty, on the other hand. Borrowing an expression used in literature, it can reasonably be stated that ASEAN legal documents on health issues result in the «lowest common denominator» being put forward and reflect the «politics of the possible»[54].

It is to be noted that this approach has been criticised in legal literature. Some scholars argued that the ASEAN Framework, along with the 'ASEAN way' inadvertently perpetuate healthcare disparities

[52] See M. HAAS, *The Asian Way to Peace*, New York, 1989; Y. SATO, *The Asian Way – or Scapegoating?,* in *New Zealand International Review,* 6, 1999, 22-25; P. PENNETTA, *Il regionalismo multipolare asiatico. Contributo al diritto della cooperazione istituzionalizzata fra Stati.* Torino, 2003, 15; E. CEREN, *ASEAN as a Method. Re-centering Processes and Institutions in Contemporary Southeast Asian Regionalism*, London, 2021; A. SCHIFANO, *Organizationhood in the Light of Asian Minimalism*, in *Chinese Journal of International Law,* 2023, 712.

[53] Asian States merely consider interstate cooperation as a means to realize carefully balanced reciprocal interests. So, they tend to participate in forms of association whose activities are regarded as concretely useful, from time to time, and to keep issues of disagreement out of cooperation.

[54] B. BOER, *Introduction to ASEAN Regional Environmental Law,* in W. Scholtz, J. Verschuuren (eds.), *Regional Environmental Law,* Cheltenham, 2015, 259.

for stateless persons, especially during COVID-19[55]. So, according to them, this emphasizes the need for the ASEAN Summit to address these gaps and prioritize the health rights of these vulnerable populations. Some other scholars commented on the lack of a cohesive and coherent regional response, particularly in the early phase of the pandemic[56]. Regional cooperation during this phase was regarded as fragmented, challenging and minimal, and the cause of this was identified in the non-binding nature of ASEAN governance instruments in the health field[57].

While acknowledging these criticisms, ASEAN's growing commitment to health security and healthcare in support of the creation of efficient and resilient national health systems is undeniable. Given its past experience in other areas (such as economy and trade[58]), it is reasonable to assume that ASEAN will succeed in achieving its goals to strengthen health system resilience, to enhance preparedness and response to public health emergencies, and to promote healthy lifestyles, while remaining faithful to the model of "Asian way".

[55] See particularly P. SUWALAK et al., *Scoping the ASEAN Framework and the 'ASEAN Way' on healthcare policies for stateless in ASEAN member states during COVID-19,* in *Discover Health Systems*, 28, 2025, 41-42.

[56] In this regard see F. KIMURA et al., *op. cit.;* F. KLIEM, *op. cit.;* R. DJALANTE et al., *op. cit.;* K. SPANDLER et al., *op. cit.*

[57] See C. CALVIN, *Handling Covid-19 Related to Regional Security According to ASEAN Political-Security Community*, in *Lex Scientia Law Review*, 4, 2020, 19–32; J. RÜLAND, *Covid-19 and ASEAN: Strengthening State-centrism, Eroding Inclusiveness, Testing Cohesion*, in *The International Spectator*, 2021, 72-92; D. DA SILVA NOGUEIRA DE MELO, M. PAPAGEORGIOU, *Regionalism on the Run: ASEAN, EU, AU and MERCOSUR Responses mid the Covid-19 Crisis*, in *Partecipazione e Conflitto,* 1, 2021, 57–78.

[58] See H. HILL, J. MENON, *ASEAN Commercial Policy: A Rare Case of Outward-Looking Regional Integration,* in *Asian Development Bank Working Paper,* 2014, n. 144, <adb.org/sites/default/files/publication/150385/reiwp-144.pdf>; S. Y. CHIA, M. G. PLUMMER, *ASEAN Economic Cooperation and Integration: Progress, Challenge and Future Direction*, Cambridge, 2015; K. ISHIKAWA*, The ASEAN Economic Community and ASEAN economic integration,* in *Journal of Contemporary East Asia Studies*, 2021, 24-41; J. MENON, *Using Regionalism for Globalisation: The ASEAN Way,* ISEAS Yusof Ishak Institute, Working Paper n. 2, 2021, <iseas.edu.sg/wp-content.pdf>.

FRANCO TRUBIANI

HEALTH DATA GOVERNANCE: TOWARDS THE CREATION OF AN INTERNATIONAL AND EUROPEAN DIGITAL SHARING ECOSYSTEM

1. *Introduction*

The issue of health data governance, within the newly articulated international and European vision of data sharing for the benefit of the community, has become central to global reflection on the challenges posed by technological innovation in public health.

Digital technology (from the digitisation of health data to the implementation of AI systems in medicine) will constitute one of the main drivers of healthcare in the future, which has three different and highly ambitious macro-objectives: a) overall improvement in the quality of patient care[1]; b) more efficient development of scientific research[2]; c) the redesign of care pathways and the reorganisation of public healthcare activities to contain the high costs borne by the pub-

[1] F. CASCINI, *Secondary Use of Electronic Health Data Public Health Perspectives, Use Cases and Challenges*, Berlin, 2025, 1 ss.

[2] On this point see see I. SANCHEZ FRIAS, *Secondary uses of health data under the European Health Data Space. Connections with the GDPR and the impact of AI*, en *Revista General de Derecho Europeo*, 65, 2025, 212.

lic purse[3]. It is therefore clear that such ambitious objectives involve a high – complex commitment for all those – stakeholders, policymakers, medical staff and users – who are involved in various ways in public healthcare: it is therefore evident that the method to be used to address these issues must be multidisciplinary and no longer sector-specific.

With specific regard to health data, attention is currently focused primarily on the new EU Regulation 2025/327 – European Health Data Space (EHDS), which follows the path already outlined by the Data Governance Act (EU Regulation 2022/868)[4] and represents one of its first concrete applications contributing to the development of a renewed conceptual framework for health data.

At the level of international law, the One Health approach to global health policy-making has also brought the issue of health data sharing to the forefront[5]. In this respect, particular attention should be drawn to the WHO Pandemic Agreement adopted by the World Health Organization on 20 May 2025[6], and specifically to Article 12

[3] S. KRAUS, F. SCHIAVONE, A. PLUZHNIKOVA, A.C. INVERNIZZI, *Digital trasformation in healthcare: analyzing the current state of research*, en *Journal of Business Research*, 123, 2021, 557 ss.

[4] On this topic see among others L. SPECHT-RIEMENSCHNEIDER, M. HENNEMANN (eds.), *Data Governance Act. Article-by-Article Commentary*, Baden-Baden, Nomos, 2025; J. RUOHONEN, S. MIKELSSON, *Reflections on the Data Governance Act*, en *Digital Society*, 2023, 465 ss.

[5] K. GINSBACH, S. NEGRI, K. ANEJA, E. CESTA, S. BONFIGLI, S. HALABI, *One Health Legal Preparedness: Evolving Legal and Institutional Frameworks for One Health*, en *Journal of Global Health Law*, 2025, 1 ss.

[6] The new WHO Pandemic Treaty was conceived as a necessary response to the serious shortcomings in coordination, transparency and solidarity that emerged during the COVID-19 pandemic. The main objective was to create a binding international legal framework to better prevent, prepare for and respond to future pandemics.

In December 2021, in the midst of the emergency surrounding the second wave of COVID-19, WHO members decided to launch a formal process to create a binding legal instrument.

This decision was formalised at the World Health Assembly (WHA), the highest decision-making authority of the WHO, which established an Intergovernmental Negotiating Body (INB) with a mandate to develop an international agreement on pandemics.

concerning the Pathogen Access and Benefit-Sharing (PABS) system, which will be analysed below.

The regulatory landscape, however, does not end at the European or international level. At national level, there exists a fragmented set of new provisions relating to the so-called Health Data Ecosystem and the Electronic Health Record, as well as the Italian Artificial Intelligence Act (Law No. 132/2025), which includes a specific provision on health data in Article 8.

This complex and layered regulatory framework calls for effective coordination among its various components, in order to identify the most appropriate rules for achieving the objectives outlined above while ensuring the lawful processing of personal data in accordance with the GDPR[7]. Against this background, the present contribution seeks to analyse the structural features of health data circulation, with a view to achieving improved data governance, while assessing both the strengths and the critical aspects of the new regulatory instruments.

The negotiations took place in several rounds between 2022 and 2025, with regular INB meetings and public consultations

The process involved Member States, experts, civil society organisations and representatives of the pharmaceutical industry.

The European Union played an active and leading role in the negotiation process of the WHO Pandemic Treaty, taking a unified position on behalf of its Member States and pushing for the adoption of an ambitious text focused on global solidarity and equitable access to health countermeasures.

The EU participated as an observer with a common negotiating voice, coordinating the positions of Member States through the European Commission and the European External Action Service (EEAS).

After three years of negotiations, the Agreement was approved with 124 votes in favour, none against and 11 abstentions, including that of Italy, which was based on concerns about the risk of damage to national sovereignty that appear to be completely unfounded.

[7] For the idea that the GDPR 'retains its role as a general statute (code) on the subject,' see I.A. CAGGIANO, *Interessi e norme nell'ecosistema europeo dei dati sanitari: la tecnoregolazione abilitativa e le sfide per l'efficacia*, en A. MORACE PINELLI (ed.), *Sanità digitale – Regolamento "EHDS" (UE 2025/327) sullo spazio europeo dei dati sanitari, I Uso dei dati e assetti organizzativi*, Pisa, 2025, 4 ss.

2. *Lessons learned during the COVID-19 pandemic and the PABS system and the circulation of data on pathogens in the Pandemic Treaty*

The COVID-19 pandemic highlighted, as is now widely recognised, a series of significant shortcomings in the public health response to the global spread of infectious diseases.

First, the rapid diffusion of the virus and the consequent prolongation of the health emergency were closely linked to serious delays in the sharing of epidemiological and genomic data by certain States. These delays resulted not only in a slower global response to the spread of the virus, but also revealed the absence of a technological infrastructure capable of supporting rapid early sequencing and effective active surveillance.

The pandemic period also posed unprecedented challenges for pharmaceutical research, which depends on access to large volumes of data, as well as for the intellectual property framework governing pharmaceutical and biotechnological innovation. On the one hand, research institutions were required to adopt entirely new operational models in order to accelerate the development of medical solutions. On the other hand, the patent-based monopoly regime applicable to pharmaceutical and biotechnological inventions came under sustained criticism from the very outset of the pandemic[8].

[8] Much has been said, and continues to be said, about two instruments that could be used to limit the monopoly granted by patent protection on vaccines and medicines: compulsory licensing and the suspension of intellectual property rights, the so-called patent waiver.

In October 2020, India and South Africa submitted a joint request to the WTO for the suspension of all intellectual property rights—not only patents—relating to technologies useful for the prevention, containment, and treatment of COVID-19, with the aim of increasing the production of medicines and vaccines needed to contain the pandemic. That declaration stated that intellectual property rights may constitute an obstacle to increasing the production of vaccines and medicines. The request was not taken into consideration by the General Council of the TRIPS Agreement.

Indeed, the European position expressed in the European Parliament resolution of 10 June 2021 points in the opposite direction to the request for a suspension of patents. It should also be recalled that in September 2021 the World Health Organization (WHO) set an ambitious global target for COVID-19 vaccination. The United

These developments prompted the launch of international negotiations on the so-called Pandemic Treaty, a comprehensive regulatory instrument that includes a provision of particular relevance for the purposes of this analysis, namely Article 12 on the "Pathogen Access and Benefit-Sharing System".

This article provides that:

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "PABS Materials and Sequence Information") and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health

Nations health agency called for 70% of the world's population to be vaccinated by mid-2022.

The idea of a patent waiver appears, in fact, difficult to implement for several reasons: a) from a procedural standpoint, the process is very complex and slow and requires the approval of three quarters of the countries party to the TRIPS Agreement, together with the related difficulty of defining the material scope of the waiver by selecting only those patents that have a direct impact on the fight against COVID-19, in order to avoid the suspension also applying to patents relating to products and processes that do not have a direct effect against COVID-19;

b) there are difficulties in quantifying compensation to private companies for their patents;

c) there is a need to grant the holders of the suspended patents the power to monitor the correct production of the vaccines by third parties, in order to prevent patent holders from being involved in liability issues related to possible harmful effects of vaccines resulting from improper production.

This last observation also allows us to discuss a further problematic aspect that certainly represents a corollary to what has already been said: the production of certain vaccines (specifically, so-called mRNA vaccines) requires substantial know-how that only the originator possesses. It is unlikely that such know-how would be disclosed to competing companies, and the imposition of a coercive obligation to do so is not a realistically viable option.

On this point, see C. GALLI, *Intellectual Property Rights Post-Brexit: From Harmonization to a "Strengthened" TRIPS Agreement*, in *Dir. ind.*, 2022, 23 ss.; C. BIGGI, *Pharmaceutical Patents and Life Sciences in the Face of the COVID Challenge*, en *Dir. ind.*, 2022, 168 ss.

purposes, the Parties hereby establish a multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (hereinafter the "PABS System"), to be developed pursuant to paragraph 2 of this Article.

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the "PABS Instrument") as an annex. The PABS Instrument shall also define the terms for the administration and coordination of the PABS System by the World Health Organization. For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international organizations and relevant stakeholders. All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument.

3. Taking into account the differences in the use of PABS Materials and Sequence Information, the development of a safe, accountable and transparent PABS System shall address traceability measures and open access to data.

The ambitious objectives of the Treaty and the measures to be implemented to achieve them are therefore clear:

- Timely sharing: obligation to report and disseminate verified data and information in a timely manner.
- Transparency in publicly funded research and development contracts: data, output (publications, repositories), licensing policies, prices of final products.
- Importance of communication in various articles, focusing on the importance of sharing information with the population.
- Use of big data in global health surveillance. Through the processing and analysis of huge amounts of data, it is possible to track diseases in real time, identify risk factors and implement preventive measures in a timely manner. In particular, machine learning and predictive analysis technologies make it possible to identify patterns and trends, helping to predict epidemic outbreaks or the evolution of disease spread.

Against this background, Italy's decision to abstain from the vote on the Pandemic Agreement represents a significant setback in the evolution towards an understanding of healthcare as a global public good requiring shared responsibility and coordinated governance. On 20 May 2025, WHO Member States adopted the Agreement with the aim of strengthening global prevention, preparedness and response to future pandemics.

On 20 May 2025, WHO member countries adopted a Global Pandemic Agreement to improve prevention, preparedness and response to future pandemics on a global scale.

The Pandemic Plan involves all Member States, defining the modalities for international coordination in terms of pandemic prevention, preparedness and response, as well as equitable and timely access to vaccines, therapies and diagnostic tools. Key points of the Agreement include: an integrated One Health approach, strengthening national health systems, promoting local production of vaccines and medical tools, creating a multilateral system for access and sharing of pathogens and benefits (PABS), and establishing a global logistics and supply network.

The global sharing of data on pathogens in order to facilitate a rapid response to the emergence of new pandemics appears to be the central point of this regulation, overcoming the inevitable limitations of the patent systems relating to the distribution of Covid-19 vaccines, which had prevented easy procurement by low- and middle-income countries.

Although it is a virtuous and extremely useful tool, if not necessary for the protection of humanity as a whole, Italy incredibly abstained from voting, believing with this (highly contested) choice that it did not want to tolerate limitations on its territorial sovereignty.

The plan was voted for by 124 countries (with the following 11 abstaining, in addition to Italy: Bulgaria, Egypt, Iran, Israel, Jamaica, the Netherlands, Paraguay, Poland, Russia and Slovakia).

An even more serious decision then came from the US, whose current administration has drastically decided to leave the WHO altogether.

The entire national scientific community has come out in favour of the Agreement, and many scientific societies and scientists have ex-

pressed disbelief and bitterness at the Italian decision, which seems all the more unjustifiable given the serious losses that our country has suffered in the Covid-19 pandemic.

This decision prompted strong reactions within the Italian scientific community, where numerous researchers and professional associations expressed concern and disappointment, particularly in light of the severe impact of the COVID-19 pandemic on the country. More broadly, this political stance risks reinforcing criticism of a national health system perceived as insufficiently responsive to scientific evidence and ill-prepared to address the challenges posed by rapid technological and epidemiological change.

3. *The EU4Health Program for the period 2021-2027*

EU4Health is a European Union action programme on health for the period 2021-2027. It is the largest programme ever implemented by the EU in the field of health in terms of financial resources. With a budget of €5.1 billion, it represents the European Union's response to the COVID-19 pandemic and will provide funding to EU countries, health organisations and NGOs.

The programme covers four general areas:

a) Disease prevention;
b) Crisis preparedness;
c) Health systems and health workforce;
d) Digital.

Specifically, the EU4Health Programme pursues the following objectives:

- improving and promoting health in the Union, with a view to reducing the burden of communicable and non-communicable diseases, supporting health promotion and disease prevention, reducing health inequalities, promoting healthy lifestyles and promoting access to healthcare;
- protecting people in the Union from serious cross-border health threats and strengthening the response capacity of health systems and coordination between Member States to deal with serious cross-border health threats, by supplementing national supplies of es-

sential crisis-relevant products and establishing a reserve of medical, healthcare and support personnel;

- Increase the availability and affordability of medicines, medical devices and crisis-relevant products in the Union and support innovation in relation to such products, as well as the efficient use of medicines.
- strengthen national health systems through better use of health data, the development of digital tools and services, and the digital transformation of healthcare; improve access to care, develop and implement Union health legislation, evidence-based decision-making mechanisms and integrated work between Member States health systems.
- strengthen health systems by improving their resilience and developing resource efficiency, in particular by promoting the implementation of best practices and promoting data sharing;
- Strengthen the use and reuse of health data for healthcare provision and for research and innovation, promote the dissemination of digital tools and services, as well as the digital transformation of health systems, including by supporting the creation of a European Health Data Space.

The establishment of the EHDS aims to ensure that everyone has easy and immediate access to their health data in electronic format, that it can be easily shared with healthcare professionals, including in different Member States, and that they have control over their data, within a framework of interoperability and security with the idea of achieving personalized medicine[9].

It also aims to promote a single market for electronic health record

[9] On this point the Council of the European Union in the document *Conclusion on personalised medicine for patients. 2015/C421/03* specifies that "Notes that there is no commonly agreed definition of the term 'personalised medicine'. However, it is widely understood that personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs".

systems and to outline a coherent, reliable and efficient legal framework for the reuse of health data in the public sphere, such as for research, innovation and public policy-making.

The EHDS regulation follows this program and specifically sets among its objectives the reuse of health data for the purpose of improving scientific research and the possibility of controlling the circulation of health data in a secure technological environment.

4. *The European Health Data Space (EHDS) (EU Reg. 2025/327): an overview*

EU Regulation 2025/327 of 11 February 2025, published in the Official Journal of the European Union on 5 March 2025, established the European Health Data Space (EHDS). This Regulation represents a landmark in EU data and health legislation and reflects the increasingly close interconnection between law and digital technology.

As part of the broader EU digital regulatory framework, the EHDS Regulation is the result of a lengthy legislative process aimed at creating, at the legal level, a secure and interoperable digital environment for the processing of health data, which is a prerequisite for the effective digitalisation of healthcare systems[10].

The establishment of the EHDS seeks to ensure that individuals enjoy simple and immediate access to their electronic health data, that such data can be easily shared with healthcare professionals, including across borders, and that individuals retain effective control over their data[11]. These objectives are pursued within a framework that guarantees interoperability, security and trust. At the same time, the Regulation aims to promote a genuine single market for electronic health record systems and to establish a coherent, reliable and efficient legal

[10] M.A. SANDULLI, *Introduzione*, en A. THIENE, S. CORSO (eds.), *La protezione dei dati sanitari. Privacy e innovazione tecnologica tra salute pubblica e riservatezza*, Naples, 2023, 1 ss.

[11] See on this profiles C. PERLINGIERI, *Transizione digitale nella sanità ed ecosistema dei dati sanitari: profili ricostruttivi del fenomeno circolatorio ed implicazione sui dati genetici*, en *Tecn. dir.*, 2024, 485 ss.

framework for the reuse of health data in the public interest, including for research, innovation and policy-making [12].

The objectives of the EHDS are multiple, but they may be conceptually grouped into two core categories that underpin the entire regulatory architecture: the primary use and the secondary use of electronic health data.

By establishing the EHDS, the European Union intends to unlock the previously underexploited potential of health data processing for the benefit of society as a whole. This ambition requires a careful balancing of collective and supra-individual interests with the fundamental rights and freedoms of data subjects, in particular the right to the protection of personal data. Acknowledging that such an ambitious project cannot succeed without a high level of trust, the EU legislator has introduced new rights for individuals, alongside new duties and obligations for entities processing electronic health data, with a strong emphasis on transparency, accountability and liability.

The structure of EU Regulation 2025/327 reflects the logical and teleological distinction between the processing of electronic health data for "primary use" and for "secondary use". Thus, immediately after the "General provisions" in Chapter I (Articles 1 and 2), the rules concerning primary use are found in Chapter II (Articles 3-24). First of all, the "Rights of natural persons" are regulated here. in relation to the primary use of their personal electronic health data and related provisions' (section 1). It then regulates 'Governance relating to primary use' (section 2) and 'Cross-border infrastructure for the primary use of personal electronic health data' (section 3).

Chapter III (Articles 25–49) regulates electronic health record systems and wellbeing applications and is structured into six sections, covering: scope and general provisions; obligations of economic operators; conformity of harmonised software components; market surveillance; interoperability requirements; and the registration of electronic health record systems and wellbeing applications.

The rules governing secondary use are contained in Chapter IV (Articles 50–81), which addresses, in turn, the general conditions for

[12] F. Cascini, M.A. Arcuri, *Uso secondario dei dati personali relativi alla salute: panoramica della normativa europea e nazionale*, en *Dir. inf.*, 2024, 837 ss.

secondary use, governance and procedural mechanisms, access to data, cross-border infrastructure, data quality and utility, and complaints.

The subsequent chapters largely build upon the foundational distinction between primary and secondary use. These include Chapter V on other actions (Articles 82–91), Chapter VI on European governance and coordination (Articles 92–96), Chapter VII on delegated powers and committee procedures (Articles 97 and 98), Chapter VIII on miscellaneous provisions (Articles 99–104), and Chapter IX on deferred application and transitional and final provisions (Article 105).

5. *Secondary use of health data*

As anticipated, the EHDS Regulation expressly complements and specifies the GDPR. The provisions of Regulation (EU) 2016/679 continue to apply in full insofar as they are not modified by the EHDS Regulation, while a more detailed and sector-specific framework is introduced with regard to the processing of electronic health data.

One of the key provisions with which the EHDS must be coordinated is Article 9 of the GDPR, which prohibits the processing of special categories of personal data, including health data, unless specific conditions are met. According to recital 19 of the EHDS Regulation, the provision of access services for healthcare professionals constitutes a task carried out in the public interest and requires the processing of personal data pursuant to Article 6(1)(e) GDPR. The conditions and safeguards applicable to such processing, in accordance with Article 9(2)(h) GDPR, are laid down in the EHDS Regulation itself, including obligations relating to access logging and transparency towards data subjects.

Similarly, recital 20 clarifies that the provision of services enabling patients to access their electronic health data is also carried out in the substantial public interest. Accordingly, the processing of such data is considered necessary for the performance of a task in the public interest pursuant to Articles 6(1)(e) and 9(2)(g) GDPR. In this case as well, the EHDS Regulation defines the relevant conditions and safeguards, including requirements relating to the electronic identification of individuals accessing the services. The processing of personal electronic

health data through the MyHealth@EU platform, which facilitates cross-border healthcare, likewise constitutes a task carried out in the public interest and is necessary for the provision of healthcare in cross-border contexts under Article 9(2)(h) GDPR.

Furthermore, recital 52 provides that the EHDS Regulation may constitute the legal basis, within the meaning of Article 6 GDPR, for the secondary use of personal electronic health data, including the safeguards required under Article 9(2)(g) to (j) GDPR to enable the secure processing of special categories of data.

A particularly significant innovation concerns the limitation of Member States' regulatory discretion. The EHDS Regulation expressly provides that Member States may no longer maintain or introduce additional conditions or restrictions pursuant to Article 9(4) GDPR in relation to secondary use, including requirements for the consent of the data subject. It is explicitly stated that national provisions mandating the consent of natural persons for secondary use processing are no longer permissible.

Consent therefore ceases to be the primary legal basis for the secondary use of electronic health data. While it may still be relevant in specific contexts, it can no longer be imposed as an additional condition for processing under Article 9(4) GDPR. In this respect, the EHDS Regulation marks a decisive departure from national models still centred on consent and effectively excludes ex ante consent as a general requirement for secondary use under EU law[13].

A central role in the secondary use framework is played by the data access authorisation issued by the competent body pursuant to Article 68, following an application and the assessment of a series of substantive requirements. Among these, the necessity of the requested data for the stated purpose is of particular importance. Where the data are not necessary, the application must be rejected.

Of particular importance with regard to the secondary use of electronic health data is the role played by the authorisation issued by the responsible body, pursuant to Article 68, on the basis of the application and following the assessment of a series of requirements.

[13] A. MORACE PINELLI, *Lo spazio europeo dei dati sanitari (reg. UE 2025/327)*, en *Nuova giur. civ. comm.*, 2025, 1017 ss.

Among the assessments that the responsible body must carry out in order to issue the authorisation is that of the necessity of the data for the purpose indicated, as provided for in paragraph 1 of Article 68. If the data are not necessary, the application is rejected. The EHDS Regulation thus appears to reflect a general principle that is one of the cornerstones of the rules on the processing of personal data set out in the GDPR: the principle of necessity. This principle characterises the entire data protection framework and is particularly important in relation to the processing of special categories of data, such as health data.

Access to electronic health data is guaranteed in accordance with the principles of data minimisation and purpose limitation, as set out in Article 66, which distinguishes between cases where data must be anonymised and those where it may be pseudonymised[14].

Access is provided only through a secure processing environment that is subject to technical and organisational measures and complies with security and interoperability requirements, pursuant to Article 73.

Data authorisation is very important within the EHDS framework because it also performs a regulatory function for the related data processing. According to the provisions of paragraph 10 of Article 68, it is data authorisation that establishes the general conditions applicable to the data user. In this respect, data authorisation may, in some ways, be reminiscent of the general authorisation of the National Data Protection Authority. Beyond the substantial differences between the two types of acts, there seems to be a functional parallel, i.e. the attempt to respond to the need to regulate the methods of data processing as concretely as possible through the instrument of administrative law.

Access to electronic health data for secondary use, i.e. for the purposes of achieving the very broad objectives of general interest indicated in Article 53 (public interest in the field of public health or occupational medicine, health policies, statistics, education and training, sci-

[14] On this point see R. RAK, *Anonymisation, Pseudonymisation and Secure Processing Enviroments Relating to the Secondary Use of Electronic Health Data in the European Health Data Space*, en *European Journal of Risk Regulation*, 2024, 328 ss.; E. CALZOLAIO, *Il regolamento sullo spazio dei dati sanitari nella prospettiva della cittadinanza europea*, en *Dir. inf.*, 2025, 328 ss.

entific research, better provision of care), has its legal basis in the same regulation and does not require the consent of the data subject, as Member States may only introduce "stricter measures and additional safeguards at national level to protect the sensitivity and value of certain data", such as genetic data, which, as is well known, cannot be anonymised or pseudonymised[15]. This is due to the recognised public nature of the purposes identified by the European legislator for the secondary use of health data.

The promotion of public interest in healthcare is shared by the Italian legislator who, in order to facilitate scientific research, expressly considered and promoted by Article 9 of the Constitution, has recently amended Article 110 of the Privacy Code, removing the obligation to consult the Data Protection Authority in advance in the case of clinical studies (so-called "clinical trials") for which it is impossible to obtain the consent of the data subjects[16]. In legal theory, with regard to the social need to promote scientific research, the "unethical nature of non-research" in the name of the absolutisation of privacy has been pointed out[17].

In this way, anyone who intends to carry out scientific research in cases where it is not possible to obtain the consent of the interested party, will be able to proceed without prior opinion from the Data Protection Authority but will in any case have to comply with the guarantee measures established by the Data Protection Authority itself in general terms with a specific provision.

[15] S. ORLANDO, *Il Regolamento EHDS nel sistema del nuovo diritto europeo dei dati*, in A. MORACE PINELLI (a cura di), *Sanità digitale. Regolamento "EHDS" sullo spazio europeo dei dati sanitari*, Pisa, 2025, 93-94.

[16] L. FRACASSA, *Le problematiche applicative dell'articolo 110 Codice della privacy: la farmacovigilanza e le sperimentazioni cliniche*, ivi, 341 ss.

[17] A.A. MOLLO, *Prime riflessioni sul Regolamento europeo sullo spazio europeo dei dati sanitari: l'uso secondario e il diritto di esclusione riguardo al trattamento dei dati sanitari elettronici personali*, en *BioLaw Journal*, 2025, 20; C. DI SOMMA, *EHDS: opportunità e sfide per il riuso dei dati sanitari in ambito di ricerca scientifica*, in F. TRUBIANI (ed.), *Sistemi di intelligenza artificiale in medicina verso lo spazio europeo dei dati sanitari. Un dialogo multidisciplinare*, Turin, 2025, 164 ss.

Through this system the intention is to reduce the role of the interested party's consent[18].

With specific reference to the secondary use of electronic health data – and therefore also for genetic and genomic data – a complex procedure has been structured in which, instead of the consent of the interested party, the central role is entrusted to the Bodies responsible for access to health data (art. 55 EHDS).

It therefore seems desirable to interpret Article 110 differently, which today should be applied, in a opposite sense, only with reference to those data for which the EHDS highlights the need to proceed with the legal basis of the consent of the data subject (e.g. genetic data, biobanks data[19], health apps)[20]. Consequently, it is clear that operators will be required to comply more strictly with the principle of accountability under Article 24 of the GDPR[21] by mapping the processing of personal data carried out and the categories of personal data processed within the organisation, identifying only those necessary for the purposes pursued.

[18] On this point see A. BERNES, *Dati e ricerca genetica. Dalla tutela individuale alla gestione procedurale*, en *BioLaw Journal*, *Special Issue*, 2022, 71.

[19] On the need to use the word bioarchives instead of biobanks see P. FEMIA, *Il campione biologico come oggetto di diritti. Bene giuridico e processi di valorizzazione*, en D. FARACE (ed.), *Lo statuto etico-giuridico dei campioni biologici umani*, Rome, 2016, 192.

[20] The legal complexity of the biobank phenomenon also refers to the breadth of consent to processing to allow the subject to whom the data refers to maintain control over them: on this point see M. CIANCIMINO, *Circolazione "secondaria" dei dati sanitari e biobanche. Nuovi paradigmi contrattuali e istanze personalistiche*, en *Diritto fam. pers.*, 2022, 36 ss.; I. RAPISARDA, *Ricerca scientifica e circola-zione dei dati personali. Verso il definitivo superamento del paradigma privatistico*, en *Eur. dir. priv.*, 2021, 310 ss.; F. GASPARI, *La circolazione dei dati genetici e delle biobanche: limiti e prospettive de iure condendo*, en *Federalismi.it*, 2022, 155 ss.
See also the decision of the Italian Supreme Court of Cassation with reference to the transfer of a biobank and the related genetic database 7th of october 2021, n. 27325, en *Dir. fam. pers.*, 2022, 37 ss., with annotation of M. CIANCIMINO, *Circolazione "secondaria" di dati sanitari e biobanche. Nuovi paradigmi contrattuali e istanze personalistiche*.

[21] R. CARLEO, *Il principio di accountability nel GDPR: dalla regola alla autoregolazione*, en *Nuovo dir. civ.*, 2021, 359 ss.

With regard to other health data, the EHDS no longer allows Member States to require the express consent of the data subject.

The general interest in their use tends to prevail over the individual interest of the person to whom the data refer. The general rule is the circulation of electronic health data, without the need for the express consent of the data subject for processing. However, the individual is recognised as having the right to object (the so-called right of exclusion), but this right is waived when there is a particularly qualified overriding public interest "in the pursuit of legitimate scientific and social objectives" (Article 71 of the EHDS Regulation).

6. *The right of exclusion and the opt-out mechanism*

The right of exclusion, enshrined in Article 71 of the EHDS Regulation, plays a pivotal role in the governance of secondary use. As stated in recital 54, its purpose is to balance the need for comprehensive and representative datasets with the individual's autonomy over personal electronic health data, which are considered particularly sensitive. The right of exclusion may be exercised at any time, does not require justification and is reversible. Through the opt-out mechanism provided for in Article 71(2), individuals may express their wish to exclude their personal electronic health data from secondary use.

Once the right of exclusion has been exercised, the data concerned may no longer be made available or otherwise processed for secondary purposes. Member States may, however, in exceptional cases, establish alternative mechanisms allowing access to such data, provided that strict conditions are met and that specific and appropriate measures are adopted to safeguard the fundamental rights and personal data of the individuals concerned[22].

After exercising the right of exclusion, such data shall not be made available or processed in any other way. Member States may, in exceptional cases, provide for other mechanisms to make data available for which the right of exclusion has been exercised. In this case, the Regu-

[22] A.A. MOLLO, *Prime riflessioni sul Regolamento europeo sullo spazio europeo dei dati sanitari*, cit., 21 ss.

lation stipulates that a series of strict conditions must be met to protect data subjects and that specific and appropriate measures must be taken to protect the fundamental rights and personal data of natural persons[23].

The exception is justified in view of "certain purposes closely related to the public interest, such as activities to protect against serious cross-border threats to health or scientific research for important reasons of public interest". The rules allowing for the override of the exclusion, in any case, pursuant to Article 71(5), 'must respect the essence of fundamental rights and freedoms and constitute a necessary and proportionate measure in a democratic society to serve reasons of public interest in the pursuit of legitimate scientific and social objectives'. In the light of the public interest, therefore, the processing of personal electronic health data may take place regardless of the exercise of the right to exclusion, even if the person concerned objects.

The relationship between the right of exclusion and the rights already recognised in the GDPR is characterised by its particular connection with some of them, in terms of nature, similarity and purpose pursued. In particular, the relationship between exclusion and opposition referred to in Article 21 of the GDPR appears to be very significant. While opposition is exercised in a more or less proceduralised form, through a specific communication to the data controller, in which the data subject indicates the reasons related to his or her particular situation, exclusion generally disregards the reasons of the data subject and is exercised more immediately. Objection applies to processing that has already begun, while exclusion may also refer to processing that has not yet begun. Both are a primary expression of the individual's self-determination in relation to data processing and an expression of their will.

Unlike opposition, however, exercising the right of exclusion does not necessarily entail deletion. In other words, personal electronic health data must no longer be processed, but not in any way. The fact that the provisions of the EHDS Regulation allow, in exceptional cases, access to such data even after exclusion has been exercised

[23] S. FAILLACE, *Prospettive civilistiche in ordine agli spazi di condivisione dei dati sanitari alla luce del Regolamento EHDS*, Milan, 2025, 225.

means that processing must still take place, i.e. at least collection and storage.

The right to exclusion is therefore related to the right to erasure of data (referred to in Article 17 of the GDPR). While the erasure of data determines the cessation of all data processing and the removal of the data, exclusion does not entail the removal of data, but only prevents certain data processing operations[24].

In other words, since the EHDS Regulation provides for the possibility that personal electronic health data for which the right of exclusion has been exercised may still be accessed, albeit exceptionally and subject to strict conditions and procedures, such data can never be permanently removed[25]. Within the EHDS, exercising the opt-out does not therefore result in the deletion of data from the space itself, but only prevents the processing of that data. The health data remains within the space and is not deleted[26].

The exercise of the opt-out remains in any case a means of self-determination for the individual, who can thus, albeit in a limited way, have control over information relating to their health.

As expressly recognised in Article 71, the opt-out is based on the will of the individual. In this sense, it is similar to the traditional consent of the data subject, which constitutes an expression of the individual's will. However, while the consent of the data subject is the legal basis for the processing of personal data and a basis for derogation from the processing of sensitive data, and therefore operates ex ante to legitimise the processing itself, the opt-out does not affect the source of legitimacy or the legal basis, but operates, so to speak, ex post, taking the form of dissent.

[24] C. PERLINGIERI, *Transizione digitale nella sanità ed ecosistema dei dati sanitari: profili ricostruttivi del fenomeno circolatorio e implicazioni sui dati genetici*, cit., 498 ss.

[25] S. CORSO, *Lo spazio europeo dei dati sanitari. Prime riflessioni sul Regolamento UE 2025/327*, en *Nuove leggi civ. comm.*, 2025, 392.

[26] S. FAILLACE, *Prospettive civilistiche in ordine agli spazi di condivisione dei dati sanitari alla luce del Regolamento EHDS*, cit., 220.

7. *Unlawful processing of electronic health data and civil liability*

Article 100 of the EHDS Regulation is expressly devoted to compensation, providing that *"any natural or legal person who has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to obtain compensation in accordance with Union and national law."*

A comparison with Article 82 GDPR—successor to Article 23 of Directive 95/46/EC—is essential. While a comprehensive reconstruction of the EU regime of civil liability for unlawful data processing falls outside the scope of this analysis, it is clear that Regulation (EU) 2025/327 is firmly embedded within that conceptual framework and draws much of its meaning from it, while at the same time reshaping it in light of the specificities of electronic health data[27].

The explicit reference to both natural and legal persons removes any doubt as to the standing of entities that have suffered damage as a result of infringements of the EHDS Regulation. Implicitly, the provision recognises that unlawful processing may cause harm not only to data subjects but also to other actors involved in the health data ecosystem. Data circulation involves multiple, and sometimes competing, interests, yet it may be analysed as a single phenomenon from the perspective of liability[28].

Unlike Article 82 GDPR, which expressly identifies the data controller and the data processor as the parties liable for compensation, Article 100 of the EHDS Regulation does not explicitly designate the liable parties. Guidance is instead provided by recital 101, which refers to the digital health authority, the body responsible for access to health data, the controller of health data and the user of health data as potential entities liable to compensate for damage.

[27] G. NAVONE, *Ieri, oggi e domani della responsabilità civile da illecito trattamento dei dati personali*, en *Nuove leggi civ. comm.*, 2022, 162.

[28] C. SCOGNAMIGLIO, *Danno e risarcimento nel sistema del Rgpd: un primo nucleo di disciplina eurounitaria della responsabilità civile?*, en *Nuova giur. civ. comm.*, 2023, 1151.

The interpreter is aided by recital 101, according to which compensation for damages should be paid by "the digital health authority, the body responsible for access to health data, the controller of health data or the user of health data". However, while the holder of health data and the user of health data are entities that directly or indirectly benefit from the processing of electronic health data within the framework of the EHDS, the digital health authority and the body responsible for access to health data are institutional entities of the EHDS and are responsible for implementing the regulation.

The failure to explicitly state the parties liable for compensation and the implicit extension of liability to a group of parties that is, in principle, undefined is accompanied by the absence of provisions on the possible relationship between those who, in various ways, have violated the EHDS regulation, on exculpatory evidence, on joint and several liability for compensation, on recourse and on the competent court, which are instead set out in Article 82 of the GDPR in paragraphs 2, 3, 4, 5, and 6 respectively. The EHDS thus becomes an arena for agents with a wide variety of characteristics, for whom it is impossible to predict the type of relationship that binds them and connects them to the person who has suffered damage as a result of their conduct.

Added to this is the lack of any reference to the subjective element, with the most sparse wording possible, which leaves almost every possible argument about the nature of liability itself open to interpretation. The indication in recital 101 confirms the indispensability of hermeneutic work, which must be sufficiently flexible and in line with the case law of the Court of Justice.

The constituent elements, moreover, appear to be the same as those in the corresponding case concerning the protection of personal data: damage (consequence), classified as material or immaterial; conduct that violates EU law; a causal link between the harmful event, which constitutes a violation of the Regulation, and the prejudicial consequence suffered. The interpretation of Article 82 of EU Regulation 2016/679 offered by the case law of the Court of Justice therefore appears to be relevant for the interpretation of Article 100 of EU Regulation 2025/327.

Thus, as clarified by the judgment of 4 May 2023 in the Oster-

reichische Post case[29], even in the case of liability for breach of the EHDS Regulation, the damage must be proven and will not be resolved by the breach itself. In other words, it is not a case of damage in re ipsa, but in order to obtain compensation, the injured party must prove that they have actually suffered damage[30]. Furthermore, compensation for non-material damage will not be subject to the condition that the damage suffered has reached a certain degree of seriousness. Therefore, the injured party may also obtain compensation for minor damage[31].

It will be up to the national courts to determine the quantification of the damage, applying the internal rules of each Member State relating to the amount of financial compensation, but on condition that the principles of equivalence and effectiveness of Union law are respected[32].

Furthermore, as clarified in the context of personal data protection, it can also be said for the rules on the processing of electronic health data that compensation does not have a punitive or deterrent function, but only a compensatory one, and that the seriousness of the infringement is not relevant for the purposes of determining the amount of compensation.

Given a similar correspondence – albeit limited – with the system of administrative penalties, it can also be stated that, in order to determine the amount of compensation due, on the one hand, the criteria for setting the amount of administrative fines should not be applied mutatis mutandis and, on the other hand, the fact that multiple violations of the regulation attributable to the same processing operation

[29] CJEU, 4th of May 2023, C-300/21, *UI* c. *Osterreichische Post AG*, en *Foro it*., 2023, IV, c. 268 f., with annotations of AL. PALMIERI, R. PARDOLESI, *Mai futile il danno non patrimoniale da violazione della privacy (purché lo si provi!)*; S. PAGLIANTINI, *Un altro palcoscenico della « guerra » tra le corti: il danno (immateriale) bagatellare dell'art. 82 Gdpr*; M. FEDERICO, *«La tempesta perfetta »: ultime dalla Corte di Lussemburgo su danno (non patrimoniale) da illecito trattamento dei dati personali e possibili risvolti in tema di tutela collettiva*.

[30] CJEU, 4th of october 2024, C-507/23.

[31] CJEU, 20th of june 2024, C-182/22 e C-189/22.

[32] N. MUCCIOLI, *La responsabilità civile sanitaria nell'ecosistema digitale*, en *La sanità digitale*, cit., 424.

concern the person claiming compensation should not be taken into account.

In order to determine the amount of compensation for non-material damage, it will be considered that such damage, also caused by a breach of personal electronic health data, is not, by its nature, less serious than personal injury. Compensation may also be awarded for non-material damage resulting from the loss of control over personal electronic health data, even for a short period of time, provided that the injured party can prove the damage suffered[33].

The express reference to the law of the Member States marks a point of contact between the two areas and the conceptual contamination, which can be found at the applicative level, between the supranational and the domestic rule. This does not mean that the unity of the concept in Union law is lacking; indeed, its existence is confirmed by the reference to the interpretative work of the Court of Justice. Rather, it means that the institutions of civil law interact directly, within the rules governing the compensatory remedy, and are aimed, beyond the boundaries of the legal system, at the fullness and effectiveness of compensation for the damage suffered[34].

In approaching the categories of national tradition, the reflection allows us to question the injustice of the damage. From the wording of the provision, it is clear that the activation of the compensatory remedy is linked to the conduct carried out in violation of the EU norm and not so much to the damage to a protected subjective situation[35].

In line with the view expressed by Mirko Faccioli[36], Article 100 of Regulation (EU) 2025/327 and Article 82 GDPR, both of which lack an explicit reference to the concept of "unlawfulness" as understood

[33] CJEU, 14th of december 2023, C-340/21.

[34] C. CAMARDI, *Illecito trattamento dei dati e danno non patrimoniale. Verso una dogmatica europea*, en *Nuova giur. civ. comm*., 2023, II, 1136.

[35] S. CORSO, *Lo spazio europeo dei dati sanitari*, cit., 595.

[36] M. FACCIOLI, *La responsabilità civile per violazione della disciplina sull'utilizzo dei dati sanitari elettronici nell'European Health Data Space (art. 100 Reg. 2025/327/UE)*, en *Resp. civ. prev*., 2025, 15. In a different mode see S. CORSO, *Lo spazio europeo dei dati sanitari*, cit., 589.

in domestic legal systems[37], refer instead to material and non-material damage, categories that broadly correspond to pecuniary and non-pecuniary damage under national classifications.

Recital 101 of Regulation (EU) 2025/327 and recital 146 GDPR employ almost identical language in stating that the concept of damage should be interpreted broadly in light of the case law of the Court of Justice, in order to ensure full and effective compensation for the damage suffered. Consequently, the interpretative principles developed in relation to Article 82 GDPR may, at least in principle, be transposed to the liability regime under Article 100 of the EHDS Regulation"[38]. That being said, it seems that the interpretative guidelines developed by the EU Court of Justice around Article 82 of the GDPR can then be, at least in principle, transposed to the liability referred to in Article 100, Regulation 2025/327/EU[39], to affirm that in this area too, as in the case of unlawful processing of personal data[40]: for a claim for compensation to arise, it is not sufficient that the defendant's conduct be unlawful, but it is also necessary for the injured party to prove that they have actually suffered some damage as a result of the infringement[41], in line with the established domestic principle that only

[37] With regard to Article 82 of the GDPR, see G. BUSET, *Ingiustizia del danno e antigiuridicità del fatto nella responsabilità da trattamento dei dati personali*, en *Riv. dir. civ*., 2024, p. 1008 ss., who concludes hisanalysis by stating that "ultimately, looking at it with disenchantment, in the provision of Article 82 of the GDPR one can easily find a rule of liability, far from eccentric, based on the selective model of the unlawfulness of the fact (as such): capable of supplanting, and not just of accompanying, when unexpressed, that of the unjustness of the damage. The violation of the provisions of the Regulation by the injuring party is, in fact, a constitutive element of a situation that positive law explicitly contemplates, together with the damage (-consequence) and the causal link between the violation and the harm; while there is no trace of a mandatory violation of the legally protected interests of the injured party".

[38] M. GAMBINI, *Principio di responsabilità e tutela aquiliana dei dati personali*, Naples, 2018, 46 ss.

[39] M. RATTI, *La responsabilità da illecito trattamento dei dati personali*, in G. FINOCCHIARO (ed.), *La protezione dei dati personali in Italia. Regolamento UE n. 2016/679 e d.lgs. 10 agosto 2018, n. 101*, Bologna, 2019, 776 ss.

[40] M. FACCIOLI, *La responsabilità civile per violazione della disciplina sull'utilizzo dei dati sanitari elettronici nell'European Health Data Space*, cit., p. 11.

[41] S. CORSO, *Lo spazio europeo dei dati sanitari*, cit., p. 395.

consequential damage is compensable and not mere event damage; a national rule or practice that makes compensation conditional on the damage reaching a certain minimum threshold of seriousness is incompatible with EU law[42]; the fear of a single potential misuse of one's data by third parties, nurtured by the claimant following the breach of the regulation, may in itself constitute compensable non-material damage, provided that the national court verifies its validity in relation to the specific circumstances and in relation to the data subject[43]; the quantification of compensation, although left to national legal systems, must be carried out with a view to compensation and not punishment, so that the level of seriousness or the possible malicious nature of the infringement committed by the defendant or the fact that he has committed a number of infringements of the Regulation should not be taken into account, nor may the criteria for determining the amount of administrative fines for non-compliance with European legislation be used. In other important respects, the two rules differ even more markedly.

The subjective scope of Article 82 of the GDPR and Article 100 of Regulation 2025/327/EU is different. In the first case, standing is attributed to "anyone", mainly therefore to the data subject to whom the personal data affected by the breach belong[44], while in the second case it is attributed to "any natural or legal person", which "removes any doubt as to the possibility of seeking compensation even by entities that have suffered damage" and "recognises that non-compliance with the Regulation may also cause damage to persons other than natural

[42] M. FACCIOLI, *La responsabilità civile per violazione della disciplina sull'utilizzo dei dati sanitari elettronici nell'European Health Data Space*, cit., p. 12.

[43] CJEU, 14th of december 2023, C-340/21, *VB* c. *Natsionalna agentsia zaprihodite*, en *Danno resp*., 2024, 566 ss., with annotation of C. BRIGNOLO, *Violazione di dati personali: responsabilità e danni risarcibili*.

[44] There is, however, debate as to whether the reference to "anyone" confers the right to bring an action pursuant to Article 82 of the GDPR also to all other parties who indirectly suffer harm as a result of the unlawful processing of others' personal data, or whether the latter can only act pursuant to Article 2043 of the Italian Civil Code: on this point, see M. FACCIOLI, *Civil Liability for the Unlawful Processing of Personal Data*, in R. BOCCHINI (ed.), *Trattato sulle piattaforme digitali. e-Agorà*, Turin, 2025, 899.

persons and therefore also to persons other than those to whom the health information refers"[45].

In terms of passive legitimacy, on the other hand, Article 82 of the GDPR expressly mentions the data controller and data processor, while Article 100 of Regulation 2025/327/EU, is completely silent on this point, although it could be supplemented by the reference in recital 101 of the measure to the digital health authority, the body responsible for access to health data, the controller of health data and the user of health data as parties liable for compensation[46]. In this regard, however, it cannot be not be noted that this places entities in clearly different positions on the same level, given that the latter two are entities that, directly or indirectly, benefit from the processing of electronic health data within the framework of the EHDS, while the digital health authority and the body responsible for access to health data are institutional entities responsible for implementing the new regulation[47].

The reference to 'Union and national law' in Article 100 of Regulation 2025/327/EU, therefore opens the door to the formation of a markedly varied, disorganised and fragmented framework of civil liability, which in any case appears to be nothing more than a reflection of the complexity that characterises the subject matter regulated, namely the EHDS. It must therefore be concluded that while Article 82 of the GDPR, as mentioned at the beginning of this paper, appears to have introduced a (first) fragment of a European Union civil liability system, Article 100 of Regulation 2025/327/EU, the direction taken would instead appear to be the traditional opposite, with EU legislation intervening in the matter in question in a fragmented and unsystematic manner[48].

[45] S. CORSO, *Lo spazio europeo dei dati sanitari*, cit., 592.

[46] M. FACCIOLI, *La responsabilità civile per violazione della disciplina sull'utilizzo dei dati sanitari elettronici nell'European Health Data* Space, cit., 12.

[47] S. CORSO, *Lo spazio europeo dei dati sanitari*, cit., 593.

[48] F. BRAVO, *Riflessioni critiche sulla natura della responsabilità da trattamento illecito di dati personali*, en N. ZORZI GALGANO (ed.), *Persona e mercato dei dati. Riflessioni sul GDPR*, Milan, 2019, 383 ss.

8. *Concluding remarks*

At this stage, some concluding observations are warranted. The analysis of both international and European regulatory developments reveals a clear shift in approach compared to the past. The concepts of "sharing" and "protection" of health data now occupy a central position in efforts to improve patient care and to prevent future pandemics.

At the same time, there is an evident move away from a model of health data governance based exclusively on patient consent, towards a framework that recognises the legitimacy of secondary use for scientific research and other public interest purposes[49].

The regulatory framework shaped by the Pandemic Agreement and the EHDS Regulation demonstrates that health data governance is not merely a technological challenge, but also requires a profound rethinking of the categories of European private law. The transition from a static conception of data as an extension of individual privacy to a dynamic, solidarity-based understanding calls for a reassessment of notions such as ownership and the availability of personality rights.

The EHDS thus appears to propose a new paradigm for the secondary use of health data for scientific research, no longer based on consent as a general rule, but on the notions of general societal interest and public interest.

When providing access to a data set, the responsible body must use state-of-the-art pseudonymization or anonymization technology, ensuring to the maximum extent possible that a natural person cannot be re-identified by users of the health data. However, this presupposes a shared European standard on the definition of anonymous data.

Legal definitions and requirements for anonymization and pseudonymization vary considerably from one country to another. Therefore, more precise guidance is needed at the EU level on how to

[49] On the difficult line of demarcation between pure research and research with profit-making aims see F. MOLLO, *Il trattamento dei dati genetici tra libera circolazione e tutela della persona*, en *Jus Civile*, 2022, 89 which specifies how the boundaries between research serving a "common good" and private research are blurred. See also F. VITERBO, *Principi di trattamento e di* governance *dei dati personali in ambito sanitario*, en *Rass. dir. civ.*, 2023, 1460 ss.

meet the GDPR requirements in this area, so as to achieve a reasonable balance between risks and benefits, to eliminate legal uncertainty and the resulting fear of litigation for secondary users of the data[50].

Moreover, anonymization, especially if particularly rigorous, can reduce the usefulness of the data for scientific research[51].

The opt-out mechanism definitively marks the overcoming of consent as the sole pillar of sensitive data circulation. At the same time, the complexity of the EHDS's multi-level governance structure highlights the urgent need for a more advanced civil liability regime. The fragmentation of roles among data holders, access bodies and data users renders traditional fault-based liability models increasingly inadequate to ensure effective compensation in the event of harm[52].

The hypothesis of strict liability or joint and several liability of the network, appears to be the only viable way to prevent the opacity of algorithms and digital infrastructures from resulting in unfair damage to the data subject.

In conclusion, the European Health Data Space is a legal laboratory where private law must demonstrate its resilience and raises the question for the interpreter as to whether it is possible to hypothesize negotiation models related to the circulation of health data[53].

[50] I.A. CAGGIANO, *Interessi e norme nell'ecosistema europeo dei dati sanitari: la tecnoregolazione abilitativa e le sfide per l'efficacia*, cit., 4 ss.

[51] It should be noted that the regulation adopts a rather broad definition of this concept, referring to research that contributes not only to public health, but also "to the evaluation of technologies in the health sector or that ensures high levels of quality and safety of healthcare, medicinal products, or medical devices, with the aim of benefiting end users." These include, by way of example, development and innovation activities for products or services and those involving the training, testing, and evaluation of algorithms including in the field of medical devices, in vitro diagnostic medical devices, artificial intelligence systems, and digital health applications. For an analysis of the subject matter prior to the advent of the EHDS Regulation, see S. ESPOSITO, *Tutela dei dati personali e ricerca scientifica in ambito sanitario: il GDPR e il Regolamento sullo Spazio Europeo dei Dati Sanitari (EHDS)*, en *Jus Civile*, 2024, 932 ss.

[52] S. ORLANDO, *Il regolamento EHDS nel sistema del nuovo diritto europeo dei dati*, en *Sanità digitale*, cit., 99.

[53] V. RICCIUTO, *Base giuridica del trattamento del dato sanitario nel contesto dell'EHDS*, en *Sanità digitale*, cit., 16.

The success of this ambitious reform will depend on the balance between the efficiency of data circulation and the robustness of remedies to protect individuals.

Only through transparent governance and certain compensation protection can technological innovation truly be said to serve the individual and their fundamental right to health.

The challenge for legislators and interpreters will be to ensure that refusal of secondary use remains an accessible and non-penalising option, preserving the relationship of trust between citizens and health institutions that is essential for the stability of the system.

While the new regulatory framework undoubtedly deserves recognition, it is also clear that significant legal uncertainties remain. Addressing them will require a constructive and forward-looking approach, not only from legal scholars, but also from healthcare professionals and Member States, all of whom will play a crucial role in implementing and enforcing the complex rules governing the circulation of health data[54].

In essence, a genuine alliance between lawyers, healthcare professionals and technology developers is required—one that is firmly oriented towards technological progress and the protection of patients.

More generally, on the thesis of the capitalization of personal data, see V. RICCIUTO, *L'equivoco della privacy. Persona* vs *Dato personale*, Naples, 2022; in a different sense see C. PERLINGIERI, *Transizione digitale nella sanità ed ecosistema dei dati sanitari: profili ricostruttivi del fenomeno circolatorio e implicazioni sui dati genetici*, cit., 493 ss.; F.G. VITERBO, *Principi di trattamento e di governance dei dati personali in ambito sanitario*, cit., 1474 ss.

[54] F. CASCINI, *L'uso dei dati nel nuovo Regolamento (EU) 2025/327 sullo Spazio europeo dei dati sanitari. Finalità primarie e secondarie e loro implicazioni per gli Stati membri*, en F. TRUBIANI (ed.) *Sistemi di intelligenza artificiale in medicina verso lo Spazio europeo dei dati sanitari. Un dialogo multidisciplinare*, Turin, 2025, 146 ss.

IDA SANTALUCIA, MICHELE SORRENTINO, PAOLO MONTUORI,
MARIA FIORE, MARGHERITA FERRANTE, MARIA TRIASSI

THE 'ONE HEALTH' PRINCIPLE: APPLICATIONS IN THE INTERNATIONAL HEALTH REGULATIONS

1.1. *The International Health Regulations*

The International Health Regulations (IHR) are the cornerstone framework for global health security, established as a nearly universally recognized World Health Organization (WHO) treaty with 196 States Parties[1]. The primary purpose of the IHR is to safeguard global health by preventing, protecting against, and responding to international public health threats in a way that minimizes disruptions to international traffic and trade[2]. One of the IHR's critical functions is the declaration of Public Health Emergencies of International Concern (PHEIC), which enables a coordinated global response to significant health risks[3].

Initially adopted by the World Health Assembly in 1969, the IHR has undergone several amendments in response to evolving global

[1] World Health Organization (WHO), *International Health Regulations*, https://www.who.int/health-topics/international-health-regulations#tab=tab_3.

[2] L.O. GOSTIN, R. KATZ, *The International Health Regulations: The Governing Framework for Global Health Security*, Milbank Q, vol. 94, no. 2, 264–313, Jun. 2016, doi: 10.1111/1468-0009.12186.

[3] World Health Organization (WHO), *Emergencies: International health regulations and emergency committees*, https://www.who.int/news-room/questions-and-answers/item/emergencies-international-health-regulations-and-emergency-committees.

challenges, such as the expansion of international trade and travel. Following the 2002-2004 SARS outbreak, significant revisions were made in 2005 to bolster global preparedness and response mechanisms. These updates, which came into force in 2007, created a legal framework for managing public health events with the potential to cross international borders[4]. Notably, the IHR is the only international legal instrument that empowers the WHO to function as the main global surveillance system for health threats[5] [6].

The COVID-19 pandemic exposed significant weaknesses in the IHR and their monitoring systems, leading to widespread demands for reform. It became evident that the existing tools for pandemic prevention and response were inadequate. In response, both the IHR Review Committee and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme have recommended changes, incorporating lessons from the pandemic to enhance global health preparedness for future outbreaks.

So the systematic review process to identify improvements to be made was launched in early 2021 and was the priority topic at the 77th WHO Assembly on 27 May – 1 June 2024.

After arduous negotiations the seventy-seventh World Health Assembly (WHA) announced on June 1 that it had reached consensus over amendments to the International Health Regulations (IHR) on the last day of its annual meeting in Geneva.

The amendments adopted by the Seventy-seventh World Health Assembly through resolution WHA77.17 (2024) became operative 12 months following the notification by the Director-General to all States

[4] World Health Organization (WHO), *International Health Regulations (2005): IHR monitoring and evaluation framework*, 2018. Accessed: Oct. 22, 2024. [Online]. Available: https://iris.who.int/bitstream/handle/10665/276651/WHO-WHE-CPI-2018.51-eng.pdf?sequence=1.

[5] K.S. KOHL, R. R. ARTHUR, R. O'CONNOR, J. FERNANDEZ, *Assessment of Public Health Events through International Health Regulations*, United States, 2007–2011, Emerg Infect Dis, vol. 18, no. 7, 1047–1053, Jul. 2012, doi: 10.3201/eid1807.120231.

[6] J. YOUDE, *The International Health Regulations*, in *Biopolitical Surveillance and Public Health in International Politics*, New York: Palgrave Macmillan US, 2010, pp. 147–175. doi: 10.1057/9780230104785_7.

Parties, which occurred on 19 September 2024 so the amendments came into force on 19 September 2025.

WHO Director-General Dr Tedros Adhanom Ghebreyesus said: "The strengthening of the International Health Regulations represents a historic commitment to protect future generations from the devastating impact of epidemics and pandemics. We know that no one is safe until everyone is safe. The IHR amendments reaffirm our shared responsibility and solidarity in the face of global health risks."

According to WHO: "Eleven of the 196 IHR States Parties rejected the 2024 amendments. For them, previous versions of IHR continue to apply, though rejections may be withdrawn at any time. WHO will support IHR States Parties, as requested, in integrating the amendments to the regulations into national legal frameworks and strengthening institutional capacities to work together to build a safer, healthier future for all".

The Italian government, like that of the USA, has officially notified the World Health Organization of its rejection of the 2024 amendments to the International Health Regulations.

1.2. *The IHR Monitoring and Evaluation Framework*

Through the IHR, countries have agreed to build their capacities to detect, assess and report public health events[7] and, to ensure that, signatory countries develop the necessary capabilities for detecting, assessing, and reporting public health events, the IHR Monitoring and Evaluation Framework was established. This framework includes several tools: the State Parties Annual Report (SPAR) and three voluntary tools, i.e. Joint External Evaluation (JEE), After Action Reviews (AAR), and Simulation Exercises (SimEx) to assess weaknesses and gaps in national health systems[8].

[7] A. WILDER-SMITH, S. OSMAN, *Public health emergencies of international concern: a historic overview*, in *Journal of Travel Medicine*, Volume 27, Issue 8, December 2020, taaa227, https://doi.org/10.1093/jtm/taaa227.

[8] M. N. UTHEIM, M. GAWAD, K. NYGÅRD, E. MACDONALD, M. FALK, *Assessing public health preparedness and response in the European Union- a review of regional*

In accordance with the objectives declared by the WHO[9], the IHR monitoring and evaluation framework (MEF) has the following objectives: Support States Parties in evaluating their status of IHR implementation and determining their progress towards fully developed, sustainable IHR capacities ; assist States Parties with a qualitative examination of the functionality of IHR capacities; provide States Parties with information relevant to the development and maintenance of capacities required under the IHR; help build mutual trust and accountability among States Parties; provide States Parties with a uniform format for annual reporting to the World Health Assembly on the status of IHR implementation.

It also has the purpose of: to provide a common approach to implementing IHR monitoring and evaluation activities in countries; analyse and disseminate information generated and ensure their use; enable WHO to report annually to the World Health Assembly on the status of IHR implementation by States Parties; enable WHO to better identify possible support for capacity development in countries; provide a common approach to supporting countries in implementing IHR monitoring and evaluation; enable partner agencies and institutions to target and prioritize their support for capacity development in countries, and ensure alignment in this support.

Under Article 54 of the IHR, each State Party must annually report its progress in implementing the required capacities using the SPAR tool. The SPAR tool evaluates 35 indicators across 15 core capacities necessary to detect, assess, notify, report, and respond to public health risks and acute events. These indicators are broken down into attributes that measure the level of achievement for each capacity. The SPAR questionnaire is issued annually after the World Health Assembly, and States Parties use a multisectoral approach to gather infor-

simulation exercises and after action reviews, in *Global Health*, vol. 19, no. 1, 79, Oct. 2023, doi: 10.1186/s12992-023-00977-y.

[9] International Health Regulations (2005) IHR MONITORING AND EVALUATION FRAMEWORK: Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

mation from all sectors involved in implementing the IHR core capacities[10].

The updated IHR States Parties self-assessment annual reporting tool consists of the capacities needed to detect, assess, notify/ report and respond to public health events of national and international concern. These cover: IHR legislation and financing, IHR strategic coordination, Zoonotic events and the human-animal interface, Food safety, Laboratory, Surveillance, Human resources, Emergency preparedness for response, Health service provision, Risk communication, Points of entry (POE), Chemical events, Radiation emergencies. The information obtained through the States Parties self-assessment annual reporting tool is submitted by States Parties to the WHO Secretariat. Each year it is analysed and presented by capacity, and country, in a report of the Director-General to WHO governing bodies, and is also published on the WHO Global Health Observatory.

JEE (Joint External Evaluations) is a voluntary, external and peer-reviewed evaluation, all of which are essential components of the IHR monitoring and evaluation framework. JEE's purpose is to measure country-specific progress toward the completion of strategic goals that include the prevention and detection of public health threats and the response to them. Each State should report on the status of these objectives completed after making a voluntary request. This report includes 19 technical areas and each capacity contains one or more indicators, each of which is divided into five levels of achievement, defined through a series of attributes. The implementation status of each capacity is represented by a score that indicates the country's progress, its ability to embed technical competencies within institutions, and its efforts to ensure their long-term sustainability.

An after-action review (AAR) is a qualitative assessment of the measures taken in response to an event. It provides a detailed examination of the actions carried out during a real public health incident to identify gaps, lessons learned, and effective practices. An AAR offers a

[10] A.A. Khan, F.A. Alamri, A.A. Alahmari, Y.S. Almuzaini, S.A. Al Omary, H.A. Jokhdar, *Historical Evolution and the Future of Global Health Security*, in *Journal of Nature and Science of Medicine*, vol. 5, no. 4, 322–327, Oct. 2022, doi: 10.4103/jnsm.jnsm_55_22.

structured process through which individuals and organizations involved in preparing for and responding to the event can reflect on their experiences and perspectives. This reflection helps systematically and collectively determine what worked, what did not, the reasons behind these outcomes, and ways to improve. The ultimate goal is to pinpoint actions needed to enhance plans and response capacities for future acute public health events.

A simulation exercise (SimEx) is a method of practising, training, monitoring, or evaluating response capabilities by describing or mimicking an emergency and enacting a corresponding response. SimEx provides an evidence-based evaluation of functional capacities for managing emergencies and for reinforcing preparedness and response measures. Such exercises serve as valuable tools for identifying and assessing preparedness levels and can be used throughout all phases of emergency preparedness development to test whether proposed plans and procedures are practical, adequate, sufficient, and efficient.

1.3. *State Parties Self-Assessment Annual Reporting Tool*

The SPAR (State Parties Self-Assessment Annual Reporting Tool) assumes a distinctive role in pandemic management because, within the architecture of the International Health Regulations (IHR 2005), it represents the primary mechanism through which States monitor and annually report their level of preparedness. During the COVID-19 pandemic, this tool gained practical relevance not so much as a predictor of health outcomes, but as a lens through which to interpret the strength or fragility of each country's response capacities. The self-assessment process embedded in SPAR makes it possible to reconstruct, both retrospectively and in real time, the maturity of surveillance systems, laboratory capacity, the presence of operational rapid-response mechanisms, the resilience of essential health services, and the coherence of risk-communication strategies.

Within this framework, several empirical studies have shown that SPAR scores were not merely descriptive elements but had an identifiable relationship with some epidemiological dynamics observed during COVID-19. Analyses demonstrate that higher SPAR scores were gen-

erally associated with lower COVID-19 incidence and slower growth in case peaks, while the effective implementation of IHR-required capacities contributed to reducing confirmed cases and deaths, although such effects tended to diminish over time. Moreover, high scores in specific areas—such as legislation, financing, coordination, food safety, human resources, public health emergency management frameworks, points of entry, and radiological emergencies—proved particularly significant in influencing case trajectories and reported mortality. However, despite these overarching trends, notable discrepancies persist, as evidenced by the fact that some countries with high SPAR scores nonetheless recorded very high cumulative mortality rates. The analysis of score variations between 2019 and 2020 further highlighted significant improvements in middle-income countries, while capacities related to zoonotic events and the human–animal interface remained largely unchanged. Finally, examples such as Lebanon—whose management of the pandemic proved more effective than that of regional nations with lower IHR scores—underscore the crucial role that socioeconomic and regional contexts play in shaping overall crisis response.

Nevertheless, the pandemic also exposed the intrinsic limitations of SPAR, showing that self-assessment, although useful for tracking progress and fostering accountability toward IHR obligations, may at times provide a more optimistic picture than reality. The discrepancy observed in several countries between high SPAR scores and underperforming pandemic responses indicates that structural measurement of capacities alone fails to capture essential dimensions such as the quality of political-institutional governance, levels of public trust, decision-making speed, and adaptability under uncertain conditions. SPAR, moreover, by virtue of its annual and synthetic nature, does not measure dynamic parameters crucial in a pandemic context, such as the speed of laboratory scale-up, the actual operability of supply chains, the robustness of information systems, or the capacity of health authorities to communicate effectively and consistently with the population.

COVID-19 therefore transformed SPAR into an indispensable interpretive tool for understanding the baseline from which countries entered the crisis, as well as for identifying which system components require strengthening to ensure that declared capacities can be trans-

lated into effective actions during a global emergency. In this sense, SPAR served as a bridge between declared preparedness and observed preparedness: it made it possible to compare expectations with reality, to reconstruct where the major bottlenecks emerged, and to highlight that an annual assessment, in the absence of external audits or indicators of operational performance, may not be sufficient to capture the complexity of factors determining the success of a pandemic response.

After the pandemic, SPAR has been reinterpreted as an essential part of a broader monitoring ecosystem, useful not only for evaluating capacity status but also for guiding necessary investments, institutional reforms, restructuring of command chains, and multisectoral integration. Its role during COVID-19 demonstrated that preparedness is not a static condition but an ongoing process, and that SPAR can function as the metronome of this process—provided it is integrated with external evaluations, regular exercises, operational analyses of real-time data, and independent validation mechanisms. Ultimately, in pandemic management SPAR was neither a perfect predictor nor a substitute for external assessment, but it acted as a structural foundation for interpreting the ability of health systems to absorb shock, as a tool of institutional narrative to understand emerging vulnerabilities, and as a methodological basis for reformulating prevention and response strategies in anticipation of future global threats.

2.1. *One Health*

The One Health approach is a comprehensive, multisectoral, and transdisciplinary framework that acknowledges the fundamental interconnectedness of human, animal, and environmental health. Its conceptual origins date back to the 19th century with pioneers of comparative medicine, yet the modern formulation of One Health emerged in the early 2000s as a direct response to accelerating ecological disruption, global mobility, and the increasing frequency of zoonotic spillover events. International agencies such as WHO, FAO, and WOAH formalized and institutionalized One Health collaboration following major epidemics—including avian influenza, SARS, Ebola, MERS, and more recently COVID-19—demonstrating that fragmented sectoral

responses are insufficient to confront complex biological threats. In public health, One Health principles inform an array of strategic applications, ranging from integrated surveillance systems and early warning mechanisms to coordinated outbreak preparedness and cross-sector governance of biological risks. This approach has become essential in addressing infectious and zoonotic diseases, as it allows for simultaneous monitoring of animal reservoirs, human populations, and environmental drivers such as land-use change, biodiversity loss, and climate variability. Furthermore, One Health plays a central role in combating antimicrobial resistance through joint stewardship programs involving human healthcare, veterinary practices, and agriculture. Additional fields of application include food safety, water sanitation, vector control, and the mitigation of chemical and ecological hazards. By promoting sustained collaboration among epidemiologists, clinicians, veterinarians, ecologists, environmental scientists, and policymakers, the One Health framework strengthens the capacity of health systems to prevent, detect, and respond to emerging threats, ultimately contributing to more resilient societies and sustainable global health security.

2.2. *The institutionalization of the One Health principle*

At the international level, four United Nations agencies—the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Organisation for Animal Health (WOAH, formerly OIE), and the World Health Organization (WHO)—collaborate to drive the change and transformation necessary to mitigate the impact of current and future health challenges at the human–animal–environment interface at global, regional, and national levels.

In response to international calls to prevent future pandemics and to promote health in a sustainable manner through the One Health approach, the four organizations developed the "One Health joint plan of action 2022–2026" (OH JPA)[11], the Plan emphasizes the

[11] https://www.who.int/publications/i/item/9789240059139.

commitment of the four organizations to collectively support and advance the implementation of One Health. It builds upon, integrates, and adds value to existing global and regional One Health initiatives and coordination mechanisms, aiming to strengthen the capacity to address complex, multidimensional health risks through more resilient health systems at the global, regional, and national levels.

The European Union has progressively institutionalized the One Health approach, establishing it as a guiding principle of its policies in the fields of public health, animal health, food safety, and environmental protection. This approach stems from the acknowledgement of the interdependence between human, animal, and ecosystem health, and it now constitutes a cross-cutting element of the Union's regulatory, scientific, and administrative action.

First, the integration of the One Health paradigm is evident within the European Health Union, which situates prevention, preparedness, and response to health emergencies within an intersectoral framework. Programmes such as EU4Health (2021–2027) finance initiatives aimed at strengthening health systems and enhancing response capacities to emerging threats through coordinated mechanisms across the human, veterinary, and environmental sectors.

A central role is played by the main EU agencies operating in the health and food domains. The ECDC (European Centre for Disease Prevention and Control) coordinates surveillance of human infectious diseases and systematically collaborates with the EFSA (European Food Safety Authority) on analyses concerning zoonoses, vector-borne diseases, and risks associated with the food chain. In parallel, the EMA (European Medicines Agency) contributes to the implementation of the One Health approach by regulating the use of antimicrobials in food-producing and companion animals, supporting integrated monitoring systems for antimicrobial resistance. Together, these agencies have formalized their cooperation through joint statements and frameworks that emphasize the necessity of interdisciplinary coordination.

The sector in which the One Health approach is most advanced is the fight against antimicrobial resistance (AMR), recognised as a priority threat at both European and global level. The EU One Health Action Plan against AMR (2017) adopts coordinated measures across

human, animal, and environmental health, promoting a significant reduction in antimicrobial use and improved biosafety practices. Within this context, a key legislative reference is Regulation (EU) 2016/429, known as the Animal Health Law, which provides a coherent and modernized legal framework for the prevention and control of animal diseases, including zoonoses. This regulation strengthens epidemiological surveillance, risk management, and cooperation between veterinary and public health authorities, and represents one of the principal legal pillars of the One Health approach in the EU.

The EU also applies the One Health principle in the area of food safety and agricultural supply chain regulation, following the "farm to fork" model, which integrates health, environmental, and animal welfare considerations. The Farm to Fork Strategy, part of the European Green Deal, seeks to reduce the use of pesticides and antimicrobials, promote sustainable practices, and ensure high levels of protection for both animal and human health.

Regarding preparedness, the establishment of the HERA (Health Emergency Preparedness and Response Authority) represents an additional institutional consolidation of the One Health paradigm. HERA enables integrated monitoring and response to health threats of human, animal, or environmental origin, including emerging zoonotic events. In parallel, research programmes such as Horizon Europe support projects focusing on the interactions between human health, climate change, biodiversity, and the emergence of new zoonotic diseases.

Finally, the European Union promotes the One Health approach within its external action, cooperating with organisations such as WHO, FAO, WOAH, and UNEP, and supporting partner countries in strengthening their health systems through an integrated and multisectoral perspective.

In summary, the application of the One Health principle in the European Union is now systematic, multilayered, and legally structured. It is grounded in both political and scientific initiatives and binding regulations, such as the Animal Health Law, and constitutes one of the central pillars of contemporary European health governance.

Italy, thanks also to its membership in the European Union, is a

legislatively advanced nation in terms of environmental protection, veterinary health, and food safety.

Among the many initiatives, we can highlight the Italian National Prevention Plan (PNP) 2020–2025, adopted through an agreement within the State–Regions Conference, that identifies the One Health principle as the guiding framework for addressing potential or existing risks arising from the environment–animal–ecosystem interface; then there are the annual "guidelines" of the Ministry of Health which expressly indicate the application of the One Health principle in multiple fields.

In June 2023, the Parliamentary Intergroup "One Health" was presented at the Chamber of Deputies. Its purpose is to develop legislative measures aimed at establishing a governance model capable of overcoming the current fragmentation in initiatives concerning environmental, human, and animal health protection. The challenge is to integrate the environmental dimension into the agendas of institutions responsible for health-related matters.

Moreover, as part of the reorganization of the Ministry of Health, in September 2023 the establishment of the Department for Human Health, Animal Health, and the Ecosystem (One Health), and for International Relations, was established. The One Health Department has been assigned numerous functions and responsibilities for the practical implementation of the principle and also manages relations with the World Organisation for Animal Health (WOAH) and the Food and Agriculture Organization (FAO) and, for matters within its competence, with the European Union, the Council of Europe, the World Health Organization and other international organisations.

A notable and significant step forward in the recognition of One Health principles was achieved with Constitutional Law No. 1 of 2022, which amended Article 9 of the Constitution by introducing the protection of the environment, biodiversity, and ecosystems, also in the interest of in more or less recent times future generations, as well as the protection of animals, to be regulated according to the forms and procedures established by national legislation.

It should be underscored that this reform affected the fundamental constitutional principles of the Italian Republic and that such an intervention, consistent with the systematic nature of codification,

was not accidental, but rather the result of deliberate and considered choice.

From a comparative perspective, it is worth noting that this constitutional amendment aligns with a broader trend observed in numerous countries that, in more or less recent times, have adopted similar constitutional reforms aimed at safeguarding the same principles, in some cases with even more far-reaching provisions.

Consistently the reform also modified Article 41 of the Italian Constitution, specifying that private economic initiative must not cause harm to health or the environment and that both public and private economic activities may be directed and coordinated for environmental purposes.

With regard to the amendment of Article 41 of the Constitution, it should be noted that, in defining the limits to private economic initiative, the legislator has expressly chosen, in the new formulation, to place the terms health and environment before security, freedom, and human dignity.

It can therefore be stated that Italy has sought in various ways to incorporate the One Health principle into its legal framework and/or to orient policymaking accordingly. This development should not be regarded as an endpoint but rather as a foundation for increasingly substantial application, particularly within sectoral legislation.

3.1. *Application of One Health in the IHR*

The One Health approach, that is, the systemic integration of human, animal, and environmental health, assumes a fundamental role in the implementation of the IHR during pandemics, because many emerging threats—particularly zoonotic ones—continuously traverse species boundaries. According to the World Health Organization, strengthening global health security at the human–animal interface is essential for enhancing countries' ability to prevent, detect, and respond effectively to outbreaks of animal origin. In particular, the IHR Monitoring and Evaluation Framework (MEF), of which SPAR is a component, relies heavily on multisectoral collaboration: annual reporting activities, external

evaluations (JEE), simulation exercises, and after-action reviews all require the involvement not only of the human health sector, but also of veterinary and environmental services.

To facilitate this integration, WHO and the World Organisation for Animal Health (WOAH) have developed specific tools, including a manual that harmonizes SPAR reporting with the PVS (Performance of Veterinary Services) pathway, enabling a more efficient combination of veterinary capacity assessments with those required under the IHR. During the COVID-19 pandemic, the adoption of a One Health approach proved strategic not only for understanding the zoonotic origin of the virus, but also for activating coordinated national responses. Through the so-called National Bridging Workshops (NBW), organized by WHO, FAO, and WOAH, leaders from the health, veterinary, and environmental sectors met to analyze synergies, identify gaps in collaboration, and develop shared multisectoral roadmaps. This process of joint capacity building strengthened intersectoral coordination precisely in areas—such as zoonoses, food safety, and antimicrobial resistance—that are particularly critical during a pandemic.

The effectiveness of this One Health model is further reinforced by an international governance framework: the joint Operational Framework proposed by WHO and WOAH provides a structured methodology for assessing and strengthening the interfaces between human and animal health, promoting national adherence to shared and sustainable policies. In this sense, SPAR is no longer merely an annual report of health capacities, but becomes part of a broader One Health governance mechanism, in which veterinary and environmental authorities contribute systematically to the assessment process and to continuous improvement.

The practical contribution of this integration also manifested during the pandemic through multisectoral simulation exercises and After-Action Reviews, in which national teams jointly evaluated responses to zoonotic events, analyzing points of breakdown and opportunities for improvement. This made it clear that genuine pandemic preparedness cannot rely solely on capacities declared within the human health sector, but requires effective operability of veterinary and environmental institutions, integrated governance, and a structured dialogue among all relevant actors.

In the International Health Regulations, the One Health principle is not explicitly mentioned; however, it is applied within the IHR MEF.

As stated by WHO[12] the output of the four MEF tools (SPAR, AAR, SimEx, JEE) must be considered holistically and interpreted together to obtain a comprehensive picture of the current status of IHR implementation; indeed all the components complement each other to evaluate IHR capacities and their functionality, and these evaluation findings can serve as one of the bases for countries to develop and implement national action plans in collaboration with multiple sectors, using a One Health approach and strategic partnership.

In fact, one of the purposes of the framework—which provides complementary qualitative and quantitative information for States Parties and the WHO Secretariat—is also to offer guidance for public health. WHO recommends that the gaps and recommendations identified following the application of the MEF tools be addressed through a multisectoral National Action Plan for Health Security (NAPHS), consistent with a One Health approach. The implementation of national plans, developed also by considering the tools' outputs and viewed through a One Health lens, is essential to strengthen countries' preparedness and response capacities for health emergencies. Naturally, the national plan must be economically sustainable and therefore must take into account the national budget and be aligned with national public health strategies.

A key element of an effective multisectoral approach is acknowledging that threats to human health may arise not only from other people, but also from domestic animals, livestock, wildlife, food sources, chemicals, and radiation. For this reason, the ability to prevent, detect, and respond to such events or hazards must be present across all relevant sectors, supported by established and functioning mechanisms that allow regular collaboration and coordination among them.

Moreover, it should be noted that, with the aim of bridging the

[12] International Health Regulations (2005) IHR MONITORING AND EVALUATION FRAMEWORK: Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

human–animal interface, WHO and international organizations such as the World Organisation for Animal Health (OIE/WOAH) and the Food and Agriculture Organization of the United Nations (FAO) are working jointly to reinforce cooperation between the human and animal health sectors in implementing the IHR and enhancing global health security.

Together, these organizations contribute to the development of tools and methodologies that ensure veterinary sector involvement across all components of the IHR MEF. Such tools facilitate joint assessments to identify synergies and existing gaps in cooperation between the two sectors at local, national, and international levels.

Among these instruments is the International Health Regulations–Performance of Veterinary Services Pathway (IHR-PVS) National Bridging Workshop, used within countries to design roadmaps that strengthen coordination mechanisms for IHR implementation at the human–animal interface. This workshop plays a crucial role in engaging countries in applying and sustaining a One Health approach.

WHO applies the One Health framework to reinforce IHR core capacities—including zoonotic disease management, antimicrobial resistance, and food safety—and supports this work by providing tools that help integrate multisectoral perspectives into these processes.

More specifically, Annual Reporting (SPAR), as mentioned above, is obligatory and assesses 13 core capacities, many of which require contributions from several sectors, particularly the animal health sector, within a One Health framework. To facilitate this process, WHO and the World Organisation for Animal Health (WOAH) created a handbook designed to support countries in evaluating those capacities in which veterinary services play a role in IHR implementation. This guide aligns the IHR Annual Reporting Tool with the Performance of Veterinary Services (PVS) Pathway, a widely recognized system for assessing national veterinary services.

Furthermore, the Joint External Evaluation (JEE), a voluntary and cooperative mechanism, is a multidisciplinary process through which WHO assists countries in reviewing their capacities across 19 technical areas. To support this evaluation, WHO and WOAH developed a handbook that highlights the areas where veterinary services contribute to IHR implementation. This document underscores the comple-

mentarities between the JEE Tool and the Performance of Veterinary Services (PVS) Pathway, a long-established framework used by national veterinary authorities to measure and strengthen their performance.

Likewise, simulation exercises (SimEx) place strong emphasis on multisectoral collaboration, as they simulate public health emergencies to develop and test the operational capabilities of emergency systems and procedures needed for an effective response—particularly in the case of zoonotic outbreaks.

Lastly, the After-Action Review (AAR) consists of a structured dialogue among stakeholders aimed at systematically examining preparedness, the actions taken during the response, achievements, gaps, contributing factors, and potential areas for improvement, with a particular focus on health events that occur at the human-animal-environment interface, in agreement to One Health principles.

3.2. *Critical issues and conclusions*

The International Health Regulations (IHR) already embed, in multiple dimensions, the principles of a One Health approach—particularly through the Monitoring and Evaluation Framework, which systematically integrates human, animal, and environmental health considerations into the assessment of States Parties' preparedness and response capacities. Instruments such as SPAR, JEE, AAR, and SimEx demonstrate that the WHO has long recognized the interdependence of sectors and has operationalized this recognition through multisectoral evaluation, coordinated capacity-building, and cross-cutting governance mechanisms.

However, the extensive negotiations conducted in the aftermath of the COVID-19 pandemic, culminating in the amendments entering into force on 19 September 2025, represented a unique opportunity to consolidate and elevate the One Health paradigm within the binding normative architecture of the IHR. Despite this potential, the adopted amendments stop short of fully strengthening the legal and operational centrality of One Health, leaving several structural and conceptual gaps unaddressed.

Given the increasing frequency of health threats emerging at the human–animal–environment interface, a more explicit, ambitious, and enforceable integration of One Health principles within the IHR framework remains essential. Future amendment cycles should therefore prioritize the systematic incorporation of One Health across surveillance, preparedness, governance, data-sharing, and capacity-building obligations. Only through such strengthened, forward-looking reforms can the IHR evolve into a truly comprehensive instrument capable of guiding global health security in an era of complex and interdependent risks.

FEDERICO FRANCESCO GUZZI

CARE AND PREVENTION IN THE NATIONAL CONTEXT [1]

1. *Introduction*

This article focuses on the national system of health protection in relation to care and prevention. To understand the dynamics, the evolution and the critical issues of the system, the analysis perspective is not limited to legislative and administrative aspects; it is necessary to consider personal and medical, political-institutional, technological, environmental and economic factors. About this last aspect, it is necessary to highlight its relevance and the related critical issues: the matter is attracted by formal logics in which the substantial aspects are put in the background.

It is necessary to avoid that the economic aspect sacrifices the essential levels of care and to avoid an exclusive focus on the calculation profiles rather than on the real care response.

Another critical aspect is connected to effective coordination, which remains a wish (which is the main objective of the European strategy). Just think of the (unresolved) relationship between State and Regions (that the pandemic has highlighted) and, in general, between institutions; to the problem of rationalising spending; to the coordina-

[1] This scientific essay is a summary, and an updated version of a wider essay (still related to the PRIN in question) published on *Ambientediritto*, 1, 2025.

tion between institutional actors; to the concrete implementation of healthcare digitalization and the "new" territorial healthcare.

The legislator and the administration lack a synthesis approach that establishes the priority of interventions and implementation mechanisms that instead "dissolves" into a multiplicity of objectives and strategies and lines of intervention. The implementation technique in the various programming plans has a 'fluvial' and redundant character.

2. *Right to health, national health service, particularly the spending profiles*

Referring to previous contributions (and to the indicated bibliography) the analysis of the general principles on health protection (art. 32 of the Constitution), in this article we focus on some economic and planning data.

With regard to the first aspect, general taxation supports the national health system; obviously, we must consider the resources available to which the controversial notion of health as a "financially conditioned right" is associated.[2]

With regard to the second aspect, programming (although the National Health Plans 2006-2008 is still in force today, which was remedied by the so-called Pact for Health, most recently the 2019-2021), has a central value as a fundamental principle in terms of health protection, a qualifying aspect of the National Health Service. It is developed on a double track: a National Health Plan and a Regional Plan.

The first is prepared by the Government on the proposal of the Minister of Health, considering the proposals coming from the Regions; it is adopted by Decree of the President of the Republic follow-

[2] Critic B. PEZZINI, *Il diritto alla salute a quarant'anni dall'istituzione del servizio sanitario nazionale*, in *Rivista di BioDiritto*, 2, 2019, in part. 126 - 127; G. CREPALDI, *Dai lea ai livelli essenziali delle prestazioni concernenti i diritti civili e sociali (art. 117, II Co., lett. M), Cost.),* in M. ANDREIS (a cura di), *La tutela della salute tra tecnica e potere amministrativ,* Milano, 2006, in part. 67.

ing deliberation by the Council of Ministers, in agreement with the Unified Conference and has a three-year duration.

About financial aspects, it is necessary to highlight the profound transformations of the system, also to the influence of European legislation; there has been a profound review in terms of health expenditure (which in all countries of the world, represents one of the largest items of the overall public expenditure).

Governments have acted. Italy has introduced the principle of balanced budgets into the Constitution. The attention (from an economic view) to the budget has led to a reduction[3] that has put the implementation of the principles of protection of the right to health.

From 2012 until the pandemic emergency (healthcare spending in 2020 was in fact equal to 123,474 billion, with an increase of 6.7 per cent compared to 2019), there was a reduction of about thirty billion. This made the country among those that have reduced health spending (public and private) the most.

In 2025, however, there was an increase compared to the previous year: health spending went from 130 billion to 143 billion euros, with a ratio to GDP equal to 6.4% and therefore slightly increased compared to 6.3% in 2024.

Conversely, healthcare spending paid by citizens has increased, from 28.13 billion in 2016 to 40.26 billion in 2022. Out-of-pocket spending paid by Italians out of pocket and not reimbursed by the National Health Service equal to 30.48 billion in 2017, 32.29 billion in 2018, 34.85 billion in 2019, 30.79 billion in 2020 and 37.16 in 2021.

These data result from the monitoring of health expenditure in 2023, published by the State Accounting Office, which also shows that after the slowdown recorded in 2020 (-11.6% compared to 2019), the growing trend of private health expenditure continues throughout the country.

Regardless of the PNRR investments, to which an increase in intensive and sub-intensive care beds and other equipment is linked, the

[3] About it, Constitutional Court n. 309/1999, according to which financial constraints can influence and guide the discretionary choices of the legislator, but not to such an extent as to assume burden too high to compress the right to health. Previously, Constitutional court n. 304/1994.

2021 Public Finance Document planned a decrease in spending of 7.3% in 2021, 6.7% in 2022, 6.6% in 2023 and 6.3% in 2024.

The medium-term structural budget plan (2025-2029), approved on 27 September 2024, compared to the 2024 Public Finance Document, foresees that the healthcare expenditure/PIL will go from 6.3% (in the two-year period 2024-2025) to 6.2% (in the two-year period 2026-2027).

A critical element concerns the aseptic cut in regional spending (over which the central power continues to have maximum control by establishing how much and how to allocate).

On this point, the Constitutional Court n. 154/2017 has underlined the need to avoid interventions aimed at redefining - according to the ordinary time frames of budget cycles - the framework of financial relations between the State, the Regions and local authorities based on the economic situation of the country.

About it, sentence n. 169/2017 of the Constitutional Court highlighted the continuing failure to implement law no. 42 of 2009, which does not allow the full application of the financing instruments for regional functions provided for by art. 119 of the Constitution.

In this regard, it has been highlighted that this is "a heavy conclusion", because it denounces the absence in the Italian legal system of a "necessary separation of the LEA requirement from the costs of other health services"[4].

In essence, a careful evaluation of health expenditure is necessary, distinguishing essential expenditure - through an adequate investigation - to avoid that public finance needs assume priority value.

Ultimately, the adequate and 'considered' determination of essential levels becomes strategic to establish a constitutional limit to aseptic and horizontal reductions in public spending.

About the planning on prevention (and the National Plan 2020 - 2025, for the implementation of the Essential Levels of Performance), this will be discussed later when the topic of the management of the various health risks is analysed within the macro-objective of environment health and the prevention of infectious diseases.

[4] L. ANTONINI, *Il diritto alla salute e la spesa costituzionalmente necessaria: la giurisprudenza costituzionale accende il faro della Corte*, in *Federalismi.it*, 22, 2017, 7.

Now – with reference to the spending profiles – two data points can be highlighted.

The first concerns national planning, which provides that the Regional Health Fund assigns only 5% of the total resources for health to prevention activities (both for communicable and non-communicable diseases); moreover, except for some regions, the remaining ones are unable to spend this 5% (the average is 2.9).

For prevention, Italy spends as much as countries that do not have a public health service. Less than 2% of the Regional Health Fund is dedicated to the surveillance and prophylaxis of infectious diseases. According to data processed by the Ministry of Health, in Italy, in 2018, approximately 5.5 billion euros were spent on prevention, equivalent to 4.37% of total health expenditure. This figure is short of almost one billion euros, although each Region should allocate 5% of health expenditure to prevention activities and programs as established in the agreement between the State and the Regions (of December 2009) and as subsequently provided for by Legislative Decree no. 68/2011.

However, the regions have never considered this percentage as binding. Data from the Ministry of Health shows - in the decade 2008-2018 - that spending on prevention has always been less than 5% of total health spending.

The framework does not seem to be affected even by the PNRR[5] which has no dedicated expenditure items for prevention. Mission 6 (Health) has in fact provided funding of 19.7 billion, divided into two components: *Proximity networks, intermediate structures and telemedicine for territorial healthcare* and *Innovation, research and digitalization of the national health service.*

The strengthening of structures has been foreseen (to implement territorial healthcare) which includes interventions to strengthen the services provided in the territory; the strengthening and creation of structures such as Community Houses: out of 1717 planned, only 485

[5] About it, M. NOERA, M. ONADO, *Una crisi annunciata: analisi economica della sanità italiana dopo la pandemia,* in *Merc. Conc. Reg.*, 2, 2022; A. SAPORITO, *Il Piano Nazionale di Ripresa e Resilienza ed il diritto alla salute, nuova evoluzione?,* in *www.amministr@tivamente.com*, 1, 2024.

were active, and Community Hospitals: out of 428 planned, 124 are active (report AGENAS); the strengthening of home care; the development of telemedicine[6] and a more effective integration with all social and health services.

Measures were then envisaged for the renewal and modernization of existing technological and digital structures; the completion and dissemination of the Electronic Health Record (EHR)[7]; a better capacity for providing and monitoring the Essential Levels of Care through more effective information systems.

Significant resources are earmarked for scientific research, technology transfer and strengthening the skills and human capital of the NHS (staff training).

Nothing has been envisaged in the area of prevention: this raises doubts because the problems caused by the pandemic are linked to prevention, in addition to the fact that, in introducing the Mission, the text underlines that "*the pandemic has made some critical aspects of a structural nature even more evident, which in perspective could be aggravated by the increased demand for care resulting from demographic, epidemiological and social trends*". The focus has been on the structural deficits of the national health system.

In any case, it should also be noted that the above-mentioned interventions can still be traced back to aspects connected to prevention when, for example, new prevention paths are planned in the community homes. Also, telemedicine can take on the function not only of treatment but also of prevention through monitoring (blood pressure,

[6] About telemedicine, D. MARINO, A. MICELI, D. NACCARI CARLIZZI, G. QUATTRONE, *Telemedicina, cos'è e come farla in Italia: tecnologie e finalità, un modello possibile*, in *www.agendadigitale.eu*, 2023; L. FERRARO, *La telemedicina quale nuova (e problematica) frontiera del diritto alla salute,* in *Dir. inform. e inf.*, 2022; S. IARIA, *Le potenzialità del PNRR ed il progetto "One Health" nella prospettiva del rilancio dell'assistenza sanitaria territoriale*, in *www.amministrazioneincammino.luiss.it*; C. NICOLOSI, *Telemedicina, PNRR e Piani di rientro sanitari: uniformità versus autonomia nell'organizzazione sanitaria?*, in *Amministr@tivamente*, 3, 2024; R. SENIGAGLIA, *Telemedicina ed essenza fiduciaria del rapporto di cura*, in *Pers. e merc.*, 2023.

[7] About EHR, N. POSTERARO, *La digitalizzazione della sanità in Italia: uno sguardo al Fascicolo Sanitario Elettronico (anche alla luce del Piano Nazionale di Ripresa e Resilienza*), in *Federalismi.it*, 26, 2021.

etc.) that technological systems (e.g., mobile phone apps) can perform on the patient.

Similarly, the Electronic health record (HER) can be fundamental for prevention because the expansion of the information processed, associated with the integration with other data (for example online reports and electronic health card) is functional to a multi-level and multidisciplinary protection which, more generally, is guaranteed by the new technological approach (e-Health, understood as the provision of services through ICT - Information and Communication Technologies) which, precisely with reference to the so-called EU4Health, aims at the prevention of diseases and the fight against serious health threats and cross-border nature (as well as strengthening the response capacity of health systems, accessibility of medical devices and medicines).

As regards e-Health, the EHR plays an important role; the PNRR defines it as "*cornerstone for the provision of digital health services and the valorisation of national clinical data*"; the healthcare digitalization (particularly health services) is a European objective.

The digitalization and the use of artificial intelligence are a useful element in the planning and decision-making phase because some operational research models can be exploited to decide how to organize healthcare facilities with advantages in the efficiency of administrative action.

3. *Regional profiles (notes)*

After the reform of Title V Constitution ("anticipated" by the regionalization of health services pursuant to Legislative Decree no. 502/1992 and Legislative Decree no. 229/1999), the right to health depends on the State that finances the National Health Fund[8]; on the

[8] There are differences in distribution between regions. For example (in the year 2020) in the initial distribution of the health fund, Liguria received 127 euros per capita above the national average, Molise 56 euros and Basilicata 37 euros. Below average are Sicily (minus 39 euros), the province of Trento (minus 41 euros), that of Bolzano (minus 72 euros) and Campania (minus 59 euros).

other hand, the regions create the care systems (regions that have seen their role grow significantly over time[9]).

About programmatic aspects, the regions within 150 days of the entry into force of the National Health Plan must adopt their own Regional Health Plan, the preparation of which is the responsibility of the regional council based on art. 1, paragraph 13, of Legislative Decree no. 502/1992, as replaced by Legislative Decree no. 229/1999: "*the Regional Health Plan represents the strategic plan of interventions for health objectives and the functioning of services to meet the specific needs of the regional population also in reference to the objectives of the National Health Plan".*

An important participatory role is played by local authorities, private non-profit social groups engaged in social and health care, trade unions of public and private health workers, and structures accredited by the National Health Service.

The project areas with the highest priority for intervention, on which to direct e-health initiatives, at regional and local level, focus along the following lines: feeding the new health information system with the appropriate timeliness to effectively monitor health phenomena; identification of the citizen and collection of individual health information, through the use of the health card and its evolution into a health card on the National Service Card support, also preparatory for the purposes of monitoring health expenditure and access to online health services; availability of the patient's medical history through the Electronic Health Record (EHR) systems, aimed at collecting and making available, to the various subjects responsible for taking charge of the patients and the governance of the system, socio-health information and clinical data associated with the patient's medical history, generated by the various actors of the health system; access to health services through Single Booking Centre systems, which facilitate access to services throughout the national territory by increasing the citizen's ability to choose and reducing average waiting times; telemedicine services that can contribute substantially to the development of the territory; innovation in primary care through the networking of National

[9] About it, F. SAITTA, *Autonomie territoriali e governo della sanità,* in *Istituzioni del federalismo*, 3-4, 2018.

Health Service doctors and the digitalization and telematic transmission of medical certificates, as well as the digital management of the entire life cycle of the prescription through e-Prescription systems, including those referred to in the Health Card System; dematerialization of the health documentation produced as part of the diagnostic-therapeutic pathways carried out in the various healthcare settings.

As already mentioned, the aseptic and horizontal cuts to the regional system have led to many critical issues, appropriately highlighted by the Constitutional Court.

This profile is one of the 'sensitive' ones: competitiveness and obsessive attention to remuneration and the balance sheet, as well as to obtaining bonuses, have accentuated asymmetries, contributing to the fragmentation of the system, which has lost its strategic inspiration and therefore its overall vision. Critical issues that can also be traced back to the regional organization itself, which, for the management of the health system and the provision of services, has increasingly resorted to private structures[10].

The aspects concerning regional health expenditure are impacted by the law on differentiated autonomy (law no. 86 of 2024), which provides for provisions (partly deemed unconstitutional by the Court with ruling no. 192/2024[11]) relating to the implementation of art. 116, third paragraph of the Constitution, establishing the access of ordinary Regions to further forms and particular conditions of autonomy.

The ruling impacts healthcare because the Essential Levels of Performance include the Essential Levels of Assistance (which also include those relating to health). On the one hand, this could have a positive impact, avoiding asymmetries; on the other hand, the fact that the Court has not excluded the possibility of transferring healthcare functions to the Regions could cause some concern. In this case, there could be a risk of greater differentiation between regional healthcare systems and inequalities in access to care.

[10] Critic, E. CECCOTTI, *Il servizio sanitario nazionale e le sue criticità*, in *Astrid – Rassegna*, 9, 2024, 16.

[11] About it, A. MORRONE, *Lo stato regionale dopo la sent. n. 192 del 2024*, in *giustiziainsieme.it*.

4. *Positive and critical elements of the system*

From the economic data listed above and from the information published on the Ministry of Health website, there are still positive aspects.

Italy is among the first places in the world for life expectancy in good health, the second longest-lived country in Europe, after Spain with an average life expectancy, at birth, of 83.4 years (81.0 years for men and 85.6 for women). In Italy, seven out of ten people declare themselves to be in good health. Compared to other European countries, there is greater homogeneity in the state of health with respect to economic conditions (Source: Istat Report 2018).

Italy also leads the way in Europe in terms of the number of free medicines, and has the richest pharmaceutical handbook paid for by the public health system: the National Health System offers citizens all medicines for the treatment of serious and chronic diseases (including the latest generation of innovative medicines). The overall and public per capita expenditure on medicines in Italy is in line with the European average. 69% of national pharmaceutical expenditure is paid for by the National Health System: total pharmaceutical expenditure reached 28.1 billion euros in 2017 (464 euros per capita), of which 19.5 are paid for by the National Health System (322 euros per capita) and 8.6 (142 euros per capita) are paid for by the patient (Source: Annual Report of the Drug Observatory for the year 2017 - Bocconi Centre).

There are excellent results in organ transplants, in the management of donor databases and in the availability of organs.

There are also excellent results in paediatrics, in high-tech diagnostics (Italy is among the countries with the highest number of public CT and nuclear magnetic resonance equipment per million inhabitants in Europe).

Important results have been achieved in the fight against passive smoking with a significant decrease in respiratory and cardiovascular diseases associated with smoking.

We have over 5,000 public operators committed to health and safety in the workplace.

There are also significant critical issues (which the pandemic emergency has tragically highlighted).

First, the principles of equality and equity are undermined by the different percentages of mortality within the national territory where there is an evident penalization of the weakest geographical areas and communities.

Another critical element concerns the number of hospital facilities (996 in 2023), which has significantly decreased with the consequent reduction in hospital beds: in percentage value per thousand inhabitants from 5.8 in 1998 to 4.3 in 2007 and 3.6 in 2017 and in absolute number from 311,000 active in 1998 to 191,000 in 2017 (Statistical Yearbook of the SSN - 2019). However, looking at more recent data, in 2023 we had 215,827 (Statistical Yearbook of the SSN relating to the year 2023).

With reference to medical personnel, the average in Italy (2020 data) is 4 doctors per 1000 inhabitants (therefore a higher number than the European average which is 3.5), but we are below with reference to nurses 5.8 per 100 inhabitants, compared to the 8.5 of the European average.

With reference to medical personnel, the average in Italy (2020 data) is 4 doctors to 1000 inhabitants (therefore a higher number than the European average, which is 3.5), but we are below with reference to nurses: 5.8 per 100 inhabitants, compared to the 8.5 of the European average.

Added to the critical issues highlighted is the slowness in the implementation of the new 1800 structures referred to in the PNRR relating to community homes and community hospitals whose role is essential given that their "filter" function would allow hospitals (hubs) to operate at their best as they are decongested (in this perspective, a filter is much more important than an intervention to simply increase staff, an increase which, although useful, would still not solve the problems of patient care and management in the presence of such high numbers).

Another critical aspect is linked to the PNRR funding (which, moreover, in proportion to the overall sum, is not as impressive as one would have expected after the pandemic shock). The funding does not in fact seem to be part of a strategic plan; instead, it suffers from excessive fragmentation that also reverberates at the organizational level.

On this last aspect it is necessary to insist on the proposals aimed at improving the functions of assistance and health protection.

The national health system, in fact, should be seen (related to the principles of *universality*, *equality*, *equity* and *solidarity*) as a single system within which the territorial articulations must assume an integra-

tive-improving value; instead, it seems that the territorial disarticulation and differentiation (as well as the regulatory, administrative and programming stratification) have ended up 'distorting' the model, which has taken on an eminently economic connotation (as of mere distribution of funding and attention to the budget), competitive and not collaborative.

Based on the analysis made, healthcare (the implementation of the constitutional precept of the right to health) seems to respond exclusively to economic reasons and calculation tools.

On the organizational front, the role of the private sector does not assume a critical value; however, it must be inserted into a logic of substantial improvement and valid integration of the system, not in merely substitutive terms.

Finally, a further critical element can be traced back to the so-called healthcare digitalization; consider the poor effective use of the Electronic Health Record connected to its poor knowledge, the lack and diversification of contents and data.

As well as – at an organizational level – the poor centrality given to operational research mechanisms which, through algorithms and models (based on collections of various data) would instead favour more thoughtful and efficient choices.

5. *The national system for the prevention and management of health risks*

A further profile concerns the theme of health promotion as prevention and management of health risks. Health has, in fact, a broad connotation; it concerns both the aspect of care and that of prevention and promotion[12].

About this last profile, the World Health Organization (WHO) has defined (in the "Ottawa Charter" of 1986) Health Promotion as "*the process that enables people and communities to exercise greater*

[12] About it, R. SARACCI, *Prevenzione e Servizio sanitario nazionale: un'integrazione da rifondare nel prossimo decennio,* in E&P- *Rivista dell'associazione italiana di epidemiologia*, may/june 2021.

control over their health and to improve it"[13].

The prevention profile is of significant interest, highlighted by the National Prevention Plan (2020 - 2025, implementing the Essential Level System, identified in three large Levels, including "*Collective prevention and public health*".

The strategic element of the Plan: "*lies in the choice to support the reorientation of the entire prevention system (in its articulation of tasks and responsibilities that involves all the social and health services of the territory, developed and/or oriented by the Prevention Departments) towards a Health Promotion "approach", thus making the development of empowerment and capacity-building strategies recommended by international literature and by the WHO transversal to all the Macro Objectives, consistently with the development of the principles set out in the Ottawa Charter*".

The National Prevention Plan and the Regional Prevention Plans therefore play a governance and orientation role, promoting the connection and integration between the actions envisaged by laws, regulations and sector plans.

The point is to establish strategies, rules, and healthcare stakeholders (prevention departments, GPs and PLS, USCA-Special units for continuity of care, intermediate territorial structures, laboratories, hospitals, university clinics, etc.) and non-healthcare stakeholders (Mayors, Prefects and law enforcement, Civil Protection, associations/volunteers, civil society, businesses, industrial relations, etc.).

The National Health Plan intends public health: "*the result of a harmonious and sustainable development of the human being, nature and the environment (One Health)*"; they are interconnected factors that imply multidisciplinary, intersectoral and coordinated strategies and interventions (by setting[14], with an interaction therefore between

[13] The document specifies the five objectives to be pursued to substantiate this definition: 1. Build a public policy for health; 2. Create favourable environments; 3. Strengthen community action; 4. Develop personal skills; 5. Reorient health services.

[14] "The setting is the place or social context in which people engage in daily activities in which environmental, organizational and personal factors interact with each other to influence health and well-being and in which it is easier to reach individuals and priority groups to promote health and carry out prevention interventions; at the

school, work environment, community and health services) to address health risks (potential or already existing). Is connected also the flexibility of the consequent responses and the "*ability to recall human resources on emerging issues for the tasks to be carried out quickly?*"[15]

As anticipated in the first part of the analysis, digitalization, technology and operational research can play an essential role, not only in the assessment but also in the coordination of measures and choices.

The objectives are therefore shareable and ambitious, but their implementation becomes problematic considering the multiplicity and complexity of the areas of intervention. Interventions highlighted in the plan with a "fluvial" and redundant technique. A widespread technique that is reflected in many plans and that Regions have criticized; consider what was stated – in April 2025 – by the Regional Health Commission, in relation to the ministerial draft relating to the update of the Pandemic Plan, namely that the contents *would be redundant, excessively discursive, making it difficult to consult.*[16]

The National Health Plan does not excel in its ability to synthesize; the numerous statements of principle risk not being implemented if the implementation interventions are not specified clearly and concisely; also because the main areas of integration listed in the National Health Plan are many: chronicity and connection with the related National Plan; food-borne diseases; vector-borne diseases; management of human and animal epidemic emergencies, including COVID-19; veterinary urban hygiene; production, trade and use of chemical prod-

same time, the setting itself constitutes the target of changes to be implemented in environments, organizations, centres of responsibility". PNP 2020-2025, p. 6.

[15] It is necessary for the territory to be able to respond promptly and immediately to the needs of the population "*both in the event of an infectious emergency (identification of suspected and/or positive cases and control of contacts, management of home isolation, appropriate hospitalization, etc.), and to guarantee prevention interventions (oncological screening, vaccinations, identification of subjects at risk, environmental protection, etc.) and to face the challenges of health promotion and early diagnosis and integrated management of chronic conditions*".

[16] "The document proposed by the Ministry of Health, as already reiterated on several occasions in technical settings, is excessively discursive, redundant and difficult to consult. It is therefore necessary to make it much more concise and schematic to facilitate its use, avoiding redundancies and repetitions of concepts or aspects already covered in other reference documents". Health Regional Commission.

ucts including plant protection products; prevention of "chemical risk"; relationships with the oncology network, tumour registries, Districts and General Practitioners and Freely Chosen Paediatricians (MMG and PLS); health promotion during pregnancy and in the first 1000 days; integration of environmental issues with those relating to health promotion; relationships with INAIL regarding workers' exposure to chemical or physical risks.

To this it must be added that in line with the current legal framework (attentive to environmental aspects) the plan focuses on social and environmental aspects; profiles linked to the so-called intersectoral which, as emerges from the Plan: "*is based on the recognition of health as a complex and dynamic process that implies interdependence between personal, socio-economic and environmental factors and determinants. This therefore results in a co-responsibility on the part of all sectors whose policies, in various ways, have an impact on these determinants (governments at all levels, third sector, associations, business, commerce, mobility, research, social and health system, education, etc.).*"

On the basis of what has been highlighted so far, if the budgetary requirements and the containment of public spending could have a (negative) impact also on prevention profiles, in reality in this area many resources have not been used; there is an even greater need for rationalization and management of resources which are placed – with those intended for treatment – in a 'circular' relationship, in the sense that if the prevention activity is managed and organized in an optimal and effective way (in this, as mentioned in the first part of the analysis, telemedicine assumes considerable importance), there will be a positive impact (also in terms of savings) in relation to the management and treatment of patients.

It is therefore essential to rationalise the needs for promotion and prevention so that there is not an aseptic approach that loses sight of the real positive impact of spending on the prevention system.

Returning to the complexity and multiplicity of themes, problems and strategies – which become a critical factor in terms of coordinating interventions – the Plan includes 13 lines that focus precisely on the aspect of exchange and interaction:

The Plan also includes 6 so-called Macro-objectives (MO), including the related strategies. MO1: *Non-communicable chronic diseases*;

MO2: *Addictions and related problems;* MO3: *Domestic and road accidents*; MO4: *Accidents and incidents at work, occupational diseases*; MO5: *Environment, climate and health*; MO6: *Priority infectious diseases*. Here we will focus on the last two: *Environment, climate and health* (MO5) and *Priority infectious diseases* (MO6).

Based on the lines of intervention and the macro-objectives, there is a risk of dispersion; the multiplicity becomes even more difficult to manage and coordinate when a work of synthesis is not sought with targeted and timely objectives. The "*promotion of the coordination of health and environmental programs*", "*technical tables for health promotion strategies*", "*guidelines*", "*integration of information*", "*shared national plans*", etc., if objectively they are useful and necessary factors and activities, become elements of dispersion if the times and specific methods of intervention are not defined in a precise, detailed way.

Finally, it is necessary to make a methodological consideration: is it certain that for the purposes of prevention the plan is the most appropriate tool? Given the necessary flexibility of the measures (different in order of events) it seems difficult to plan.

6. *The problem of governance and (integrated) management of prevention interventions, particularly Environment, climate and health (M05) and Priority infectious diseases (M06)*

Recognizing the complexity of the interventions, the objective is that of sharing and exchange, at multiple levels, in order to effectively address the problems relating to prevention and health management in its various declinations; as specified in the introductory part of the Plan: "*the COVID-19 emergency has highlighted the need to remodel and strengthen, in the short and medium term, risk prevention and health promotion interventions based on integrated networks of social and health services and on the involvement of the population in empowerment processes.", again: "it is essential to plan and design increasingly in an integrated way and in terms of a coordinated and integrated network between the different structures and activities present in the Territory and the Hospitals, which if isolated from each other and separated from the surrounding territory cannot represent the only response to the*

new needs imposed by demographic and epidemiological evolution. It is therefore necessary to have flexible response systems with the ability to recall human resources for emerging issues for the tasks to be carried out quickly. This ability to react to emergencies must be prepared with the training of operators from all sectors who, at the right time, can work in synergy on the same objective".

The problem is that of governance of prevention and integration of national, regional and local policies, with a view to achieving health results (in this framework we then include the levels of planning and governance at global and European level, which are not the subject of this analysis) and of implementation interventions: coordinated, integrated and flexible, in order to provide complete and timely responses.

For example, MO-05: *Environment*, *climate and health*, where it is possible to highlight the complexity and multifactorial nature that characterises it (given the impact of social, economic and health aspects) in which actors and measures are different; coordination is not easy; if "*the health sector can make a decisive contribution to safeguarding biodiversity and improving the built environment by operating systematically, promoting environmentally friendly technologies, sustainable consumption, green building and urban green spaces and more efficient management of health systems"* it is clear that interaction with other actors, other rules and sectors (construction, urban planning, procurement and concessions, transport) is necessary.

Similarly, with reference to the MO-06: *Priority infectious diseases*, coordination is not easy given that "*the fight against the spread of diseases requires an integrated set of interventions that include, to varying degrees, the correct information and education of the subjects, the health literacy of the population, the promotion of active immunization and prophylaxis of exposed subjects, the timeliness and quality of diagnoses, the appropriateness and completeness of therapeutic treatments and the monitoring of the outcomes of the interventions and of any adverse events*"[17].

[17] National Health Plan 2020-2025, 100.

7. *Public contracts-environment relationship*

About multi-sectorial and integration between disciplines, with reference to the first of the areas on which we wish to focus our attention (M05), the contribution of the legislation on public contracts in terms of prevention and environmental protection is interesting, especially from the point of view of administrative law.[18].

[18] About normative and jurisprudential analysis of the topic, E. BELLOMO, *Appalti verdi in urbanistica ed edilizia: criteri ambientali minimi*, in *Riv. giur. urb.*, 1, 2020; M. CAFAGNO, *L'ambiente nei contratti pubblici: due angoli visuali e una morale*, in *Dir. e proc. amm*., 4, 2021; T. CELLURA*, L'applicazione dei criteri ambientali minimi negli appalti pubblici,* Santarcangelo di Romagna, 2016; M. CLARICH, *La tutela dell'ambiente attraverso il mercato*, in *Dir. pubbl*., 2007; R. COSTANZO, *Lo sviluppo sostenibile negli appalti pubblici. I criteri ambientali minimi*, in *AmbienteDiritto,* 1, 2023; G. CREPALDI, R. MICALIZZI, E*co-sostenibilità e contratti pubblici: la selezione delle imprese e delle offerte secondo criteri ambientali*, in *Federalismi.it*., 14, 2023; F. DE LEONARDIS, *Criteri di sostenibilità energetica e ambientale,* in *Trattato sui contratti pubblici. Soggetti, qualificazione, regole comuni alle procedure di gara*, II, Milano, 2019; ID., *L'uso strategico della contrattazione pubblica: tra GPP e obbligatorietà dei CAM*, in *Riv. quadrim. dir. amb.,* 3, 2020; A. DI GIOVANNI, *L'ambiente sostenibile nel nuovo codice degli appalti: green public procurement e certificazioni ambienta*li, in *Il dir. dell'econ*., 1, 2018; R. DI PACE, *Profili ambientali nella procedura di realizzazione delle opere pubbliche*, in P. DELL'ANNO, E. PICOZZA (diretto da), *Trattato di diritto dell'ambiente*, Vol. II, Padova, 2013; G. FIDONE, *Gli appalti verdi all'alba delle nuove direttive: verso modelli più flessibili orientati a scelte eco-efficienti*, in *Riv. it. dir. pubbl. comunit*., 5, 2012; F. FRACCHIA, S. VERNILE, *I contratti pubblici come strumento dello sviluppo sostenibile*, in *Riv. quadrim. amb.,* 2, 2020; G. FRANCHINA, *Contratti pubblici e criteri ambientali minimi*, in *AmbienteDiritto*, 2, 2022; I. GRIGOUT, *Profili di rilevanza ambientale nella disciplina dei contratti pubblici*, in *giustamm.it*, marzo 2021; F.F. GUZZI, *La rilevanza ambientale nel settore dei contratti pubblici,* in *Ambientediritto*, 2, 2024; M. LUPO, *La disciplina delle clausole ambientali*, in *La riforma dei contratti pubblici (D. lgs. n. 36/2023),* a cura di F. Manganaro, N. Paolantonio, F. Tigano, Messina, 2024; M. RENNA*, Autonomia contrattuale e sostenibilità. Alcune ricadute in termini di fattispecie, effetti e funzioni*, in *Astrid – Rassegna*, 4, 2024; S. TRANQUILLI, *La rilevanza degli aspetti ambientali. Il codice dei contratti pubblici è «sostenibile»?,* in *Innovazione e conservazione nel nuovo Codice dei contratti pubblici* - Atti dei seminari di studio tenuti presso l'Università della Calabria il 16 maggio 2023 e il 22 novembre 2023 - (a cura di) F. F. Guzzi, Napoli, 2024; L. VENTURA, *Public procurement e sostenibilità. Convergenze trasversali dei sistemi giuridici contemporanei*, in *Dir. comm. int*., 2020; S. VERNILE, "*Nuovo" Codice dei contratti pubblici e criteri ambientali minimi per l'economia circolare*, in *Riv. giur. amb*.,

In the European law, the Green Paper on Public Procurement of 1996 stated that environmental protection can be achieved through procurement; in detail: "*in this specific field, Member States (and their bodies) are paying increasing attention to environmental considerations in the awarding of public contracts. Due to their size, such contracts may in fact have very important repercussions on certain economic activities or even prove to be decisive for the commercial development of certain products".*

There are, also, many communications, COM (1998) 143, that affirmed the legitimacy of elements that contribute to qualifying the object of the service: the minimum environmental criteria in contracts and the possibility of including environmental criteria in the most economically advantageous offer, as well as excluding economic operators convicted of 'environmental crimes'. COM (1999) 263, COM (2000) 576, COM (2001) 68, COM (2003) 302, COM (2008) 397, COM (2008) 400, COM (2019) 640.

About Directive, Directive 2014/24, and before, Directive 2004/17 (about concessions Directive 2014/24 and before Directive 18/2004), has provided for the possibility of taking environmental aspects into consideration by subordinating the principle of economic efficiency to environmental and social protection aspects.

Recital 37: "*in view of an adequate integration of environmental, social and labour requirements in public procurement procedures, it is particularly important that Member States and contracting authorities take relevant measures to ensure compliance with environmental, social and labour law obligations".*

Recital 38: "*monitoring of compliance with environmental, social and labour law provisions should be carried out at the relevant stages of the procurement procedure, when applying the general principles governing the selection of participants and the award of contracts, when applying the exclusion criteria and when applying the provisions on abnormally low tenders. The necessary verification for that purpose should be car-*

3, 2023; S. VILLAMENA, *Appalti pubblici e clausole ecologiche. Nuove conquiste per la «competitività non di prezzo» anche alla luce della recente disciplina europea,* in *Il dir. dell'econ.*, 2, 2015; ID., *Codice dei contratti pubblici 2016. Nuovo lessico ambientale, clausole ecologiche, sostenibilità, economicità*, in *Riv. giur. edilizia*, 3, 2017.

ried out in accordance with the relevant provisions of this Directive, particularly those relating to means of proof and self-declarations".

It is established that tender procedures must give adequate space to environmental protection through "relevant" measures and that it is necessary to monitor compliance with the so-called environmental obligations in all phases of the tender procedure (preparation of the tender notice, participation requirements, evaluation criteria for offers, product characteristics and technical specifications, execution conditions).

The directive's recitals can also be cited: 41, on environmental measures; 67 and 68, on environmental criteria in the most economically advantageous offer; 91, on sustainable development; 96, on life cycle costs. The European requests have been implemented at national level (already with the 2006 Code) so that the contractual discipline could precisely 'orient' the market towards sustainable conduct in terms of environmental protection and therefore also health.

In detail, the regulation affects the participation requirements when it is foreseen as a possible cause for exclusion: the violation of environmental obligations.

A most important role in the prevention and protection of the environmen~~tal~~ (which concern health protection) has "minimum environmental requirements" (about it, Council of State n. 1635/2019: environmental protection expands the scope of art. 32 of the Constitution, which has allowed the scope of protection guaranteed to public health to be extended also through product certifications). "Minimum environmental requirements" are obligatory requirements of the product (relative to the product categories provided for by the various ministerial decrees) and concern the offer; consequently, their absence makes the procedure invalid.[19]

"Minimum environmental requirements" are a way to orient the public procurement market (the purchase of public goods represents 17% of the PIL and 14% of the European PIL) and contribute to sustainable development in production and consumption processes with effects on health and the environment. Are an 'indirect' way to orient-

[19] About it, Council of State, III, n. 8773/2022, Council of State, V, n. 972/2021; Administrative Court Veneto, n. 329/2019.

ing the market towards the purchase of eco-sustainable products by stimulating the study and research of so-called green products.

This is very interesting for our purposes, to demonstrate the multidisciplinary nature of the system with reference, in this case, to the environment-health relationship.

8. *Prevention and management of infectious diseases: integration and coordination*

About others to focus attention (M06: *prevention and management of infectious diseases*), the pandemic has highlighted the need for integration and coordination. The regulatory framework is complex and layered.

Article 117 of the Italian Constitution divides the protection of health between the State and the Regions; the law provides for the State to be responsible for: "*the prophylaxis of infectious and diffusive diseases, for which mandatory vaccination or quarantine measures are imposed, as well as interventions against epidemics and epizootics*" (while delegating the exercise of administrative functions to the regions) and divides the competence to issue contingent and urgent ordinances on hygiene and public health respectively on the national territory and on the regional and municipal territory between the Ministry of Health, the Mayors and the Presidents of the Regional Councils.

It is necessary to consider also Legislative Decree no. 1/2018 that regulates the Civil Protection Code, providing for the role and powers of the Prime Minister in adopting protection ordinances on public health, also through the involvement of regional governments.

It is a centralized but also stratified system, whose coordination is not easy; this is demonstrated by the conflict between the State and the Regions which the administrative judge has intervened in several occasions[20] on.

Coordination has not been effective because (also due to an unclear health framework) there has been a wavering between centraliza-

[20] About it, E. LONGO, *Episodi e momenti del conflitto Stato-Regioni nella gestione della epidemia da Covid 19*, in *Osservatoriosullefonti,* fasc. speciale, 2020.

tion and territorial autonomy[21]; the steps forward made by the regions are well known - in the pandemic period (in light of the 'greater knowledge' of the territorial framework) both in a more restrictive and less restrictive sense; with reference to the first case, consider the decision of the Marche Region with which already on February 25, 2020 (therefore well before the national lockdown) the closure of schools, museums and all public events of any nature were prohibited in order to combat the spread of the coronavirus; a decision deemed illegitimate by the Administrative Court Marche (decree of February 27, 2020).

Regarding the second, consider the decision of the Calabria Region to anticipate (also for reasons of 'economic recovery') the reopening of the activity already from 30 April 2020 this decision was also deemed illegitimate by the Administrative Court Calabria (ruling no. 841/2020). Steps forward are always declared illegitimate by the administrative judge.

The Constitutional Court - sentence n. 37/2021[22] - ruled on the conflicts between the State and the regions, clearly affirming the state's competence.

The conflict illustrated is an indication of the objective difficulty of coordination and the crisis of the principle of loyal collaboration. The international dimension of the pandemic has affected these relationships, the State's competence (as also stated by administrative and constitutional jurisprudence) has been affirmed as a priority.[23]

It should be noted that although the judges' decisions were supported by normative elements (especially the reference to "international prophylaxis") aimed at configuring the centrality of the state,

[21] About it, M. GOLA, *Pandemia, Stato e Regioni: quando la 'materia' non basta (nota a Corte Costituzionale n. 37/2021),* in *www.giustiziainsieme.it.*

[22] About it, M. GOLA, *Pandemia, Stato e Regioni: quando la 'materia' non basta (nota a Corte Costituzionale n. 37/2021),* cit.; E. LAMARQUE, *Sospensione cautelare di legge regionale da parte della Corte costituzionale. Nota a Corte cost. 14 gennaio 2021* n. 4, *in www.giustiziainsieme.it.*

[23] About relationship State-Regions (also comparative perspective): E. SZMULEWICS, S. PITTO, *Relazioni intergovernative e settore sanitario. Il modello italiano alla prova della crisi*, in *DPCE online,* 4, 2024.

some doubts remained regarding the relationship between institutions in terms of collaboration and territorial framework analysis.

This confirms that the organizational structure was not fully satisfactory; it was excessively restrictive for the regions; in this regard, there was talk of "marginalization of the possibility of regional influence on the regulatory measures adopted"[24], of a crisis in centre-periphery relations in light of the absence of "particular forms of concertation or coordination tools"[25], of the principle of loyal collaboration as "the true institutional victim of the epidemic"[26].

9. *Conclusions*

The aim of this analysis was to provide an overview of the topic, highlighting its complexity linked to legal, medical, economic, political-social, technological profiles, and to the presence of different actors (institutional and non-institutional), of numerous lines of intervention.

There is an awareness that health is connected to a multiplicity and interdependence of factors: personal[27], institutional, socio-economic, technological, environmental and contractual. As emerged from the analysis, however, it seems that the system is not yet able to establish full and effective coordination of the different strategies. The objectives are a wish that does not correspond to clear and concrete measures.

The numerous statements of principle (for example, those of the prevention plan) risk remaining unimplemented if the interventions are not specified clearly and concisely. This is an aspect well highlight-

[24] E. CATELANI, *Centralità della Conferenza delle Regioni e delle Province autonome durante l'emergenza Covid-19? Più forma che sostanza*, in *Osservatorio sulle fonti*, 2, 2020.

[25] E. LONGO, *Episodi e momenti del conflitto Stato-regioni nella gestione della epidemia da Covid-19*, cit.

[26] G. COINU, *Un nuovo capitolo nel variegato conflitto Stato-Regioni: le ordinanze regionali "contro" gli spostamenti verso le seconde case*, in *Federalismi.it*, 14, 2021.

[27] Critic, S. TOMELLERI, *Quando l'habitus fa il monaco: mutamenti sociali, stili di vita e disuguaglianze,* in *BioLaw Journal – Rivista di BioDiritto*, 2, 2019.

ed by the regions themselves when (to update the pandemic plan) the Health Commission stated that "*the document proposed by the Ministry of Health, as already reiterated on several occasions in technical settings, is excessively discursive, redundant and difficult to consult. It is therefore necessary to make it much more concise and schematic to facilitate its use, avoiding redundancies and repetitions of concepts or aspects already covered in other reference documents*".

The critical aspects concern the relationship between State and Regions (and, more generally, that between the various institutions); the problem of rationalizing spending; coordination between institutional actors in prevention; the concrete implementation of healthcare digitalization[28] (the process, which should have been completed in January 2025, is actually suffering delays in the development of the Gateways necessary for the integration of healthcare data. Furthermore, the Authority has requested further measures for data protection, which could influence the implementation times; in any case, by 2026 all Regions will have to adopt and actively use the Electronic Health Record) and the "new" territorial healthcare.

We have tried to highlight the general characteristics of the system, analysing its evolutions and critical issues (for example, it is necessary to rethink programming in prevention because events are difficult to regulate and program).

The analysis was partial; in fact, it is completed by transnational aspects.

At the European level, for example, despite the traditional 'weak' approach of the EU on health (the function based on art. 168 TFEU has traditionally been placed in complementary terms, supporting the States and the exchange of information) – precisely because of the damage caused by the covid-19 pandemic – numerous packages of regulations[29] have been put in place aimed at strengthening coordina-

[28] For example, with reference to the EHR, its development should have been completed in January 2025, but it has suffered delays also due to the intervention of Authority who has requested further measures for data protection. Anyway by 2026, the Regions will have to actively use the Electronic Health Record. Currently, only 42% of citizens have given their consent to sharing their data.

[29] Reg. 2022/2370, 2022/2371 e 2022/2372

tion and the role of EU agencies in order to improve preparation to counter cross-border health threats. Consequently, the need for coordination extends to transnational areas with the ambitious objective of carrying out adequate monitoring to adopt rapid and timely intervention measures to combat and respond to serious cross-border health threats[30].

At global level, the European Council, in 2021, decided to support the launch of negotiations for an International Treaty on the fight against pandemics, negotiations that suffered a setback in 2023 and 2024 and which resumed, successfully, in April 2025 and culminated in the approval of the Treaty on Pandemics in May 2025.

[30] On 30 November 2022, the European Commission adopted a Communication on a new "EU Global Health Strategy - Better health for all in a changing world", designed to improve global health security and ensure better health for all. On 24 January 2024, the European Council endorsed conclusions on the above-mentioned strategy, recognising that "physical and mental health are a human right and that health is a prerequisite for sustainable development" and welcoming the Communication on the EU Global Health Strategy, while also highlighting that the EU and all its Member States must play a leading role in ensuring that global health remains at the top of the international agenda. Global health implies multilateralism and inclusive multi-stakeholder partnerships, becoming an essential pillar of the EU's external policy. A comprehensive approach that must include the promotion of health and well-being based on three priorities: 1. Improving people's health and well-being throughout their life cycle; 2. Strengthening health systems and promote universal health coverage; 3. Preventing and combating health threats, including pandemics, by applying a "One Health" approach.

LUCA ALBINO

THE PROTECTION OF THE RIGHT TO HEALTH BETWEEN STATE AND REGIONAL COMPETENCES

SUMMARY: Premise. The multilevel dimension of the right to health in the italian Constitution. – 1. The choice of the Constituent Assembly of the multi-level model for the healthcare system. – 2. The establishment and implementation of the National Health Service and the structuring of the division of competences between the State and the Regions. 3. The 2001 reform of Title V of the Constitution and the new competences division. – 4. The Constitutional Court, *sui generis* arbiter of the institutional dialectic between State and Regions. – 5. The LEAs (Essential Levels of Assistance) between legislative provisions and constitutional jurisprudence. Guaranteeing healthcare services amidst financial constraints and respect for the principle of equality. – 6. Regional differentiation and Constitutional court judgment no. 192 of 2024.

Premise. The multilevel dimension of the right to health in the Italian Constitution

The constitutional framework of the right to health (Article 32 of the Constitution) makes its multidimensional nature clear, since there are several subjective legal situations that must be guaranteed in this area. These 'dimensions' can be identified as follows:

1. The right to enjoy one's state of health; that is, the negative claim that public authorities or third parties refrain from behaviours that may prejudice one's physical integrity.

2. The right to be treated, that is, the right to healthcare services; in other words, the positive claim that the Republic arrange adequate structures, therapeutic means, and treatments, which must also be free for the indigent.

3. The right to abstain from maintaining one's state of health (the so-called right not to be treated), that is, the negative claim not to be forced to undergo certain medical treatments.

4. The obligation to undergo medical treatments established by law, with respect for the human person.

5. The collective claim that every individual takes care of their health in order not to cause harm to the psycho-physical integrity of the other members of the community.

Article 32 configures a complex, composite legal situation, but bound by a unitary *ratio* which is the protection and promotion of the human person. Consequently, but this is true for all constitutional rights, it is necessary to carry out a systematic reading of these dimensions, as the adjective 'fundamental' in the provision of Article 32 of the Constitution, and absent in the other constitutional provisions on rights, cannot be interpreted as 'superordinate'. In the Italian constitutional system, there is in fact no hierarchy between rights. The adjective 'fundamental', consequently, must be interpreted to mean that health is a logical prerequisite for the enjoyment of other rights.

The provision of Article 32 is therefore framed within the personalistic principle pursuant to Article 2 of the Constitution as a factor for the full development of human personality without any functionalist meaning (as happens instead for the right to property). This structure, as is known, is the result of jurisprudential and regulatory evolution. It started, in fact, from the so-called 'reductionist' readings of Article 32 of the Constitution in the 1950s and 1960s, which were based on the productivist idea of protecting health as a defence of the so-called society of the healthy against those who could not be useful to that society. In the 1970s, the discussion began on the right to health as an absolute and primary right of the individual, no longer limited to the idea of 'absence of disease', directly protected by the Constitution with the consequent immediate operability also in inter-private relationships[1].

Among the many aspects pertaining to the right to health, for the purpose of the present work, those arising from the combined provisions of Articles 32, 2, and 3 of the Constitution assume central im-

[1] In this regard, one can recall Judgment No. 88 of 1979, in which the Constitutional Court clarified that health is protected by Article 32 of the Constitution not only as a collective interest but also and above all as a fundamental right of the individual, configuring it as a primary and absolute right, fully effective also in relationships between private individuals, to be included among the subjective legal positions directly protected by the Constitution.

portance, as the right to healthcare services is a clear explication of the principle of substantive equality; healthcare services, despite their cost not always being accessible to everyone, must be guaranteed, also by providing for their free provision for the indigent, in implementation of the equal dignity of individuals. This was one of the starting points for the scientific, but above all political, reflection that later led to the establishment of the national health service in the 1970s[2].

1. *The choice of the Constituent Assembly of the multi-level model for the healthcare system*

The first issue that must be addressed is the one relating to the reasons for choosing a so-called multi-level model for the healthcare system, an absolute novelty for Italy, which had never had experience with regionalism. The debate in the Constituent Assembly inevitably suffered from the lack of a consolidated model on this point and had to inevitably unfold on a dogmatic and comparative level.

In general, the choice of an articulation of political power across multiple institutional levels – at least in the constitutional provisions – found its root in the opposition to the strongly centralist structure that existed during the Regno d'Italia and especially during the fascist regime. The debate was complex as the political positions on territorial

[2] This connection had already emerged in the Constituent Assembly. The member of Constituent Assembly Fausto Gullo, in the session of April 17, 1947, underlined the link between the effectiveness of the guarantee of services related to social rights—including health—and the protection of the right itself, stating: 'It is inconceivable that there can be greatness of a Nation, greatness of a people, where every citizen does not have the possibility to create a family and does not feel protected in their health, and where every citizen does not have the possibility to satisfy their desire for knowledge. I see this part of the Constitution as the one of most vital importance. (...) All other parts of the Constitution become null, vain, superfluous, if we do not give the most precise execution to these norms, which are the most important and which specifically protect the citizen, ensuring them a family nest that is truly such and not a place of pain and suffering, giving them the means to preserve their physical health, thus cancelling the shame of mortality statistics that are horrifying; and finally ensuring them the possibility of satisfying their will to know. Only in this way will we have ensured that all the other norms also have their effective application.

autonomies ranged from the most markedly federalist stances to those contraries to the establishment of the Region as an intermediate entity between the State and Local Authorities, preferring instead a strengthening of administrative decentralization through an increase in the powers of Municipalities and Provinces.

The institutional debate began prior to the election of the Constituent Assembly. The Ministry for the Constituent Assembly, established by Legislative Decree no. 435 of July 31, 1945, was assigned the tasks of preparing the political electoral law, preparing for the convocation of the Constituent Assembly, and collecting Italian and foreign documentation necessary for the study of the new constitution.

To carry out these tasks, a Commission for the drafting of the political electoral law and study commissions for the new constitution were established. The study commissions were originally three. Subsequently, they were increased to five, and among the latter, on February 26, 1946, the Fifth Subcommittee, for Healthcare Organization, was added.

In its final report, this subcommittee proposed a system for healthcare organization problems based on a balance between unity and autonomy according to the following proposition: "Every healthcare activity is supervised and coordinated by the State. All healthcare activities of the State and public bodies report to a single technical administration separate from the other organs of the executive power." The report then explained how unity should not be achieved with a single, cumbersome administration that had to absorb and stifle everything, but rather that it should be realized, on the one hand, in the need for control and coordination of all private healthcare activities by the state healthcare administration, and on the other hand, in the dependence of all public healthcare activities on a single administration. However, the suggestion of the Subcommittee members was to provide for the possibility that healthcare legislation could be integrated with rules dictated by local bodies. Essentially, the idea was consolidating that the unity of healthcare administration, necessary to guarantee equal right to health, was not incompatible with a decentralized system, both from a bureaucratic and institutional perspective. This approach was also consistent with the more general idea, which most political forces had already adopted at the time, of

abandoning the centralized structure of the State. The warning emphasized by several parties was to include the essential principles for the healthcare structure and administration directly in the Constitution, avoiding leaving them to what was defined as the "fluctuations of ordinary legislation.".

The election of the Constituent Assembly allowed the debate to resume with greater political representativeness. The majority option that emerged both in the work of the Second Subcommittee and later in the Assembly was, in any case, the institution of regions (with special and ordinary autonomy) endowed with legislative powers that could be articulated with various degrees of scope and effectiveness. The so-called multi-level structure of the health protection system had, in truth, already been sketched out in the constitutional text where the phrase "The Republic protects health" foreshadowed the intention to implement such a model.

In the field of healthcare, during the work of the Second Subcommittee, right from the first sessions (July 30, 1946), the rapporteur Ambrosini proposed including the subject 'Hygiene and healthcare assistance' within the scope of those competences that would later be defined as concurrent. The debate was broad and detailed, and the definitive texts of the Draft Constitution elaborated by the Commission provided for the following articulation of healthcare competences:

According to Article 110 of the draft, the Regions were granted the power to issue legislative norms regarding hospital assistance, limited by harmony with the Constitution and the general principles of the State's legal system, respect for international obligations and the interests of the Nation and other Regions, and compliance with the principles and directives that the Republic deemed necessary to establish by law for the purpose of uniform regulation.

According to Article 111 of the draft, the Regions were granted the power to issue legislative norms for the integration and implementation of the Republic's law provisions, to adapt them to regional conditions, in the matter of public hygiene and health. Furthermore, the laws of the Republic could delegate to the Regions the power to issue regulatory norms for their execution.

The debate on what would later become Article 117 of the Constitution continued from March to July 1947, and as is known, the final text, in the part concerning healthcare assistance, read:

"The Region issues legislative norms for the following matters within the limits of the fundamental principles established by the laws of the State, provided that the norms themselves are not in contrast with the national interest or that of other Regions:
(...)
public charity and healthcare and hospital assistance"

In the original text of the Constitution, regarding the division of competences, the Regions were assigned the concurrent power of detail in the matter of 'healthcare and hospital assistance'. However, the failure to establish the Regions with Ordinary Statute until the 1970s hampered its concrete implementation and led to the central State occupying spaces in the matter, which inevitably could not be limited only to legislating principles but extended to detail and also to administrative functions that could not be allocated at the regional level given the lack of establishment of the Entity. At the time, the Constitutional Court itself ruled that challenges to the constitutional legitimacy of various state norms that did not limit themselves to identifying fundamental principles were unfounded, invoking the national interest, the function of policymaking and coordination, and the necessity for the Government to activate substitute powers[3].

In the first decades of the Republic's history, the legislative and administrative structure of the healthcare system was essentially based on mutual aid organizations (so called 'mutue') and on a view of the claim to benefits as 'insurance-corporate' rather than universalistic. It must be said, however, that these organizations nonetheless guaranteed a certain level of health protection to most citizens. Essentially, the main obstacle to the full implementation of the constitutional provision and the model was above all cultural. In other words, health protection was essentially the protection of public health, and the underlying idea was the productivist one of protecting health as a defense

[3] See, above all, the Constitutional Court's Judgment no. 116 of 1967.

of the so-called society of health against those who could not be useful to that society. The prevailing jurisprudence also moved along these lines. Ex multis, we can cite a judgment by the Tribunale di Firenze of January 5, 1967, which denied compensation for an injury sustained by a pensioner of about seventy years, stating that "in the case of the human person, the asset whose compromise forms the basis of the right to compensation is not the organism in itself, but its efficiency, that is, the set of those capacities which, when exercised, can produce economically useful effects" [4].

The establishment of the Regions with Ordinary Statute led to a renewed favor for a different constitutional interpretation, one closer to the original spirit of the Constituent Assembly, and the reading of Article 32 of the Constitution also began to change in the direction of its concrete and effective implementation. The fundamental idea was that the right to health is an absolute and primary right of the individual, no longer limited to the idea of 'absence of disease,' and is directly protected by the Constitution, with the consequent immediate effectiveness even in inter-private relations (the so-called *Drittwirkung*). In addition to the renewed political climate, the transformation of the healthcare assistance structure was also driven by the financial unsustainability of the mutual aid system, which had begun to show more than a few cracks[5].

This marked the beginning of the so-called season of great healthcare reform laws. First, with Law no. 132 of February 12, 1968, which established hospital bodies ('enti ospedalieri'), the State's functions of supervision and protection in the matter of hospital assistance were transferred to the Regions, with the State retaining only the function of high-level oversight over healthcare activity. Notably, this law moved decisively towards guaranteeing the right to health as an expression of equal social dignity and equality among citizens. In this regard, Article 2 of the law can be cited, which stated that "Hospital bodies, subject to limitations arising from the specialization of the

[4] Tribunale di Firenze, January 5, 1967 in Archivio della Responsabilità Civile 1969, 130

[5] See on this point G.G. SANTONOCITO, *Storia del diritto alla salute (History of the Right to Health)*, Milano, 2022, 128 et seq.

hospital or the particular technical needs related to the specific morbid condition, have the obligation to admit, without special agreement or request for any documentation, Italian and foreign citizens who require urgent hospital care for any illness, injury, or maternity, whether or not they are assisted by mutual aid or insurance bodies or by other public and private entities."

Then, D.P.R. no. 4 of January 14, 1972, completed the transfer of state administrative functions in the matter of healthcare and hospital assistance to the Regions with ordinary statute. Law no. 349 of June 29, 1977, abolished the mutual aid organizations, simultaneously transferring their functions to the Regions. The culmination of this season was undoubtedly the institution of the National Health Service ('Servizio Sanitario Nazionale') with Law no. 833 of December 23, 1978.

2. *The establishment and implementation of the National Health Service and the structuring of the division of competences between the State and the Regions*

The primary objective that the legislature of Law 833 of 1978 set for itself was to ensure the equal guarantee of the right to health, overcoming the previous system based essentially on mutual aid organizations. However, the problem of the impact of regional differentiations on the guarantee of the right to health did not specifically emerge, even though the existence of deep territorial differences was well known to all.

Law 833/1978 came into force not many years after the real functioning of the Regions with Ordinary Statute, in a constitutional context characterized, on the one hand, by hopes for the construction of effective regionalism, and on the other hand, by political and administrative resistance to the decentralization of powers. Moreover, the original constitutional text of 1948, as previously mentioned, was not characterized by pronounced regionalism, and already in those years, the prevailing interpretation tended to favor the central level over the local ones, through the use of the national interest clause which lim-

ited the normative space in matters subject to concurrent jurisdiction, such as healthcare and hospital assistance.

From a planning perspective, Law 833/1978 provided for the institution of a National Health Plan (PSN - Piano Sanitario Nazionale). The PSN was intended to be the strategic framework for national health policies, defining the priorities and guidelines for the National Health Service (SSN). The Regional Health Plans (PSR - Piani Sanitari Regionali), on the other hand, were the tool to implement the PSN's strategies, adapting them to the specificities and needs of the local context through the programming of activities and resources in their respective territories.

From an administrative and managerial organization perspective, the main innovation of Law 833/1978, in terms of decentralization, was the establishment of the Local Health Units (USL - Unità Sanitarie Locali) and the basic Health Districts (Distretti sanitari). The USLs were newly established entities, controlled by the Region through the Regional Control Committees but managed by the Municipalities, either individually or in an associated form. Hospitals were also integrated into the USL structure.

The implementation of Law 833/1978 was not simple. As previously mentioned, the political-institutional context was not extremely favorable to the full implementation of the regional model. Furthermore, the Regions themselves began to transform from programming bodies into management bodies, disregarding the constitutional model which seemed to foresee the normal exercise of administrative functions through delegation to local authorities.

Critical issues also began to emerge from a financial perspective. On the one hand, the need to guarantee the universality of the healthcare service led to an increase in expenditure. On the other hand, the newly established USLs did not always prove to be financially efficient managers. More generally, the 1980s and 1990s were characterized by a reduction in economic growth and tax revenues and, consequently, there was an increase in public debt and the need to intervene with containment measures. This was due both to needs related to debt financing and the increase in interest rates on government bonds, and to the progressive emergence of European constraints on

public finances, which were necessary precursors for the construction of the Economic and Monetary Union in the early 1990s.

As healthcare spending was the main expenditure item for the Regions, the model of a largely free-of-charge National Health Service (SSN) was progressively abandoned with the adoption of laws aimed at introducing mechanisms of cost-sharing (the so-called ticket) and measures to reform the organizational structure of the USLs.

At the end of 1992, the reform known as "reform-bis" (Legislative Decree no. 502/1992) came into force. The main innovations of this reform were, first, the introduction of a management style for the USLs that was intended to be more managerial, particularly through the introduction of the new figure of the General Director. It is no coincidence that the USLs began to be called Local Health Authorities (ASL - Aziende Sanitarie Locali).

As mentioned earlier, due to financial criticalities, the reform marked a scaling down of the universality of the healthcare service with the introduction of a multi-level system, featuring the introduction of healthcare tickets and the differentiation of access based on income, with some brackets exempted and others excluded. It was thus decided to finance the expenses of the SSN through a portion of the revenue from the IRAP (Regional Tax on Productive Activities), with integrations from the National Health Fund, financed by shares of direct tax participation, for Regions whose tax revenue was insufficient to cover expenditure.

The Regions were granted greater autonomy, but also greater responsibility. In particular, it was stipulated that they had to cover, with their own funds, the costs deriving from the provision of assistance levels higher than the standard ones, from the adoption of different organizational models, and above all, those deriving from any management deficits of the Local Health Authorities (ASL) and Hospital Authorities (AO), with inevitable repercussions on the citizens of the Region itself.

In Legislative Decree 502/92, reference is made for the first time to "uniform levels of assistance". The State was assigned the responsibility to establish, within the National Health Plan, health planning and the definition of uniform levels of assistance (Livelli Essenziali di Assistenza - LEA), relating them to the volume of available resources.

Major hospitals saw an expansion of their autonomy with their separation from the Local Health Authorities (ASL) and their transformation into Hospital Authorities (Aziende Ospedaliere) with economic and financial autonomy. Furthermore, the possibility was introduced for private entities to provide SSN services through mechanisms for the recognition of these structures.

The 1992 healthcare system reform redefined the distribution of responsibilities among the different territorial entities. The State maintained the role of guidance and coordination at the national level. Its main function was to establish the general guidelines through the National Health Plan (PSN), which defined the main objectives, funding, and levels of assistance. The Minister of Health also had the task of supervising and coordinating regional initiatives.

The Regions, in this new organizational structure, acquired a much more significant role. They were entrusted with new and broader normative and administrative powers in the field of healthcare and hospital assistance. The Regions thus became the reference point for defining the organizational principles of healthcare services and the financing criteria for the Local Health Authorities and Hospital Authorities; they were responsible for issuing the Regional Health Plan (PSR), which, always in harmony with state regulations, served to regulate the organization and functioning of the ASLs, as well as the Hospital Authorities and facilities.

Conversely, the role of Local Authorities (and especially the Municipalities) was scaled down. These Entities, deprived of almost all organizational and managerial functions, the ownership of which was transferred to the ASLs and the Regions, retained some competences in the planning and management of socio-assistance activities and services.

The National Health Service was reformed a second time with Legislative Decree no. 229 of June 19, 1999 (the so-called Bindi Decree). Regarding the articulation of competences, Legislative Decree 229 of 1999 certainly increased regional competences, particularly concerning the ASLs. The Regions were granted powers to determine the organizational principles of the services, the financing criteria, the territorial division, and the ASL supervision mechanisms. This substantially continued the line of the first 1992 reform, which, it is re-

called, had diminished the role of the municipalities as entities directly involved in the provision of healthcare services through the USLs. Legislative Decree 229, however, attempted to recover a role for the municipalities, essentially through their participation in the planning phase. The ASLs were confirmed as public legal entities with entrepreneurial autonomy.

In those years, subsequent legislative acts (Law no. 133 of 1999 and Legislative Decree 56 of 2000) fully defined the SSN funding model, which is substantially the one currently in force. This model is based primarily on collecting resources through various forms of taxation:

– Direct taxes, such as the IRPEF surcharge (Personal Income Tax) and the IRAP (Regional Tax on Productive Activities).

– Indirect taxes, particularly the regional share of participation in VAT revenue (Value Added Tax).

These revenues are supplemented by funds derived from ticket payments (co-payments) and other healthcare services fully charged to citizens.

One of the main innovations introduced was that the funding quotas disbursed by the State to the Regions, as well as the resources derived from regional taxes, were considered the Regions' own revenue. This meant that these funds were no longer subject to earmarking constraints, except for the portion strictly necessary to guarantee the Essential Levels of Assistance (LEA), which are the healthcare services that the National Health Service must ensure to all citizens across the national territory.

3. *The 2001 reform of Title V of the Constitution and the new competences division*

The reform of Title V of the Constitution is a turning point in the history of State-Region's relations, including in the area of healthcare.

First, it must be said that the previous constitutional text (in particular, concerning the topic in question, in Arts. 127, paragraph 3; 117, paragraph 1 of the Constitution) was conceived too abstractly and was already obsolete. Indeed, the constituent legislator had outlined a

model of relations between the State and the Regions based on a tendency towards separation between the two entities but, at the same time, inspired by a centralistic logic, tending to ensure a substantial correspondence of political direction between the state and regional levels. The operational start of the Regions with ordinary statute had begun to subject this model to strong tensions, which immediately showed a tendency to assume conflictual patterns that found their main outlet in the judgments before the Constitutional Court [6].

In other words, the original model had gradually lost its regulatory capacity over time and, consequently, the task of giving systematic order to this framework had been – substantially – entrusted to the Constitutional Court [7].

The reform of Title V, however, is inspired by the attempt to achieve a – not easy – balance between two opposing principles. On the one hand, the principle of autonomy and thus of differentiation, which finds its explanation in the Regions' residual power and concurrent power, and on the other hand, the principle of equality, which is embodied in the provision for the Essential Levels of Performance (Livelli Essenziali delle Prestazioni - LEP) referred to in Article 117, paragraph 2, letter M. It can thus be said that the LEPs represent the concrete implementation of the principle of equality in guaranteeing services related to rights, within a regional context that must be characterized by political autonomy and organizational decentralization. As the Constitutional Court specified, the State's competence in healthcare is exhausted in the definition of the Essential Levels of Performance (LEP), while their organization and implementation fall to the Regions [8].

Surely, one of the main elements of discontinuity in the constitutional reform of Title V can be found in the fact that the State's legislative power only exists where an independent title of legitimacy can be

[6] Cfr. W. NOCITO, *Dinamiche costituzionali ed esigenze unitarie. Il regionalismo italiano come federalismo incerto*, Cosenza, 2005, 50.

[7] R. BIN, *L'interesse nazionale dopo la riforma: continuità dei problemi, discontinuità della giurisprudenza costituzionale*, in *Le Regioni*, 2001, 1217.

[8] Constitutional Court, sentence no. 88 of 2003

found [9]. A literal analysis of the reformed constitutional text could thus lead to the conclusion that center-periphery relations should no longer be based on a principle of State supremacy but exclusively on the division of competences, and control over the legislation of the State and Regions should only concern the *vindicatio potestatis* (and in particular hypotheses, interference) [10]. However, since its entry into force, a series of problems have emerged, the solution of which has been entrusted, above all, to the jurisprudence of the Constitutional Court. This time too, the absence in the reformed text of a regulation, albeit general, of mechanisms and circuits for connection and coordination between the state and regional levels has inevitably handed over to interpreters the task of identifying procedural and substantive mechanisms[11].

It can therefore be stated that, even in 2001, there was a poor drafting of the constitutional text[12]. The logic of the rigid separation of competences cannot take due consideration of the problem of coordination and collaboration[13]. The language of the constitutional provisions seems much closer to the lexicon of politics than to that of law. It is true that this is in a certain sense inevitable, given the nature of Constitutions as halfway between a political manifesto and a legal norm, but it is also true that there is a fundamental 'flaw' in the entire question of federalism in our legal system. In fact, the political and institutional debate has largely focused, over the years, on a concept of so-called federalism that should have entailed the 'liberation' of the regions (or some regions in particular) from the invasive and centralizing

[9] Constitutional Court (sent. no. 1 of 2004) "As is well known, Constitutional Law 18 October 2001, no. 3 (Modifiche al titolo V della Parte Seconda della Costituzione) changed the order of relations between state and regional legislation, in the sense that the legislative power of the State exists only where a precise title of legitimacy can be derived from the Constitution." On this point, cfr. M. LUCIANI, *L'autonomia legislativa*, in *Le Regioni*, 2004, 356.

[10] Cfr. A. SACCOMANNO, *Il controllo di costituzionalità della legge regionale*, Roma, 2005.

[11] P. VERONESI, *I principi in materia di raccordo Stato-Regioni dopo la riforma del Titolo V*, in *Le Regioni*, 2003, 1008.

[12] M. LUCIANI, *L'autonomia legislativa*, in *Le Regioni*, 2004, 355.

[13] Cfr. R. BIN, *L'interesse nazionale dopo la riforma: continuità dei problemi, discontinuità della giurisprudenza costituzionale*, in *Le Regioni*, 2001, 1217.

State. The reform of Title V thus arose as an attempt to curb the – at least verbally – secessionist pressures of some regions or parts of the country. In other words, the 'dualistic' tones were accentuated, forgetting – or pretending to forget – that no federal-type model can function without coordination institutions and circuits.

The underlying problem of this constitutional reform is that it was approved laboriously with a 'compromise at the bottom' during a period of great tension regarding the unity of the State. At that time, as mentioned, some political forces even feared the secession of the so-called richer territories. Consequently, the redesign of the division of political power and competence could not help but be affected by this tension. A reference for a generically and formally 'federal' model was thus expressed and formalized to curb the so-called centralizing State. Consequently, a formal (but not substantial) equalization of the Entities that constitute the Republic was sanctioned.

Therefore, if, as already mentioned, a first reading of the newly revised constitutional text seems to suggest a clear division of tasks, the complexity of contemporary state systems presupposes a necessary integration of competences. This structure not only leads, as will be sought to demonstrate, in extreme cases, to the power of substitution of the central State for peripheral bodies, but above all requires a kind of 'concertation' in the very exercise of competences, which is not always easy to structure[14].

The two main turning points, at the level of competence, are the exhaustive enumeration of state legislative competences and the residual legislative competence clause in favor of the Regions. Unfortunately, however, the division of competences was carried out following a model that soon manifested a series of dysfunctions.

First, regarding concurrent competences – which include the matter of 'protection of health' – the boundary of competence, principle (State) - detail (Region), already in force in the previous constitutional text, was reiterated, a boundary which had shown a whole series of operational limitations. Essentially, the parameter in force in the pre-

[14] A. SACCOMANNO, *Il controllo di legittimità alla luce del nuovo art. 127 Cost.,* in AA. VV. (coordinated by S. Gambino), *Diritto regionale e degli enti locali*, Milano, 2003, 233 ff.

vious system remains, which is that what the legislator defines as a principle is what is not fragmentable, meaning it corresponds to the national interest and requires uniform regulation, also called "not a leopard spot" regulation. Therefore, the variable level of interests can allow the State to enact principle legislation that goes beyond the theoretically understood principle but can also regulate very specific aspects that nonetheless require uniform regulation.

Secondly – and this also has a strong impact in the healthcare sector – the change in the constitutional framework has also led to the identification, within the exclusive state competences referred to in Article 117, paragraph 2, of cross-cutting material areas ('ambiti materiali trasversali'), among which, under letter (m), we find the 'determination of the essential levels of performance concerning civil and social rights that must be guaranteed throughout the national territory,' which has a profound impact on healthcare, where essential levels are defined in terms of LEA (Essential Levels of Assistance)[15].

These material areas cannot, as such, be configured as 'matters' in the strict sense, since they are more accurately state legislative competences capable of impacting a plurality of matters[16]. It is not possible

[15] As the Constitutional Court affirmed as early as 2002 (judgment no. 402), "not all the material areas specified in the second paragraph of Article 117 can, as such, be configured as 'matters' in the strict sense, since, in some cases, they are more accurately state legislative competences capable of impacting a plurality of matters (cf. judgment no. 282 of 2002). In this sense, legislative evolution and constitutional jurisprudence lead to the exclusion of identifying a 'matter' in the technical sense, qualifiable as 'environmental protection,' since it does not appear to be configurable as a strictly circumscribed and delimited sphere of state competence, as, on the contrary, it inextricably involves and intertwines with other interests and competences. In particular, from the Court's jurisprudence preceding the new formulation of Title V, it is easy to deduce a configuration of the environment as a constitutionally protected 'value,' which, as such, outlines a kind of 'cross-cutting' matter, regarding which different competences manifest themselves, which may well be regional, with the State being responsible for the determinations that respond to needs worthy of uniform regulation throughout the national territory."

[16] By way of example only, reference can be made to judgment no. 407 of 2002 regarding the environment. "In this sense, legislative evolution and constitutional jurisprudence lead to the exclusion of identifying a 'matter' in the technical sense, qualifiable as 'environmental protection,' since it does not appear to be configurable as a strictly circumscribed and delimited sphere of state competence, as, on the contrary, it

here to explore all aspects of the theme of the cross-cutting nature of material areas; however, it is recalled that this attribute has been recognized for sectors such as environmental protection, protection of competition, scientific research, and especially the determination of essential levels of performance concerning civil, economic, and social rights[17].

The uniform regulation throughout the national territory is founded on the principle of safeguarding the conditions of equality of citizens' rights[18]. In effect, "the determination of competence responds to the teleological criterion of the aim to be pursued or the value to be protected, whereby the state intervention can exceed the merely objective boundaries of the matter, thus extending to a plurality of objects

inextricably involves and intertwines with other interests and competences. In particular, from the Court's jurisprudence preceding the new formulation of Title V of the Constitution, it is easy to deduce a configuration of the environment as a constitutionally protected 'value,' which, as such, outlines a kind of 'cross-cutting' matter, regarding which different competences manifest themselves, which may well be regional, with the State being responsible for the determinations that respond to needs worthy of uniform regulation throughout the national territory (cf., most recently, judgments no. 507 and no. 54 of 2000, no. 382 of 1999, no. 273 of 1998). The preparatory works relating to letter (s) of the new Article 117 of the Constitution suggest, moreover, that the legislator's intent was to nonetheless reserve to the State the power to set uniform standards of protection throughout the national territory, without thereby excluding the regional competence in this sector to look after interests functionally linked to those properly environmental. Ultimately, it can therefore be considered that with regard to environmental protection, there was no substantial intention to eliminate the pre-existing plurality of titles of legitimacy for regional interventions aimed at simultaneously satisfying, within their own competences, further needs than those of a uniform nature defined by the State." On this point, cf. P. CARETTI, *La Corte e la tutela delle esigenze unitarie: dall'interesse nazionale al principio di sussidiarietà*, in *Le Regioni*, 2004, 383.

[17] The Constitutional Court, since judgment no. 282 of 2002, clearly stated that "it is not a 'matter' in the strict sense, but a competence of the state legislator capable of impacting all matters, with respect to which the legislator must be able to establish the necessary rules to ensure that everyone, throughout the national territory, enjoys guaranteed services, as the essential content of these rights, without regional legislation being able to limit or condition them

[18] Thus C. PINELLI, *Sui "livelli essenziali" delle prestazioni concernenti i diritti civili e sociali (art. 117 co. 2 lett. m Cost.)*, in *Diritto Pubblico*, 2002, 881.

pertinent also to other matters, but nonetheless responding to the aim ultimately assigned to the State" [19].

It must also be said that, in the cross-cutting areas, the state competence, on the one hand, constitutes a limit to the regional legislative power, even in exclusive matters, and on the other hand, identifies the so-called "maximum threshold that the State cannot exceed for matters of regional competence" [20].

Third, concerning administrative action, the Government is recognized as a substitute power "when the protection of legal or economic unity, and in particular the protection of the essential levels of performance concerning civil and social rights, require it, disregarding the territorial boundaries of the governments" (Art. 120.2)[21].

The mechanisms described above have not always functioned fully, and after 25 years, it can be reiterated that there was a poor drafting of the constitutional text, which designed an abstract model with opera-

[19] Thus A. CELOTTO, *Appalti di lavori pubblici, governo del territorio e riforma del Titolo V della Costituzione*, in *www.giustamm.it,* 2005.

[20] Thus A. RUGGERI, *Neoregionalismo, dinamiche della normazione, diritti fondamentali,* in *www.federalismi.it*, 2002. On the problem of whether residual competence is also exclusive or whether there may be prerequisites for state intervention, see also the considerations of L. CUOCOLO, *Gli interessi nazionali tra declino della funzione di indirizzo e coordinamento e potere sostitutivo del Governo*, in *Quaderni Regionali*, 2002, 423 ff.

[21] For example, most recently, see Constitutional Court, judgment no. 32 of 2025, with which the Court confirms its consolidated jurisprudence (e.g., judgments no. 20 of 2023, no. 200 of 2019, nos. 247 and 199 of 2018, nos. 190 and 14 of 2017), according to which, taking into account the binding nature, for the regions, of the agreements stipulated with the State, which led to the signing of the plan for the recovery of the healthcare deficit and the subsequent operational programs (in the case of failure to achieve the plan's objectives in the three-year period), the appointment of the 'commissario ad acta' constitutes an exercise of the extraordinary substitute power of the Government, aimed at guaranteeing, in the event of "persistent inertia of the Region with respect to the activities required by the aforementioned agreements," economic unity and the protection of the essential levels of performance inherent to the fundamental right to health. Therefore, the functions entrusted to the same commissioner, defined in the mandate conferred upon him and "specified by the operational programs," must remain, until the completion of the commissioner's tasks, safe from any interference by regional bodies – even if the latter were to act through legislation – under penalty of violating Article 120, second paragraph, of the Constitution.

tional deficiencies. The 2001 reform is an ill-structured compromise between secessionist pressures to be weakened and a desire for centralism to be mitigated. In general, the major criticalities reside in the re-proposition of the idea that competences can be clearly distinguished without having introduced, at the constitutional level, a venue for political-legislative dialogue and coordination.

Furthermore, still in the name of autonomist-secessionist ambitions, the formal cancellation of the national interest was conceived, but without providing for those mechanisms for guaranteeing the unity of choices and the so-called implied powers present in all federal systems. In fact, the national interest that, as is commonly said, went out the door, inevitably came back in through the window, considering the variable level of interests which, as seen, impacts both concurrent competences and the cross-cutting material areas provided for in exclusive state competences[22].

From the point of view of administrative competences, the idea was to replace the previous system, which was based on the so-called parallelism of functions, with a system centered on an even more complex (not to say confusing) principle: the principle of subsidiarity, adequacy, and differentiation.

However, while there are undeniable profiles of continuity between the old and the new constitutional framework, others of discontinuity also exist. The reference to the national interest, in fact, can no longer be considered "an autonomous limit on regional legislation, nor

[22] As R. BIN states (*Le materie nell'art. 116 della Costituzione*, Text of the lecture given at the Seminar of Studies and Parliamentary Research «Silvano Tosi» - Course in Regional Law, March 6, 2019): In essence, what limits regional legislative power is not the scarcity of "objects" to legislate on (the matters, filled with content), but the thick weave of limits deriving from State laws and the interests exclusively attributed to it: that label "national interest," whose invocation once sufficed to justify the carving out of a matter, formally no longer exists today, having been canceled by the 2001 reform, but its content has poured in everywhere and proceeds through a thousand streams to stiffen regional legislative action.

can it be an autonomous foundation for a state legislative intervention in matters of regional competence"[23].

In other words, the problem of unitary interests (whose foundation must be found in Article 5 of the Constitution) remains, but the old solutions based on the principle of State supremacy can no longer be applied. That is, it can no longer be said that national interest automatically equals state competence. Consequently, the co-presence, within the same material area, of interests attributable to different levels of government must necessarily be achieved through the forms of loyal cooperation (leale collaborazione)[24].

[23] Cfr. judgments no. 370 of 2003; 16 of 2004; 87 of 2006. On this point, see also F. BENELLI, *Interesse nazionale, istanze unitarie e potestà legislativa regionale: dalla supremazia alla leale collaborazione*, in *Le Regioni*, 2006, 940.

[24] Cfr. e.g., judgment no. 228 of 2004 on the national civil service. This area is undoubtedly complex, and its regulation presupposes the involvement of the state level of government and that of the autonomous provinces. In fact, "The challenged regulations, since they are aimed at regulating the organizational and procedural aspects of the national civil service, find their foundation, first, in Art. 52 of the Constitution, and do not preclude the Autonomous Province from the possibility of regulating the exercise of specific functions, concerning material aspects that fall within its competence. (...) However, the reservation to the State of the competence to regulate the national civil service, a form of fulfillment of the duty to defend the Fatherland, does not imply that every aspect of the activity of citizens performing said service falls under state competence. The organizational and procedural aspects of the service certainly fall within it. This, in concrete terms, involves the performance of activities that impact the most diverse material areas, such as social assistance, environmental protection, civil protection: activities which, for aspects of public relevance, remain subject to the regulation dictated by the respective competent entity, and therefore, if applicable, to regional legislation or the regulations of local authorities, with the sole exception of the specificities directly connected to the organizational structure of the service and the rules provided for accessing it. (...) Furthermore, it should be noted, in this case, that the need to ensure the participation of the levels of government involved through tools of loyal cooperation or, in any case, through adequate cooperation mechanisms for the concrete exercise of administrative functions allocated to the central bodies, is nevertheless satisfied precisely through the attribution to the care of the Regions and the Autonomous Provinces of Trento and Bolzano, according to their respective competences, of the implementation of civil service interventions. Furthermore, it is evident that, in cases where the performance of civil service activities falls within areas of competence of the Regions or the Autonomous Provinces of Trento and Bolzano, the exercise of the functions pertaining, respectively, to the State and to the aforemen-

Regarding the production of acts, it can be said that it focused mainly on the regulatory level (legislative and administrative), but little on concrete results, partly because a cultural and methodological structure for the evaluation of these results does not yet appear consolidated.

Regarding the right to health, this reorganization of competences must operate in necessary coherence with the provisions of Article 32 of the Constitution, which, it is recalled, mandates that this right be equally guaranteed and protected throughout the national territory. Given the division of legislative and administrative competences between the State and the Regions, the guarantee of the Republic's unity in the protection of this right requires a reasonable balancing/weighing between uniformity and differentiation.

This is a point that must never be forgotten because the moment spaces for autonomy are recognized, the possibility of differentiation is admitted. On the other hand, the principle of equality itself, under Article 3 of the Constitution, is not only definable in terms of uniformity, but in terms of reasonable uniformity and reasonable differentiation.

Consequently, as in all assessments inspired by the reasonable balancing of interests, one must first ask: Is the State's exclusive normative intervention a necessary condition to guarantee the equal protection of the right when indivisible interests exist, and how much normative uniformity can be accepted without unreasonably compressing the spheres of constitutional autonomy recognized to the Regions?

Secondly, how much differentiation among the Regions can be accepted without running the risk of failing to ensure all citizens the equal protection of the right to health?

Let's now analyze the profiles connected to these two problems. All services guaranteeing constitutional rights have a cost, both for social and civil rights. The State must determine, through specific acts, what the essential level of the individual services is, below which one cannot descend in any part of the national territory (an explication of the Principle of Equality under Art. 3 Const.); the Regions, within

tioned entities, must be based on respect for the principle of loyal cooperation between entities equally constitutive of the Republic (Art. 114, first paragraph, of the Constitution).

their competences (and especially financial possibilities), can increase the level of services. The Government can substitute for the bodies of the Regions and Local Authorities when required by the protection of the essential levels of performance concerning civil and social rights (Art. 120, paragraph 2, Const.).

However, equality in the guarantee of the right, from a theoretical point of view, is expressed on multiple levels: that of the normative discipline and that of the evaluation of the concrete results produced by the implementation of the normative prescriptions. It must never be forgotten, in fact, that the citizen is interested in the guarantee of the service, not the abstract normative determination. From this point of view, a direct correlation is not always verified between a uniform normative discipline and concretely uniform results, or between differentiated normative disciplines and concretely differentiated results.

Concretely uniform results (i.e., the objective of guaranteeing reasonable equality in services concerning rights) can also stem from regulations that possess a certain degree of differentiation (because adopted at the regional level), or a uniform regulation, precisely because of its 'rigidity,' can lead to differentiated concrete results due to its application in non-homogeneous territorial areas.

It is therefore necessary to verify, case by case, (Articles 5 and 117 of the Constitution) whether the degree of differentiation produced by the application of a regulation is not unreasonable, meaning it does not call into question, on the one hand, the unity and indivisibility of the Republic; and whether the degree of uniformity concretely produced by the application of a regulation does not unreasonably compress the spaces of autonomy recognized especially to the Regions.

Another essential profile, present in all assessments inspired by reasonable balancing, is the search for the minimum content of the interests subject to weighing, and the adequacy and appropriateness of the levels of services; and this leads to the problem of the LEAs (Essential Levels of Assistance).

4. *The Constitutional Court,* sui generis *arbiter of the institutional dialectic between State and Regions*

The Constitutional Court, institutionally, has an arbitral role in State-Regions relations. However, it is a special arbitrator (sui generis) because it does not limit itself to merely reconstructing the issue submitted to its judgment by interpreting the provisions and applying the rules of the division of powers, but actively contributes to defining, in a mobile and flexible manner, the extent of the individual spheres of competence and the boundaries between state and regional domains.

In other words, cases of overlapping and intertwining of competences become frequent because of the difficulty of a given object, which requires normative regulation, falling into only one matter. The healthcare matter is precisely one of these areas.

In such cases, the expansion of the Constitutional Court's role has become inevitable, and it has developed a series of criteria to resolve several highly complex issues submitted to it.

The Criterion of Material Preponderance ('Criterio della prevalenza materiale'). The Constitutional Court uses this criterion when the legislative regulation being challenged primarily pertains to a specific matter, based on the analysis of the prevailing object, the so-called "hard core". In this case, that object is absorbed into one matter, and consequently, the regulation for that type of competence will be applied.

The Criterion of Prevalent Purpose ('Criterio della finalità prevalente'). In other cases, the Court has instead used the criterion of prevalent purpose, noting that the legislative regulation being challenged concerns a plurality of different matters without any of them being quantitatively prevalent. In such cases, the Court attributes the regulation to a particular legislative competence by identifying the prevalent purpose as the unifying element. This purpose is derived from the ratio of the law as a whole and its fundamental aspects, considering above all the interests that the regulation is aimed at protecting, without considering marginal or reflected aspects in the norm's scope of application.

The Principle of Loyal Cooperation ('Leale collaborazione'): In cases where the intertwining of competences manifests itself in such an

inextricable way that it is impossible to find a material or purposive preference (because a law or provision is inspired by multiple purposes), the Constitutional Court invokes the necessity of loyal cooperation between the State and the Regions to resolve such issues. This principle has a precise constitutional foundation, being traceable to the principle of unity and autonomy under Article 5 of the Constitution. However, it must be specified that this principle can be invoked for the failure to provide for or the failure to comply with forms of collaboration and coordination in the performance of administrative activities, both preventive (opinions, understandings, agreements) and in the implementation phase (adoption of regulations) or application phase (adoption of administrative measures).

The principle of loyal cooperation, however, cannot be invoked with reference to the exercise of legislative power. The Constitutional Court has, in this regard, affirmed (see for example judgment no. 196 of 2004) that 'there is no identifiable constitutional basis for the obligation of legislative procedures inspired by loyal cooperation between the State and the Regions' [25].

The only tempering to this assumption that the Court has so far admitted (judgment no. 251 of 2016) relates to cases where the State chooses to adopt a legislative decree in a material area that includes an inextricable intertwining of state and regional competences for which it is not possible to identify a prevalent competence. In such cases, the Government must reach an understanding ('Intesa') within the State-Regions Conference in order to agree on the contents of the legislative decrees in question.

It seems preferable to favor the solution according to which the new Title V offers, as a response to the problem of unitary interests,

[25] As R. BIN affirms (*Le materie nell'art. 116 della Costituzione*, Text of the lecture given at the Seminar of Studies and Parliamentary Research «Silvano Tosi» - Course in Regional Law, March 6, 2019), one must note the interpretative expansion of the 'matters' reserved to the State, which take the form of 'cross-cutting' matters, 'liquid' matters that penetrate everywhere. In this sense, the prevalence criterion allows the Court to establish the State's competence wherever it comes into contact with regional matters. If the criterion of prevalence applies, loyal cooperation is not mandatory; and if, despite this, the law provides for it, it only entails an opinion on a regulation that is destined to apply integrally, nullifying the normative spaces of the Regions.

the legal concepts of subsidiarity and adequacy[26]. In other words, unitary interests (but also differentiated ones) would find their concrete satisfaction in the weighing of interests in the individual cases. This weighing would have its implementing instrument in the equal forums and forms of the so-called loyal cooperation. The Constitutional Court should thus guarantee the protection of unitary needs only through the control of these procedural forms, leaving the choice of options to the political bodies. That is, the Court should return to being only the custodian of the rules and not the body that constantly rewrites them. Furthermore, the Regions can at most take charge of regional interests, and indivisible interests cannot be left to agreements between Regions[27].

In summary, the connection circuit should be structured as follows: loyal cooperation entails an exercise of legislative competences according to proportionality and adequacy considering the principle of subsidiarity. This implies a dynamic distribution of competences, not rigidly anchored to formal qualifications or labels[28].

Finally, we must also mention, as a further factor of flexibility in the division of legislative competences and, consequently, as an element of greater complexity in detecting violations of competence, the institution of the so-called legislative subsidiarity or call to subsidiarity ('chiamata in sussidiarietà'). This concept was introduced by the Constitutional Court with judgment no. 303 of 2003 and subsequently further developed in other rulings.

According to this institution, the State may attract administrative competences by virtue of the principle of subsidiarity; when it does so, it also attracts legislative competences, by virtue of the principle of legality. As the Court stated in this well-known judgment, this derogation is only justified if the evaluation of the public interest underlying the assumption of regional functions by the State is proportional, is not affected by unreasonableness according to a strict constitutional

[26] R. BIN, *L'interesse nazionale dopo la riforma: continuità dei problemi, discontinuità della giurisprudenza costituzionale*, in *Le Regioni*, 2001, 1219 ff.

[27] M. CARLI, *I limiti alla potestà legislativa regionale*, in *Le Regioni*, 2002, 1370.

[28] Cfr. F. BENELLI, *Interesse nazionale, istanze unitarie e potestà legislativa regionale: dalla supremazia alla leale collaborazione*, in *Le Regioni*, 2006, 939.

review and is the subject of an agreement stipulated with the Region concerned. Indeed, one cannot simply invoke subsidiarity and adequacy to modify the constitutionally established division in favor of national law, because this would be tantamount to denying the very rigidity of the Constitution[29].

5. *The LEAs (Essential Levels of Assistance) between legislative provisions and constitutional jurisprudence. Guaranteeing healthcare services amidst financial constraints and respect for the Principle of equality*

The issue of the determination and guarantee of certain levels of healthcare services is intimately connected to the idea of the universality of the health service. This idea emerges, even in normative language, as early as Law no. 833 of 1978. Previously, as mentioned, the system structured according to a mutualistic-insurance logic inevitably brought with it differentiation by sectors and categories. It should, moreover, be remembered that the very elimination of differences is one of the cornerstones of the law establishing the National Health Service (SSN). Essentially, the preparation of standard indices was intended to guarantee certain levels of services in all Regions, and thus financial resources were to be instrumental to the services to be provided. This mechanism then had to fit into a division of competences that was, in fact, under the exclusive competence of the State. Even where the State's legislative power should have been limited only to principles, their identification through very detailed normative provisions inevitably reduced the Regions' legislative scope. As previously mentioned, the issue of dividing legislative spaces cannot be reconstructed in the abstract with the mere definition of principle-norm vs. detail-norm, but only concretely, by paying attention to the individual laws.

[29] Furthermore, R. BIN (*Le materie nell'art. 116 della* Costituzione, Text of the lecture given at the Seminar of Studies and Parliamentary Research «Silvano Tosi» - Course in Regional Law, March 6, 2019) affirms that where the Court brings out the call to subsidiarity, the obligation of loyal cooperation for implementing acts immediately follows; but the Court only triggers the call to subsidiarity if it has not used the criterion of prevalence. Where the criterion of prevalence applies, nothing remains.

As said before, the ratio of the constitutional reform, regarding the protection of health, can be traced back to the attempt to guarantee the autonomy of the Regions, while avoiding the inequality of services by attributing to the exclusive competence of the State the determination of the Essential Levels of Performance (LEP) concerning civil and social rights (also called, in the healthcare sector, LEA - Livelli Essenziali di Assistenza) (pursuant to Art. 117, paragraph 2, letter m), Const.). These areas cannot be considered 'matters' in the strict sense, but rather a 'task' or a 'cross-cutting value.' They are therefore areas in which State competence is manifested as connected with other regional interests and competences, both concurrent and residual. In this sense, the attribution of legislative power to the State's exclusive competence is justified because these areas are sectors of legislation where the identification of the competent source cannot derive from insertion into one of the 'containers' listed in Article 117 of the Constitution, but from the idea that the cross-cutting material area identifies an interest of national relevance that overlaps with the interests entrusted by the Constitution to the regional legislator.

If the idea was to guarantee the equality of services, it must be said that it has not achieved the objective. Regional differentiations persist, and in the face of formal enforceability of services, there are in fact considerable differences among the Regions, which, in some contexts, lead to a material non-enforceability. It can thus be said that from the old mutualism by categories before Law 833/1978, we have moved to a kind of regional-style mutualism that manifests factual inequality; the citizens' right to health, in fact, suffers significant compression in territories where the organizational and administrative capacity is lower.

A part of the citizens "vote with their feet" and move across the national territory from the Regions that guarantee these services less to those that guarantee them more, to have their constitutional rights (especially the right to health) guaranteed. Another part does not move (essentially because they cannot) and must settle for lesser services, often below the established LEAs. Furthermore, all this entails a transfer of wealth from less efficient areas to more efficient ones. This situation, which has now become consolidated over time, appears difficult to solve, so much so that one might even question the effectiveness of structuring the NHS on a regional basis and, *de jure condendo* (regard-

ing the law to be enacted), discuss whether a restructuring on a state basis might be preferable instead, to better guarantee equality in healthcare services.

In any case, *de jure condito* (regarding the existing law), let's try to understand the critical issues of the system that have contributed to the persistence of strong differentiations among the Regions; differentiations which, it should be remembered, have an ancient origin. The starting point is the structure of the LEA system, as these are the minimum safeguards for guaranteeing the principle of equality in the healthcare sector.

First, it must be said that the LEAs should not be confused with the essential content of the right to health. The essential content of the right, as is known, is that minimum threshold below which the right is clearly violated. It is that component that cannot be subjected to balancing by the legislator and refers to the concept of 'sufficiency' of the service. LEAs are something more. In their aim to guarantee the equality of a certain level of services, they are more reminiscent of the concept of 'adequacy' or 'appropriateness' of the service.

The architecture of the essential levels system can be configured as follows:

– All services guaranteeing constitutional rights have a cost, both for social and civil rights.

– The State must determine, through specific acts, what the level considered essential of the individual services is, below which one cannot descend in any part of the national territory (an explication of the Principle of Equality under Art. 3 Const.).

– The Regions, within their competences (and especially financial possibilities), may increase the level of services.

– The Government may substitute for the bodies of the Regions and Local Authorities when required by the protection of the essential levels of performance concerning civil and social rights (Art. 120, paragraph 2, Const.).

In practice, the State has decided to proceed with the identification of the LEPs (and, relevant to us, the Essential Levels of Assistance [LEA] in healthcare) through the mechanism of loyal cooperation within the Conference system and adoption via DPCM (Decree of the President of the Council of Ministers). Unfortunately, even in this ar-

ea, the State has not always monitored and activated the substitute powers necessary to ensure the concrete respect of these LEPs.

In any case, for the system to function, it inevitably requires continuous monitoring. From 2008 to 2019, the so-called "LEA grid" (griglia LEA) was used, structured around 34 indicators divided among collective prevention and public health activities, district assistance, and hospital assistance.

Since 2020, the LEA grid has been replaced by the so-called CORE indicators subset of the New Guarantee System (NSG) (Nuovo Sistema di Garanzia). The New Guarantee System is a tool that, drawing on data from the New Health Information System (NSIS), is intended to measure the adequacy and effectiveness of the services included in the LEAs through 88 indicators. In theory, this system should therefore ensure more accurate monitoring due to the increased number of indicators. However, it must also be said that only the so-called CORE indicators, which number 22, are then used to evaluate compliance with the LEAs. As stated, 'the NSG, limited to the CORE indicators, is more a tool for political agreement between the Government and the Regions than a faithful mirror capable of providing a timely, systematic, and multidimensional reflection of the quality of assistance provided and guaranteeing citizens the right to health protection'[30].

Beyond the formal or content-related aspects, the central problem for guaranteeing healthcare services—both those attributable to the LEAs and additional ones—is the financial one. All rights cost money, but, as the Constitutional Court states, financial conditioning is central for the right to health. The Constitutional Court itself has thus been called upon multiple times to intervene regarding the complex balancing act between financial constraints and the guarantee of the right to health.

The Constitutional Court's Judgment no. 62 of 2020 appears central in this regard. The Constitutional Court ruled on the appeal lodged by the President of the Council of Ministers against a series of provisions in the Sicilian Region's Stability Law for violating Article

[30] Cfr. 7° Rapporto GIMBE sul Servizio Sanitario Nazionale, 8 Ottobre 2024.

81, paragraph 3, and Article 117, paragraph 2, letters (e) and (m), and paragraph 3, of the Constitution.

The question of constitutional illegitimacy was upheld concerning the part where the regional law provided for the use of the funds intended to guarantee the essential levels of healthcare and hospital assistance that was different from the purpose for which these resources were assigned by the State.

Beyond the specific issue addressed, the Court reiterated that the protection of health as a fundamental individual right and an interest of the entire community is guaranteed by the National Health Service (SSN), which ensures essential and uniform levels of assistance, as defined in the National Health Plan, and identifies the necessary financial resources to be allocated. This right is founded on the constitutional principle of Article 2, which affirms the centrality of the human person, not only in their individuality but also in their relational aspects, as is the case precisely for the health service.

The content of the right to health is also defined by the determination of the LEAs (Essential Levels of Assistance). Adequate funding of the LEAs constitutes the 'necessary but not sufficient condition for ensuring services directly attributable to the fundamental right to health.' Consequently, the right to healthcare services, once normatively identified, is fundamental in nature and cannot be financially conditioned in absolute and general terms, as the Constitutional Court itself had already affirmed in Judgment no. 275/2016.

The determination of the essential levels of social-healthcare assistance (LEAs) is an obligation of the State legislator, but its projection in terms of regional needs necessarily involves the Regions. Consequently, the principle of prior programming of financial needs and the obligation of continuous monitoring to verify the sufficiency of resources and the level of services have their own specific binding force.

Furthermore, in Order no. 178 of 2024, the Court criticized—albeit in a judgment declaring the proceedings terminated—a law of the Puglia Region for violation of the principle of harmonization of public budgets and coordination of public finance under Article 117, paragraph 3, of the Constitution. This was because, by introducing an additional level of healthcare assistance compared to the LEAs and charging it to the Regional Health Service (SSR), it violated the regula-

tion concerning the financial deficit recovery plans in healthcare, to which the Puglia Region is subject, which imposes a prohibition on non-mandatory expenditure[31].

The current framework, unfortunately, shows that the National Health Service (SSN), in the various implementations it has had so far, has failed to guarantee equal provision of services connected to the protection of the right to health in all Regions. One gets the impression that the choice to structure the health service on a regional basis has given rise to 21 regional health systems held together only by an institutional and regulatory framework.

he main problem, therefore, is the constitutional and financial sustainability of the SSN within a framework of underfunding. However, this problem must be framed within the broader issue of public revenue and expenditure. On the one hand, it is evident that tax evasion and avoidance deprive the State of important resources. On the other hand, there is the need to respect the constitutional and European constraints contained in the Stability and Growth Pact and the overall financial sustainability of a State burdened by considerable public debt, whose financing depends almost daily on the decisions of financial markets.

Moreover, financial constraints do not only affect the so-called less virtuous Regions subject to recovery plans or commissioners, but also those with a financial framework that nonetheless forces them to increase tax pressure, where possible, or to cut services. As has been stated, 'in the face of an NHS (National Health Service) inspired 45 years ago by the founding principles of universality, equality, and equity, today we find ourselves with 21 profoundly unequal regional health systems, with residents in most Southern Regions not even guaranteed

[31] Similarly, see Judgment no. 197 of 2024 concerning the unconstitutionality of a law of the Sicilian Region, and no. 191 of 2024. The same Court, in Judgment no. 141 of 2024 (relating to a law of the Sardinia Region), specified that the spending constraints contained in State legislation, being functional to preventing budget deficits, preserving the economic-financial balance of all public administrations, and guaranteeing the economic unity of the Republic, also apply to Special Autonomy Entities. However, since the Sardinia Region provides for the full financing of its own regional health service and is not subject to health deficit recovery plans, the State has no authority to dictate financial coordination norms.

the LEAs (Essential Levels of Assistance). And this "structural North-South divide" contributes to fueling the unfortunate phenomenon of health mobility. Despite this, politics continues to delude itself into thinking it can maintain a public, equitable, and universalistic NHS with healthcare spending that places us first among the poor countries in Europe and without implementing courageous reforms. And that it can guarantee, with such low public spending, a "basket" of healthcare services and provisions (LEAs) that is among the richest in Europe' [32].

Furthermore, those who cannot move for economic or other reasons must, in fact, settle for lesser services, often below the established LEAs, and health mobility results in a further transfer of resources from the 'less efficient' Regions to the 'more efficient' ones.

6. *Regional differentiation and Constitutional court judgment No. 192 of 2024*

As is known, Article 116, paragraph 3, of the Constitution provides for the possibility of granting Regions with ordinary statutes 'further forms and particular conditions of autonomy' (the so-called 'differentiated regionalism' or 'asymmetric regionalism') based on an agreement (Intesa) between the State and the Regions that request it.

The areas over which further forms of autonomy can be activated concern some matters of exclusive state legislative competence (organization of peace justice, general norms on education, protection of the environment, ecosystem, and cultural heritage) and all matters that Article 117 of the Constitution attributes to concurrent legislative competence between the State and the Regions, and thus the 'protection of health'.

The activation of this possibility was implemented with Law no. 86 of 2024 which, even in the phase preceding its approval, had generated a broad and, at times, bitter debate. The conflict continued even after its entry into force, and, beyond the political-scientific debate,

[32] Cfr. 7° Rapporto GIMBE sul Servizio Sanitario Nazionale, 8 Ottobre 2024.

took the form of an appeal to the Constitutional Court by a number of Regions and a request for an abrogative referendum.

The Constitutional Court ruled on the question of constitutional legitimacy with Judgment no. 192 of 2024. According to the Constitutional Court, the Italian regional system entails a certain competition among the regions, which can stimulate diversified policies to achieve better results. However, the implementation of Article 116, paragraph 3, of the Constitution, must aim to achieve a reasonable balance between equality/uniformity and differentiation.

In particular, the mechanism of differentiated autonomy cannot and must not compromise the legal and economic unity of the State, solidarity among the regions, and the equality of citizens, which are essential elements for social cohesion and national unity. The Italian regionalism is, in fact, based on a cooperative logic whose turning point is loyal cooperation between the State and the regions to implement constitutional principles and protect individual rights.

In this sense, the implementation of greater autonomy in the healthcare sector, carried out precisely by the Regions with the best healthcare performance, risks amplifying all existing inequalities. The fundamental point that cannot be ignored is that it is not admissible to violate the principle of equal guarantee of the right to health, effectively consolidating the North-South divide normatively.

Consequently, the progressive overcoming of this structural condition inevitably passes through the problem of funding the NHS (National Health Service) and thus the FSN (National Health Fund) and its distribution. Without uniformly determining the LEAs (Essential Levels of Assistance) and without guaranteeing their adequate funding, it is unlikely that the differentiated autonomy mechanism can generate virtuous mechanisms and circuits of imitation. On the contrary, as mentioned, the risk is that of increasing the gaps between Regions.

The further consequence could be a progressive loss of centrality and efficiency of the NHS in favor of private and insurance solutions, which, although legitimate, would not be accessible to citizens with lower incomes, leading to heavy social consequences.

THE AUTHORS

Sabrina Tranquilli
Associate Professor of Administrative Law, University of Naples "Parthenope".

Giordana Strazza
Associate Professor of Administrative Law, University of Salerno

Stefania Negri
Associate Professor of International Law, University of Salerno.

Enza Romano
Associate Professor of Administrative Law, University of Salerno

Elisa Tino
Associate Professor of International Law, University of Naples "Parthenope".

Franco Trubiani
Senior Researcher in private law, University of Naples "Parthenope".

Ida Santalucia
Researcher in Hygiene and Preventive Medicine, University of Pavia.

Michele Sorrentino
Consultant in Hygiene and Preventive Medicine, University of Naples "Federico II".

Paolo Montuori
Full Professor of Hygiene and Preventive Medicine, University of Naples "Federico II".

Maria Fiore
Associate Professor of Hygiene and Preventive Medicine, University of Catania.

Margherita Ferrante
Full Professor of Hygiene and Preventive Medicine, University of Catania.

Maria Triassi
Full Professor of Hygiene and Preventive Medicine, University of Naples "Federico II".

Federico Francesco Guzzi
Associate Professor of Administrative Law, University of Calabria.

Luca Albino
Senior Researcher in Constitutional Law, University of Naples "Parthenope".

Finito di stampare nel mese di febbraio 2026
dalla Vulcanica srl - Napoli

On the cover: Hieronymus Bosch, *The Haywain Triptych*, 1512-1515
Oil, Panel, Alto con marco: 147.1 cm; Ancho con marco: 224.3 cm
Número de inventario: P002052. Madrid, Museo Nacional del Prado.

ISBN 979-12-235-0592-2

euro 16,00