GPN
GLOBAL PANDEMIC NETWORK

Legal Policy & Pandemics

The Journal of the Global Pandemic Network

In this Volume:

One Health. International, Supranational, Regional and National Experiences

aracne

2023
Volume 3
Issue 1–2–3

2024
Volume 4
Issue 1–2–3

2023 – Volume 3 – Issue 1–2–3
2024 – Volume 4 – Issue 1–2–3

Legal Policy & Pandemics

The Journal of the Global Pandemic Network

Legal Policy & Pandemics
The Journal of the Global Pandemic Network

four-monthly review

Subscriptions

Tele: 06 87646960
e–mail: info@adiuvaresrl.it

Publisher

Adiuvare S.r.l.
via Colle Fiorito, 2 – 00045 Genzano di Roma (RM)
06 87646960
www.aracneeditrice.eu
info@adiuvaresrl.it

All contributions, with the exception of the opening editorial, have undergone double blind peer review.

ISBN 979-12-218-2352-3

This work was financially supported by the University of Urbino Carlo Bo and by the University of Macerata [Projects name: "GPN" and "Glovess"].

Journal registered at no. 53 of the press register of the Court of Naples on 7 October 2021 – Direttore Responsabile Elisa Scotti

Table of Contents

Legal Policy & Pandemics
The Journal of the Global Pandemic Network – LPPJ
2024, Vol. 3–4 pp. 107-117
ISSN 2785-2628
DOI 10.53136/97912218235239

SECTION I
ESSAYS

Public Health Regulatory and Organizational Challenges in the Prism of the One Health Approach in Italy

Benedetta Celati

Abstract. The COVID-19 pandemic has shown clearly the urgency of adopting a unifying and holistic "One Health" approach to improve global preparedness for health and climate emergencies. The paper investigates the contribution of this approach to address current unmet public health issues, examining, from a regulatory and organizational perspective, both the need to strengthen the territorial network of services, in line with a comprehensive public health care strategy, and the scope for public intervention to improve citizens' access to medicines and pharmaceutical innovation. Attention will be paid to the relationship between proximity and new technologies, in terms of prevention and treatment, focusing on telemedicine as a service activity to support widespread healthcare delivery and the integration of multiple sectors, disciplines and communities.

Keywords: One Health, territorial health care, comprehensive public health care strategy, innovation, telemedicine.

1. Lessons learnt from the Covid-19 pandemic: the relevance of the integrated One Health approach

The Covid-19 pandemic has brought to the fore the intrinsic relationship between human, animal and environmental health, or more specifically, ecosystems[1].This interconnectedness is exemplified by several factors, including the overuse of antibiotics in farm animals, which increases the risk of infection by antibiotic-resistant bacteria, the adverse effects of climate change, and the growing awareness of the necessity to preserve balanced and functional ecosystems to safeguard human health[2].

In a scenario of this kind, an interdisciplinary vision is indispensable to producing fundamental and comprehensive scientific and epidemiological knowledge. In the same way, it is essential an overall reassessment of the institutional and regulatory framework, with the aim of integrating these issues into organizational and regulatory choices.

However, the recognition of such interdependence has long been taken into consideration, particularly in the European Union law, with the «protection of human health» as one of the objectives of EU environmental policy[3].

A comparable perspective can be observed in the recent reform of Articles 9 and 41 of the Italian Constitution, as set forth in Constitutional Law No. 1 of 11 February 2022[4]. In addition to enshrining the protection of the environment, biodiversity and the ecosystem within the Constitution, this reform stipulates that economic activity may be subject to limitations to safeguard human and environmental

[1] E. Chiti, 'Oltre la disciplina dei mercati: la sostenibilità degli ecosistemi e la sua rilevanza nel Green Deal europeo' (2022) Rivista della Regolazione dei Mercati, 2.

[2] See World Health Organization 2022 'A health perspective on the role of the environment in One Health', <https://www.who.int/europe/publications/i/item/WHO-EURO-2022-5290-45054-64214>.

[3] See Article 191 (ex-Article 174 TEC). 1. «Union policy on the environment shall contribute to pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment;
- protecting human health;
- prudent and rational utilization of natural resources;
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change».

[4] Constitutional Law No. 1 of 11 February 2022 'Amendments to Articles 9 and 41 of the Constitution on environmental protection'.

health[5]. As Guido Alpa has observed[6], the same results were achieved with the doctrinal elaboration of the right to the environment by Massimo Severo Giannini[7] and Alberto Predieri (who employed a broad notion of "landscape")[8], as well as with the Constitutional Court's jurisprudential guidelines, as demonstrated in the famous Ilva case[9].

This renewed integrated approach to the protection and promotion of health serves to further confirm the multidimensional structure of this relevant legal field. At the same time, it represents an evolution driven by the assertion of the "One Health" concept[10].

As defined by the One Health High Level Expert Panel[11], this concept refers to:

> (an) integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development[12].

The dissemination of this concept brings a substantial progression in our comprehension of the intricate interrelationship between climate change, infectious diseases and the social determinants of health[13].

Certainly, the transition from theory to practice presents an obvious complexity and the risk that the development of a coherent One Health policy is only cosmetic. To operationalize the principles of One Health in practice (beyond their promotion within political conferences) and respond to people's health needs, it is indeed necessary to address not only the clinical problem but also the multiple environmental, social and economic variables that impact on wellbeing. This assumption is supported by the increasing number of documented ecological disasters and the impact of pandemics, which show how human health is dependent on a complex multiplicity of factors.

The development of interdisciplinary and intersectoral strategies aimed at the prevention, surveillance, monitoring and mitigation of diseases is therefore vital. This implies a shift in focus from the mere treatment of pathology to the promotion of health in a broad sense[14]. To achieve this goal, the system of prevention in the health, environmental and climatic spheres must be strengthened, along with strengthening research activity. The perspective is founded on the principle of equity, which entails reducing disparities in access to health services and fostering intergenerational solidarity. Furthermore, this latter concept is explicitly referenced in the Italian Constitution (art. 9, as reformed in 2022).

---

[5] M. Delsignore, A. Marra, M. Ramajoli, 'La riforma costituzionale e il nuovo volto del legislatore nella tutela dell'ambiente' (2022) Rivista Giuridica dell'Ambiente, 1.

[6] G. Alpa, 'Note sulla riforma della Costituzione per la tutela dell'ambiente e degli animali' (2022) Contratto e impresa, 2.

[7] M.S. Giannini, 'Aspetti giuridici dell'ambiente' (1973) Rivista trimestrale di diritto pubblico, 1.

[8] A. Predieri, 'Paesaggio' in Enc. dir. (Milano Giuffrè 1981), vol XXXI.

[9] In this case, the Court carried out a balancing act between opposing interests, noting that the legislator had privileged the continuity of production over the protection of health and the environment (Constitutional Court, 2018, no. 58).

[10] See L. Violini (ed.), *One Health. Dal paradigma alle implicazioni giuridiche* (Torino Giappichelli 2023); F. Aperio Bella (ed.), *One health: la tutela della salute oltre i confini nazionali e disciplinari. Per un approccio olistico alla salute umana, animale e ambientale.* (Napoli Editoriale Scientifica 2022).

[11] In 2021, the World Health Organization (WHO), the World Organization for Animal Health (WOAH), the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) established the One Health High-Level Expert Panel (OHHLEP), a group of 26 independent experts on One Health, which has produced an official definition of the concept, published in December 2021. "One Health" represents an evolution of the One Medicine approach, which is primarily focused on disease treatment rather than disease prevention and encompasses only two dimensions of human and animal health.

[12] Joint Tripartite (FAO, OIE, WHO) and UNEP Statement – Tripartite and UNEP support OHHLEP's definition of "One Health", available at <https://www.fao.org/3/cb7869en/cb7869en.pdf>.

[13] The term "social determinants of health" is used to describe the various factors that influence an individual's health status, as well as the broader health of communities and populations.

1.1. The Alma Ata comprehensive primary healthcare model

A closer examination reveals that the grounds for this approach can be traced back to the primary health care model that was outlined at the Alma Ata Conference in 1978[15]. Nevertheless, despite its conceptualization, the model was never fully implemented, due to factors beyond only economic and financial constraints[16]. Even more relevant is the fact that the model in question was notably "innovative", representing a transition from a more traditional biomedical approach to a distinct bio-psycho-social one[17]. It was established on the creation of intersectoral strategies, which were not focused solely on the clinical aspects of diseases, as exemplified by the concept of "Selective Primary Health Care". Rather, they were focused on the "horizontal" openness to individuals and communities, in accordance with the model of the Comprehensive Primary Health Care, and on the centrality of the territory[18].

Although a selective approach has become the dominant paradigm[19], the emergence of One Health in the political and legal discourse of the European Union[20] suggests a potential shift towards a more comprehensive model. This approach, which considers the preparedness and resilience of health systems, the demand for services and the actual health needs of the population, could mark a transformation towards the implementation of the primary health care principles just as identified at the Alma Ata Conference.

The aforementioned change in the Italian system shows with particular evidence in the restructuring of organizational models of territorial care and in the necessity to coordinate the holistic perspective of One Health with technological innovations and telemedicine tools. This is also intended to ensure the full implementation of the principle of substantial equality in access to (socio-)health services.

The objective of this paper is to examine the role of the One Health approach in addressing current unmet public health issues. In doing so, it will consider both the necessity to reinforce the network of services within a given territory in accordance with a comprehensive public healthcare strategy and the scope for public intervention to enhance citizens' access to medicines and pharmaceutical innovation. Furthermore, the relationship between proximity and new technologies is examined, with a particular focus on their role in prevention and treatment. From this angle, telemedicine is discussed as a service activity that has the potential to support the delivery of healthcare on a wider scale and facilitate integration across multiple sectors, disciplines, and communities.

---

[14] In this regard, it should be noted that as early as 1946, when the WHO was founded, health was defined as a state of complete physical, mental and social well-being, which does not merely consist of the absence of disease or infirmity.

[15] According to the Alma-Ata declaration: «Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care process».

[16] The Primary Health Care approach promoted in the Alma Ata Declaration was judged to be inefficient and unsustainable from an economic point of view, and the so-called Selective Primary Health Care approach, based on cost-effectiveness as the main tool for evaluating and validating health care choices, was preferred.

[17] G. Maciocco, 'A trent'anni da Alma Ata. Cure primarie: evoluzione storica e prospettive' (2008) Ann Ig., 4.

[18] In addition to the Alma Ata Declaration of 1978 on primary health care, it is also important to consider the Ottawa Charter of 1986 on health promotion. Both documents articulated the necessity of integrating health and social justice to ensure the universal accessibility of essential health services, to acknowledge the influence of socio-economic determinants on health outcomes, and to engage communities at the local level.

[19] J.A. Walsh, K.S. Warren K.S., 'Selective primary health care: an interim strategy for disease control in developing countries' (1979) The New England Journal of Medicine, 18.

[20] The One Health approach is mentioned in 8 regulations, 1 directive, 7 decisions and 22 communications. See F. Coli, H. Schebesta, 'One Health in the EU: The Next Future?' (2023) European Papers, 1.

2. Territorial health care reform in Italy

The Italian National Health Service (INHS or SSN in Italian) is currently structured in a way that attempts to balance two competing objectives: on one hand, the need to ensure a uniformity in guaranteeing the right to health; on the other, the need to achieve complete territorial differentiation[21]. In this context, two distinct approaches have emerged. The first one places considerable emphasis on the role of accredited private entities, as evidenced by the model adopted in Lombardy[22]. The second one is characterized by a restriction in recourse to external private facilities, as exemplified by the model adopted in Emilia-Romagna[23]. Nevertheless, both models maintain the centrality of the hospital as a site of care, at least until the outbreak of the pandemic[24], which has underlined the necessity of transitioning away from hospital-centric systems towards integrated care[25].

The complex dialectic that emerges from this process contributes to the formation of a healthcare governance structure that is primarily focused on the autonomous decision-making of the regions with regard to the organization of their respective healthcare systems. Nevertheless, this autonomy is constrained by the involvement of the State in establishing the fundamental standards of health care and social rights to be provided across the country[26]. Furthermore, the recent crisis has served to highlight the necessity to ensure equality in the enjoyment of fundamental rights[27].

In that respect, a centralizing influence can be observed in the predictions of the "Mission 6 – Health" of the National Recovery and Resilience Plan (NRRP)[28] and of the Ministerial Decree no. 77 of 23 May 2022 ("Regulation establishing models and standards for the development of territorial care in the National Health System"). The aforementioned acts are intended to delineate new directions in the field of healthcare that are consistent with the cross-cutting and holistic approach to health established by the international and European recognition of the integrated One Health methodology[29]. Indeed, for the first time, total funding for primary healthcare exceeds that for hospital healthcare[30].

---

[21] See R. Bin, D. Donati, G. Pitruzzella, *Lineamenti di diritto pubblico per i servizi sociali e sanitari* (Torino Giappichelli 2021); A. Pioggia, 'Il diritto alla salute alla prova della differenziazione: autonomie, organizzazione e diseguaglianza' (2020) Istituzioni del Federalismo, 1. Furthermore, the issue is delicate in light of the prospects of implementing a system of differentiated regionalism, as outlined in the third paragraph of Article 116 of the Constitution and addressed in Law No. 86 of 26 June 2024.

[22] See C. Buzzacchi, 'La sanità nella Regione Lombardia' (2023) Le Regioni, 2-3.

[23] Some Regions, like Emilia-Romagna and Tuscany, have invested in community care in the past and are already close to the standards set by the central government while others start from little more than zero. C. Tubertini, *Pubblica amministrazione e garanzia dei livelli essenziali delle prestazioni. Il caso della tutela della salute* (Bologna BUP 2008).

[24] Article 8 of Decree-Law No. 14 of 9 March 2020 and Article 4 bis, Decree-Law No. 18 of 17 March 2020, converted with amendments by Law No. 27 of 24 April 2020, provided for the establishment of the so-called Special Continuity of Care Units, aimed at strengthening the home management of Covid-19 patients for whom hospitalisation is not necessary.

[25] In this context, regional systems that were more focused on hospital care have presented obvious difficulties in adapting See C. Tubertini, 'L'assistenza territoriale in trasformazione. Il ruolo delle comunità e delle istituzioni' (2024) Lavoro e diritto, 3.

[26] See art. 117 of the Italian Constitution «The State has exclusive legislative powers in the following matters: […] m) determination of the basic level of benefits relating to civil and social entitlements to be guaranteed throughout the national territory».

[27] See A. Pioggia, 'Diseguaglianze nell'eguaglianza. Il ruolo dell'amministrazione pubblica' (2023) EtnoAntropologia, 1.

[28] The Sixth Mission of the National Recovery and Resilience Plan is dedicated to the reform of the health system – Reform 1.1: Proximity health services, structures and standards for care in the territory: «The implementation of the reform intends to pursue a new health strategy, supported by the definition of an adequate institutional and organisational set-up, which allows the country to achieve adequate quality standards of care, in line with the best European countries and which increasingly considers the NHS as part of a broader community welfare system».

[29] S. Gabriele, 'L'assistenza sanitaria territoriale: una sfida per il Servizio sanitario nazionale' (2023) Ufficio Parlamentare di Bilancio, Focus tematico, 2.

[30] However, C. Tubertini (2024) draws attention to the fact that the resources made available by the NRRP only relate to investments in infrastructure. The costs associated with the personnel who will be responsible for managing and operating the new healthcare facilities must be considered as part of current expenditure and, as a result, must be charged outside the scope of NRRP resources.

The objective of this legislation is to establish the reference framework for the new territorial healthcare system, with the ultimate goal of standardizing regional systems through the construction of unified models[31]. This will inevitably entail the regulation of organizational aspects. The objective is not only to achieve a level of homogeneity that facilitates providing essential services respectful of qualitative and quantitative criteria throughout the national territory, but also to attain greater homogeneity in the organizational models that are used to provide assistance[32].

If the fundamental objective of the NRRP is the elimination of the disparities that have emerged in the social structure because of the 2020 pandemic, the tools to achieve this result in the health sector are identified in precise strategies. These are centered on the need to bridge the gaps between the various regional healthcare systems through the reinforcement of local structures, such as Community Homes[33] and Hospitals[34], and the advancement of technological innovation through telemedicine as a distinctive service offering that is accessible across the entire territory, with the home as the primary point of care[35]. The reform also redefines the role of districts[36] as organizational units of Local Health Authorities. In accordance with the Decree, Districts are responsible for the coordination of all community healthcare services within their designated territories[37]. This encompasses primary health services and social care programs that incorporate relevant healthcare components, such as integrated domiciliary care. They are responsible for the delivery and purchase of services within a defined budgetary framework. Finally, they serve as the principal forum for needs assessment and service planning, in accordance with population health management and chronic care models[38].

Furthermore, it is planned to strengthen integration mechanisms, initially in the socio-health sector, with the deployment of personnel from the areas responsible for the management of basic social services within the community houses[39]. Subsequently, and more broadly, in accordance with the One Health approach[40], the establishment of the National System for Health Prevention of environmental and climate risks, as indicated in Legislative Decree 36/2022[41]. This system is integrated with the National Environmental Protection System.

To fulfil Italy's commitment to the One Health approach, a shared Steering Committee was established in March 2023[42]. The purpose

---

[31] See M. D'Arienzo, 'Verso un sistema di unità sanitaria? Luci e ombre del DM 77/2022' (2023) Corti Supreme e Salute, 2.

[32] See C. Tubertini (2024), 399, and A. Pioggia, 'La sanità nel Piano Nazionale di Ripresa e Resilienza'. (2022) GDA, 2.

[33] The first experiences of community care date back to the 'Case della Salute' (Health Homes), the experimentation of which was provided for in Annex A to the Ministerial Decree of 10 July 2007, implementing Law 296 of 27 December 2006 (2007 Budget Law).

[34] Community Hospitals were already envisaged in Ministerial Decree No. 70 of 2 April 2015 (annex 1. paragraph 10).

[35] See A. Pioggia, 'La casa come primo luogo di cura: un passo avanti o un pericoloso balzo all'indietro?' (2024) Diario di Diritto Pubblico, <https://www.diariodidirittopubblico.it/la-casa-come-primo-luogo-di-cura-un-passo-avanti-o-un-pericoloso-balzo-allindietro/>.

[36] A socio-health district is a territorial unit that brings together different structures and socio-health services with the objective of guaranteeing integrated and personalized care for people in need. The primary objective is to facilitate continuity of care and coherence between the various services, thereby promoting a holistic approach to health and well-being.

[37] F. Dalponte, L. Ferrara, V.D. Tozzi, 'La trasformazione del Distretto Socio Sanitario' (2022) Rapporto Oasi, Università Bocconi.

[38] See the Ministerial Decree no. 77 of 23 May 2022.

[39] Ministerial Decree no. 77 of 23 May 2022, in the list of professions indicated in the table 'Functional cooperation of the figures constituting the multiprofessional team' in Annex 1, provides for the social worker. Moreover, among the services of the Community Homes, integration with the Social Services is envisaged as mandatory.

[40] Moreover, in September 2023, the Department of Human Health, Animal Health and Ecosystem (One Health) and International Relations was established at the Ministry of Health.

[41] Containing "Further Urgent Measures for the Implementation of the National Recovery and Resilience Plan", converted with amendments into Law no. 79 of 29 June 2022. By decree of the Minister of Health of 9 June 2022, adopted after agreement with the State-Regions Permanent Conference, the tasks of the National System for Preventing Health from Environmental and Climatic Risks were defined.

[42] Prime Minister's Decree of 29 March 2023, published in the "Gazzetta Ufficiale Serie Generale" no. 113 of 16/05/2023. "Definition of the modalities of interaction of the National System for Prevention of Health from Environmental and Climate Risks

of this Committee is to facilitate strategic and operational coordination between the National Health Prevention System for environmental and climatic risks and the consolidated National System of Environmental Protection. The Steering Committee is responsible for the promotion of initiatives that facilitate interaction and integration between regional environmental and climate risk prevention systems and regional environmental protection agencies. Additionally, the Committee adopts directives that foster and harmonize the policies and strategies implemented by the aforementioned two bodies.

3. From cure to care

The importance of proximity is therefore clear to see. Indeed, daily life environments and territory become pivotal in ensuring the well-being of humans, animals and ecosystems.

This approach entails a reorientation of the organizational structure of services, accompanied by a reduction in the centrality of the hospital and the enhancement of non-institutionalized services, whether provided at home or near the home.

The realization of such a model is dependent upon the capacity to consider the multifaceted needs of the people within a conceptual framework of care that extends beyond the scope of mere health interventions, providing assistance in accordance with the specific requirements of each individual[43]. This strategy represents an action of "initiative medicine"[44], based on prevention and early diagnosis, as well as education[45], capable of proactively addressing potential risk factors.

In order to facilitate progress in this direction, it is critical to create an increasingly coordinated system that enables the interoperability of environmental and health information, even before the comparison and balancing of interests phase, as is the case, for example, of issuing of certain authorization-type measures linked to specific industrial activities. Similarly, it is essential to guarantee the effective implementation of socio-health integration, which represents a comprehensive conceptualization of health that encompasses the social dimension[46]. This is one of the areas where the greatest variation between territories occurs. Some regions have demonstrated an effective coordination of health and social services, while others have struggled to do so. In fact, many regions still draw up the health plan, the social plan, and various other plans, but in a "separate" manner. It should no longer be possible to think and act in this way.

It's worthy to note that the National Prevention Plan 2020-2025[47] – a central planning tool for the implementation of prevention and health promotion interventions within a defined geographical area – adopts an innovative approach, namely the implementation of the principle of "Health in all policies"[48]. This strategy involves the formation of interdisciplinary collaborations with the objective of not only preventing the emergence of diseases but also of fostering the capacity of individuals to engage in self-care and collective health promotion. Furthermore, it aims to promote interactions between individuals and the health system through the establishment of trust-based relationships. Consistent with such an approach is the Guideline document for urban planning from a public health perspective – Urban Health, approved by the Unified Conference with the State-Regions Agreement of

with the National Environmental Protection System and establishment of the Steering Committee".

[43] A. Pioggia, *Cura e pubblica amministrazione. Come il pensiero femminista può cambiare in meglio le nostre amministrazioni* (Bologna il Mulino 2024).

[44] As opposed to wait-and-see healthcare, which is based on the ability to provide answers to a need expressed by the patient.

[45] Initiative medicine represents a care model that seeks to address the pressing concerns associated with an ageing population and the prevalence of chronic diseases. It aspires to transcend the limitations of the conventional 'waiting medicine' paradigm.

[46] V. Molaschi, 'Integrazione socio-sanitaria e COVID-19: alcuni spunti di riflessione' (2020) Il Piemonte delle Autonomie, 2.

[47] The "National Prevention Plan 2020-2025" was adopted by the State-Regions Agreement of 6 August 2020.

[48] Consistent with Article 168(1) TFEU, which states: «A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities». In this sense, and still with a view to the One Health approach, it is recalled that Art. 11 TFEU states that «environmental protection requirements must be integrated into the definition and implementation of other Community policies», while Art. 13 TFEU provides that «(i)n formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals».

22 September 2021, which represents a significant development in the field of urban planning with a public health perspective. The document is designed to facilitate the integration of actions to protect and promote public health into urban planning, recognizing the intrinsic link between urban planning and public health, ensuring, also in this way, the implementation of the principle of substantive equality enshrined in the Constitution.

Furthermore, the document emphasizes that the pandemic has underlined the necessity for a novel conceptualization of community wellbeing in relation to the built environment and public health. This entails a shift from a medical model that focuses on the individual to a social model in which health is seen as the outcome of the interaction between various socio-economic, cultural and environmental factors. It thus becomes evident that it is necessary to reinforce the multidisciplinary collaboration between designers (urbanists, architects, transport specialists, etc.), public health experts (epidemiologists and healthcare professionals) and policy makers, developing systemic operational capabilities capable of addressing the complexity of urban management.

4. Public intervention to improve citizens' access to medicines and pharmaceutical innovation

What has been said so far, in emphasizing the importance of prevention, including working on social factors, also highlights the central role of companies operating in specific sectors, such as biomedical innovation and the pharmaceutical industry, which today are almost exclusively left to the market. However, the new European industrial strategy – presented in March 2020 and updated in May 2021 – considers industrial biotechnology, biomedicine and pharmaceuticals to be key enabling technologies.

For this, the One Health approach appears to offer a promising perspective for fostering the implementation of a novel paradigm of action and knowledge production. By leveraging the insights gained from the pandemic scenario, this approach has indeed the potential to drive transformative changes in the existing structure of innovation policies.

One Health, therefore, may be conceived of as a strategic model which valorizes the role played by scientific progress in anticipating pandemic events and thus protecting public health interests, in contrast to the trend of the emergency logic that usually accompanies the management of such critical situations.

The emergency approach is what characterized most of the measures taken in the context of the Covid-19 pandemic. Instead, the challenges represented by innovation as an essential factor for improving the prevention and management of health crises should be taken into consideration.

To demonstrate this assumption, one might consider the question of supplying products necessary to contain the spread of the virus. The legislative framework governing intellectual property and patents has proved to be a significant driver of innovation. However, it also presents a substantial obstacle to the efficient dissemination of research outcomes, data and innovative technologies. As evidenced by the doctrine, the rate of innovation in the pharmaceutical market has reached a notable plateau. Some commentators have postulated that this phenomenon may be attributed to a malfunction of the patent system. Such an approach would, to some extent, turn into an obstacle to the ultimate purpose it was established for[49], no longer being able to stimulate sufficient sequential innovation and thus unable to guarantee adequate collective benefits.

The solution proposed to reconcile the demands protected by the TRIPs Agreement's rules on intellectual property with the need to protect the fundamental right to health is the well-known instrument of compulsory licences for the production of medicines or medical devices in the event of a health crisis[50]. In the Italian legal system, this flexibility was introduced by the "Simplification Decree" (D.L. n. 77/2021), which added Article 70-bis of the Industrial Property Code (as set forth in Legislative Decree No. 30 of February 10, 2005), introducing a mandatory licensing regime for the use of essential medicinal and medical

[49] C. Desogus, 'Nuove frontiere tra regolazione, proprietà intellettuale e tutela della concorrenza nel settore farmaceutico: le pratiche di brevettazione strategica' (2015) Rivista della Regolazione dei mercati, 1.

[50] Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on intellectual property – the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

devices patents in the event of a national health emergency[51].

The One Health approach allows us to move beyond the limitations of a narrow focus on flexibility and exceptions. It permits us to consider the insights of the doctrine on global public knowledge and the necessity of reforming institutions such as the WHO[52], so that it can effectively facilitate the coordination of health systems and provide them with technical assistance.

Furthermore, it is pertinent to recall the role played by the antitrust authorities during the pandemic, which safeguarded innovation through their vigilance against both competition-distorting practices and abuses of patent law[53].

In this sense, it is relevant to consider the European Commission's Temporary Framework of 8 April 2020 on commercial cooperation in response to the Coronavirus pandemic[54]. This framework provides a useful point of reference in terms of emergency law. In highlighting the necessity of taking decisive action against businesses that exploit the health emergency to engage in anticompetitive conduct, the Commission also encourages the conclusion of collaborative agreements between the pharmaceutical industry and other stakeholders with the objective of ensuring citizens' access to essential goods[55]. Consequently, the instrument of the Comfort letter is reintroduced, offering guidance on the competitive admissibility of the agreements adopted by enterprises to address the public health emergency.

From a different perspective, it would be beneficial to consider what could stimulate innovation and improve the protection of citizens' health beyond the scope of monitoring anti-competitive activities. This is particularly true in a sector where European industrial policy appears to be able to exert its greatest influence, as is the case with the biomedical and pharmaceutical industry[56].

The hypothesis of this paper is that the One Health approach could represent a "recovery and resilience strategy" capable of generating a change in public intervention in this field in the name of the so-called "common European interest". In this regard, the role played by state aid is important, with the establishment, for example, of "Important Projects of Common European Interest", which allows Member States to support highly innovative transnational projects aimed at the development and implementation of products and processes, under the conditions set out by the European Commission in specific guidelines provided in 2014[57].

A further tool, this time of vertical nature and more closely aligned with a strategic industrial approach, is the "joint undertaking", which is established, in accordance with Article 187 TFEU, for the enactment of European research and development programmes in specific sectors, that explicitly adopts the One Health approach[58].

This instrument enables the establishment of institutionalized partnerships between private and public enterprises, as evidenced by the Innovative Medicines Initiative (IMI) and

---

[51] Art. 70-bis *of the Italian Industrial Property Code «*In the event of the declaration of a national state of emergency motivated by health reasons, in order to cope with proven difficulties in the supply of specific medicines or medical devices deemed essential, compulsory licences may be granted, in compliance with international and European obligations, for the non-exclusive, non-saleable use, primarily aimed at supplying the domestic market, of patents relevant for production purposes, with a validity bound to the continuation of the emergency period or up to a maximum of twelve months from the end of the emergency period».

[52] See in this sense, Professor Luigi Ferrajoli's proposal which aim to transform them into genuine global institutions of guarantee, capable of engaging in equal dialogue with other universal institutions such as the World Trade Organization (WTO). See in particular, L. Ferrajoli, *Per una Costituzione della Terra. L'umanità al bivio* (Milano Feltrinelli 2022). Article 21 of the WHO Constitutions states that: «The Health Assembly shall have authority to adopt regulations concerning: (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease».

[53] See M. Passalacqua, B. Celati, Stato che innova e stato che ristruttura prospettive dell'impresa pubblica dopo la pandemia (2019/2020) Concorrenza e mercato.

[54] (Communication) 2020 C/116/02.

[55] M. Hosseini, 'The evolution of EU competition law and policy in the pharmaceutical sector: long-lasting impacts of a pandemic' (2025) Journal of Antitrust Enforcement, 13.

[56] See M. Passalacqua, B. Celati, cit.

[57] Communication from the Commission – Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest (2014/C 188/02).

[58] Such as Horizon Europe or the EU4Health Programme (2021-2027).

the public-private "Initiative for Innovation in the Health Sector" partnership[59].

The issue has recently gained traction in a study commissioned by the European Parliament[60], which focused on a proposed public research infrastructure designed to address the entire drug development cycle. This infrastructure, known as the "European Medicines Infrastructure", is to be established through a treaty among participating States.

Such an "enterprise" should act in a complementary manner to the functions ascribed to the recently established Health emergency and preparedness response authority (HERA)[61], charged with preventing, detecting and responding rapidly to health emergencies. Indeed, the European authority, precisely because of its preparedness and response function, seems to be in line with the emergency logic referred to above, even if, in order to fully understand future health threats, it will necessarily have to adopt a One-Health approach, that is considered central to the construction of the European Health Union, of which the HERA is a fundamental pillar[62].

In any case, in April 2024 the plenary session of the European Parliament failed to approve the amendment to the report on the revision of pharmaceutical legislation, which would have led to the establishment of a European public infrastructure for pharmaceuticals, vaccines and biomedical research (so called "European Medicines Facility")[63].

However, the proposed legislation on pharmaceuticals would establish the HERA as an autonomous and independent entity from the Commission, reporting to the European Centre for Disease Prevention and Control[64]. This new structure may be regarded as a prototype for the development of a public infrastructure.

It is important to recall that the ninth principle of the "Manhattan Principles on One World, One Health" of 2004[65] has already emphasized the necessity of increasing global health infrastructure investments, «improving the coordination between governmental and non-governmental agencies, vaccine and pharmaceutical companies, and all relevant partners».

In the light of the above, the concept of One Health may be regarded as a potential catalyst for the emergence of new paradigms of action, capable of delineating structures for the protection and promotion of innovation that extend beyond the scope of incentives determined by patent rights or antitrust supervision, but are founded on the recognition of knowledge as a strategic asset that should be invested in.

5. Telemedicine as a tool to facilitate community care and cross-sectoral integration

The provision of healthcare services using ICTs has been one of the core pillars of the strategy adopted to ensure resilient post-pandemic recovery. As early as 2008, in a Communication on "Telemedicine for the benefit of patients, health systems and society"[66], the European Commission highlighted the substantial contribution that telemedicine could make to the quality of life of its citizens, e.g. by improving access to healthcare in areas that are difficult to reach or where there is a shortage of qualified personnel; reducing hospitalization for people with chronic diseases through telemonitoring; and reducing waiting lists for some diagnostic services.

After the Covid 19 crisis, as mentioned above, Territorial Healthcare Infrastructures gained a stronger and more central role. In this sense,

[59] <https://research-and-innovation.ec.europa.eu/researcharea/health/innovative-health-initiative_en>.

[60] https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2021)697197.

[61] HERA is s a new Directorate-General within the European Commission. See the Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (2021/C 393 I/02).

[62] See M. McKee, A. de Ruijter 'The path to a European Health Union' (2024) The Lancet Regional Health – Europe.

[63] The proposal, after having been set aside by the compromise reached in the ENVI committee, was resubmitted with an amendment by 50 MEPs from different groups.

[64] <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52025DC0147>.

[65] In 2004, the Wildlife Conservation Society (WCS) brought together stakeholders to discuss global health challenges at the nexus of human, animal, and ecosystem health. The symposium "Building Interdisciplinary Bridges to Health in a Globalized World" at The Rockefeller University gave birth to the "Manhattan Principles" (http://www.oneworldonehealth.org/sept2004/owoh_sept04.html, n.d.). These detailed a collaborative, trans-disciplinary approach, coined "One World – One Health", or simply "One Health".

[66] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM/2008/0689 final.

telemedicine has acquired a specific function for the implementation of a health system based on the centrality of the home as the first place of care[67].

In terms of the transition from cure to care, telemedicine is in fact the best means of gathering, decoding and classifying needs[68]. Therefore, it is very important that its use is equitable and homogeneous, and that regional solutions are interoperable with each other, in order to help reduce territorial disparities[69].

All of this is made even more complex by the fact that the regions remain the main institutional actor, but it is necessary to ensure territorial proximity responses that enhance the differences between territories (e.g. by adapting organization and interventions according to their urban or suburban specificity and the needs of users).

Nevertheless, the use of these tools has been promoted for years as a solution to the problems of providing health care in remote areas, where distance or the uneven distribution of resources makes quality health care difficult or precludes high quality medical service[70].

However, the use of telemedicine does not automatically mean the democratization of care. In this sense, it is important to focus more on the most disadvantaged to avoid the paradox that those who could benefit from digital health tools are actually those who use them least.

During the pandemic, it became also increasingly clear that reliable and timely information on the health status of the population is key for the formulation of public health policies and the dissemination of accurate information to the public knowledge[71].

In the context of the One Health approach, prevention is, indeed, essential. Therefore, telemedicine appears to be a powerful tool to enhance the ability to prevent and mitigate health risks in all areas of human, animal and environmental health, helping in the early detection of potential health threats.

In that regard, the concept of One Digital Health has been developed as a framework to focus on the digitalization of One Health and to provide data-driven solutions to challenges at the human-animal-ecosystem interface[72]. Ensuring real-time surveillance of human, animal and environmental diseases is in fact of paramount importance, and data are crucial for assessing the risks associated with the (re-) emergence of infections.

Data are also critical for the effective implementation of a multidisciplinary approach, as demonstrated by the tripartite cooperation between the World Health Organization (WHO), the World Organization for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO), which is based on interoperability of information[73].

6. Final remarks

One Health approach shows that individual well-being is also, and above all, common well-being[74]. In this respect, the Italian Constitution, which, in Article 2, calls for «the fulfilment of the inalienable duties of political, economic and social solidarity», expresses a principle of cohesion[75] that seems very much in line with the approach analyzed in the paper.

Indeed, One Health appears to be an instrument for a fuller realization of the social rights of the individual[76], enabling the implementation of cohesion policies between institutions and citizens, realized through the prescription of «public

[67] See Ministerial Decree of 29 April 2022 approving the organisational guidelines containing the "digital model for the implementation of home care".

[68] F. Aperio Bella (2023), 'The Role of Law in Preventing "Remote" Defensive Medicine: Challenges and Perspectives in the Use of Telemedicine', Federalismi, 1.

[69] See the Guidelines for submitting regional telemedicine projects – Regional/provincial operational plan of AGENAS.

[70] See J. Preston, F.W. Brown, B. Hartley (1992), 'Using telemedicine to improve health care in distant areas', Hosp Community Psychiatry, 1.

[71] See N. Peek, M. Sujan, P. Scott 'Digital health and care in pandemic times: impact of COVID-19' (2020) BMJ Health Care Inform., 1.

[72] See A. Benis A, O. Tamburis, C. Chronaki, A. Moen (2021), 'One Digital Health: A Unified Framework for Future Health Ecosystems', J Med Internet Res., 2.

[73] See David T.S. Hayman *et al.*, 'Developing One Health surveillance systems' (2023), One Health, 17.

[74] See S. Valaguzza, *One Health: Scenari di policy*, in L. Violini (ed) *op. cit.*, 46.

[75] See D. Donati, 'Coesione e collettività: elementi inscindibili o elementi occasionali?', *Materiali del Panel "Coesione economica, sociale e territoriale nella società civile in trasformazione" nell'ambito della IV Conferenza annuale Icon-S Italian Chapter. "Politica e istituzioni tra trasformazioni e riforme" Università Bocconi, Milano 13 e 14 ottobre 2023*.

[76] G. Ragone, M. Ramajoli, *One Health e ordinamento italiano: il livello costituzionale, la normazione primaria e la fase dell'implementazione amministrativa*, in L. Violini (ed) *op. cit.*, 15.

services aimed at eliminating the causes of social inequality, in accordance with the program of substantive equality announced in Article 3.2»[77].

However, many challenges still remain to be met in order to translate this approach into concrete organizational and regulatory measures capable of ensuring the protection of the three components of the ecosystem (environment, humans and animals).

With this in mind, the regions must be provided with adequate infrastructural and financial resources. Otherwise, there is a risk that organizational and functional differentiation will not be a correct translation of the principle of substantive equality, but a counterproductive fragmentation, caused by disparities between better-equipped geographical areas and those that are struggling to cope.

[77] R. Bin, D. Donati, G. Pitruzzella, *op. cit.*, 175.