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# HEALTH IN ALL POLICIES 20 YEARS LATER

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## HEALTH IN ALL POLICIES – 20 YEARS LATER

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INTERNATIONAL SCIENTIFIC CONFERENCE

# HEALTH IN ALL POLICIES – 20 YEARS LATER

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Claudia Seitz\*

## **FROM HEALTH IN ALL POLICIES TO ONE HEALTH: REGULATORY INTEGRATION ACROSS FRAGMENTED LEGAL REGIMES**

The “Health in All Policies” (HiAP) approach, introduced at the European level two decades ago, represented a significant shift in the understanding of health as a cross-cutting societal concern rather than a matter confined to health law or healthcare systems. Initially linked closely to environmental protection and preventive public health policies, HiAP sought to ensure that health considerations were systematically integrated into decision-making across policy areas. Over time, however, structural limitations of this approach have become apparent, particularly in light of increasingly complex and interconnected health risks.

Recent global developments – in particular the COVID-19 pandemic, the rise of antimicrobial resistance, and the growing impact of environmental degradation on human health – have underscored the need for more comprehensive and integrated regulatory responses. Against this background, the World Health Organization has promoted the “One Health” approach as a unifying framework that explicitly links human, animal and ecosystem health. One Health has gained prominence not only as a public health strategy, but also as a governance concept aimed at addressing systemic risks that transcend sectoral and jurisdictional boundaries.

This presentation examines the evolution from Health in All Policies to One Health from a legal and regulatory perspective, with particular emphasis on the role of the WHO in shaping integrated health governance. It argues that while HiAP and One Health share a common integrative ambition, they differ in their legal and institutional implications: HiAP largely operates as a coordination principle within existing policy silos, whereas One Health challenges the adequacy of fragmented legal regimes by calling for deeper forms of regulatory integration across domains such as public health, environmental law, animal health, food safety and research regulation.

\* Professor at Private University in the Principality of Liechtenstein, [claudia.seitz@ufl.li](mailto:claudia.seitz@ufl.li)

Focusing on the European and international legal context, the presentation analyses how WHO-led One Health initiatives interact with EU law and national regulatory frameworks. It highlights key governance challenges arising from overlapping competences, diverse institutional mandates and the absence of clearly defined legal responsibilities. In particular, the presentation explores how legal fragmentation may hinder the effective implementation of One Health strategies, despite strong political and scientific consensus on the need for integrated approaches.

Rather than advocating the creation of a unified and comprehensive “One Health law”, the presentation adopts a governance-oriented approach. It examines legal and institutional mechanisms that can facilitate coordination while respecting existing divisions of competence and regulatory autonomy. These include procedural integration requirements, enhanced cooperation between regulatory authorities, and the strategic use of soft law instruments developed by the WHO and other international actors to guide national and regional implementation.

By reflecting on the two decades of Health in All Policies and the growing influence of the WHO’s One Health agenda, the presentation contributes to current debates on the future of health governance in Europe and beyond. The presentation argues that the effectiveness of integrated health strategies depends less on substantive harmonisation than on the capacity of legal systems to manage interdependence, ensure accountability and operate coherently across fragmented regulatory landscapes.

**Keywords:** One Health Governance, Health in All Policies (HiAP), Regulatory Fragmentation, WHO and Global Health Law, Integrated Health Governance in the EU

André den Exter\*

## CURRENT ISSUES IN MEDICAL LAW AND PUBLIC HEALTH: THE RELEVANCE OF COMPETITION LAW IN FIGHTING HIGH-PRICED PRESCRIPTION MEDICINES

Ideally, this session explores the interface between human rights law and economic law, as well as the impact of economic activities on human rights. The interface examines how economic activities affect human rights, and conversely, how human rights principles can shape more just and ethical economic outcomes in healthcare. Excessive pricing of prescription medicines is a generally known phenomenon both in Europe and the US. Safeguarding equal access to these medicines as a fundamental human right necessitates specific legal measures that address the availability and accessibility of prescription drugs. For several reasons, price control measures have so far remained problematic and appear less effective. Is there a legal alternative?

In Europe, an alternative strategy is to challenge excessive pricing at national and European antitrust authorities, arguing that excessive pricing constitutes an abuse of a dominant position, prohibited by EU Treaty law. That strategy has appeared successful on several occasions, resulting in price caps. Apart from the European approach of triggering antitrust rules, this paper examines the US experiences in regulating excessively priced drugs and their effectiveness. The primary objective of the comparative study of prescription drug regulation is to gain a deeper understanding of how to mitigate drug prices and enhance access to medicines for all.

**Keywords:** Competition Law, High Priced Medicines, Access to Healthcare

\* Professor at Erasmus University Rotterdam, the Netherlands, [denexter@law.eur.nl](mailto:denexter@law.eur.nl)

Marko Milenković\*, Marta Sjeničić\*\*

## THE EVOLUTION OF “HEALTH IN ALL POLICIES” IN THE EUROPEAN UNION: FROM COORDINATION TO THE EUROPEAN HEALTH UNION AND BEYOND

Public health policy in the European Union has undergone a fundamental transformation, evolving from a peripheral supportive competence into a mandated cross-sectoral pillar. This paper examines the trajectory of the “Health in All Policies” (HiAP) approach, a concept that implies that health issues are systematically taken into consideration in decision-making across diverse sectors such as agriculture, transport, environment, and the digital economy. While already the 1999 Treaty of Amsterdam (then Article 152 EC, now Article 168 TFEU) provided the first legal mandate for health mainstreaming, the principle was formally promoted as a strategic framework during the 2006 Finnish EU Presidency. Spanning more than twenty years, the correlation between policy rhetoric and legal development has shifted from soft-law coordination among Member States to the increasingly robust, structural framework of the European Health Union.

The paper argues that the evolution of HiAP is not merely a policy trend, but a constitutional necessity anchored in Article 168 of the Treaty on the Functioning of the European Union (TFEU). This article stipulates that a “high level of human health protection shall be ensured” in the definition and implementation of all Union policies. The research analyses how this mandate has transitioned from an aspirational goal into a more concrete legal standard. Furthermore, the paper explores the contemporary evolution of HiAP toward more integrated frameworks, including emerging references to “Health for All Policies” (H4AP) and the “One Health” principle promoted by the World Health Organisation. Recent legislative milestones, accelerated by the COVID-19 pandemic, have demonstrated this shift toward greater reliance on hard law integration.

\* PhD, Principle Research Fellow, Institute of Social Sciences, Belgrade, Serbia, mmilenkovic@idn.org.rs

\*\* PhD, Principle Research Fellow, Institute of Social Sciences, Belgrade, Serbia, msjenicic@idn.org.rs

Examples include the adoption of the Health Technology Assessment (HTA) Regulation and the establishment of the European Health Data Space (EHDS). These instruments move beyond voluntary cooperation, creating binding requirements that embed health standards into the EU's industrial and digital strategies.

The paper concludes that the EU has moved beyond mere coordination, progressively consolidating health as a key determinant of future EU governance, albeit within the ongoing competence and implementation constraints. As the EU faces new challenges—including climate change, antimicrobial resistance, and an aging population—the HiAP approach will become increasingly significant, requiring even deeper intersectoral synergy to ensure the long-term sustainability of the European social model.

**Keywords:** Health in All Policies, Article 168 TFEU, European Health Union, Health mainstreaming, EU health law

Carmela Pagano\*

## **FROM HEALTH IN ALL POLICIES TO ONE HEALTH: LEGAL CHALLENGES IN INTEGRATING PUBLIC HEALTH, ENVIRONMENTAL PROTECTION, AND GLOBAL GOVERNANCE AFTER COVID-19**

The COVID-19 pandemic has forcefully demonstrated that health can no longer be addressed as a sectoral issue confined to health-care systems alone. Rather, it is deeply intertwined with environmental protection, labour conditions, data governance, social protection, and global economic dynamics. Against this background, the “Health in All Policies” (HiAP) approach, first introduced at the European level in 2006, has regained renewed relevance, while simultaneously revealing persistent legal and institutional challenges in its practical implementation across different levels of governance.

This contribution critically examines current issues in medical law and public health through the lens of the evolving relationship between HiAP and the more recent One Health approach promoted by the World Health Organization. While HiAP seeks to incorporate health considerations across all policy domains, One Health further expands this perspective by explicitly recognizing the interconnectivity of human, animal, and environmental health. Despite their conceptual complementarity, the analysis shows that their legal translation remains fragmented and uneven, often relying on soft coordination mechanisms rather than binding legal obligations at both national and international levels.

With specific reference to post-pandemic regulatory developments, the contribution explores key challenges emerging at the intersection of public health law, environmental law, and global health governance. Particular attention is devoted to problems of institutional coordination, regulatory coherence, and the distribution of responsibilities across sectors and governance layers. The analysis highlights how existing normative arrangements frequently struggle to address cross-sectoral health risks, such as zoonotic diseases, climate-related health threats, and antimicrobial

\* Research Fellow, University of Salerno, Italy, cpagano255@gmail.com

resistance, which inherently exceed traditional regulatory boundaries and demand integrated legal responses.

Methodologically, the contribution adopts a qualitative legal approach, drawing on international and European policy instruments, soft law initiatives, and selected national responses. By examining both normative frameworks and governance practices, it seeks to demonstrate that the effectiveness of HiAP and One Health depends not only on political commitment, but also on the development of legal tools capable of fostering genuine cooperation, coordination, and accountability across policy areas.

The contribution concludes by arguing that current debates in medical law and public health require a rethinking of legal integration strategies, moving beyond symbolic references to HiAP and One Health toward more coherent and operational normative frameworks. In this sense, the round table offers an opportunity to reflect critically on how law can better support holistic health governance in an era marked by complex, interconnected global risks and increasing pressure on public health systems.

**Keywords:** Health in All Policies (HiAP), One Health approach, Global health governance, Policy integration, Post-pandemic health regulation

Rosanna Amato\*, Marco Cavallo\*\*, S.A.F.E. Study Group\*\*\*

## HOW HEALTHCARE INSTITUTIONS SHAPE JUDICIAL RESPONSES AND PROTECTION PATHWAYS: TESTING HEALTH IN ALL POLICIES AT THE CLINICAL–JUSTICE INTERFACE

The HiAP approach holds that population health is shaped by policies adopted in the sectors traditionally regarded as “non-health” domains. At the same time, it recognises that health is an enabling condition for achieving objectives pursued in other sectors.

Taking this two-way causal relationship as a starting point, a largely underexplored issue emerges: can individuals’ access to justice be shaped by the functioning of the healthcare system? And, conversely, can their health depend on judicial action? These questions point to a potential structural nexus between two pillars of the social contract—the protection of health and administration of justice—which have rarely been examined in an integrated manner.

HiAP has paid limited attention to the justice sector, leaving the relationship between health and justice at the EU and national levels largely fragmented and weakly systematised. This proposal brings this interface into focus by treating health and justice as systems whose interaction becomes particularly consequential under conditions of vulnerability and institutional complexity.

This interface is approached through the empirical lens of Intimate Partner Violence (IPV), a field in which criminal justice concerns, public health priorities, and clinical practice intersect, and which is increasingly recognised as a social determinant of health. Characterised by repeated harm, vulnerability, and fragmented institutional responses, IPV is a domain in which clinical encounters

\* Institute of Legal Informatics and Judicial Systems of the National Research Council of Italy (IGSG CNR, Italy), [rosanna.amato@cnr.it](mailto:rosanna.amato@cnr.it)

\*\* IRCCS Rizzoli Orthopaedic Institute (IRCCS IOR, Italy), [marco.cavallo@ior.it](mailto:marco.cavallo@ior.it)

\*\*\* S.A.F.E. (Screening for domestic Abuse in Orthopaedic Emergency) Study Group includes Dr Marco Cavallo (PI), Dr Vania Maselli, Dr Francesco Castagnini, Dr Alice Ritale, Dr Anna Maria Chiesa, Ms Tania Sabbatini, Dr Laura Maria Beatrice Belotti, Ms Luisa Tuozzo, Dr Fabio Tortorella, Ms Valentina Brunello, Dr Loredana Mavilla, Dr Irene Quattrini, Ms Martina Piccinni Leopardi and Ms Serena Santoro (IRCCS IOR), and Dr Rosanna Amato (IGSG-CNR).

often represent the first (sometimes the only) point of contact with institutions.

In these contexts, health and justice function not as adjacent policy domains, but as reciprocally constitutive fields that jointly shape pathways of protection and access to rights. Clinical activities such as injury assessment and medical documentation, extend beyond therapeutic purposes, shaping information flows, risk assessment, and the activation of protective and judicial responses. Judicial practices, in turn, translate clinically grounded knowledge into decisions that may either reinforce or undermine protection.

Drawing on preliminary findings from the BRIDGE project, conducted at a specialised orthopaedic hospital in Italy, the proposal adopts a systems-oriented perspective that treats clinical practice as an institutional measure shaping how harm is recognised, recorded, and acted upon across sectors. The analysis combines an organisational examination of procedures and information systems with qualitative insights into professional practices and an analysis of musculoskeletal injury patterns potentially attributable to IPV. Factors such as recurrence, injury localisation, and discrepancies between clinical findings and reported causes are analysed as organisational signals that may activate—or fail to activate—protective and judicial responses, highlighting how routines shape the translation of clinical knowledge into institutional action.

By examining the challenges at the interface between health and justice through everyday practices in IPV cases, this proposal highlights how the effectiveness of intersectoral approaches largely depends on organisational settings, routines, information infrastructures, and institutions' capacity to translate clinically grounded knowledge into coherent, coordinated action. The analysis is situated within the EU and Italian regulatory and policy frameworks on IPV, while using a local institutional setting as an empirical site to examine the ways that these frameworks are interpreted, operationalised, and reshaped in practice.

**Keywords:** Health–Justice interface, Access to Justice, Intimate Partner Violence (IPV), Medical Documentation and Evidence, Institutional Response to Vulnerability

Martin Rusnak\*

## **SYSTEMS APPROACHES TO NCD PREVENTION: INTEGRATING HIAP AND ONE HEALTH IN THE NEW EU AND BALKAN CONTEXT**

Twenty years after the introduction of the Health in All Policies (HiAP) framework, its relevance is particularly pronounced in new EU Member States and Western Balkan countries, where rapid political, economic, and institutional transitions continue to shape population health outcomes. These countries face a dual burden: persistently high rates of noncommunicable diseases (NCDs) and accelerating environmental changes linked to industrial restructuring, climate vulnerability, and uneven regulatory enforcement. Re-examining HiAP through the One Health lens offers a strategic opportunity to address these intertwined challenges by integrating human, environmental, and animal health considerations into policy processes.

Although EU accession has driven significant improvements in environmental legislation, food safety systems, and public health institutions, implementation capacity in several new EU and Balkan countries remains constrained by limited resources, fragmented intersectoral coordination, and competing political priorities. Meanwhile, One Health initiatives are often concentrated in veterinary and infectious disease domains, with limited integration into environmental health or chronic disease prevention. Yet shared upstream determinants—air pollution, water quality, industrial emissions, land-use change, and dietary transitions—directly influencing both ecological health and NCD risk profiles. Aligning HiAP with One Health therefore provides a coherent framework for generating multi-sectoral co-benefits in the settings where institutional reforms and EU alignment processes are still evolving.

This contribution examines how a combined HiAP–One Health approach can strengthen NCD prevention in a region by embedding health considerations into agriculture and food system transitions, energy and climate policies, urban development, and

\* Professor at Faculty of Health Care and Social Work, University of Trnava, Slovakia, martin.rusnak@truni.sk

environmental governance. Examples relevant to Central and Southeastern Europe show how cross-sector strategies can reduce exposure to environmental hazards, promote healthier food environments, support active mobility, and increase resilience to climate-related health risks.

Critical research gaps persist, particularly regarding the structural factors that shape policy implementation in transition economies. Priority areas for research include: (1) comparative implementation studies to identify the governance models effective in post-transition contexts; (2) development of metrics capturing cross-sector impacts in settings with variable data quality; (3) systems modelling to assess interactions between socio-economic change, environmental stressors, and NCD pathways; and (4) equity-sensitive evaluations addressing rural/urban disparities, vulnerable groups, and socio-political determinants. Strengthening this evidence base is essential for guiding feasible, context-specific policy interventions.

Twenty years later, HiAP remains a critical strategy for the region. Leveraging One Health can help new EU Member States and Western Balkan countries design integrated, resilient, and evidence-informed policies that advance population health and environmental sustainability.

**Keywords:** One Health, Noncommunicable Diseases, Health in All Policies, Policy, Implementation Study

Magdalena Greco\*

## HEALTH IN ALL POLICIES APPROACH: LEADING THE WAY TO STRENGTHENING LOCAL MANUFACTURING CAPACITIES OF PHARMACEUTICALS IN DEVELOPING COUNTRIES

The “Health in All Policies Approach” has underlined that health implications should be thoroughly taken into consideration in all policy-making at the European Union level, clarifying to decision makers the connections between policies and interventions, determinants of health and their consequences over (global) health outcomes. In recent years, the European Union has launched the “Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa”, which aims at working both on the demand and supply sides, and on the enabling environment to facilitate access to quality, safe, effective and affordable health products in the African Continent. The initiative also claims to support the mRNA Hub created in 2021 by the World Health Organization (WHO) and the Medicines Patent Pool (MPP), including through an increased focus over technology transfer and intellectual property management.

Against this backdrop, the paper adopts a multidisciplinary approach based on legal epidemiology, as well as market economic and policy theories applied to intellectual property law, to offer new perspectives in the fight against Neglected Tropical Diseases (NTDs). First, in a *destruens* phase, the paper combines a legal epidemiological and a market economics and policy perspective applied to patent law in order to describe the genesis and features of traditional normative and institutional approaches to NTDs. The paper analyses the role of innovation and investment with regards to NTDs, focusing on the function of patents in promoting research and development (R&D) for neglected tropical diseases. Then, with a pragmatic example, it analyses the role of the institutions of endemic countries in dealing with the problem as an endogenous factor related to the innovation-investment couple (IN-IN-IN approach) that (negatively) affects the presence of treatments for

\* PhD Candidate in Legal Studies at Bocconi University, Italy, [magdalena.greco@phd.unibocconi.it](mailto:magdalena.greco@phd.unibocconi.it)

NTDs. Second, in a *costruens* phase, the paper applies the theoretical reasoning to the current efforts made by the WHO and MPP to build an mRNA Hub in 15 developing countries, supporting the recently-advocated tendency that stands for building local manufacturing capacities of pharmaceuticals in endemic (developing) countries. The paper is topical due to the utmost importance of fighting the spread of communicable infectious diseases that, as the COVID-19 pandemic showed, travel faster to traditionally non-endemic countries due to globalization dynamics. Dengue, as an example, was raised to an emergency in Brazil and reached a peak of cases in Italy in 2024. Also, the presentation highlights the necessity of multidisciplinary approaches in solving global health challenges. Indeed, the work adopts a focus that first takes into account the interaction between intellectual property law and medicines' accessibility, and then applies its findings through economic market and policy theories to a concrete new strategy for creating more resilient health systems. Besides, such a strategy supports the dynamic approach to health challenges that is embraced by the Health for All Policies Approach.

**Keywords:** Neglected tropical diseases, Local manufacturing, Incentives, Intellectual property, Access

Katarzyna Miaskowska-Daszkiewicz\*

## HEALTH IN ALL POLICIES AND CONSTITUTIONAL GUARANTEES OF HEALTH PROTECTION IN POLAND

The principle of Health in All Policies (HiAP), formally embedded in Article 168(1) of the Treaty on the Functioning of the European Union, requires that a high level of human health protection be ensured in the definition and implementation of all Union policies and activities. While this horizontal clause has shaped the normative architecture of EU public health governance over the past two decades, its domestic translation within Member States has been uneven. This paper examines the Polish response to the HiAP agenda through the lens of constitutional and administrative law, focusing on the interaction between EU-level cross-cutting obligations and Article 68 of the Constitution of the Republic of Poland.

Article 68 of the Polish Constitution establishes the right to health protection and imposes duties upon public authorities to ensure equal access to healthcare services and to combat epidemic diseases. Unlike Article 168 TFEU, which operates primarily as a programmatic and interpretative clause binding EU institutions, Article 68 functions as a constitutional guarantee addressed to national authorities and potentially enforceable through judicial review. The paper argues that this constitutional provision provides a stronger normative basis for institutionalising HiAP domestically than has thus far been realised in administrative practice.

Through an analysis of selected public policy domains—including environmental protection, alcohol regulation, spatial planning and public health programming—the presentation demonstrates that Poland has implemented elements of HiAP in a fragmented and sector-specific manner. Although strategic documents, such as the National Health Programme, reflect awareness of intersectoral health determinants, Poland lacks a legally embedded mechanism for systematic health impact assessment, or a formalised

\* Professor at Department of Administrative Law, Faculty of Law, Canon Law and Administration, The John Paul II Catholic University of Lublin, [katarzyna.miaskowska-daszkiewicz@kul.pl](mailto:katarzyna.miaskowska-daszkiewicz@kul.pl)

cross-ministerial coordination structure. As a result, HiAP operates more as a policy narrative than as a binding administrative principle.

The speech further explores whether Polish courts, particularly administrative courts and the Constitutional Tribunal, could play a role in reinforcing HiAP through constitutional interpretation grounded in Article 68. It concludes that, while EU law constitutionalises health as a horizontal principle at supranational level, the Polish Constitution offers a potentially more robust legal foundation for its enforceable domestic application. The Polish case thus illustrates the tension between soft coordination at the EU level and the unrealised potential of constitutional guarantees at the national level, raising broader questions about the judicialisation and institutionalisation of Health in All Policies within Member States.

**Keywords:** Constitutionalisation of public health, Health in All Policies, Polish Constitution, Right to health protection, TFEU

Larisa Pătru\*

## **INSTITUTIONALIZING HEALTH IN ALL POLICIES: ROMANIA BETWEEN STRATEGIC COMMITMENT AND GOVERNANCE PRACTICE**

Launched at the European Union level in 2006, the “Health in All Policies” (HiAP) approach was conceived not merely as a programmatic principle, but as a process of institutional transformation aimed at integrating health considerations across all domains of public governance. Twenty years later, the central question is no longer whether Member States have discursively embraced this paradigm, but to what extent they have effectively institutionalized it within their administrative and regulatory architectures. Romania offers a relevant case study of the tension between strategic commitment and concrete governance practice.

Developments in Romania demonstrate significant strategic alignment with European public health priorities. The National Health Strategy 2022–2030 incorporates key concepts such as social determinants of health, equity in access, prevention, and the strengthening of primary and community care. While the strategy reflects a conceptual recognition of the interdependence between health and broader socio-economic factors, the translation of these principles into a coherent institutional framework remains partial.

From a policy-instrument perspective, Romania does not yet operate a comprehensive and mandatory Health Impact Assessment (HIA) mechanism embedded within the general intersectoral policymaking cycle. Health impact evaluations exist in specific contexts—particularly in investment and environmental procedures—but they are not systematically applied across sectors with significant health implications, such as education, labour, urban development, or digital governance. This limitation points to an incomplete institutionalization of HiAP principles.

One area of visible structural progress is the digital transformation of the health sector. The implementation of the Unique Integrated Information System (SIUI), the nationwide introduction of the

\* PhD, Lecturer, University of Medicine and Pharmacy of Craiova, Romania, [larisa.patru@umfvcv.ro](mailto:larisa.patru@umfvcv.ro)

National Health Insurance Card (operational since 2015), and the development of the Electronic Health Record have aimed at enhancing transparency, reducing fraud, and improving continuity of care. More recently, through the National Recovery and Resilience Plan (NRRP), health has been embedded within the broader digital transformation agenda via investments in eHealth infrastructure, telemedicine, and data interoperability. Digitalization thus represents the most tangible channel through which health policy has been connected to a wider administrative reform.

Nevertheless, recurring technical disruptions, limited interoperability, and fragmented data governance constrain the transformative potential of these reforms. Furthermore, the absence of a permanent interministerial coordination structure dedicated to integrating health considerations across public policies suggests that intersectoral cooperation remains largely reactive and crisis-driven, rather than structurally embedded.

The paper argues that Romania's trajectory reflects strategic Europeanization without full institutional consolidation. It advances four policy recommendations: institutionalizing mandatory health impact assessments within the national regulatory framework; strengthening data interoperability and unified health data governance in line with EU standards; establishing a permanent cross-government coordination mechanism; and investing in administrative and digital capacity to support integrated health governance.

Ultimately, the Romanian case highlights the core challenge of the HiAP paradigm: transforming strategic commitment into a durable institutional integration.

**Keywords:** Health in All Policies (HiAP); EU Public Health Law; Institutional Architecture; Health Impact Assessment; Digital Health Regulation

Igor Milinković\*

## **HEALTH IN ALL POLICIES IN BOSNIA AND HERZEGOVINA: THE ROLE OF LOCAL AUTHORITIES WITHIN A COMPLEX CONSTITUTIONAL ORDER**

The concept of Health in All Policies (HiAP) was introduced at the European level in 2006 under the Finnish Presidency of the European Union. As defined in the Helsinki Statement, HiAP represents an approach to public policymaking across sectors that systematically considers the health implications of decisions, seeks intersectoral synergies, and avoids adverse health impacts, in order to improve population health and advance health equity. The HiAP framework calls upon all levels of government to demonstrate a sustained commitment to health and equity by strengthening institutional capacities, establishing transparent accountability mechanisms, and ensuring engagement of citizens and stakeholders throughout the processes of policy formulation, implementation, and assessment.

While national governments play a crucial role in establishing the strategic and legal foundations of HiAP, municipal authorities also exercise significant competences in areas directly affecting the social determinants of health, such as urban planning, environmental protection, local infrastructure, education, and social services, and are therefore well positioned to integrate health considerations into public decision-making, thereby strengthening the effectiveness and sustainability of HiAP implementation.

In the context of Bosnia and Herzegovina (BiH), although certain elements of intersectoral cooperation relevant to health can be identified within the existing legal and policy frameworks across various levels of government, HiAP has not yet been systematically established as an overarching governance principle. This paper analyses the current state of HiAP in BiH and examines the legal, institutional, and practical possibilities for its implementation across all levels of government. Particular attention is devoted to the level

\* Full Professor at Faculty of Law of the University of Banja Luka, Bosnia and Herzegovina, igor.milinkovic@pf.unibl.org

of local government, with a focus on the role of municipalities in promoting intersectoral action for health, identifying existing initiatives, and analysing examples of good practice, as well as the potential of local authorities to act as a catalyst for a more coherent and effective HiAP implementation.

**Keywords:** Health in All Policies, Intersectoral cooperation, Social determinants of health, Bosnia and Herzegovina, Entity legislation, Local government

Katarzyna Melgiesz\*

## ON THE IMPLEMENTATION OF THE HIAP APPROACH IN HEALTH POLICY – THE POLISH PERSPECTIVE

The Health in All Policies (HiAP) concept is an approach to public policy in all sectors that systematically takes into account the impact of policy decisions on human health, seeks synergies between public policies, and strives to avoid harmful effects on health. Its aim is to improve the health of the population and strive for health equity. By its very nature, this approach increases the responsibility of decision-makers for health, its determinants and the functioning of the health system. The approach is based on the assumption that the health of the population depends not only on the health care system, but also on decisions in the education, transport and environment sectors. Hence, this approach assumes that actions beyond medical care will be taken.

As a rule, Polish legislation and public strategic documents implement the Health in All Policies (HiAP) approach, which is primarily reflected in the provisions of the Act of 11 September 2015 on public health. The Act defines public health tasks broadly, covering both the analysis of the health situation, promotion, prevention and monitoring of health determinants, as well as taking action to identify, eliminate or reduce risks and damage to physical and mental health in the environment of residence, education, work and recreation.

The key strategic document is the National Health Programme (NHP) – the current programme covers the period 2021-2025 – as the most important strategic document implementing the HiAP concept in Poland. The strategic objective set for public authorities by this document is to increase the number of years lived in good health, and to reduce health inequalities. Within the framework of the operational objectives set, public health tasks are carried out by the minister responsible for health, in cooperation with the relevant ministers, in accordance with the departments of government

\* PhD. Faculty of Law and Administration War Studies University, Poland, katarzyna.melgiesz@gmail.com

administration and other entities operating in the local government administration sector, as well as non-governmental entities. However the adopted strategic framework for implementing the assumption that the health of the population depends not only on the health care system, but also on the decisions made at the implementation stage in the education, transport and environment sectors, faces real difficulties.

The purpose of this presentation is to show how in Poland the process of implementing the HiAP approach has evolved, to illustrate the directions of its development, and to attempt to determine the degree of implementation, bearing in mind that in practice this is a major inter-ministerial challenge.

In this context, it should be noted in particular that cross-sectoral initiatives within the Health in All Policies concept are a key response to the challenges posed by an ageing population, which is becoming a significant problem in Poland.

**Keywords:** Health policy, National Health Programme, Public cooperation, Cross-sectoral public initiatives, Ageing society

Luka Janeš\*

## THE “ONE HEALTH” CONCEPT EVALUATED THROUGH THE PSYCHIATRIC PATIENTS’ RIGHTS AND THE MENTAL HEALTH IN COMMUNITY SCOPE

In this presentation, the “One Health” concept will be evaluated through the wide scope of psychiatric patients’ rights issues, challenges and opportunities in contemporary, as well as in the future EU policy framework. This scope will be approached basically as the interdisciplinary field which undoubtedly requires the inclusion of perspectives and tools from various biomedical, social and humanistic disciplines.

Namely, the link between human life, (mental) health systems, and the political entanglements has been researched and elaborated by various thinkers through various perspectives in the last half century, beginning with the Foucault’s analysis of the human body in the context of the biopolitical pressures and the control of the subject, through representatives of the anti-psychiatric movement of the late 1970s – Cooper, Laing and Szasz who thematised issues of the diagnostic classification of the psychiatric disorders (and its political and social inducement), up to Ivan Illich who critically situated the patient in the position of a passive, heteronomous consumer of the health services, with the lack of the ownership regarding his own body. The discussion and the topic scope have been further complicated after the experience of COVID-19 pandemic, which brought with it a handful of questions, but also quite a few answers and orientations for the future.

Special emphasis of this presentation will be placed on the mental health care and the human psyche phenomena which will be observed as a kind of tangent that connects the physical, mental, emotional, social and cultural elements of a person. The given elements will be taken as the ideal ground for analysing the law status of being a patient, which often brings by-product repercussions in the form of ones’ (auto)stigmatisation, heteronomy, potential diagnostics manipulation and falsification. As a part of the provided

\* Assistant Professor, University of Zagreb, Faculty of Philosophy and Religious Studies, Croatia, lukajjan@gmail.com / luka.janes@ffrz.unizg.hr

analysis, I will question and evaluate the rights of the psychiatric patients, with the emphasis on free consent as a key issue of the appointed scope of the problematics. In doing so, I will argue that the life phenomena as the basic teleological point with inherent value, should not be subordinated to the political, social and economic interests regarding the ill person.

As argumentative support in proving the given thesis I will use, among others, the example of multi-sectoral paradigm present in the mental health system of Island, as well as the example of organization and implementation of the Croatian mental health strategy for the 2023-2033 period. Both examples emphasise a community-based mental health framework as a key paradigm for the future. The given paradigm involves interdisciplinary dialogue and cooperation between multiple sectors and perspectives (medicine, social work, law, educational system), and I will endeavour to show that it could be used as a fruitful paradigm in setting some long-term guidelines for mental health law policies within the global All Policies context.

**Keywords:** Psychiatric Patients' Rights, "One Health", Interdisciplinarity, Mental Health in the Community

Sebastian Czechowicz\*

## HOW NOT TO IMPLEMENT THE HEALTH IN ALL POLICIES CONCEPT – THE EXAMPLE OF POLISH LEGISLATION EXPERIENCES IN THE CONTEXT OF INTERNATIONAL LEGAL STANDARDS

Public health is one of the most important tasks faced by both state and society, as it directly affects the quality of life, social stability and economic development. The protection of public health has undergone a significant transformation over recent decades, particularly in response to globalization, demographic changes, emerging infectious diseases and the growing burden of non-communicable diseases. These challenges have led to the development of numerous concepts and strategic approaches aimed at strengthening health systems and improving population health outcomes. A leading role in shaping these approaches has been played by international organizations, in particular the World Health Organization, which has consistently emphasized the need for comprehensive and coordinated action beyond the healthcare sector.

One of the most influential strategic frameworks promoted at the international level is the concept of *Health in All Policies* (HiAP). This approach is based on the assumption that health outcomes are determined not only by healthcare services, but also by policies implemented in other sectors, such as transport, education, environmental protection, labour, urban planning and public safety. As a result, HiAP calls for the systematic inclusion of health considerations in all public policies, regardless of whether their primary objective is related to health. In this sense, public health becomes a horizontal value that should permeate the entire system of public governance.

The implementation of Health in All Policies, which is conceptually linked to the broader One Health framework, requires specific systemic and institutional measures. From a legal perspective, this necessitates ensuring coherence and consistency within the legal framework governing public health protection. Such a framework encompasses provisions of public law in the broad sense, including

\* Assistant Professor, Department of Criminal Law, University of Łódź, Poland, [sebastianczechowicz.official@gmail.com](mailto:sebastianczechowicz.official@gmail.com)

both administrative and criminal law. Administrative law plays a key role in regulating preventive measures, supervision, and the organization of public authorities, while criminal law provides instruments for responding to serious violations that endanger public health. The effectiveness of HiAP therefore depends on the ability of the legal system to integrate health protection objectives across different branches of law and policy areas.

In Poland, however, the implementation of international public health standards, including Health in All Policies, has been both protracted and fragmented. Legal solutions related to public health protection are dispersed across numerous sector-specific statutes, often lacking a common conceptual framework. The adoption of the Public Health Act in 2015 was intended to serve as a flagship legislative initiative that would consolidate and systematize public health policy. Despite these intentions, the Act has been amended multiple times, and it has not resulted in the comprehensive implementation of the HiAP approach. In practice, the Act functions more as a coordinating instrument with limited normative impact, than as a robust legal foundation for cross-sectoral health governance.

An additional problem within the Polish legal system is the significant dispersion of public health regulations across legal acts originating from different historical periods. Some of these acts date back to the 1970s and were drafted under fundamentally different political, social and epidemiological conditions. This temporal inconsistency contributes to normative incoherence and hinders the effective alignment of domestic law with contemporary international standards.

This paper presents selected examples of problems related to the implementation of Health in All Policies in Poland, with a particular emphasis on the role and limitations of the Public Health Act. The analysis is based on dogmatic and legal research, focusing on the structure, content and interrelations of public health regulations within the Polish legal system. The findings are assessed in light of international standards and strategic recommendations, with the aim of identifying key legal barriers to the effective realization of Health in All Policies.

**Keywords:** Public health, Polish legislation, Health in All Policies, Legislation mistakes, Amendment to the act

Sofija Nikolić Popadić\*, Ivana Stjelja\*\*, Petra Stanojević\*\*\*

## CLIMATE CHANGE AND PUBLIC HEALTH: OPERATIONALIZING THE HEALTH IN ALL POLICIES, THE CASE OF SERBIA

The relationship between climate change and public health is complex, requiring governance approaches that extend beyond the traditional boundaries of health policy. Climate change increasingly affects population health through altered climatic conditions. These impacts manifest unevenly across generations and social groups, with younger populations experiencing heightened mental health challenges, such as climate-related anxiety, while older adults facing disproportionately increased risks of heat-related illness and mortality. At the same time, public health and healthcare systems are not merely passive recipients of climate impacts but also active contributors to climate change. Greenhouse gas emissions associated with energy consumption in healthcare facilities, transportation, pharmaceuticals, and medical technologies position the health sector as a significant, though often overlooked, source of emissions. This dual role of public health, as both a sector affected by and contributing to climate change, underscores the need for integrated policy responses that address health protection and climate action simultaneously.

In this regard, the Health in All Policies (HiAP) approach provides a strategic and normative framework for systematically integrating health considerations into policymaking across sectors that are crucial for climate change mitigation and adaptation. From a legal perspective, HiAP emphasizes the importance of institutionalized intersectoral cooperation, shared responsibility and evidence-based decision-making based on health equity. Our research examines how legal and regulatory frameworks can operationalize the HiAP approach within climate change governance by incorporating health objectives into climate policies and, conversely,

\* PhD, Research Associate, Institute of Social Sciences, Belgrade, Serbia, snikolic@idn.org.rs

\*\* PhD, Research Associate, Institute of Social Sciences, Belgrade, Serbia, istjelja@idn.org.rs

\*\*\* Junior Research Assistant, Institute of Social Sciences, Belgrade, Serbia, pstanojevic@idn.org.rs

climate considerations into public health policies in Serbia. One of the key questions is whether there is sufficient sectoral coherence to enable the implementation of the HiAP approach when it comes to health and climate change in Serbia.

In our research, we argue that embedding the HiAP approach within climate-related and public health legal frameworks can enhance policy coherence, strengthen the resilience of public health systems, and promote more equitable and sustainable outcomes. By leveraging law as an enabling tool, HiAP can function as a critical bridge between climate action and public health protection, ensuring that climate policies deliver tangible health co-benefits, while minimizing the climate footprint of the health sector itself.

**Keywords:** Climate change, Public health, Health in All Policies, Climate legislation, Health equity

Francesca Ferretti\*

## THE MANAGEMENT OF TECHNOLOGICAL RISK IN HEALTHCARE AS AN IMPLICIT FORM OF HEALTH IN ALL POLICIES: THE ITALIAN EXPERIENCE

Twenty years after the formulation of the “Health in All Policies” (HiAP) approach, European and international debates call for reflection not only on its explicit implementation within public policies, but also on its implicit manifestations within national legal systems. From this perspective, the paper analyses the Italian experience, arguing that, despite the absence of a formally declared HiAP strategy, the right to health has progressively assumed a transversal function through the management of technological risk.

Within the Italian legal system, the protection of health, constitutionally guaranteed by Article 32 of the Constitution, has evolved from the right to healthcare services into a fundamental personal value. This evolution has enabled health to operate as a guiding criterion beyond the narrowly conceived healthcare sector, influencing areas such as the market and technological innovation.

This expansive function is also evident in the legal governance of new medical technologies, particularly artificial intelligence and medical devices. A significant step in this direction is represented by the Gelli-Bianco Law (Law No. 24/2017), which strengthened the right to health through the introduction of the concept of “safety of care”, encompassing both medical device safety and prevention of technological risks.

The paper shows how risk, as a central legal criterion, translates health protection into preventive, organisational and regulatory obligations involving multiple actors – manufacturers, healthcare institutions and professionals – across different regulatory fields. In particular, the European Medical Devices Regulation (Reg. No. 2017/745) and the AI Act (Reg. No. 2024/1689) outline a model of protection based not only on *ex post* liability, but primarily on *ex ante* risk assessment and the safe design of healthcare technologies. Medical device safety, including AI-enabled devices, is

\* Post-doc research fellow in Private Law, Scuola Superiore Meridionale, Naples, Italy, [f.ferretti@ssmeridionale.it](mailto:f.ferretti@ssmeridionale.it) / [francescaferretti1995@gmail.com](mailto:francescaferretti1995@gmail.com)

conceived as an intrinsic feature throughout the product life cycle, in line with the principle of built-in safety. This approach is further reflected in the recent Italian Law on AI (Law No. 132/2025), which adopts a risk-prevention framework oriented towards the protection of fundamental rights and recognises health as a guiding criterion for the use of AI systems in healthcare.

Risk thus assumes a circular function, operating both downstream as a criterion for the attribution of liability, and upstream as an instrument of *ex ante* regulation. It constitutes a fundamental parameter in both the classification of medical devices, based on technical and clinical criteria, and the qualification of AI systems, based on their impact on health, safety and fundamental rights. This reflects an axiological functionalisation of the risk-based approach, moving beyond neutrality to protect specific legal interests.

The paper concludes that this model represents an “implicit” form of Health in All Policies, in which health – understood in terms of risk prevention and elimination – guides policies concerning products, new technologies and innovation. The Italian experience shows how the right to health can function as a factor of intersectoral coordination even in the absence of formally labelled HiAP policies, within a context that is likely to be further strengthened by European digital health strategies and the integrated “One Health” approach.

**Keywords:** Digital Health Regulation, Artificial Intelligence, Technological Risk, Medical Liability, Right to Health

Małgorzata Ganczar\*

## PATIENT CONTROL OVER MEDICAL DATA: GDPR IN THE ERA OF EHDS

The dynamic development of the European Health Data Space (EHDS) introduces a new framework for sharing, processing, and reusing health data across the European Union, while redefining how patients can exercise control over their medical records. The EHDS envisages the creation of a unified infrastructure that will enable easier access to data, its interoperability, and the ability for patients to manage access. At the same time, the healthcare sector remains one of the most sensitive areas in terms of personal data protection, which means that the GDPR with its catalogue of patient rights and administrator obligations continues to be the regulatory foundation for all activities related to information security.

The presentation analyses how the two regulations, the GDPR and the EHDS, overlap and complement each other, and how they change the practical possibilities for patients to control their medical data. It will discuss the existing patient rights under the GDPR, including the right of access, rectification, data portability, and restriction of processing, and how the EHDS extends their practical application through new digital tools. Of key importance here are mechanisms that allow patients to decide which data is shared and with whom, as well as mechanisms that enable patients to view access logs and set preferences for the exchange of documentation.

At the same time, the EHDS introduces a number of new technological and organizational requirements that affect the scope of patient control. The presentation will highlight the differences between the general security requirements set out in the GDPR such as “appropriate technical and organizational measures,” risk assessment, DPIA, and the principle of data minimization – and the more specific obligations under the EHDS, including interoperability, infrastructure requirements, security levels for secondary access, and the role of Health Data Access Bodies. Particular emphasis will be placed on the practical aspects of implementing

\* Professor at Department of Public Commercial Law, Faculty of Law, Canon Law and Administration, The John Paul II Catholic University of Lublin, Poland, malgorzata.ganczar@kul.pl

pseudonymization and anonymization in multi-entity environments, incident management in cross-border networks, and ensuring the resilience of medical systems to cyber threats.

In my presentation, I will also show how the EHDS redefines the very concept of “security” through mandatory data exchange standards, service certification, and new access management models. Participants will learn how to reconcile the flexibility of the GDPR with the more detailed, technical requirements of the EHDS, and what actions organizations should take to truly empower patients while ensuring compliance with the new regulations.

**Keywords:** Personal data protection, Medical data, Patient data rights, Health information security, Healthcare cybersecurity

Meliha Sermin Paksoy\*

## **IS AI THE NEW MEDICAL STANDARD IN RADIOLOGY? AN EXAMINATION OF THE IMPACT OF ARTIFICIAL INTELLIGENCE APPLICATIONS ON MEDICAL STANDARDS: THE CASE OF RADIOLOGY**

Artificial Intelligence (AI) is precipitating structural transformations across the healthcare sector, influencing everything from diagnostic workflows to hospital administration. Radiology has emerged as the primary frontier for AI integration, providing radiologists with critical assistance in report drafting, image quality enhancement, automated measurement, and diagnostic decision support. The exponential surge in academic literature and the dominance of radiology-specific tools among FDA-cleared AI devices—with approximately 873 approvals by mid-2025—underscore the magnitude of this shift. Furthermore, frequent media coverage of scientific studies is reshaping public and legal expectations by suggesting that AI may soon outperform human experts in specific diagnostic tasks.

In light of these developments, it is imperative to evaluate the extent to which AI redefines the “medical standard”. Medical standard is defined as the fundamental, tried, and established rules of the profession that reflect the current level of medical experience and natural sciences, are proven through practice, and are necessary for the physician to achieve the therapeutic objective. Medical standards are dynamically shaped by the guidelines and manuals of professional organizations and the teachings of universities, evolving alongside widely accepted practices and technological advancements. Currently, prominent professional bodies emphasize that the success of AI in controlled research environments does not always translate to clinical efficacy and demands rigorous, real-world validation. For an AI application to be fully integrated into the medical standard, it must be substantiated by robust meta-analyses and demonstrate consistent effectiveness in clinical practice.

\* Associate Professor, PhD, Managing Partner at Paksoy + Partners Law Firm, [ms.paksoy@paksoypartners.com](mailto:ms.paksoy@paksoypartners.com)

A critical dimension of this evolution is its impact on the legal liability of physicians and healthcare institutions. From the perspective of the radiologist, the “duty to inform” is expanding; patients may increasingly expect to be briefed on alternative AI-supported diagnostic options. Furthermore, the standardization of AI raises the bar for “organizational liability”. Just as the Turkish Council of State (Danıştay) has identified the lack of essential technical equipment as an “organizational deficiency”, while the Turkish Constitutional Court (AYM) has ruled the absence of technologically advanced features in health services as a “fault of service”, the failure of a hospital to provide proven AI diagnostic tools may soon be scrutinized under these legal doctrines. This study concludes that as AI systems achieve high-success benchmarks, their absence or misuse will transition from a technological choice to a potential breach of the contemporary medical standard, necessitating a comprehensive re-evaluation of medical negligence and institutional responsibility.

**Keywords:** Artificial Intelligence, Radiology, Medical Standards, Legal Liability, Organizational Fault, Duty to Inform

Paola Asja Butera\*, Arianna Zanon\*\*

## GOVERNING ARTIFICIAL INTELLIGENCE IN HEALTH AND SOCIAL CARE: OPPORTUNITIES, RISKS AND POLICY IMPLICATIONS FROM THE PERSPECTIVE OF FRONTLINE PROFESSIONALS

The increasing integration of artificial intelligence (AI) tools – such as chatbots and large language models (LLMs) – into health and social care services is reshaping the organisation, delivery and governance of welfare systems. While digital innovation offers significant potential to improve efficiency, personalisation and coordination of care, it also raises critical policy challenges related to data protection, accountability, algorithmic reliability and the risk of digital exclusion, particularly for vulnerable populations.

This paper analyses the adoption of AI-based technologies in health and social care through the lens of the *Health in All Policies* (HiAP) approach, framing AI as a cross-cutting policy issue at the intersection of health, social protection, digital regulation and workforce development. Particular attention is paid to the role of frontline professionals, whose perceptions, concerns and training needs remain underexplored despite being crucial for the responsible and effective implementation of AI in public services.

The study adopts an exploratory mixed-methods design. A web-based survey was administered to a sample of health and social care professionals to investigate familiarity with AI tools, perceived benefits and concerns related to privacy, data security, transparency and decision-making processes. This quantitative phase was complemented by in-depth online interviews aimed at capturing professionals' narratives and critical reflections on the practical implications of AI in everyday service provision.

Preliminary findings indicate that AI applications are mainly valued for the automation of administrative tasks, support to resource planning and assistance in home-based care settings, in line with the existing literature. At the same time, professionals express significant concerns regarding algorithmic errors, lack of

\* Synergia s.r.l. (Milan, Italy), paolaasja.butera@gmail.com

\*\* Synergia s.r.l. (Milan, Italy), arianna.zanon28@gmail.com

transparency, costs and the governance of sensitive personal data. These tensions highlight the limits of technology-driven approaches and point to the need for policy frameworks capable of addressing ethical, legal and organisational dimensions simultaneously.

The paper argues that effective AI integration in health and social care requires participatory and transparent governance models consistent with the principles of *Health in All Policies*. Actively involving professionals in the design, regulation and evaluation of AI tools is essential to ensure inclusive, rights-based and socially sustainable digital transformation.

**Keywords:** Artificial intelligence; Health in All Policies; Health and social care services; Digital governance; Data protection; Frontline professionals

Olga Kubik\*

## HERITABLE GENETIC INTERVENTIONS IN HUMAN BIOTECHNOLOGY: REGULATORY CHALLENGES AND SOCIAL IMPLICATIONS

The aim of this paper is to analyse the legal permissibility of therapeutic interventions in human genetic material that result in the inheritance of modified traits, with a particular emphasis on the current regulatory framework of European Union law, including Regulation (EU) 2024/1938 on Substances of Human Origin (SOHO) and Regulation (EU) 2021/2282 on Health Technology Assessment. This issue has gained particular importance in the context of the dynamic development of biotechnology, especially genome editing technologies, as well as their increasingly close integration with artificial intelligence, which accelerates research processes and enhances their effectiveness and accessibility.

Over the past two decades, the development of tools enabling precise interventions in genetic material has created a realistic prospect of eliminating the genetic causes of many serious diseases. At the same time, these technologies generate new and specific risks, particularly in the case of heritable interventions, which extend beyond the individual therapeutic dimension and may affect future generations. This raises questions regarding the adequacy of existing legal instruments and the limits of permissible interference with the human genome.

The analysis takes as its starting point the Convention on Human Rights and Biomedicine of 1997, whose provisions are commonly interpreted as establishing a prohibition on germline therapy, although alternative interpretations allowing for its therapeutic use may also be offered. The paper highlights the limited contemporary relevance of this legal instrument, resulting both from technological progress and from the fact that the Convention has not been ratified by all European states. These circumstances prompt a search for normative guidance in more recent EU regulations, despite the fact that none of them addresses heritable genetic modification directly or comprehensively.

\* Master of Laws, Jagiellonian University in Krakow, Poland, o.kubik@student.uj.edu.pl

The paper examines whether, and to what extent, current EU regulations may serve as indirect protective frameworks capable of mitigating the risks associated with biotechnological misuse. An important dimension of the analysis is the social context, including the evolving hierarchy of legally protected interests, shaped inter alia by the experience of the SARS-CoV-2 pandemic and the ongoing debates concerning access to advanced medical therapies. The paper seeks to develop a proposal for a regulatory standard that would enable the responsible development of genetic technologies while simultaneously safeguarding human dignity, equality, and social justice.

**Keywords:** Heritable Genome Editing, Regulatory Framework for Emerging Genetic Technologies, EU Substances of Human Origin (SOHO) Framework, EU Health Law and Biotechnology Governance, Human Dignity and Biotechnological Risk Governance

Erik Hahn\*

## **TELEMEDICINE AS A BRAKE OR ACCELERATOR FOR ANTIBIOTIC PRESCRIPTIONS: LEGAL RESPONSES TO AVOIDABLE ANTIBIOTIC USE AND ANTIMICROBIAL RESISTANCE IN DOMESTIC AND CROSS-BORDER CARE**

Antimicrobial resistance (AMR) is a paradigmatic ‘One Health’ challenge. The mechanisms influencing AMR extend beyond clinical decision-making to include legal frameworks that govern professional conduct, care organisation, digitalisation, and cross-border collaboration. Telemedicine is a prime example of this complexity. It can promote more targeted prescribing and prevent incorrect dosing, including overdosing by facilitating input from external specialists. However, remote care can also lead to increased antibiotic prescribing, particularly when diagnostic uncertainty, patient expectations, and time pressure coincide. Empirical studies show that the effects of telemedicine care models on antibiotic prescribing are ambivalent, with both increases and decreases observed (Shah et al., 2024).

Against this background, this paper examines telemedicine in terms of legal accountability and regulatory design rather than as a technological issue. It is based on the premise that the individual doctor–patient relationship involves an obligation to avoid unnecessary therapy, including avoidable antibiotic exposure. Nevertheless, breaches of such duties often do not result in provable, compensable loss. The primary harm of unnecessary antibiotic use is often collective and temporally displaced. Consequently, contractual or delictual liability is unlikely to effectively reduce avoidable antibiotic prescribing in routine practice, even where a breach of duty can be demonstrated. Therefore, the paper emphasises the role of public health or medical law (e.g. professional or disciplinary regulation and quality governance) as the primary legal framework capable of stabilising restrictive prescribing in telemedical settings.

\* Professor of Health Law and Social Law, Zittau/Görlitz University of Applied Sciences, Görlitz, Germany, and co-opted professor at the Faculty of Medicine and the Institute for International Law, Intellectual Property and Technology Law of the Faculty of Philosophy at Dresden University of Technology, Dresden, Germany, erik.hahn@hszg.de

The analysis highlights three clusters of questions. First, it addresses the allocation of responsibilities between the primary treating clinician and the telemedical consultant. Second, it considers the conflict-of-laws dimension where primary medical care or teleconsultations are requested or provided across borders. This includes the possibility that the consultant's conduct may be subject to foreign professional rules and standards, which may have lower requirements. Third, based on this, the paper argues that the most effective legal response is not to extend private liability, but rather to clearly formulate, as a matter of public law, the professional duty to restrict antibiotic prescribing. In many jurisdictions, professional law explicitly links medical practice to codified professional and ethical standards. In order to interpret the often broadly formulated professional legal obligations regarding an individual duty to prevent AMR, the paper suggests referring to historical sources, such as the Hippocratic Oath, as well as international sources, such as the World Medical Association's Statement on Antibiotic Resistance. This could help to define the concept of 'restrictive antibiotic use' as a specific requirement for good medical practice in telemedicine.

**Keywords:** Antimicrobial resistance, One Health, Telemedicine, Legal accountability, Harm of unnecessary antibiotic use

Hajrija Mujović\*

## **WHAT DOES MEDICAL LAW TELL US ABOUT THE EXERCISE OF PATIENTS' RIGHTS IN THE HEALTHCARE SYSTEM OF SERBIA IN LIGHT OF EUROPEAN PERSPECTIVES?**

The state of human rights in the field of health in Serbia has certain characteristics that are reflected in both positive and negative outcomes. What is generally stated is that the health regulations have developed in the most general sense. However, difficulties in exercising patients' rights still exist to a significant extent. The causes are not only in direct and therapeutic procedures, but also in the work of supporting services, administration and organizational aspects of work in healthcare.

The problems are numerous. They can be illustrated by cases in the areas of transplantation, rare diseases and paediatric care. The question is well-founded of the extent to which an approach from the perspective of European documents and experiences of good practice in comparative law can help in overcoming the problems encountered by patients in the Serbian healthcare system. The fact is that patients' rights in Serbia were codified in 2013, modelled after the European Charter on Patients' Rights and with the ratification of the European Convention on Human Rights and Biomedicine. In this sense, a large number of legislative matters have been harmonized and given their own framework.

However, the implementation of regulations and the effectiveness of adopted legal solutions appear as a significant problem in practice. This is essentially a question of the extent to which legal solutions have been implemented, and to what extent they remain declarative and non-existent in practice. In terms of activities that need to be undertaken, several conclusions emerge. One of the most important is to strengthen the segment of assistance to patients in exercising their rights in the health system itself through a network of advisors and coordinators. This would also represent

\* Principal Research Fellow, Institute of Social Sciences, Belgrade, Serbia, hajrija.mujovic@gmail.com

a strengthening of the work of health services and organizational capacities.

**Keywords:** Patients, Rights, Health system, Serbian law, EU law

Vesna Filipović\*

## RECENT CASE LAW DEVELOPMENTS IN THE FIELD OF MEDICAL LAW IN THE REPUBLIC OF SERBIA

In recent years, medical law has assumed an increasingly significant and well-deserved role within domestic civil law jurisprudence. This development is reflected not only in the growing number of claims for damages arising from medical malpractice, but also in the expanding range and complexity of legal grounds invoked in such proceedings.

Whereas a decade ago disputes concerning medical liability were relatively rare, contemporary judicial practice demonstrates a marked increase in litigations related to diverse medical services, particularly in the area of aesthetic surgery. This expansion has led to a more intensive and nuanced application of civil law principles within medical law adjudication.

Earlier case law was predominantly limited to claims for non-material damages—such as compensation for mental anguish due to diminished life activity, disfigurement, pain and fear—as well as reimbursement of medical treatment costs. Recent jurisprudence, however, reflects a broader approach. Claims now frequently encompass compensation for additional treatment-related expenses, lost earnings during temporary incapacity for work, and, where applicable, monetary annuities in cases of permanent or partial incapacity, increased needs, or diminished prospects for professional advancement. Moreover, courts are increasingly addressing violations of personality rights, including the rights to physical and psychological integrity, health protection, dignity, and personal autonomy.

A particularly significant doctrinal shift concerns the legal evaluation of informed consent. Earlier judicial practice did not systematically examine the absence of informed consent as an autonomous basis for liability. Contemporary case law, however, recognizes that even in the absence of malpractice in the narrow technical sense—where no professional error or omission causally linked to

\* Judge of the Court of Appeal in Belgrade, filip68bg@gmail.com

the damage is established—the failure to obtain valid informed consent may independently give rise to civil liability.

Recent decisions further clarify the substantive content of informed consent, emphasizing that generalized or formal consent does not suffice. Courts have taken the position that although a medical procedure may have been performed in accordance with professional standards, liability may nonetheless arise if the physician failed to act with the due care of a prudent professional, which includes the obligation to provide comprehensive and comprehensible information regarding the nature of the intervention, its risks, and possible consequences. Acceptance of standard procedural risks cannot be presumed where those risks were not adequately disclosed.

These developments indicate a progressive strengthening of patient autonomy within civil law protection. They also underscore the need for harmonization in the application of legal standards, greater engagement with the jurisprudence of the European Court of Human Rights, and continued professional education of both judges and medical practitioners. Such measures are essential to ensuring legal certainty, enhancing the quality of medical services, and reinforcing trust in the healthcare system.

**Keywords:** Case law; Medical malpractice; Court claims; Informed consent

Nina Mladinić\*

## **CURRENT ISSUES OF THE REGULATION AND APPLICATION OF CONSCIENTIOUS OBJECTION IN CROATIAN MEDICAL LAW AND PUBLIC HEALTH (RIGHT TO CONSCIENTIOUS OBJECTION VS. RIGHT TO HEALTH)**

In the Croatian general and professional public, conscientious objection is most often mentioned because of its application in medicine, especially in the field of women's reproductive health (refusal of abortion, assisted reproduction, prenatal diagnostics, contraception, etc.). Although the Constitution of the Republic of Croatia in Article 47 explicitly allows conscientious objection only to those who, due to their religious or moral beliefs, are not ready to participate in the performance of military duties in the armed forces, the right to such objection in other activities, including medicine, arises from Article 40, which guarantees freedom of conscience to everyone. At the same time, the Constitution allows for legal restrictions on freedoms and rights in order to protect the freedoms and rights of other people in the field of health. A number of laws, professional codes of ethics and even ordinances that regulate health care in the Republic of Croatia provide medical professionals with the right to conscientious objection. In Croatia, for a decade now, the application of negative conscientious objection (refusal to perform a medical procedure) has been a highly topical issue, especially in those cases in which doctors, nurses and midwives have the right to conscientious objection, but also a pregnant woman has the right to a legal and safe abortion.

Particularly negative connotations to the right to conscientious objection were caused by the actions of not only public hospitals but also the Croatian healthcare system in general, in a case from 2022 in which the health system, believing that it would be fetidial euthanasia, did not provide a pregnant woman with the right to a legally permitted abortion despite the child's terminal diagnosis and a possible threat to her health. This raises questions about

\* Associate Professor, Faculty of Forensic Sciences, University of Split, Croatia, nina.mladinic@forenzika.unist.hr

the role that conscientious objection plays in medical practice, and whether medical professionals should have an unlimited right to refuse permissible treatments. In particular, the question arises of the extent of conscientious objection in a publicly funded health system, i.e. how to reconcile the private beliefs of health professionals in the provision of public services and find a compromise between the right to legal and publicly available health care and the right to refuse health for reasons of conscience. The right to conscientious objection is an individual, not a collective right. Its regulation in reproductive medicine is a priority, due to cases in which all gynecologists in a health institution whose activity is performing abortions on demand are called to conscience. Data show that in Croatia almost 60% of gynaecologists invoke conscientious objection, while in Slovenia this figure is below 10% and such a possibility of collective conscientious objection certainly threatens women's right to health care. It is necessary to prevent the abuse of the rights through the practice of so-called "divided conscientious objection" with certain gynaecologists invoking conscientious objection in the public health institutions of their employment, while performing abortions in private practices. Given that there is no official register of conscientious objections, it is necessary to regulate the procedure, form and timing of conscientious objection and to exclude the possibility of selective conscientious objection. Medical law should certainly strike a balance between individual freedom and the right to health protection in light of the decisions of the European Court of Human Rights that have set the limits of the right to conscientious objection. The legislative regulation of the limits of conscientious objection is particularly relevant in medical criminal law, pertaining to the complex issue of criminal liability of health professionals.

**Keywords:** Right to legal and publicly available health care, Right to conscientious objection, Right to a legal and safe abortion, Abuse of the right to conscientious objection in Croatian medical practice, Decisions of the European Court of Human Rights

Jelena Simić\*

## CONDITIONS FOR POST-MORTEM HUMAN ORGAN DONATION: MINE, YOURS, OURS?

Public trust in the validity of transplant medicine and its associated procedures is best achieved through appropriate legislation. Consequently, nearly all civilized nations have regulated this field through specific legal frameworks. While these regulations differ in content and scope, they share certain fundamental principles. Deceased persons are the most significant source of transplantable organs, since such acts do not pose health risks, which is not the case with living donors.

However, it is observed that the supply of transplantable organs, tissues, or cells from the deceased is insufficient to meet the demands of potential recipients. Some authors attribute this to inadequate legal regulation, citing unsystematic methods for recording the donor's will during their lifetime. On the other side, an increasing number of authors point out that the family's role in organ transplantation practice has proven to be crucial. Family refusal to consent to the retrieval of organs and tissues from the deceased is one of the primary factors limiting organ donation rates. Therefore, in this paper, the author analyses comparative legal solutions regarding the family's role in post-mortem organ procurement.

The author points out that, in many countries, experience has shown that approaches to the end of life can vary significantly within the same family, making it difficult for transplant teams to navigate family conflicts. Furthermore, the author notes that the role of relatives is limited to expressing the actual or presumed wishes of the deceased, rather than their personal views on organ procurement, and that the expressed wishes of the potential donor are of paramount importance in deciding whether organs or tissues can be retrieved or not.

The author concludes that relatives must not act as autonomous holders of rights, but rather as guardians of the rights that belonged to the deceased. Otherwise, the body of the deceased is

\* Associate Professor of Law, Union University Law School, Belgrade, Serbia, jelena.simic@pravnofakultet.edu.rs

reduced to an object of arbitrary decisions by relatives. Relatives should act in accordance with the wishes of the deceased, as suggested by Article 8 of the European Convention on Human Rights (“Protection of family life”), which “encompasses the right to respect for the dignity of a deceased close relative”.

**Keywords:** Post-mortem organ procurement, Family, Transplant medicine, Autonomy of will, Bodily integrity

Nino Lipartia\*

## VACCINATION POLICY AND HUMAN RIGHTS: NATIONAL AND INTERNATIONAL PERSPECTIVES

Vaccination policy is a cornerstone of public health, providing protection against infectious diseases while contributing to herd immunity. However, the imposition of mandatory vaccination raises complex legal and ethical issues, particularly regarding the protection of individual rights. Under Article 8 of the European Convention on Human Rights (ECHR), individuals are guaranteed the right to respect for their private and family life, which can include the right to make personal medical decisions. Mandatory vaccination measures, while intended to protect public health, represent a direct interference with this right and must therefore be carefully justified under the principles of necessity, proportionality, and legality.

The European Court of Human Rights addressed this issue in *Vavříčka and Others v. the Czech Republic* (2021). In this landmark case, the Court upheld the Czech Republic's policy of mandatory childhood vaccination, emphasizing that although compulsory vaccination constitutes an interference with private life, it can be justified as "necessary in a democratic society" to protect the health of children and the broader population. The Court highlighted the "margin of appreciation" afforded to states in designing public health measures, recognizing the discretion of national authorities in implementing policies tailored to specific societal needs, while remaining consistent with human rights obligations.

National experiences illustrate diverse approaches to balancing public health and individual rights. In France, the introduction of COVID-19 vaccination requirements, coupled with the health pass, sparked public debate and judicial scrutiny over the compatibility of these measures with individual liberties. In Italy, workplace vaccination mandates were implemented with careful consideration of proportionality and legal safeguards. In the United States, historical precedents such as *Jacobson v. Massachusetts* (1905) and *Zucht v. King* (1922) have long supported compulsory vaccination, while

\* Professor of Grigol Robakidze University, Tbilisi, Georgia, nino.lipartia@gmail.com

allowing limited exemptions on medical or religious grounds. These cases highlight the enduring tension between individual autonomy and the collective interest in preventing disease.

Internationally, vaccination policies are guided by principles ensuring that interventions are lawful, necessary, and proportionate, while minimizing infringements on individual rights. Legal frameworks often incorporate medical, religious, or conscientious exemptions, but these must be carefully balanced against the societal imperative to protect public health, particularly during pandemics. The COVID-19 crisis has reinforced the relevance of the Health in All Policies and One Health approaches, emphasizing the need to integrate public health considerations across social, legal, and environmental policies.

This presentation will examine judicial and legislative responses to vaccination policies over the past twenty years, comparing European and international case law and highlighting lessons from the ECHR and national courts. The discussion will explore how states can reconcile individual rights with public health objectives, emphasizing the importance of proportional, evidence-based measures. By analysing legal frameworks, court decisions, and public health strategies, the presentation will provide insights into the evolving relationship between law, ethics, and public health, demonstrating the critical role of judicial oversight and policy design in safeguarding both individual liberties and societal wellbeing.

**Keywords:** Vaccination Policy, Human Rights, ECHR Article 8, Mandatory Vaccination, Public Health Law, Proportionality, Judicial Review, COVID-19

Taysier Roberto Mahajnah\*

## COVID-19 ANTI-VACCINATION LITIGATION AND CONSTITUTIONAL ADJUDICATION

The litigation brought by anti-vaccination activists and movements during the COVID-19 pandemic has been one of the main testing grounds for public health law. Disputes over vaccination requirements have forced constitutional and supreme courts to grapple with a recurring issue in recent case law concerning the role of courts in reviewing health policies based on contested scientific assessments. In this context, constitutional adjudication has become a privileged space through which anti-vaccination dissent has attempted to translate into legally relevant arguments.

This paper analyses this problem through a comparison between the United States and Italy. For the US context, the analysis examines decisions such as *Does 1–6 v. Mills* (2021) and *Dr. A v. Hochul* (2021), both relating to COVID-19 vaccination requirements introduced at the state level and challenged by appellants who contested the legitimacy of the measures on the grounds of alleged insufficient consideration of individual interests. For the Italian context, the contribution focuses on the case law of the Constitutional Court on vaccination requirements adopted during the COVID-19 pandemic, with particular reference to judgments nos. 14 and 16 of 2023 and no. 199 of 2025, in which the Court is called upon to assess the constitutional legitimacy of the measures introduced by the legislator on the basis of technical and scientific assessments. The comparative analysis focuses on the arguments put forward in court by anti-vaccination activists and on the ways in which the courts responded to these challenges. The focus is not exclusively on the outcomes of the decisions, but on the legal language through which anti-vaccination dissent is reworked, neutralised or partially reconfigured in judicial reasoning. In this context, the institutional structure of the courts takes on central importance, as it affects the ability of anti-vaccination arguments to gain visibility and circulation, even beyond the formal outcome of the judgements.

\* PhD Student at Bocconi University, Italy. Affiliated Researcher at Center for Constitutional Studies and Democratic Development (CCSDD), taysier.mahajnah@phd.unibocconi.it

Starting from these cases, the article examines two central issues. Firstly, the legal treatment of scientific expertise by courts, analysing whether and in what way it is considered as a relevant element for judicial review, or as an area removed from the judge's assessment. Secondly, the article investigates the different methods of scrutiny adopted about the legislator and health authorities, observing how the courts modulate the intensity of their review in the presence of scientific uncertainty and health conflicts. The aim is not to establish whether courts should defer to legislative choices on public health matters, but to reconstruct comparatively the legal techniques through which anti-vaccination dissent is received, transformed and, in some cases, reinforced through the judicial process.

**Keywords:** COVID-19 Anti-vaxxer legal mobilisation, Constitutional Adjudication, Contested science, Comparative public health law

Ranko Sovilj\*, Aleksandar Vukadinović\*\*

## RETHINKING MEDICAL LIABILITY IN ELECTIVE COSMETIC SURGERY: LEGAL GAPS AND ETHICAL CHALLENGES

The increasing global prevalence of elective cosmetic procedures has reshaped traditional conceptions of medical liability in cosmetic surgery. This trend challenges established doctrines of professional responsibility. This expansion has occurred within a fragmented and inconsistent regulatory landscape, generating significant legal, ethical, and policy concerns, particularly with respect to physicians' duties to prioritize patient welfare and uphold both legal and professional standards of conduct. Elective cosmetic interventions carry significant risks of harm, with potentially serious consequences where procedures are performed by inadequately qualified practitioners or involve the use of unsafe or substandard products, thereby raising critical questions concerning breach of the duty of care and the applicable standard of professional conduct.

These challenges are further compounded by the fact that cosmetic procedures are primarily driven by patients' expectations rather than therapeutic necessity. As a result, the legal and ethical assessment of informed consent, the content of the physician's duty to disclose, and the determination of the appropriate standard of care assume particular significance. Within this context, physicians engaged in cosmetic procedures, including plastic surgeons, face a disproportionately high risk of litigation and formal complaints compared with other medical specialties. This elevated risk of legal liability has been attributed to a convergence of factors, including unrealistic patients' expectations, increasingly adversarial litigation practices, deficiencies in preoperative assessment, and substandard professional conduct by a minority of practitioners. Patient representatives and legal scholars further argue that the growing commoditisation of medicine, the endorsement of contested aesthetic norms, the euphemistic framing of outcomes,

\* PhD, Senior Research Associate, Institute of Social Sciences, Belgrade, Serbia, rsovilj@idn.org.rs

\*\* Junior Research Assistant, Institute of Social Sciences, Belgrade, Serbia, avukadinovic@idn.org.rs

and departures from established informed consent procedures undermine fundamental principles of professional responsibility and heighten the risk of legal and ethical accountability.

This paper critically analyses the adequacy of the existing legal frameworks governing medical liability in elective cosmetic interventions, focusing on physicians' duty of care, standards of professional responsibility, and informed consent obligations, and assesses whether these frameworks sufficiently address the distinctive risks posed by elective, expectation-driven interventions. The analysis employs a doctrinal approach, drawing on legislation, case law, and ethical guidelines. This analysis highlights gaps in current liability frameworks and identifies areas where legal and ethical standards may need reform to adequately protect patients and clarify physicians' responsibilities.

**Keywords:** Elective cosmetic surgery, Medical liability, Informed consent, Duty of care, Ethical and professional responsibility

Anđelija Stevanović\*, Sanja Zlatanović\*\*

## MENTAL HEALTH OF MEDICAL PERSONNEL IN ARMED CONFLICTS – INTERNATIONAL HUMANITARIAN AND LABOUR LAW PERSPECTIVE

Medical personnel operating in armed conflicts face severe and multidimensional risks that extend beyond physical danger. Exposure to violence, mass casualties, resource shortages, ethical dilemmas, and prolonged professional stress significantly affect the psychological well-being of healthcare workers. Despite the growing global recognition of mental health as an essential component of public health, the legal protection of the mental health of medical personnel in conflict settings remains insufficiently addressed within the existing international humanitarian and labour law frameworks.

International humanitarian law (IHL) establishes a comprehensive regime aimed at ensuring respect and protection for medical personnel during armed conflicts. The Geneva Conventions, their Additional Protocols, and customary international humanitarian law prohibit attacks against medical personnel and facilities, guarantee the provision of medical care to the wounded and sick, and prohibit punishment of healthcare workers for performing their professional duties. These norms reflect the fundamental humanitarian objective of safeguarding access to medical care during hostilities. However, the primary focus of the IHL protection remains the preservation of the functional role and neutrality of medical services, rather than the working conditions and psychological well-being of medical personnel as individuals and workers.

The authors will examine the extent to which the mental health of medical personnel in armed conflicts is addressed through the combined application of international humanitarian law and international labour law. The study analyses the normative scope of IHL rules concerning the protection of medical personnel and identifies

\* LLM., Research Assistant, Institute of Social Sciences, Belgrade, Serbia & Junior Researcher at Central European Academy, Budapest, Hungary, [astevanovic@idn.org.rs](mailto:astevanovic@idn.org.rs)

\*\* PhD, Senior Research Associate, Institute of Social Sciences, Belgrade, Serbia, [szlatanovic@idn.org.rs](mailto:szlatanovic@idn.org.rs)

their limitations in addressing occupational stress, burnout, moral injury, and long-term psychological consequences resulting from exposure to armed violence. As well as, the problem of the practical challenges of implementation of the existing rules of IHL regarding protection of medical personnel. In parallel, the paper explores relevant international labour standards related to occupational safety and health, including obligations concerning psychosocial risks, safe working environments, and employer responsibilities towards workers operating in high-risk and emergency contexts.

By analysing the interaction between these two legal regimes, the paper argues that the protection of medical personnel in armed conflicts remains fragmented and insufficiently coordinated in practice. While IHL provides essential guarantees of safety and professional independence, labour law offers normative tools capable of addressing working conditions and psychosocial risks, but lacks effective application in conflict environments.

The paper recommends that stronger integration between international humanitarian and labour law is necessary to ensure comprehensive protection of medical personnel. It advocates for enhanced normative coordination, and the development of standards that explicitly address mental health risks faced by healthcare workers in contemporary armed conflicts.

**Keywords:** International humanitarian law, Labour law, Mental health protection, Armed conflict, Medical personnel







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