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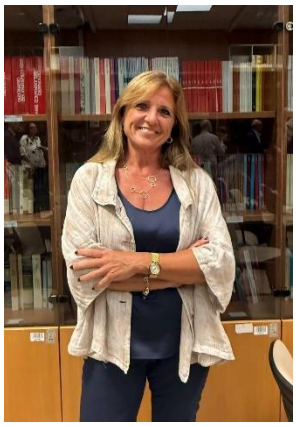
Message from the President



EAHL President
Prof. Dr. Stefania Negri

Dear Members, dear Colleagues,

six months have flown by since the new EAHL Board of Directors picked up the baton from the previous leadership and started working intensely on our common cultural project.

Ever since, our major concern has been to identify areas of possible improvement to support the Association's steady growth and success, and to meet the expectations of our Members, especially the younger ones.

We remain committed to building a strong and vibrant academic community, to value the contribution of every Member and to promote fruitful collaborations within the Association and with external partners. We are also committed to further developing our activities to multiply opportunities for learning, training, research, networking and international collaboration. In this respect, I'm thrilled to announce that we have great ideas and projects in mind for 2026, with the launch of new interest groups, new webinar series, interviews with outstanding "voices from the field", and much more.

Next year we will also celebrate the 10th EAHL Conference, to be held at Uppsala University (Sweden) from 9 to 11 of September (registration is open: https://eahl2026.com/). I look forward to meeting you all there and wish to express my deepest gratitude to our Vice-President, Prof. Santa Slokenberga, and her team for the hard work and dedication that the organisation of such an important event requires.

In the meantime, more than delighted to see that our community is growing, I gladly welcome our new Members and the newly appointed National Contact Points for Croatia and Portugal.

Warmest wishes to you all for a wonderful Christmas and a healthy, joyful and productive New Year!

Salerno, 22 December 2025

Stefania Negri

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Update on Medical and Health Law Developments in Austria

Caroline Voithofer* and Johannes Unterkofler
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I. Social Egg Freezing to Become Legal in 2027

1. Background

Currently, due to § 2b Reproductive Medicine Act (Fortpflanzungsmedizingesetz; RMA) cryopreservation of one's own eggs outside of fertility treatment is only possible for medical reasons (e.g., radiation therapy). This means that the precautionary freezing of healthy oocytes for non-medical, but personal reasons (*social egg freezing*) is explicitly prohibited. Physicians performing such procedures risk administrative penalties pursuant to § 23 RMA.

2. Ruling of the Constitutional Court (VfGH, 6.10.2025, G 52/2024-29)

In its decision of 6.10.2025, the Austrian Constitutional Court ruled that the general ban on social freezing is unconstitutional and repealed it with effect from 31.3.2027. The case originated from an individual application by a healthy woman wishing to preserve her oocytes for personal reasons. She argued that the prohibition violated her right to private and family life under Article 8 of the European Convention on Human Rights (ECHR).

The Court found that the prohibition was an interference with the right to reproductive self-determination protected by Article 8 ECHR and examined whether this interference could be justified under Article 8 (2) ECHR. It held that none of the legitimate aims listed therein – such as the protection of health, morals, or the rights of others – could justify the total ban. The Court criticized the inconsistency of the RMA, as women may donate their oocytes to third parties until the age of 30 (§ 2b (2) RMA) and use donated oocytes until the age of 45 (§ 3 (3) RMA). It was therefore incoherent and arbitrary to be allowed to donate oocytes to others but not to be allowed to preserve them for oneself.

3. Legal Consequences and Assessment

The Austrian legislator must take action to create a consistent regulation. It can be expected that social egg freezing will be permitted, as a draft to this effect was already discussed several years ago in a working group at the Ministry of Justice. There's also a case pending before the Constitutional Court that calls for access to reproductive medicine for single women. Both cases will trigger an amendment of the RMA.

II. Connecting Austria to the EU-eHealth service infrastructure (eHDSI)

The latest amendment to the Health Telematics Act 2012 and the General Social Security Act (Felder Law Gazette 71/2025) establishes the connection to the eHealth service infrastructure. This implements the social security provisions relating to the “EU prescription” and the EU patient summary. The aim of these provisions is − in addition to aspects of continuity of treatment and patient safety − the forgery-proofing of EU prescriptions issued in Austria and the reduction of bureaucratic hurdles, which also facilitates the process of reimbursement for prescriptions redeemed abroad (translations of trade names, confirmation of dispensing, etc). The translation service within the “MyHealth@EU” system is also to be made more accessible.

Date of submission: 20 November 2025

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Current Developments in Healthcare – News from Azerbaijan

PhD Lala Jafarova

EAHL NCP for Azerbaijan

Mandatory health insurance, which was introduced gradually, is now fully implemented and covers all regions of the country. To improve the system, it is constantly being updated. Below are some recent updates:

– In October 2025, new rules regulating drug provision and reimbursement mechanisms were approved. The new rules establish the regulatory framework for providing citizens with affordable medications for outpatient use (at home) funded by mandatory health insurance. These rules define the mechanisms for reimbursement of drug costs and the criteria for their inclusion and exclusion from the Service Package. These criteria include drug registration in the state registry, confirmed quality, safety, and efficacy, regulated pricing, and compliance with the financial capabilities of the mandatory health insurance fund. Preparatory work is currently underway to implement a reimbursement mechanism for medications prescribed in outpatient settings under the mandatory health insurance system. Specifically, electronic prescriptions are being integrated with the mandatory health insurance database, mechanisms for interaction with pharmacies are being created. Medications will be prescribed electronically. Patients will be able to obtain medications prescribed electronically at private pharmacies that have signed an agreement with the State Agency on Mandatory Health Insurance.

– Mandatory health insurance will cover outpatient medications for cardiovascular diseases starting in 2026, gastrointestinal diseases starting in 2028, and respiratory diseases starting in 2029. A plan is also being developed to include oncology treatment for children and adolescents in the package of services, starting in 2027.

– Starting in 2026, a new financing mechanism for the mandatory health insurance system will be introduced. According to the proposed amendments to the law, individuals who are able to work but do not have an official income will pay a mandatory health insurance premium of 4 percent of the minimum wage each month - 16 manats (about 8 EUR as of 09.12.2025). The following gropus will be exempt from payment: persons with disabilities, pensioners and children as well as internally displaced persons, students, military personnel and pregnant women. In addition, insurance for housewives and women without personal income will still be provided at the expense of state funds. Mechanisms have been established for individuals of working age but without income to apply for social assistance. The introduction of the payment mechanism is aimed at identifying individuals who are informally employed.

– Another important change will be the introduction, starting in 2026, of an additional fee for patients who seek direct access to specialists, bypassing the primary care stage. Amount of the fee has not been introduced yet.

Date of submission: 09 December 2025

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The New Law on the Protection of Personal Data in Bosnia and Herzegovina: Implications for the Healthcare System

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1. Introduction

Bosnia and Herzegovina adopted its new Law on Personal Data Protection on January 30, 2025, marking a transformative moment in the country's approach to privacy rights and data governance. Published in Official Gazette No. 12/2025, the law entered into force on March 8, 2025, and the full application began after a 210-day transitional period in October 2025. This legislative development represents more than a mere technical update, it constitutes a fundamental realignment of Bosnia and Herzegovina's legal framework with European Union standards, particularly the General Data Protection Regulation (EU) 2016/679 and the Law Enforcement Directive (EU) 2016/680.

For the healthcare sector, this new law introduces sweeping changes that will reshape how medical institutions collect, process, store, and share patient health information. Understanding these changes is essential for healthcare providers, as the stakes involve not only legal compliance but also patient trust, institutional reputation, and the fundamental right to privacy in one of the most sensitive domains of personal information.

2. Historical Context and Legislative Evolution

To appreciate the significance of the new law, it is necessary to understand the inadequacies of its predecessor. The previous Law on Protection of Personal Data (Official Gazette of BiH, Nos. 49/06, 76/11, 89/11) came into force in 2006, with subsequent amendments in 2011. While this legislation represented an important first step toward establishing a data protection framework, it suffered from significant deficiencies that became increasingly apparent as digital technologies advanced and European standards evolved.

The 2006 law contained major gaps in areas such as data transfer mechanisms, legal grounds for processing, and video surveillance regulation. More fundamentally, it failed to reflect the comprehensive approach embodied in the GDPR, which has become the global benchmark for data protection. In 2018, authorities initiated the procedure for adopting a GDPR-compliant law, but political complexities in Bosnia and Herzegovina delayed the process for several years.

The healthcare sector operated under this outdated framework, which provided limited guidance on handling sensitive health data in an increasingly digitalized environment. Medical records were transitioning from paper to electronic systems, telemedicine was emerging, and cross-border healthcare collaboration was expanding,

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yet the legal framework remained anchored in pre-digital conceptions of data protection. The new law addresses these shortcomings comprehensively.

3. Health Data as Sensitive Personal Data

The new law introduces stricter requirements for processing special categories of data, explicitly including health information, biometric identifiers, and genetic data. This classification recognizes that health data carries unique risks—its disclosure can lead to discrimination, stigmatization, social exclusion, and psychological harm. A patient's HIV status, mental health history, or genetic predisposition to certain conditions are not merely factual data points but information deeply connected to human dignity and social standing.

The law's approach to health data reflects the GDPR's recognition that such information requires enhanced protection. As a general rule, processing of health data is prohibited unless specific conditions are met. For healthcare institutions, understanding these conditions is essential because nearly all their activities involve processing this sensitive category of personal data.

4. Appointment of Data Protection Officers

Controllers and processors are obliged to appoint a Data Protection Officer in three circumstances: where processing is carried out by a public authority (except courts), where core activities consist of processing operations requiring regular and systematic monitoring of data subjects on a large scale, or where core activities consist of extensive processing of special categories of data.

For healthcare institutions, this requirement is particularly relevant. Public hospitals and health centers clearly fall within the first category as public authorities. Private hospitals and clinics will likely fall within the third category, as their core activities inherently involve extensive processing of health data. The term "extensive" should be understood not merely in terms of volume but also in terms of the proportion of patients affected and the potential impact on them.

The Data Protection Officer serves as the nexus between the healthcare institution, the supervisory authority, and data subjects. Their responsibilities include informing and advising the institution about its data protection obligations, monitoring compliance with the law, providing guidance on Data Protection Impact Assessments, cooperating with the supervisory authority, and serving as the contact point for the authority and for data subjects on issues related to processing.

Importantly, the law permits outsourcing of the DPO role to external professionals, which may be particularly valuable for smaller healthcare institutions that lack internal expertise in data protection law. However,

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whether internal or external, the DPO must possess expert knowledge of data protection law and practices, and must be able to fulfill their tasks with independence, free from instructions regarding the exercise of their functions.

5. Enhanced Security Measures

Healthcare providers must implement enhanced security measures such as encryption, strict access controls, and secure authentication methods. The law requires both technical and organizational measures appropriate to the risk, considering the state of the art, implementation costs, and the nature, scope, context, and purposes of processing, as well as the risks to individuals' rights and freedoms.

For healthcare institutions, this translates into concrete obligations. Medical records must be encrypted both in transit and at rest. Access controls must ensure that healthcare professionals can access only the patient information necessary for their specific role—a receptionist should not have access to detailed medical histories, while a treating physician should not be able to view records of patients not under their care. Authentication systems must be robust, often requiring multi-factor authentication for access to sensitive systems.

Physical security remains equally important. Paper records must be stored securely, computer terminals in patient areas must lock automatically when unattended, and policies must govern the disposal of documents containing patient information. Staff training constitutes an essential organizational measure, ensuring that healthcare workers understand their responsibilities and the procedures for handling patient data securely.

6. Data Breach Notification

The new law establishes mandatory data breach notification requirements that were absent from the previous framework. Healthcare institutions must notify the Personal Data Protection Agency of data breaches without undue delay and, where feasible, no later than 72 hours after becoming aware of the breach, unless the breach is unlikely to result in a risk to individuals' rights and freedoms.

When the breach does pose a high risk to individuals, the institution must also notify affected data subjects without undue delay, unless certain conditions are met. For healthcare providers, this creates significant challenges. A breach exposing patient medical records clearly poses high risks—patients may face discrimination, psychological distress, or other harms. The institution must therefore notify not only the supervisory authority but also potentially thousands of patients, explaining the nature of the breach, its likely consequences, and the measures taken to address it.

This requirement demands that healthcare institutions establish breach detection and response protocols before

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incidents occur. They must be able to quickly identify breaches, assess their scope and risk, contain the breach, investigate its cause, and execute notification obligations within tight timeframes. Preparation and documentation of these procedures is essential.

7. Enforcement and Sanctions

The Personal Data Protection Agency of Bosnia and Herzegovina serves as the independent supervisory authority responsible for monitoring and enforcing compliance. The new law equips the Agency with real enforcement power, including authority to conduct investigations, order blocking or erasure of data, impose temporary or permanent processing bans, issue warnings and reprimands, and impose administrative fines.

Administrative fines for non-compliance can reach up to 4% of an organization's annual global turnover or €20 million, whichever is higher. This penalty structure mirrors the GDPR and represents a dramatic increase from the modest fines possible under the previous law. For healthcare institutions, the financial exposure is substantial—a major hospital system facing a 4% of turnover fine could encounter penalties reaching into millions of euros.

8. Conclusion

The adoption of the new Law on Personal Data Protection marks a decisive step in Bosnia and Herzegovina's integration into the European data protection framework. For the healthcare sector, this law represents both a challenge and an opportunity. The challenge lies in the substantial operational, technical, and financial resources required for compliance. The opportunity lies in the potential to strengthen patient trust, improve data governance, and align practices with international standards.

Healthcare institutions that view compliance merely as a regulatory burden to be minimized will likely struggle and may face enforcement action. Those that embrace the law's principles and invest in robust data protection programs will not only achieve compliance but will also enhance the quality and security of their operations. Patient trust, which is fundamental to effective healthcare, depends significantly on confidence that personal health information will be handled with appropriate care and respect.

The law recognizes that health data occupies a special position among personal data categories. Its processing is essential for healthcare delivery, medical research, and public health protection, yet it also carries unique risks and sensitivities. The legal framework seeks to enable these beneficial uses while ensuring that processing occurs under strict safeguards, with appropriate oversight, and with respect for individual rights.

Date of submission: 12 December 2025

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Healthcare System in Croatia – Regulatory Overview

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EAHL NCP for Croatia

The healthcare system of the Republic of Croatia is normatively grounded in the principles of solidarity and equality, while the right to healthcare is constitutionally enshrined. Accordingly, the state bears a positive obligation to ensure the availability and accessibility of healthcare services to all citizens, regardless of their socioeconomic circumstances. The healthcare system is regulated through an extensive legislative framework, the core of which consists of the Health Care Act,[1] the Mandatory Health Insurance Act,[2] and the Patients' Rights Protection Act.[3] In light of the constitutional framework defining Croatia as a social state, the healthcare system aspires to the realization of the principles of comprehensiveness (the inclusion of the entire population in the effective and lawful implementation of healthcare measures), continuity (the provision of healthcare throughout all stages of an individual's life), and accessibility (the establishment of a broad network of healthcare institutions in order to ensure simple and effective access to all necessary healthcare services for every member of society). However, notwithstanding these constitutional guarantees and normative foundations, persistent structural and systemic challenges remain evident in practice, particularly in relation to access to healthcare, sustainable financing, and inequalities between the public and private healthcare sectors.[4] Furthermore, the system is confronted with a profound crisis of governance and systemic corruption of unprecedented magnitude, raising serious concerns regarding institutional accountability and the effective functioning of the rule of law.

Croatia has a mandatory social health insurance system which consolidates public financing under a single entity, the **Croatian Health Insurance Fund** (CHIF). The CHIF is the single purchaser of health services provided under the mandatory health insurance scheme. It also offers complementary voluntary insurance that covers co-payments required in the social health insurance system.[5] Every citizen of the Republic of Croatia should have regulated mandatory health insurance status as regulated by the **Mandatory health insurance Act**.[6] Rights under the mandatory health insurance in Croatia include the right to financial compensation and the right to health care services (right to primary health care, specialist-consultative health care, hospital health

[1] Official Gazette, no. 100/18, 125/19, 147/20, 119/22, 156/22, 33/23, 36/24 and 102/25. Available at: https://www.zakon.hr/z/190/zakon-o-zdravstvenoj-zastiti.
[2] Official Gazette, no. 80/13, 137/13, 98/19, 33/23 and 105/25. Available at: https://www.zakon.hr/z/192/zakon-o-obveznom-zdravstvenom-osiguranju.
[3] Official Gazette, no. 169/04, 37/08. Available at: https://www.zakon.hr/z/255/zakon-o-zastiti-prava-pacijenata.
[4] Horvat Sovilj, P. *Naglasci javnog menadžmenta u zdravstvenom sustavu Republike Hrvatske* [Key aspects of public management in the healthcare system of the Republic of Croatia], 2024. Master's thesis. University of Zagreb, Faculty of Law.
[5] Džakula A, Vočanec D, Banadinović M, Vajagić M, Lončarek K, Lukačević Lovrenčić I, Radin D, Rechel B. *Croatia: Health System Summary*, 2024. Copenhagen: European Observatory on Health Systems and Policies, WHO Regional Office for Europe; 2024. Licence: CC BY-NC-SA 3.0 IGO.
[6] Health insurance and healthcare for aliens is governed by a special act - Mandatory Health Insurance and Health Care of Aliens in the Republic of Croatia Act. Official Gazette No. 80/13., 15/18, 26/21 and 46/22. Available at: https://www.zakon.hr/z/634/zakon-o-obveznom-zdravstvenom-osiguranju-i-zdravstvenoj-zastiti-stranaca-u-republici-hrvatskoj-.

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care, medications/dental and orthopaedic prostheses determined by the basic and supplementary medicine/prostheses list of the CHIF, and the right to cross-border health care). The insurance also provides for the rights on the basis of accidents suffered at work and occupational diseases. The insured persons are obliged to participate in the costs of health care for services that are not entirely covered by CHIF. To cover the participation costs, a person is entitled to enter into an agreement with the CHIF on complementary health insurance. Croatian Health Insurance Fund is divided into the Directorate of the CHIF and 20 branch offices with The Ministry of Health of the Republic of Croatia performing supervision over the lawfulness of the CHIF.[1]

Healthcare activity is carried out on the primary, secondary and tertiary level, as well as on the level of the healthcare institutes. Healthcare at the *primary level* is provided through general/family medicine, health care of preschool children, health care of women, field nursing care, the in-house health care treatment, dental health care, sanitary-epidemiological health care service, laboratory diagnostics, pharmacy and emergency medical assistance. Healthcare activity at the *secondary level* consists of specialist-consultative and hospital health care, while at the *tertiary level* it consists of performing the most complex forms of specialist-consultative and hospital healthcare activities. Most healthcare providers (especially of secondary and tertiary care) are publicly owned. However, the number of private providers has grown, especially in primary care, dental services and specialized clinics. The majority of primary care practices have been privatized, but most are contracted by the CHIF to provide publicly paid services, which are their main source of income. The primary care practices remaining in public ownership operate as primary health care centres.[2]

The Ministry of Health has a central role in health system governance. It is responsible for developing national health policies, planning and evaluation, national public health programmes, and the regulation of capital investments for publicly owned healthcare providers and of quality standards for public and private health care providers. It is also responsible for the provision of tertiary care, which includes university hospitals and university hospital centres. Counties are responsible for the organization and management of regional health services (specialized hospitals) and primary care (health centres, public health institutes and public pharmacies). The ownership of general hospitals was transferred from the counties to central government in January 2024.[3]

The Ministry of Health of the Republic of Croatia is confronted with a long-standing and structurally conditioned deficit of public trust, stemming from chronic weaknesses in organizational design, governance capacity, and the exercise of regulatory functions within the healthcare system. Although normatively positioned as the central authority responsible for the formulation and oversight of health policy, the Ministry demonstrates in practice a limited capacity to effectively implement supervisory and corrective mechanisms.

[1] Health insurance in the Republic of Croatia | HZZO.
[2] Džakula A et al., *Croatia: Health System Summary*, op.cit.
[3] Ibid.

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At the same time, healthcare institutions enjoy a high degree of institutional autonomy that is not adequately balanced by corresponding mechanisms of accountability and external control. The system is further burdened by recurrent instances of irregularities and high-level corruption scandals,[1] including the illustrative case of a former Minister of Health who was subject to proceedings by the European Public Prosecutor's Office (EPPO)[2] and the Croatian Office for the Suppression of Corruption and Organized Crime (USKOK),[3] and who, notwithstanding ongoing criminal proceedings and prior deprivation of liberty, subsequently resumed employment in the very healthcare institution from which the alleged unlawful conduct originated. Such cases vividly illustrate the institutional deficits in oversight, sanctioning, and the safeguarding of the rule of law, while further undermining the legitimacy of the regulatory framework governing the Croatian healthcare system.

Health reform proposals usually originate at the Ministry of Health. After consultation with stakeholders or online public consultations, reform proposals are sent to the Government for further development. For the period 2020-2030, the National Development Strategy up to 2030 was developed at central government level, and adopted in February 2021. The strategy is the umbrella document determining the context, vision, direction and priorities for the implementation of all public policies in Croatia in this period. Aligned with this strategy, the **National Health Care Development Plan for 2021-2027** was adopted in December 2021. This plan was developed by the Ministry of Health as a medium-term planning tool that contains broad tasks and goals for the health sector, sets out priority areas and identifies the health needs of the population.[4]

The most significant regulatory intervention this year has been undertaken through the adoption of the **Amendments to the Health Care Act** (Official Gazette no. 102/25). The legislative amendments tighten the criminal law requirements for employment in the healthcare sector, stipulating that healthcare professionals who directly provide care or participate in diagnostic and therapeutic procedures must not be subject to criminal proceedings nor have been convicted of criminal offenses against sexual freedom or the abuse and exploitation of children. Simultaneously, the amendments abolish the obligation to complete an internship and pass a professional examination for certain occupations, allow for the recognition of internships completed abroad and liberalize and simplify the regulatory requirements within the healthcare system.[5] The adoption of these amendments emphasized the continued implementation of market liberalization under the National Recovery and Resilience Plan 2021–2026. The aim is to simplify or eliminate additional regulatory requirements, recognizing that healthcare graduates for specific professions (midwives, physiotherapy assistants, medical laboratory technicians, sanitary engineers and technicians, radiology graduates, dental

[1] E.g. https://uskok.hr/hr/priopcenja/pokrenuta-istraga-protiv-osmero-okrivljenika-i-osam-pravnih-osoba-zbog-sumnje-na.
[2] https://www.eppo.europa.eu/en/media/news/croatia-eppo-starts-investigation-against-minister-health-and-seven-others-over-medical.
[3] https://uskok.hr/hr/priopcenja/pokrenuta-istraga-protiv-trojice-okrivljenika-medu-kojima-je-i-bivsi-ministar-zdravstva.
[4] Džakula A et al., *Croatia: Health System Summary*, op.cit.
[5] https://zdravstvo.gov.hr/pristup-informacijama/savjetovanje-s-javnoscu/otvorena-savjetovanja/nacrt-prijedloga-zakona-o-izmjenama-i-dopunama-zakona-o-zdravstvenoj-zastiti-s-nacrtom-konacnog-prijedloga-zakona/6907.

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technicians pharmaceutical technicians, etc.) acquire the necessary learning outcomes and competencies upon completing their education. The **Third Action Plan for the Liberalization of Service Markets** further foresees the abolition of mandatory internships and professional examinations for healthcare professions,[1] a development that raises certain concerns, the practical impact of which remains to be seen.

Date of submission: 10 December 2025

[1] Ibid.

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Current Issues in the Field of Health Law in Denmark

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Introduction

As mentioned in my last update, in Denmark national focus has been and still is on reforms in psychiatric treatment. This has resulted in a political agreement allocating billions of DKK to psychiatric treatment: https://www.ism.dk/nyheder/2025/december/ny-aftale-sender-milliardbeloeb-til-psykiatrien. This has not yet resulted in legislation, but psychiatric treatment has nonetheless been on the agenda.

News

An easier way towards treatment for children and adolescents suffering from failure to thrive

As of 1 June 2025, new rules about free diagnosing and treatment of children and adolescents, who are not thriving due to their mental state or who are showing symptoms of a psychiatric disorder[1], entered into force. Diagnosing of psychiatric illness in Denmark normally takes place in the regional hospitals' psychiatric wards after a referral from the general practitioner, but very long waiting lists have made this option less appealing for those parents who do not think that their children receive treated fast enough[2]. With the new rules, the local authority ("kommune") must provide a public offer for those in need, and the treatment must be offered in connection with other types of relevant help – for instance if the child has problems attending school due to his/her mental challenges. The new offer does not solve the problem for those in need of more comprehensive psychiatric treatment, but it will hopefully help those suffering to a lessor degree while also shortening the waiting lists in the hospital system.

Physical restraint of patients undergoing psychiatric treatment

Last week, the Danish government settled a case with the mother of a psychiatric patient who had been restrained with a belt and died shortly after leaving the hospital. Unfortunately, Denmark has a very concerning history regarding fixation during psychiatric treatment and has several pending cases before the European Court of Human Rights. Denmark has also been convicted of breaching article 3 in that regard (see for instance Aggerholm v. Denmark[3]). Though this is known by the Danish parliament, very little has been done to prevent the use of force in psychiatric treatment, and it is not a focal point of the new agreement mentioned above.

Date of submission: 08 December 2025

[1] Section 126 a of the Danish Health Act.
[2] It has always been, and still is, possible to pay a psychiatrist, who is not part of the public system, to make the assessment, but the diagnoses made by these medical professionals do not carry the same weight as those made in the public system, and the public system is not obliged to treat according to the diagnoses.
[3] Application number 45439/18.

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EAHL Country Report: Ireland

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EAHL NCP for Ireland

Assisted Human Reproduction

The Health (Assisted Human Reproduction) Act 2024 was signed into law on 2nd July 2024, however this legislation has not fully commenced. On 13th October 2025, the Minister for Health signed the Health (Assisted Human Reproduction) Act 2024 (Commencement) Order 2025 to bring into operation Part 1 (other than section 6);[1] Part 9 (other than section 124 and section 151),[2] and Schedule 1.[3] The remaining sections of the Health (Assisted Human Reproduction) Act 2024 have not yet commenced.

As a result of the commencement of Part 9, the Assisted Human Reproduction Regulatory Authority (AHRRA) has now been established.[4] The relevant powers and functions of the AHRRA are contained in Part 9. The primary function of the AHRRA is:

> "…to protect, promote and, in so far as is practicable, ensure the health and wellbeing of – (a) children born, or to be born, as a result of AHR treatment, (b) persons undergoing, or about to undergo, AHR treatment, and (c) intending parents."[5]

Additional functions of the newly established AHRRA include the power to issue licences;[6] the ability to amend, revoke or suspend licences;[7] to promote and monitor compliance by licence holders with the legislation;[8] to set up and maintain a Database;[9] to collect and publish statistical information on assisted human reproduction (including details of the number of relevant embryo or gamete donations made in the State; details of the relevant assisted human reproduction (AHR) activities undertaken or provided by licence holders; information on the number and types of assisted human reproduction treatments provided by relevant AHR treatment providers, as well as details of the outcome of these AHR treatments).[10]

The AHRRA's powers include the preparation and publication of codes of practice for guidance for licence holders, detailing the relevant standards as well as providing information on the ethical standards applicable to the provision or undertaking of AHR activities.[11]

The remit of the AHRRA's functions include an obligation to set up and maintain the National Surrogacy Register.[12] The AHRRA has the statutory power to provide approval for surrogacy agreements in accordance

[1] Part 1 of the Act contains the preliminary and general information including the short title, collective citation, commencement; details of interpretation of terms and references to other legislation; ministerial power to issue regulations. Section 6, which is not yet commenced, enables the Minister to undertake a review of the operation of this Act after 3 years.
[2] Section 124, which is not yet commenced, makes provision for the creation of a voluntary register of relevant donors and donor-conceived persons. Section 151 (also not yet commenced) sets out the power of the Assisted Human Reproduction Regulatory Authority to specify the form of documents required for the purposes of this Act as it deems necessary.
[3] Schedule 1 sets out details pertaining to a 'Fit and Proper Person' for the purposes of determining if the applicant for a licence to provide AHR treatments, or in the case of an existing licence holder to continue providing AHR services, is suitable.
[4] Section 122, Health (Assisted Human Reproduction) Act 2024. The first Chairperson, Professor Deirdre Madden and seven Board members have also been formally appointed. https://www.gov.ie/en/department-of-health/press-releases/minister-for-health-establishes-assisted-human-reproduction-regulatory-authority/
[5] Section 123(1), Health (Assisted Human Reproduction) Act 2024.
[6] Section 123(2)(a)
[7] Section 123(2)(b)
[8] Section 123(2)(c)
[9] Section 123(2)(d)
[10] Section 123(2)(e)(i)-(iii)
[11] Section 123(2)(f)-(g)
[12] Section 123(2)(j)

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with section 53 or section 90.[1] The AHRRA may approve a surrogacy agreement where it determines that the surrogacy which is the subject of the agreement is a permitted surrogacy arrangement.[2]

The AHRRA has responsibility for reviewing applications seeking permission to extend the storage period of gametes, embryos and tissues in accordance with sections 40, 41 or 42.[3]

The scope of the AHRRA's responsibilities include setting up and maintaining a Register of Genetic Diseases for the purposes of both pre-implantation genetic testing (PGT) and sex selection (as defined by section 44).[4] The AHRRA has the power to make determinations in respect of applications submitted for HLA matching (which is defined in section 44 as " an AHR treatment using PGT to test and select an embryo for implantation in the womb of a woman for the purpose of matching the tissue of a child who is born as a result of the treatment with the tissue of an existing child who has a life limiting condition").[5]

Anti-microbial resistance plan

Ireland's third One Health National Action Plan on Antimicrobial Resistance 2026-2030 (iNAP3) was published by the Department of Health (DOH) and Department of Agriculture, Food, and the Marine (DAFM) in November 2025.[6]

Date of submission: 10 November 2025

[1] Section 123(2)(i). Sections 53 and 90 are not yet commenced.
[2] Section 53(4)(a) (not yet commenced)
[3] Section 123(2)(k). Sections 40-42 regulating the disposal of gametes, embryos and tissues are not yet commenced.
[4] Section 123(2)(m). Section 44 is not yet commenced.
[5] Section 123(2)(l). Section 44 is not yet commenced.
[6] Government of Ireland (2025). Ireland's Third One Health National Action Plan on Antimicrobial Resistance 2026 – 2030 (known as iNAP3). Available at https://www.gov.ie/en/publication/d72f1-joint-action-on-antimicrobial-resistance/

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Country Report: Italy

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According to the GIMBE Report on the National Health Service, presented in Rome on October 8, 2025, the National Health Service is close to a point of no return[1].

The Report paints a picture of an increasingly fragile, undersized National Health Service that is unable to guarantee universal and equitable access to care.

The main criticalities that emerge from the GIMBE report concern public funding, access to care, healthcare personnel, delays in spending related to the implementation of the resilience and recovery plan, financed by Next Generation EU, and healthcare spending.

Proceeding in an orderly fashion, it should first be noted that over the last three years, the National Health Fund has grown nominally, but inflation has eroded most of its resources: over €13 billion lost in real terms.

Public healthcare spending is falling in relation to GDP, widening the gap with the European average.

Secondly, it should be noted that in 2023, 5.8 million Italians gave up healthcare services, often for economic reasons. Regional inequalities are also increasing: from north to south, access to services is increasingly patchy, with healthcare migration on the rise.

Thirdly, doctors and nurses continue to leave the National Health Service. There is a shortage of professionals, especially in local services: family doctors, pediatricians, community nurses. The shortage of staff reduces supply and fuels waiting lists.

Fourthly, investment in health is lagging behind. Many objectives have been scaled back: fewer community homes, fewer community hospitals, fewer local operations centers. There is a real risk of missing a great opportunity to modernize local healthcare.

Fifthly, out-of-pocket expenditure is increasing. More and more citizens are turning to the private sector, often to circumvent waiting lists or due to the unavailability of public services. This trend calls into question the principle of universality: healthcare risks becoming a privilege.

The response to these critical issues is multifaceted and multi-level. In addition to the political dimension, which requires continuity in healthcare policies and stable investment, there is also the social dimension, which requires greater awareness among citizens of the value of the National Health Service. Finally, there is a professional dimension that requires overcoming particularism in healthcare categories.

[1] The GIMBE Foundation is a non-profit organization that aims to promote the dissemination and application of the best scientific evidence through independent research, training, and information activities. Since 1996, it shares its know-how to improve the delivery of healthcare services in Italy. The report is accessible online at https://www.salviamo-ssn.it/attivita/rapporto/8-rapporto-gimbe.it-IT.html.

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This is a challenge that is as difficult as it is important, but it is imperative to take action to manage endless waiting times, contain rising costs, and reduce disparities between regions.

Date of submission: 19 November 2025

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Current Legal Issues in the Field of Health Law in the Republic of Latvia

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1. The Current Issue of Using Internal Market Information System Data in the Certification and Recertification of Healthcare Professionals in the Republic of Latvia

In the Republic of Latvia, discussions have intensified regarding the legal framework governing the use of data from the Internal Market Information System (IMI) and its relevance to the certification and recertification of healthcare professionals.

In accordance with the data of the World Health Organization, the number of foreign-trained healthcare professionals in the European Union (EU) has increased significantly. This trend creates important opportunities but also substantial challenges – particularly in terms of how to maintain high healthcare standards and protect patients' rights, while at the same time ensuring effective information exchange on professional responsibility.

IMI is a secure, multilingual online tool that facilitates the exchange of information between public authorities involved in the practical implementation of EU law. It enables them to fulfil cross-border administrative obligations in multiple single market policy areas. Launched in 2008 to implement the Services Directive, IMI currently supports 102 administrative cooperation procedures in 21 different policy areas. The modernisation of cross-border cooperation at national, regional, and local levels by IMI has improved cooperation between public authorities, benefiting both the public and businesses alike.[1]

In the Republic of Latvia, the regulation of the IMI is governed by Cabinet Regulation No. 419 of 28 June 2016 *"Procedures for the Exchange and Supervision of Information within the Internal Market Information System, the Responsibilities of the Institutions Involved in Information Exchange, and the Procedures for Issuing the European Professional Card."*[2] The certification procedures for healthcare professionals in the Republic of Latvia are regulated by Cabinet Regulation No. 391 of 18 June 2024 *"Procedures for the Certification of Healthcare Professionals."*[3]

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[1] The European Commission. About IMI. Available: https://ec.europa.eu/internal_market/imi-net/about/index_en.htm [Viewed: 06.12.2025.].
[2] Cabinet Regulation No. 419 of 28 June 2016 "*Procedures for the Exchange and Supervision of Information within the Internal Market Information System, the Responsibilities of the Institutions Involved in Information Exchange, and the Procedures for Issuing the European Professional Card*". Available: https://likumi.lv/ta/id/283507-noteikumi-par-informacijas-apmainas-un-uzraudzibas-kartibu-iekseja-tirgus-informacijas-sistemas-ietvaros-informacijas-apmaina [Viewed: 06.12.2025.].
[3] Cabinet Regulation No. 391 of 18 June 2024 "*Procedures for the Certification of Healthcare Professionals*". Available: https://likumi.lv/ta/id/352922-arstniecibas-personu-sertifikacijas-kartiba [Viewed: 06.12.2025.].

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However, under the current regulatory framework in the Republic of Latvia, it is not fully possible to achieve the intended objectives of IMI. National legal acts require the evaluation of IMI information but do not specify how such information should be processed further, or whether it may serve as grounds for refusing certification or recertification. National legal acts also do not impose a clear obligation on certification institutions or certification commissions in the Republic of Latvia to analyse IMI system data when deciding on a specialist's certification or recertification. As a result, information exchanged through IMI does not automatically lead to legal consequences, even when another Member State has imposed restrictions on a healthcare professional's right to practise. It must also be acknowledged that the use of the IMI system varies among EU Member States, which further contributes to differing practices and outcomes.

The issue gained wider public attention in the Republic of Latvia following a 2025 media investigation, in which journalists reported that two physicians prohibited from practising by the Finnish Medical Supervisory Authority "*Valvira"*, were nonetheless able to continue working in the Republic of Latvia. The investigation also indicated that "*Valvira's*" notification had been submitted through the IMI system, but no action was taken based on the information. This situation highlights the need to strengthen the procedures for using IMI data to ensure patient safety and support professional accountability.

In response to these developments, and following the renewed public attention brought by media reporting, the Ministry of Health of the Republic of Latvia has initiated discussions on improving the legal framework governing the use of IMI data and strengthening its role in the certification and recertification process in the Republic of Latvia.

See here for more information: https://www.vm.gov.lv/lv/jaunums/parruna-arstu-resertifikacijas-jautajumus

2. A Recent and Significant Judgment of 24th October 2025 by the Constitutional Court of the Republic of Latvia in the Case Concerning Restrictions on Flavourings, Additives, and Nicotine Concentration in E-Cigarettes and Nicotine Pouches

The case concerning restrictions on flavourings, additives, and nicotine concentration in e-cigarettes and nicotine pouches arose after two corporations contested provisions in the national legal acts restricting the addition of flavourings and certain additives to electronic smoking devices and nicotine pouches, as well as limits on nicotine concentration. The applicants contended that these restrictions disproportionately infringed their property rights protected under the Constitution of the Republic of Latvia.

The Constitutional Court of the Republic of Latvia held that nicotine is highly addictive and poses significant health risks, particularly for children and young people, and that e-cigarette use among minors in

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Latvia has risen sharply in recent years. The Constitutional Court of the Republic of Latvia emphasised that the regulations aim to protect public health and reduce the appeal of nicotine products.

The Constitutional Court of the Republic of Latvia decided to uphold the contested provisions, finding that, while they restrict commercial activity, these measures are justified to protect society – especially children and young people – from nicotine addiction and associated health risks. The judgment of the Constitutional Court of the Republic of Latvia confirmed that the relevant provisions of the Law on the Circulation of Tobacco Products, Tobacco Substitutes, Plant-Based Smoking Products, Electronic Smoking Devices and Their Liquids are consistent with the Constitution of the Republic of Latvia.

See here for more information: https://www.satv.tiesa.gov.lv/press-release/satversmei-atbilst-ierobezojumi-elektroniskajam-cigaretem-un-nikotina-spilventiniem-pievienot-aromatizetajus-un-piedevas-ka-ari-noteikt-nikotina-koncentracijas-daudzumu/

3. A Case Initiated in the Constitutional Court of the Republic of Latvia on the Limitation Period for Patient Compensation Claims

On 2nd December 2025, a case was initiated in the Constitutional Court of the Republic of Latvia concerning the compliance of the first sentence of Paragraph 5 of Article 16 of the Law on the Rights of Patients with the third sentence of Article 92 of the Constitution of the Republic of Latvia.

The contested provision stipulates that a patient shall request compensation for the harm caused to his or her life or health and compensation for medical expenses from the Medical Treatment Risk Fund *not later than within two years from the date when the harm has been detected*, but *not later than within three years from the date when it was caused*.

The case was initiated following an application submitted to the Constitutional Court by the District Administrative Court of the Republic of Latvia. The applicant's case involves a complaint. The complainant had submitted a request to the Health Inspectorate of the Republic of Latvia for compensation from the Medical Treatment Risk Fund. The Health Inspectorate refused to consider the request on the grounds that the claim had not been made within the time limits specified in the contested provision. Disagreeing with this decision, the complainant challenged it before the Ministry of Health of the Republic of Latvia. The Ministry of Health upheld the decision of the Health Inspectorate.

The applicant argues that, due to the contested provision, the individual concerned has no right to claim compensation. In adopting the contested provision, the legislator emphasised the need to periodically review the functioning of the regulation on compensation for harm caused to a patient's life or health, including the guarantees provided and the time limits established in the contested provision. According to the applicant, economic conditions and state financial capacities have changed, and therefore the limitation established in the contested provision no longer corresponds to social realities and is disproportionate. Accordingly, the contested provision does not comply with the third sentence of Article 92 of the Constitution of the Republic

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of Latvia, which states that everyone, where his or her rights are violated without basis, has a right to commensurate compensation.

See here for more information: https://www.satv.tiesa.gov.lv/press-release/ierosinata-lieta-par-pacienta-dzivibai-vai-veselibai-nodarita-kaitejuma-atlidzibas-prasijuma-terminu/

Date of submission: 09 December 2025

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Lithuania: Key Health Law Highlights

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Below is an overview of the key legal and policy initiatives shaping health governance in Lithuania.

- The Seimas has approved legislative amendments that abolish additional co-payments for publicly funded health-care services, aiming to strengthen equal access to essential care. The reform removes the practice whereby patients paid extra to receive services sooner or from selected specialists, a mechanism critics argued created inequalities and blurred the boundary between public and private provision. Under the revised framework, health-care institutions are prohibited from charging such supplementary fees, and the Ministry of Health will clarify exceptions related only to non-essential or fully private services. According to the Ministry, eliminating co-payments is intended to reinforce the principle of universal access, ensure a fairer distribution of resources, and improve transparency within the health-care system. However, opponent experts in Lithuania argue that abolishing additional co-payments may worsen access rather than improve it, because without additional funding and staffing reforms, the public system could face longer queues, reduced patient choice, and an accelerated shift of medical professionals to the private sector. The amendments are set to enter into force on 1 May 2026.

- Lithuania has introduced reforms to simplify prescribing and dispensing for patients, particularly those with stable chronic illnesses. Health-care professionals may now issue longer-term prescriptions without requiring frequent in-person visits, while newly issued prescriptions for ongoing therapies become valid seven days before the previous one expires to ensure continuity of treatment. Pharmacies may dispense partial quantities when stock is limited, and in certain cases may supply regularly used medicines or medical-aid devices based on a patient's prior prescriptions. For medicines taken "as needed," prescriptions can now be valid for up to six months. Digital updates will allow doctors to correct undispensed e-prescriptions and will introduce real-time alerts on supply or reimbursement changes. Paper prescriptions will be phased out entirely by 2027, with the reform aiming to reduce administrative burdens and improve patient access.

- Lithuania's Emergency Medical Team (EMT-2) has received formal certification from the World Health Organization (WHO), marking a significant milestone in the country's emergency-preparedness and international health-response capabilities. The certification confirms that the Lithuanian team meets WHO's global standards for clinical quality, coordination, logistics, and deployment readiness. During the assessment, international experts evaluated the team's ability to provide essential medical care in crisis situations, including mass-casualty events, natural disasters, and humanitarian emergencies. Certification as an EMT-2 means that Lithuania can now be formally deployed through WHO mechanisms to support international missions, strengthening the global network of rapid medical assistance. It also reflects substantial national investment in training, infrastructure, and inter-institutional cooperation. According to the Ministry of Health, this achievement enhances Lithuania's resilience at home while positioning it as a reliable contributor to

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international emergency health operations. The certification will also facilitate deeper participation in joint exercises and EU-WHO coordinated response initiatives.

- Lithuania has strengthened its regulatory framework for managing industrial and environmental odours to better protect residents' quality of life. The updated rules introduce clearer requirements for identifying, monitoring and reducing odour emissions, alongside improved mechanisms for responding to public complaints. Municipalities will now have more robust tools to assess odour impacts and request corrective measures from operators, while businesses must implement preventive technologies and maintain transparent environmental documentation. According to the Ministry of Health, these changes aim to ensure a healthier living environment, reduce nuisance for communities located near industrial facilities, and promote more responsible environmental management practices across sectors.

- A new study by the Ministry of Health shows that Lithuanian residents spent over €84 million on medicines in September 2025, amounting to an average of €29 per person. Despite substantial state reimbursement for essential drugs, out-of-pocket spending remains high, particularly for non-compensated or partially compensated medicines and over-the-counter products. The findings also indicate that older adults and people with chronic conditions bear the greatest financial burden. These data will guide future policy decisions, including adjustments to the reimbursement list and measures to promote the use of more affordable, therapeutically equivalent medicines.

Main sources:
The Ministry of Health of Lithuania: https://sam.lrv.lt/
The Parliament of Lithuania: https://www.lrs.lt/

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Much-needed but still illusory health and SRH education in Poland

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1. Introduction

As a recently appointed EAHL NCP for Poland, I have decided to dedicate my first submission to the EAHL Newsletter to an issue that, to many, would seem obvious and non-controversial, but had been extensively debated in Poland in 2025. Starting from the 2025/26 school year, the new subject "Health education" was introduced in primary and secondary schools, with a curriculum covering, among other things, physical and mental health, nutrition, puberty, and sexual health. It replaced WDŻ (Education for Family Life). In practice, schools conduct classes, and parents may submit a withdrawal (opt-out) request. In the first part of this brief paper, I will provide an overview of the debates concerning the curriculum and present some comparative data. In the second part, I argue that health education falls within states' positive obligations stemming from international human rights standards.

2. Overview of the curriculum, debates and controversy

General aims of the subject are the following: 1) Developing health competencies: knowledge, skills, and attitudes that support physical, mental, and social health; 2) Strengthening self-efficacy, self-regulation, and responsibility for one's own health and the health of others; 3) Building the ability to make informed decisions and think critically in situations related to health; 4) Preparing students to navigate the healthcare system and assess the credibility of health information. The main thematic areas (modules) that implement these goals cover: 1) Physical health and lifestyle, 2) Mental health, 3) Puberty and sexual health, 4) Safety and first aid, and 5) Environment and public health. Why did the new subject raise controversy and a heated public debate? Critics (predominantly from conservative circles) argued that the module on puberty/sexual health "sexualises" schools or infringes on parents' convictions. This reflects tensions over reproductive health (including access to emergency contraception, sex education, perception of gender and heteronormativity) that have been visible in the Polish debate for years. Supporters of the new subject pointed to young people's needs (e.g. mental health, violence prevention, reliable knowledge on relationships, fertility, and cyber safety). Another question of a non-substantive nature was a dilemma over opting out versus universal participation. As a way of "compromise" between the opponents and supporters, the subject was eventually included in school curricula as optional for pupils. In consequence, although full statistics for the whole country are not

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yet available, it seems that the majority of pupils do not participate in the subject.[1] This brief comment will not address and analyse different arguments raised for opting out, such as individual (mostly parents') convictions and a major argument – student overload with schoolwork and extracurricular activities.

In European countries, health education is included in school curricula, as a stand-alone compulsory subject at some stages of education (in Finland[2] and the Czech Republic[3]), as an integrated component of another broader area/subject or a cross-curricular duty (e.g. in England[4], Norway[5], Sweden[6] and many more). Some countries envisage mandatory modules on sexual and reproductive health (SRH)[7].

The opt-out system, along with a lack of a wider revision of school curricula that would integrate health issues in a meaningful way, left Polish children and youth without much-needed health education.

3. Health education as a human rights obligation

Although there is no free-standing, autonomous right to health education or to SRH education in international human rights treaties, it has been recognised as one of the key elements of the right to health. The growing importance of health education for the full realisation of this right is evident in the development of international standards. Article 12 ICESCR is silent about it, however, in General Comment No. 14 (2000), the Committee on Economic, Social and Cultural Rights indicated that access to health-related education and information (including on sexual and reproductive health) is one of the underlying determinants of health. Securing health education and information falls within the positive State obligations (the obligation to fulfil). It means that States are required to play an active part and take appropriate measures and steps to realise this obligation. Although health education is not included in core obligations, the Committee indicated it is one of the obligations of comparable priority. In comparison to the ICESCR, the CRC explicitly mentions access to

[1] First data show visible differences between the statistics of primary and secondary schools, as well as between regions – see e.g. https://samorzad.pap.pl/kategoria/edukacja/w-najwiekszych-miastach-z-edukacji-zdrowotnej-wypisana-ponad-polowa-uczniow?utm_source=chatgpt.com; https://www.rp.pl/profilaktyka/art43209621-edukacja-zdrowotna-100-tys-uczniow-w-warszawie-wypisanych-z-przedmiotu; https://www.pap.pl/aktualnosci/w-najwiekszych-miastach-z-edukacji-zdrowotnej-wypisana-ponad-polowa-uczniow.

[2] https://www.coe.int/en/web/human-rights-and-biomedicine/-/teaching-health-literacy-as-a-mandatory-school-finland?utm_source=chatgpt.com.

[3] Evžen Řehulka, Eva Sollárová et al.,School and Health for the 21st century. Health education: Czech-Slovak Experiences, Brno 2011; https://www.ped.muni.cz/z21/knihy/2011/41/authors.htm. See also Rámcový vzdělávací program pro základní vzdělávání, available at: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://digitalizace.rvp.cz/files/rvp-zv-2021.pdf.

[4] https://www.gov.uk/government/publications/relationships-education-relationships-and-sex-education-rse-and-health-education/implementation-of-relationships-education-relationships-and-sex-education-and-health-education-2020-to-2021?utm_source=chatgpt.com

[5] Norway has been pioneering in this area for many decades – see: Arne Haukens, Health Education and the Environment in the Basic School Curriculum in Norway, in: G. Campvell (ed), New Directions in Health Education, London: Routledge, 1985 (e-book 24 May 2022).

[6] Varea, V., Caldeborg, A., Barker, D., & Quennerstedt, M. (2024). Health education in Swedish schools – what's on offer? *Scandinavian Journal of Educational Research*, *69*(4), 871–883. https://doi.org/10.1080/00313831.2024.2360905

[7] E.g. in Czech Republic: https://education-profiles.org/europe-and-northern-america/czech-republic/~comprehensive-sexuality-education.

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information and health education, including sexual health[1], in Article 24 on the right to health. This stronger emphasis suggests that the absence of such content may breach child health protection standards. In the General Comment No. 15 (2013), the CRC Committee made it clear that health education should be provided as a 'core part of the school curriculum [emphasis added], as well as through health services and in other settings for children who are not in school'.[2] The same applies to the SRH education of youth. The General Comment No. 20 *(2016)* sets out that 'age-appropriate, comprehensive and inclusive sexual and reproductive health education, based on scientific evidence and human rights standards and developed with adolescents, should be part of the mandatory school curriculum [emphasis added] and reach out-of-school adolescents'.[3]

Also, European human rights protection bodies, the European Committee of Social Rights (ECSR) in particular, stress the importance of health and SRH education. In interpreting Article 11(2) of the European Social Charter, the Committee emphasises that states must provide health education and awareness; it also stresses the need for universal, non-discriminatory SRH education for children. In its latest Conclusions on Poland (from 2021), the ECSR explicitly examined how the state implements health education, including SRH content.[4] Surprisingly, the Committee concluded that Poland was in conformity with Article 11§2 of the Charter. It found it satisfying that the basic curriculum implemented by schools sets out the objectives of general education and its content. According to the country report, the emphasis was on developing children's and pupils' health skills (hygiene, healthy eating, physical exercise), social and civic skills. Health education content in secondary schools, technical high schools, was included in the core curriculum for the following subjects: biology, safety education, physical education, geography, chemistry and education on family life. In reality, the very general and patchwork school curriculum during the reporting period fell short of satisfactory and did not meet international standards. As observed by the ESCR, 'the most appropriate structure for the provision of health education is the school, inasmuch as the general objective of education is to communicate knowledge which enables pupils to tackle life in its multi-faceted totality'.[5] The Committee has previously stated that Article 11§2 requires that health education in school be provided throughout the entire period of schooling and that it cover the following subjects: prevention of smoking and alcohol abuse, sexual and reproductive health education, in particular with regard to prevention of sexually transmitted diseases and AIDS, road safety and promotion of healthy eating habits.[6]

The final argument for the compulsory, comprehensive health and SRH education is equality of opportunities. A compulsory subject limits the "lottery" of access to reliable knowledge (dependent on the

[1] Article 24(2)(e)(f) CRC.
[2] UN Committee on the Rights of the Child, *General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24),* April 17, 2013, CRC/C/GC/15, para 59.
[3] UN Committee on the Rights of the Child, *General Comment No. 20 (2016) on the implementation of the rights of the child during adolescence, December 6, 2016, CRC/C/GC/20*, para 61.
[4] European Committee of Social Rights Conclusions XXII-2 (2021) Poland, p. 17-18.
[5] International Centre for the Legal Protection of Human Rights (INTERIGHTS) v. Croatia, Complaint No. 45/2007, ECSR decision on the merits 30 March 2009, para 44.
[6] Conclusions XV-2, Belgium, Conclusions 2003, Slovenia.

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school/parents) and better protects vulnerable groups. This is the direction of WHO guidance.[1] This argument is further illustrated and supported by two cases before the ECtHR, where the Court found that compulsory sex education in public schools does not violate parental freedom.[2] The Court observed that the sex-education classes aimed at the neutral transmission of knowledge regarding procreation, contraception, pregnancy and childbirth in accordance with the underlying legal provisions and the ensuing guidelines and the curriculum, which were based on current scientific and educational standards.[3] Vital health interests of children and youth (along with the) should be prioritised over parents' decision-making autonomy and personal convictions. Polish policymakers and legislature need to take the child's best interest principle seriously.

Date of submission: 15 November 2025

[1] WHO Regional Office for Europe and BZgA, Standards for Sexuality Education in Europe. A framework for policy makers, educational and health authorities and specialists, Cologne 2010.
[2] *Kjeldsen, Busk, Madsen and Pedersen v. Denmark*, appl nos 5095/71 5920/72 5926/72, judgment of 7 December 1976.
[3] *Dojan and Others v. Germany*, appl nos 319/08 2455/08 7908/10 et al., dec. of 13 September 2011.

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Recent Developments in Portuguese Health Law: Key Legislation and Case Law in 2025

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In 2025, the main developments in Portugal concerning the right to health and the protection of health stem from both legislative reforms and significant decisions issued by the Portuguese higher courts. Although other developments would also merit attention, the ones presented here illustrate with particular clarity the evolving normative and jurisprudential landscape in areas such as sexual and reproductive health, professional careers within the National Health Service (SNS), the implementation of EU regulatory instruments, medically assisted death (MMA), medical liability, the assessment of biological damage, and access to health data.

1. Legislative developments

1.1. Sexual and Reproductive Health

Law No. 53/2025, of 7 April, introduces the first amendment to Law No. 3/84, of 24 March, significantly expanding the scope and content of the State's duties regarding sexual and reproductive health and education. The law now expressly recognises sexual and reproductive health and education as integral components of the fundamental rights to education and to health. Family planning consultations are correspondingly broadened, covering matters such as genetic and marital counselling, the provision of information and means of contraception, fertility and medically assisted reproduction, the prevention of sexually transmitted infections (IST) and behaviours of risk, and screening for oncological diseases. The State must ensure that consultations addressing sexuality, IST prevention, family planning, preparation for parenthood, menopause and andropause are made available, with free access to both consultations and the means and therapies relevant to sexual and reproductive health. In doing so, the law reinforces the preventive and educational dimensions of the right to health and ensures greater material effectiveness of State obligations in this field.

1.2. Pharmaceutical Career in the National Health Service

Decree-Law No. 45/2025, of 27 March, revises the regime applicable to the special pharmaceutical career and the pharmaceutical career in public entities of the National Health Service (SNS). The reform updates the remuneration structure and enables the maintenance of contracts concluded during university residency programmes until recruitment into a permanent career position. This legislative change strengthens employment continuity, improves career attractiveness and contributes to the stability and retention of

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pharmaceutical professionals within the SNS, with clear implications for the quality and continuity of pharmaceutical services in the public health system.

1.3. Implementation of EU Law: Cosmetic Products, Medical Devices and Protection of Workers from Carcinogens, Mutagens and Reprotoxic Substances

Decree-Law No. 23/2025, of 19 March, ensures the domestic implementation of Regulation (EC) No. 1223/2009 on cosmetic products. The diploma establishes requirements concerning the organisation and activity of economic operators, the language of the product information file and the mandatory content and presentation of labelling, including for products not pre-packaged or packaged at the point of sale. A sanctions regime is created, empowering INFARMED - the Portuguese National Authority of Medicines and Health Products - to adopt precautionary measures, such as suspending activities or closing establishments where public health risks are identified. The decree thus reinforces regulatory compliance and health protection in a sector characterised by substantial consumer exposure.

Decree-Law No. 118/2025, of 13 November, amends Decree-Law No. 29/2024, of 5 April, which implements Regulation (EU) 2017/745 on medical devices. The amendment notably provides that the list of single-use medical devices whose reprocessing is prohibited will henceforth be defined by ministerial order rather than included in the decree itself. This approach allows for greater flexibility and rapid updating in light of scientific and technological developments, while ensuring alignment with European safety standards and maintaining regulatory coherence within the medical device framework.

Decree-Law No. 72/2025, of 6 May, completes the transposition of Directive (EU) 2022/431 on the protection of workers exposed to carcinogens or mutagens at work, including substances toxic to reproduction. It details the obligations of employers in contexts involving such agents, including the adoption of early-detection methods, the design of processes and technical measures that minimise exposure, the use of appropriate ventilation and extraction systems and the clear delineation of risk zones accompanied by secure methods for storage and removal of waste. The decree strengthens preventive occupational health protections and enhances the operational clarity of employers' duties in high-risk working environments.

2. Case-Law developments

2.1. Constitutional Court

One of the most significant judicial developments is Judgment No. 307/2025, of 22 April, in which the Constitutional Court declared the unconstitutionality, with general binding force, of several provisions of Law No. 22/2023, of 25 May, regulating medically assisted death (MMA). The Court held that the provisions enabling the attending physician to determine the method of MMA, referring to the patient's ability to choose the method and to the requirement that the patient decide in an informed and conscious manner, violated the principle of legal determinability inherent in the rule of law (Article 2 of the Portuguese Constitution). In light

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of the principle of subsidiarity of euthanasia, under which assisted suicide is the preferred method, displaceable only when physical incapacity prevents self-administration, the Court considered these provisions incompatible with the structure of the legislative framework.

The Court also declared unconstitutional the provision that failed to require the patient to be examined by a medical specialist, noting that Article 6(1) of the MMA Law contains no such requirement and thereby creates a serious risk that, since the attending physician is chosen by the patient and may lack specialised expertise or any prior knowledge of the patient and their clinical history, the verification of the clinical conditions for medically assisted death will fall short of the suitability, objectivity, impartiality and reliability required in a regime of this nature. This deficiency amounted to (i) insufficient protection of human life, drawn from Articles 2, 18(2) and 24(1) of the Portuguese Constitution, and (ii) a violation of the parliamentary legislative reserve, derived from Articles 2 and 165(1)(b) of the Portuguese Constitution. The existence of the Verification and Evaluation Commission (CVA) was deemed insufficient to mitigate this risk, given the limited medical composition of the Commission and the absence of personal contact with the patient. As this shortcoming was considered to undermine the very legislative decision to legalise MMA, the Court also declared unconstitutional Article 3(1).

Additionally, the Court declared unconstitutional the requirement that healthcare professionals refusing to participate in MMA specify the nature of their conscientious objection, holding that such an obligation constituted an inappropriate, unnecessary and disproportionate restriction on freedom of conscience, particularly on the right not to reveal one's convictions (Article 41(3) and (6) of the Portuguese Constitution).

The remaining norms of the regime were upheld, with the Court reaffirming its consistent understanding that the Constitution neither prohibits nor mandates the legalisation of MMA, leaving the legislature a wide but constitutionally circumscribed margin of political discretion. The judgment includes several separate opinions, reflecting a broader pattern of division within the Court on sensitive matters.

In Judgment No. 346/2025, of 6 May, the Court declined to assess the constitutionality of provisions concerning exceptional overtime by medical doctors in emergency services contained in the 2022 State Budget Law, holding that, in view of the principle of annuality, the lapse of these norms rendered constitutional review devoid of legally relevant interest.

2.2. Supreme Court of Justice: miscellaneous

In Uniform Judgment No. 7/2025, of 13 May, the Supreme Court of Justice (STJ), the highest court in the hierarchy of the ordinary courts, addressed the regime governing compulsory sports insurance under Decree-Law No. 10/2009, of 12 January concluding that compensation for partial permanent disability is determined by multiplying the percentage of disability by the insured capital, irrespective of the actual damage suffered, and that the insurance does not cover non-pecuniary damages.

Further judgments of the STJ clarified the relevance of biological damage as an autonomous head of damage in the context of civil liability for road traffic and work-related accidents. The Court confirmed that biological

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damage may warrant compensation even where earning capacity is not fully impaired, provided that there is demonstrable and permanent physical or psychological harm (see, among others, judgements of 14 January and 13 March 2025).

The STJ also held, in several judgments delivered in 2025 (namely those of 5 March and 28 May 2025) that a prisoner's state of health, although relevant to requests for modification of sentence execution, cannot ground a petition for *habeas corpus* (see Article 31 of the Portuguese Constitution), which cannot serve as an avenue to challenge refusals to modify sentence execution based on health considerations.

Equally noteworthy is a judgment of 30 January 2025, concerning noise disturbances generated by tenants and affecting neighbours' health, in which the STJ held that landlords may be ordered to prevent or cease noise emissions that significantly interfere with personality rights. The Court emphasised that rest, sleep and tranquillity within one's home are essential components of the right to health and quality of life, thereby justifying the precedence of these interests over the economic dimension of property rights when the latter is exercised in a manner detrimental to fundamental rights.

2.3. Administrative Supreme Court: Access to Health Data

In a judgment of 16 July 2025, the Supreme Administrative Court (STA), the highest court in the administrative and tax jurisdictions, considered access to clinical records held by a local health unit and reaffirmed that health information belongs to the data subject and constitutes a special category of personal data. Accordingly, in the absence of valid authorisation, access by a third party to a deceased person's clinical file requires demonstration of a direct, personal, legitimate and constitutionally protected interest of sufficient relevance. Local health units must therefore prevent improper access, including by insurers, which may not rely solely on general assertions of legitimate interest to justify access. This judgment reinforces the principle of confidentiality of clinical information, including *post mortem*.

2.4. Medical Liability (STJ and STA)

In Judgment No. 5/2025, of 3 June, the Supreme Administrative Court addressed civil liability for medical acts performed in SNS units. The Court reaffirmed that the claimant bears the burden of proving the prerequisites of liability, including unlawfulness and fault, which may arise from violations of legal norms, technical rules or objective duties of care. It stressed that medical acts constitute obligations of means rather than obligations of result, and that unlawfulness cannot be inferred solely from an adverse clinical outcome. Instead, it must be demonstrated that the clinical acts or omissions departed from the *leges artis* or the general duty of care, assessed in light of the state of medical knowledge at the time. Compliance with *leges artis* entails adherence to the theoretical and practical rules of prophylaxis, diagnosis and treatment applicable to the particular case, taking into account the patient's characteristics and the resources available.

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The STJ, in judgments of 16 January and 13 May 2025, adopted the same approach, reaffirming that medical services are defective only when performed in breach of the duties of diligence, care and technical rigour required of the medical professional. Although acknowledging the difficulty faced by patients in proving breaches of *leges artis*, the Court saw no basis for reversing the burden of proof. The mere failure of medical treatment, in the absence of proof of departure from *leges artis*, does not suffice to establish liability.

3. Concluding Remarks

On the legislative front, the broadening of sexual and reproductive health services, the fortification of occupational health protections, adjustments to pharmaceutical careers within the SNS and the domestic implementation of EU law all reflect an intensification of the State's positive obligations in health matters. Jurisprudentially, the Constitutional Court's scrutiny of the MMA framework reveals a rigorous application of constitutional principles relating to legal determinability, the protection of human life and legislative competence, while acknowledging the possibility of regulated MMA within constitutionally secure boundaries. Concurrently, the case law of the STJ and STA consolidates the construction of medical liability as an obligation of means, refines the evidentiary burden associated with compliance with *leges artis*, reinforces the confidentiality of health data and underscores the normative importance of health, bodily integrity and psychological well-being across civil liability domains, while also reaffirming that constitutional remedies such as *habeas corpus* cannot be diverted from their specific function when health considerations arise in the context of sentence execution. Collectively, these strands point to a more integrated and normatively dense architecture of Portuguese health law.

Data of submission: 08 December 2025

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Overview of Major Health-Policy and Legal Developments in Romania

Larisa Pătru, PhD

EAHL Member

1) New Medical Deontological Code forPhysicians

In November 2025, The Romanian College of Physicians adopted a completely revised Medical Deontological Code, that will enter into force starting on 1 January 2026.

The key features of the New Medical Deontological Code published in the Romanian Official Gazette no. 1141/ 10.12.2025 are:

a) Ethics updated for modern challenges: The Code prohibits the dissemination of pseudoscientific information, regulates medical advertising and the conduct of physicians on social media, clarifies the role of telemedicine, and defines clear boundaries for the use of artificial intelligence in medical practice — AI may be used as a support tool only; final diagnosis and treatment decisions remain the physician's responsibility.

b) Principle of evidence-based medicine: Physicians are required to respect and promote evidence-based medical practices; promoting unverified or pseudoscientific claims is explicitly deontologically forbidden.

c) Strengthening the physician–patient relationship: The Code reaffirms core ethical values: respect for human dignity, primacy of the patient's well-being, professional diligence, patient confidentiality, non-discrimination, empathy, competence, and solidarity among medical professionals.

d) The conscience clause: As a novel provision, physicians may declare annually (upon renewing their license to practice) any medical procedures they conscientiously refuse to perform (e.g., abortion on demand, blood transfusion), on moral, religious or ethical grounds — provided that such refusal does not endanger the patient's life or health and that continuity of care is ensured. In emergencies, the conscience clause does not apply.

e) Professional independence and internal collegiality: The Code prohibits any external administrative or economic pressures influencing medical decisions, denigration of colleagues, or "self-referral" of patients to a private practice owned by the physician for profit motives. In cases of inter-professional conflict, internal collegial dispute resolution (conciliation) is required before any public complaint.

In sum, the New Medical Deontological Code is aimed at modernizing the deontological and ethical framework of Romanian medical practice, aligning it with contemporary challenges — digital health, AI, telemedicine — and strengthening professional integrity, patient trust, and public confidence in the medical profession.

2) Reform of the Health-Insurance System — Law No. 141/2025

On 1 August 2025, Romania implemented major changes through Law 141/2025 concerning social health insurance. Law No. 141/2025 represents an effort to protect vulnerable social categories and guarantee continuity in access to healthcare services and essential medicines, while sustaining the financial viability of the health-insurance system.

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Important measures and impacts:

a) Continuation of insured status without contribution for many groups: As of August 2025, certain categories remain insured without paying the health-insurance contribution (CASS). These include children under 18; young adults 18–26 who are students, apprentices, or trainees; young people from child-protection system up to 26 years; pregnant women and new mothers (lactating); pensioners with incomes below a threshold; persons with disabilities.

b) Stabilizing access and continuity of care: The law aims to ensure sustainable financing of medical services and medicines, preserving access for vulnerable populations and reducing coverage gaps.

c) Implications for medical leave and benefit entitlements: The law also revises certain rules regarding medical leave and the calculation of benefits for incapacity for work.

3) Restructuring of Healthcare Delivery — Law No. 163/2025

On 23 October 2025, the Parliament passed Law nr. 163/2025, which amends and completes existing health-care legislation (notably Law No. 95/2006 regarding the healthcare reform) with the aim of improving organization, efficiency and cooperation among medical facilities.

a) Allowed formation of consortiums and associations between hospitals and medical institutions: Hospitals may now associate with each other or with medical-academic institutions (e.g., universities, accredited clinics), regardless of geography, to form legal entities (consortiums). These collaboration frameworks enable shared medical activity, joint investments in infrastructure, joint procurement of medicines and devices, and coordinated research.

b) Contract-based management and performance indicators: Hospital managers will operate under management contracts (maximum 4 years) potentially subject to annual evaluation. The law emphasizes performance-based contracts, seeking to stimulate efficiency, better resource utilization, improved quality of care and accountability.

c) Flexibility for small practices / family medicine units: The law also modifies limits on how many secondary medical points a family-doctor practice can open (with adjusted staffing / scheduling requirements).

These structural reforms aim at rationalizing healthcare infrastructure, fostering cooperation, improving access across regions, enhancing quality and reducing duplication of services.

The legislative and ethical reforms of 2025 mark a significant turning point for Romanian healthcare policy. The adoption of a modernised Deontological Code signals a renewed commitment to professionalism, scientific rigour, patient dignity, and public trust. Meanwhile, insurance and structural reforms seek to improve access, sustainability and efficiency of the health-care system.

Date of submission: 10 December 2025

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Slovakia Accelerates Healthcare Digitalization in 2025

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The Slovak healthcare system is undergoing a long-term process of digital transformation. The implementation of the EHDS in Slovakia is overseen by the National Center for Health Information (NCZI), which will also prepare the necessary legislative changes in cooperation with the Ministry of Health of the Slovak Republic. health data will be used for two basic purposes: primarily - directly in the provision of healthcare and secondarily - for research, innovation, or policymaking. The national system will become a key part of the pan-European data exchange. This will require better data structuring, connections with hospital systems, and new functions for patients and other entities.

Amending act to the act No. 153/2013 coll. on national health information system had been passed in November 2025.[1] Its aim is to reduce the administrative burden and expand the functionality of the eHealth system. Key data, including the electronic pregnancy record, will now be added to the electronic health record (EZK) and there are changes in terminology as well to unify health data management. The content of the EZK is expanded to include new types of digital records, which will improve the clarity and accessibility of data for both doctors and patients.

The amendment introduces a specialized Register of Certificates, which will enable the electronic issuance of documents for various purposes (for example, certificates necessary for obtaining a firearms license). One of the most important innovations is the extended eHealth function of issuing certificates of occupational medical fitness and health status electronically

The amendment also brings about the creation of the National Register of Electronic Reporting, which will serve to record medical services for statistical and information purposes at the national and international levels. Data from this register will be used for state health policy. Another innovation is the introduction of the concept of "episode", which will allow linking all relevant patient records related to one disease or health event.

The changes also affect the rules for accessing data in the EZK and set deadlines for the storage of personal data. The retention period for the personal data of the data subject is 1/ One hundred years after the death or termination of the healthcare provider, after the death of the professional representative and the statutory representative, and 2/ five years after the termination of the status of „contact person“ and „interested person“.

Date of subsmission: 19 December 2025

[1] Zákon č. 344/2005 Zbierky zákonov SR z 25. novembra 2025, ktorým sa mení a dopĺňa zákon č. 153/2013 Z. z. o národnom zdravotníckom informačnom systéme a o zmene a doplnení niektorých zákonov v znení neskorších predpisov a ktorým sa menia a dopĺňajú niektoré zákony.

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Country Report: Slovenia

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On 4 June 2025, the *Act on the Recognition of Professional Qualifications in Healthcare (ZPPKZD)* was published in the Official Gazette of the Republic of Slovenia, No. 40/25. The Act regulates the conditions and procedures for recognition of professional qualifications for all regulated healthcare professions in Slovenia. It applies to individuals who completed formal education or obtained a professional qualification in a third country, as well as to individuals who completed formal education in an EU Member State, the EEA, or the Swiss Confederation. The Act entered into force on 19 June 2025. The full text is available here: https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2025-01-1570/zakon-o-priznavanju-poklicnih-kvalifikacij-v-zdravstveni-dejavnosti-zppkzd.

Key novelties introduced for the professions of doctor and doctor of dental medicine

- The Act simplifies the existing recognition system by unifying procedures. It no longer distinguishes between candidates from third countries with or without a job offer in Slovenia. All recognition procedures will now be conducted centralised by the Ministry of Health. The procedure for recognition specialist titles obtained abroad, previously handled by the Medical Chamber under the Regulations on Medical Specialisations, will now be conducted by the Ministry of Health.
- The organisation of professional examinations for doctors and doctors of dental medicine is modified (procedural modification).
- The mandatory submission or acquisition of an **ENIC-NARIC opinion** is abolished - the Ministry decides whether such an opinion is needed.
- A new regulatory framework is introduced for the demonstrational medical procedures, which can be performed only in public providers of medical services.

Date of submission: 20 November 2025

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Report from Spain.
Spanish Health Law in 2025 – Latest Insights.

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The report focuses on the main legislative developments enacted in Spain during the second half of 2025. The first section examines the legal texts, whose innovations are centred on the field of public health, and secondly on the most significant Royal Decrees in healthcare law that have entered into force in last months.

1. Legislative Developments

Of particular significance is Law 7/2025 of 28 July, which establishes the State Public Health Agency and amends Law 33/2011 of 4 October, the General Law on Public Health, which is structured around three main areas.

As a first substantive element, the State Public Health Agency is constituted as a public institution attached to the Ministry of Health, endowed with its own legal personality, assets, and treasury, as well as managerial autonomy, in accordance with the provisions of Law 40/2015 of 1 October on the Legal Regime of the Public Sector.

The primary goal of this newly established agency, in alignment with the framework outlined in Law 33/2011, dated 4 October, is to reinforce the State's ability to advance population health, foster health equity and well-being, and protect the public from health risks and threats. Additionally, the Agency undertakes significant responsibilities in the following areas:

a) The surveillance, identification and assessment of the population's health status and its determinants, as well as of public health problems, threats and risks, with particular attention to social inequalities in health.
b) The provision of public information and communication regarding the population's health and the risks that may affect it.
c) The coordination of preparedness and response activities in the event of health crises and emergencies, in line with the National Security Strategy.
d) Facilitating collaboration, cooperation and interaction among public health services and healthcare centres, services and establishments.
e) Enhancing capacities and offering guidance and support to public administrations and civil society for effective execution of public health functions, with a particular focus on addressing social determinants of health and reducing health inequalities.

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f) The evaluation of health outcomes deriving from healthcare services, in collaboration with autonomous communities.
g) Any other purpose assigned under its statute, without affecting the public health powers of other authorities.

It should also be noted that the Agency assumes technical functions in public health surveillance, playing a key role in the coordination and evaluation of the State Public Health Surveillance Network and in strengthening the current Epidemiological Surveillance Network. In line with these competences, an obligation is established for all public administrations, institutions, entities and bodies in both public and private sectors, particularly healthcare centres, services and establishments, to provide data required for the fulfilment of its public-interest purposes.

In the area of public health emergency preparedness and response, the Act assigns the Agency particularly significant responsibilities, including the development of national plans for health preparedness and response to current and emerging alerts, risks and threats to human health, while respecting the powers vested in other public administrations. It is also responsible for supporting the enhancement of the National Health System's resilience during health emergencies, collaborating closely with autonomous communities and other relevant institutions involved in the response.

Furthermore, the Agency is responsible for coordinating the technical and scientific elements necessary to define requirements and procedures for accessing, utilizing, distributing, and replenishing the health countermeasures included in the national strategic health reserve. These activities are intended to support an effective response to public health emergencies and ensure timely and equitable access, fully consistent with the current National Security Strategy, while respecting the authorities vested in the National Security Council and other relevant departments.

The Agency also plays a vital role in several key areas:

a) Serving as a centre for international public health by facilitating information exchange.
b) Supplying information and facilitating communication involves informing the public about potential health hazards and risks, as well as giving advice on effective communication methods and addressing inquiries from government agencies and the wider community.
c) Offering advisory services and evaluating public health initiatives.
d) Supporting research and delivering professional training in public health.

Secondly, Law 33/2011, the General Public Health Act, has been revised to integrate a comprehensive One Health perspective, acknowledging the relationship among human, environmental, and animal health in managing health risks. This amendment also updates Chapter I of Title II regarding public health surveillance, broadening its scope to encompass preparedness and response measures.

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Thirdly, the Act amends Article 98 of the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Devices, as approved by Royal Legislative Decree 1/2015 of 24 July, specifically concerning the reference pricing system. The purpose of this amendment is to allow for exemptions from the reference pricing system or to apply a corrective coefficient that increases the price of those medicines which provide a strategic benefit to the National Health System or demonstrate a measurable improvement in patient outcomes. This approach enables the assessment of medicines that contribute incremental value to health or healthcare management.

2. Government Regulatory Developments

Regarding national healthcare regulations, it is important to note the Royal Decree 942/2025 of 21 October, which establishes the framework for in vitro diagnostic medical devices.

This instrument establishes the national framework for implementing Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices. While the European regulation is directly applicable, this Royal Decree addresses elements subject to national discretion. Specifically, it designates the Spanish Agency for Medicines and Medical Devices as the competent authority responsible for surveillance and control of in vitro diagnostic medical devices; reinforces health safeguards by mandating compliance with safety and performance standards; defines the linguistic requirements, stipulating that labelling and instructions must be provided at least in Spanish and regulates procedures for manufacturing devices intended for in-house use within healthcare centres.

The Royal Decree also incorporates innovations introduced by the European regulation, such as the establishment of EU reference laboratories to verify higher-risk products, and it imposes on healthcare centres and professionals the obligation to inform and advise patients prior to carrying out diagnostic genetic testing, obtaining their explicit consent.

Through this instrument, Spain fully aligns its legal framework with the new European regime for in vitro diagnostic medical devices, repealing the previous legislation (Directive 98/79/EC) and ensuring both market unity and the safety of these products' introduction, in accordance with the principle of the free movement of goods within the EU.

Finally, it is important to mention Royal Decree 969/2025 of October 28, which sets out the criteria for identifying irreversible and highly complex care processes as described in Law 3/2024 of October 30. This law focuses on improving the quality of life for people with Amyotrophic Lateral Sclerosis and other diseases or conditions that are both highly complex and irreversible.

The objective of this Royal Decree is to establish the general and operational criteria that must be satisfied by diseases and conditions of high complexity and irreversible progression in order to fall within the scope of Law 3/2024. The operational criteria outlined herein are designed to facilitate the identification of those diseases and conditions necessitating expedited administrative procedures due to their clinical progression, as standard timeframes may result in inadequate protection for affected individuals.

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In this context, the Royal Decree delineates four cumulative criteria that must be satisfied for such processes to fall within the purview of the aforementioned Act:

(1) the disease is irreversible and markedly reduces life expectancy;

(2) there is no adequate response to available treatments or therapeutic alternatives capable of improving prognosis;

(3) the condition necessitates complex, long-term health and social care, including dependence on basic activities of daily living and extended use of functional and life-support devices; and

(4) the disease progresses rapidly, thereby requiring expedited procedures for the recognition of disability or dependence.

The Royal Decree sets out the assessment procedure, with the relevant medical specialist responsible for verifying that the criteria are met. A favourable decision will be valid throughout the national territory and will entail the coordination of the appropriate health and social services to ensure comprehensive care.

In addition, Annex I provides an indicative list of diseases and processes of high complexity and irreversible course that may be subject to assessment. This list is neither exhaustive nor automatically applicable, meaning that each case must be evaluated individually in accordance with the clinical criteria established in the instrument.

Date of submission: 10 December 2025

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Recent Developments in Swiss Health Law and Governance of Innovation

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Swiss health law is evolving through a federal strategy to modernise the health system to digitalisation, amid ongoing citizens' reservations about digitalisation in general. Recent measures focus on enabling health data collection and exchange at national level while ensuring the protection of patients' fundamental rights. Concurrently, targeted updates address therapeutic product regulation and Switzerland's international public health obligations.

1. Development of Digital Health Legal Strategy

Switzerland digital health law strategy resolves around health data collection and exchange, and regulation of AI.

The **DigiSanté programme** (2025–2034), developed by the Federal Office of Public Health (FOPH) under mandate from the Federal Council, serves as the central federal initiative coordinating digital health projects, defining interoperability standards, and supporting shared digital infrastructures. DigiSanté is implemented on the basis of existing legal frameworks, in particular the Federal Act on Data Protection (FADP; SR 235.1), and budgetary decisions. Based on synergies with EU digital health regulations, Digisanté currently works on developing federal acts on the Digital Health Data Space and on the secondary use of data.

One of the main current changes in terms of digital health law is the **replacement of the Electronic Patient Record by the Electronic Health Record.** On 5 November 2025, the Federal Council submitted to Parliament a draft Federal Act on the Electronic Health Record (EHR Act; SR not yet assigned). The draft Act is intended to replace the Federal Act on the Electronic Patient Record (EPRA; SR 816.1), which has been in force since 15 April 2017 (EPRA; SR 816.1, 19 June 2015). It provides for a nationwide electronic health record for all residents of Switzerland, subject to a right to opt-out. Unlike the EPRA, the draft EHR Act introduces mandatory participation for health-care providers reimbursed under mandatory health insurance and assigns responsibility for core infrastructure and technical standards to the Confederation. The draft Act has not yet entered into force and remains subject to the parliamentary legislative process. In its current version, the Act allows patients to access their data, control who can access it, delete it, or object to the consultation of their record in case of emergency.

In parallel and regarding AI, Switzerland signed the **Council of Europe Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law** on 27 March 2025. This instrument

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will be the first text applicable to the development of AI systems at the national level, as the country has not adopted the equivalent of an EU AI Act. The Convention establishes binding principles applicable to the design, development and use of artificial intelligence systems, including requirements on human oversight, transparency, risk management and protection of fundamental rights. Although the Convention has a transversal scope, it will apply to the health sector. It will impose the creation of follow-up mechanisms at the national level and guarantee an effective possibility for individuals, including patients, to lodge a complaint to competent authorities in case of a rights violation. Switzerland will need to ratify the treaty and potentially adopt more sector-specific legislation on medical AI.

2. Revision of the Therapeutic Products Act

On 3 September 2025, the Federal Council submitted to Parliament a draft partial revision of the Therapeutic Products Act (TPA; SR 812.21). The revision aims to improve medication safety, facilitate access to innovative therapies and introduce legally binding digital processes in prescribing and dispensing. A central element of the draft is the proposed introduction of electronic prescriptions as the standard legal form for prescribing therapeutic products. While handwritten prescriptions would generally no longer be permitted, exceptions such as patient requests for printed copies with machine-readable electronic signatures are foreseen. The revision also provides the legal basis for electronic medication plans and for the integration of prescription data into electronic health records. These measures are intended to reduce medication errors, improve traceability, and support coordinated treatment.

The draft revision clarifies regulatory pathways for advanced therapy medicinal products (ATMPs) and adapts authorization procedures to scientific and technological developments. These provisions are generally aligned with EU standards, although the Swiss definition of ATMPs should be broader.

3. Strengthening Global Health Solutions and Pandemic Prevention

On 20 June 2025, Switzerland approved the Amendments to the International Health Regulations (IHR 2005, amended by WHA on 1 June 2024), focusing on measures to prevent and control the international spread of infectious diseases and strengthening collaboration between States and WHO, and transparency. The amendments entered into force for Switzerland on 19 September 2025 without the need to adopt a new legislation. Switzerland entered a **reservation** regarding the amendments' provisions dealing with misinformation/ disinformation in risk communication; the government decided not to adopt these provisions due to conflicts with constitutional protections such as freedom of expression.

Date of submission: 10 December 2025

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Country Report: United Kingdom

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EAHL NCP for the United Kingdom

The first part of 2025 has seen the introduction of potentially significant reforms – this update provides insight into how some of these are developing.

1. **Abortion**

Debates of the Crime and Policing Bill (England and Wales) have reached the Committee Stage in the House of Lords (for background see July 2025 newsletter). This Bill includes, at clause 191, "Removal of women from the criminal law related to abortion". Commentary: Verfassungsblog (July 2025).

Abortion law in Scotland includes the Abortion Act 1967 (with similarities to the equivalent statute in England and Wales), but now falls within devolution arrangements for healthcare. In November 2025, an Expert Panel commissioned by the Scottish government published its review of abortion law in Scotland. Recommendations include repeal of common law offences for registered healthcare professionals who provide an abortion(s) outwith the terms of abortion legislation, and repeal of the crime of concealment, along with the Concealment of Birth (Scotland) Act 1809.

2. **Assisted Dying**

The Terminally Ill Adults (End of Life) Bill for England and Wales makes provision for adults who are terminally ill and reasonably expected to die within 6 months to request, and lawfully be provided with, assistance to end their own life. The Bill has now reached the Committee Stage in the House of Lords (for background see July 2025 newsletter). Commentary: UKCLA and KBW (September 2025).

The Assisted Dying for Terminally Ill Adults (Scotland) Bill reached Stage 3 (final changes and vote) in the Scottish Parliament earlier in 2025. Commentary: Scottish Government (October 2025).

3. **Mental Health**

The Mental Health Bill for England and Wales is reaching its final stages - (for background see July 2025 newsletter). Concerns have been raised about the removal of people with autism from the scope of the Mental Health Act 1983 – see commentary: Beazley et al..

4. **Devolution – Northern Ireland**

The question of whether the Minister of Health for Northern Ireland has the power to revise the Deprivation of Liberty Safeguards Code of Practice has been referred to the UK Supreme Court (UKSC). More specifically, the UKSC is being asked to determine whether such revision would be compatible with Article 5 ECHR, and therefore within the Minister's powers. The wider practical effect of such a revision would be that persons aged 16 and over lacking capacity to make decisions about their care and treatment can give valid

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consent to their confinement through the expression of their wishes and feelings. Following hearings in October 2025, judgment by the UKSC is awaited.

Case ID: UKSC/2025/0042.

Practitioner Commentary: Justice Court of Protection Project.

Date of submission: 09 December 2025

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Legislative News in the Field of Health Care of Ukraine

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EAHL NCP for Ukraine

On October 3, 2025, a draft law of Ukraine "On improving certain issues of scientific and educational activities in the field of healthcare" was submitted for public discussion.

The Ministry of Health of Ukraine has submitted for public discussion a draft law "On improving certain issues of scientific and educational activities in the field of healthcare," developed with the aim of improving certain issues of scientific and educational activities in the field of healthcare, in particular in terms of ensuring the quality of practical (clinical) training of students and the functioning of the external education quality assurance system.

The draft law proposes comprehensive changes to the current legislation in order to regulate the use of deceased persons' bodies, their parts, and anatomical materials for scientific research and training in the field of healthcare.

📌 *For more details, follow the link:*

https://moz.gov.ua/uk/povidomlennya-pro-oprilyudnennya-proyektu-zakonu-pro-vnesennya-zmin-do-deyakih-zakonodavchih-aktiv-ukrayini-shodo-vdoskonalennya-okremih-pitan-naukovoyi-ta-osvitnoyi-diyalnosti-u-sferi-ohoroni-zdorov-ya

On October 6, 2025, the Law "On Verification of Data in the Field of Health Care" was submitted to the Verkhovna Rada of Ukraine for consideration.

The law was developed to ensure the fulfillment of tasks and functions in the field of health care, as defined in accordance with the Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Care."

The law proposes:

- amend Article 24-2 of the Law of Ukraine "Fundamentals of Legislation on Healthcare" in terms of expanding the list of information systems for interaction with the ESOS and the Law of Ukraine "On the Unified State Demographic Register and Documents Confirming Ukrainian Citizenship, Certifying Identity or Special Status" to supplement part six of Article 11 with a new paragraph 6 regarding the exchange of information on a person's tax number (registration number of the taxpayer's account card from the State Register of Individuals - Taxpayers) (if available) from the Unified State Demographic Register for the purpose of data verification.

📌 *For more details, follow the link:*

https://itd.rada.gov.ua/billinfo/Bills/Card/57574

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On November 6, 2025, a draft law of Ukraine "On the rotation of healthcare workers during martial law" was submitted for public discussion.

The Ministry of Health of Ukraine has submitted for public discussion a draft law "On the rotation of healthcare workers during martial law," developed with the aim of legislatively regulating the introduction and implementation of a mechanism for the rotation of healthcare workers during martial law.

The draft law provides for comprehensive changes and additions concerning the introduction and implementation of a mechanism for the rotation of healthcare workers during martial law.

📌 *For more details, follow the link:*

https://moz.gov.ua/uk/proyektu-zakonu-pro-vnesennya-zmin-do-deyakih-zakoniv-ukrayini-shodo-rotaciyi-pracivnikiv-sferi-ohoroni-zdorov-ya-u-period-diyi-voyennogo-stanu

On November 11, 2025, the Law "On Ratification of the Agreement on Joint Procurement of Medical Protection Measures" was submitted to the Verkhovna Rada of Ukraine for consideration.

The law was developed with the aim of implementing the domestic procedures necessary for the Agreement on Joint Procurement of Medical Protection Measures to enter into force for Ukraine.

The Agreement allows Ukraine to carry out joint procurement procedures with European Union member states and other parties to the Agreement for the purpose of advance purchase of critically important medicines, innovative drugs, vaccines, antiviral drugs, etc. as countermeasures to the threat of pandemics, shortages of relevant medicines, and other serious cross-border threats to public health, in particular by concluding framework contracts with contractors.

The agreement was concluded by the European Commission and EU member states, including the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, and the Republic of Estonia.

📌 *For more details, follow the link:*

https://itd.rada.gov.ua/billinfo/Bills/Card/58700

On November 14, 2025, a law was submitted to the Verkhovna Rada of Ukraine "On ensuring the right of military personnel, veterans, and prisoners of war released from captivity to adequate medical care, rehabilitation, and prosthetics."

The purpose of the law is to create a comprehensive system of legal and financial guarantees for military personnel, veterans, and persons released from captivity, which will ensure a real, rather than a declarative, right to adequate treatment, rehabilitation, and prosthetics.

The law aims to legislate the principle of full state funding for the treatment and rehabilitation of military personnel, veterans, and prisoners of war who have been released from captivity.

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Rehabilitation measures should continue during a long-term rehabilitation period to achieve the maximum possible level of functional independence and integration into society, as determined by the conclusion of the military medical commission. In addition, the document guarantees the preservation of all types of financial support for the period of treatment, including abroad, which excludes the risks of deterioration of the financial situation of military personnel.

📌 *For more details, follow the link:*

https://itd.rada.gov.ua/billinfo/Bills/Card/58727

Date of submission: 09 December 2025

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[1] *Updates do not apply to the newly joining the Association members.*

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