EUROPEAN ASSOCIATION of HEALTH LAW

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Message from the President

EAHL President
Steven Lierman

Dear members, dear colleagues,

Now the year end approaches, we look back on a well-filled year for our association. The year started with the online strategic writing school for young scholars. This was followed later in the year by the first Jean Monnet summer school at the University of Salerno and culminating in the biennial congress in Warsaw. The congress gave us the opportunity to strengthen our mutual ties and get a pulse on research findings and important developments in health law.

2025 also announces itself as an exciting year. The call for applications to host the 2nd EAHL Young Scholars Workshop attracted one very strong application from the University of Salerno. It is a great pleasure to announce that the workshop will take place in Salerno on 16 and 17 April. Please tell doctoral students and postdocs within your network!

In addition, the board has agreed to sign a Memorandum of Understanding between our association and Kyiv Medical University to strengthen cooperation between the two. This is a significant step in enhancing our joint efforts to strengthen Ukraine's healthcare and public health systems during these challenging times.

Already we are looking forward to the anniversary edition of our biennial conference in 2026. The open call attracted four applications, each of which submitted a strongly developed and competitive dossier. At the end of January, it will be announced where the 10th EAHL Congress will take place. So keep an eye on our website and social media, because there you will also find the exact date of the congress and the deadlines for abstract submission and early bird registration.

In this newsletter you will once again find the esteemed writings of our national contact points, giving insight into the latest developments in their countries. In addition, there is a

Table of content

report on the activities of the EAHL IG Supranational Biolaw in the context of the EU Health Policy Platform. This online collaborative forum is established by the European Commission to stimulate discussion and exchange of knowledge and good practices among a wide range of stakeholders in the health sector. The added value of this platform for all EAHL members and how to access it can be found at that place in our newsletter. Let me conclude by thanking you all for the many warm interactions and your valued commitment, which enable us to look to the future with confidence. Let us raise a glass together to a bright future for our association and a healthy and peaceful year for all of you!

Steven Lierman

Chair

Spotlights on changes in the Austrian legislation and jurisdiction

Caroline Voithofer (NCP for Austria) and Ayla Schimpfössl

Department of Theory and the Future of Law, University of Innsbruck

1. Changes for Healthcare and Nursing

The Healthcare and Nursing Act (Gesundheits- und Krankenpflegegesetz, GuKG) and the Prescription Requirement Act (Rezeptpflichtgesetz) were amended by Federal Law Gazette I 109/2024. The main focus is on the reorganisation of the competencies of the healthcare and nursing professions (§ 15 GuKG), and the reorganisation of the specialisations of qualified healthcare and nursing staff. The following aspects deserve to be briefly highlighted:

The amendment clarifies that relevant professional experience has to be taken into account when nostrificating foreign-trained healthcare and nursing staff at the university of applied sciences.

The competencies of the higher service for health and nursing care in medical diagnostics and therapy have been redesigned, and adequately regulated for an academically trained professional group and include the following key elements: competence orientation instead of activity orientation; a move away from fragmentation towards general solutions that expand the scope for action in practice; boundaries regarding medical prerogative and the core areas of other health care professions; medical prescription: possibility of a general order for certain standardised measures, debureaucratisation of the professional requirements for written form; cooperation: possibility of recommendation to other healthcare professions, delegation to assistant professions and trainees, further delegation and instruction of laypersons.

In line with the amendment's aim of expanding competencies, an authorisation for qualified health care and nursing professionals to (further) prescribe medicinal products in certain care-related areas has now been created (§ 15b GuKG). The scope of practice for nursing assistants has been expanded to include the administration of infusions without a medicinal agent for hydration purposes with peripheral venous vascular access, and assistance with surgical wound care.

2. Changes in pharmacy legislation

The Pharmacy Act was extensively amended by the amendments published in 2024 (Federal Law Gazette I 22/2024 and 100/2024), which aim to ensure nationwide access to pharmaceuticals for the population and to optimise organisational processes. In addition to numerous smaller changes, there were several significant innovations in the area of opening hours (maximum permissible opening time per week: 72 hours), various expansions of competencies, and the creation of decentralised dispensing points for pharmaceutical.

The introduction of an age limit for obtaining a concession (submission of the concession application before the age of 65) is intended to ensure generational change. The revision of § 5 ApoG undoubtedly marks one of

the most significant changes in the Pharmacy Act. The scope of activities reserved for pharmacists now includes the dispensing of medicinal products and medical devices reserved for pharmacies; clinical pharmacy including medication management and medication analysis, the development, manufacturing and testing of medicinal products; the provision of advice and information on medicinal products and the review of stocks of medicinal products in hospitals. New in this context is medication management and medication analysis. This includes the 'repeated analysis of the overall medication to improve the safety of drug therapy and adherence to improve drug-related issues'; or, to put it another way, to check the effectiveness of pharmacotherapy.

The COVID-19 Transfer Act 2023 ('COVID-19-Überführungsgesetz 2023') has already provided for the authorisation of pharmaceutical professionals to carry out and evaluate COVID-tests on their own. This competence has now been extended to comparable standardised examinations using rapid test procedures, specifically by taking blood from a capillary and secretions by swabbing the nose and throat, and to enable pharmacists to collect basic medical data (pulse, blood pressure, temperature, weight, height) in pharmacies.

Hospital pharmacists are now authorised to replace prescribed medications with medications available at the hospital upon a physician's order or standard instructions, adjust the dosage form, quantity and strength, and discontinue, continue or interrupt a medication therapy.

3. Jurisdiction: Right to a free first copy of medical records

Austria's Supreme Court ruled (OGH 27.08.2024 6 Ob 233/23t) based on the General Data Protection Directive (Directive 95/46/EC), that every patient has a right to a first free copy of their medical records (= "Krankengeschichte).

The plaintiff requested a copy of his medical records from the hospital but refused to pay a fee. The defendant was the regional public authority (= "Gebietskörperschaft") that operates the hospital where the plaintiff was treated as an inpatient. In order to assert claims arising from an occupational accident, he requested a copy of his medical records from the hospital, but refused to pay a fee. The defendant hospital operator based its entitlement to demand payment on the Vienna Hospital Act. Although this provides for the free transmission of medical records in many cases – in particular to referring or treating physicians – it allows for a fee to be charged in other cases.

At the time of the Austrian Supreme Court's decision, the European Court of Justice (ECJ) had already ruled that the right to a free initial copy of the personal data processed includes the medical history of patients (ECJ 26.10.2023 C-307/22).

The Austrian Supreme Court denied an exception, and granted the patient the right to receive an initial copy of his medical history without paying a fee. The main reason for this is that the exemption must be interpreted restrictively and that the fee currently charged covers only a very small portion of the total costs incurred by the defendant operator in producing copies of medical histories in the defendant's hospitals. Exercising the

data protection right to a free copy, i.e. the discontinuation of the cost contributions collected so far, therefore does not achieve the required weight of an important public interest.

Date of submission: 23 November 2024

COP29 in Azerbaijan to stress climate goals to protect health

PhD Lala Jafarova

NCP for Azerbaijan

The connection between climate change and public health was one of the central themes at the COP29 conference held in Baku, Azerbaijan. The *COP29 Special Report on Climate Change and Health* highlighted the urgent need for governments and policymakers to prioritize health within climate strategies. This includes tackling challenges such as air pollution, extreme weather, and the spread of infectious diseases. Although not explicitly tied to health law, these discussions stressed the importance of embedding health considerations into climate policies, with potential implications for future legal frameworks.

A notable outcome was the creation of the *Baku COP Presidencies Continuity Coalition for Climate and Health*. The coalition seeks to ensure health considerations are integrated into climate action.

Baku Breakthrough

Significant achievement made during COP29 involves the agreement on *the Baku Finance Goal (BFG)*, which sets a new global target to channel $1.3 trillion of climate finance to developing countries by 2035. This includes a core finance goal of $300 billion annually from developed countries. The Baku Finance Goal aims to support the least developed countries and small island developing states, with a focus on accessibility and transparency.

Key outcomes of the Ministerial Roundtable on Climate and Health at COP29:

- Signature of a Letter of Intent for the establishment of the Baku COP Presidencies Continuity Coalition for Climate and Health.
- Exploration of new climate and health financing opportunities through multilateral and bilateral platforms, including the Health Impact Investment Platform (HIIP).

Global Initiatives

- Joint Solemn Appeal by the COP29 Presidency for a COP Truce
- COP29 Global Energy Storage and Grids Pledge
- COP29 Green Energy Pledge: Green Energy Zones and Corridors
- COP29 Hydrogen Declaration
- COP29 Declaration on Green Digital Action
- COP29 Declaration on Reducing Methane from Organic Waste
- COP29 Declaration on Multisectoral Actions Pathways (MAP) to Resilient and Healthy Cities
- COP29 Declaration on Enhanced Climate Action in Tourism
- COP29 Declaration on Water for Climate Action
- The Climate Finance Action Fund

- The Baku Initiative for Climate Finance, Investment and Trade (BICFIT)
- The Baku Initiative on Human Development for Climate Resilience
- Baku Harmoniya Climate Initiative for Farmers
- The Baku Global Climate Transparency Platform (BTP)

Other highlights during COP29:

- As part of the negotiations the UN COP29 featured a Health Day on 18 November.
- Azerbaijan was appointed as a co-founder of ATACH for 2024-2026 following a joint decision.
- In collaboration with the Wellcome Trust, WHO hosted a Health Pavilion.

Other news from Azerbaijan

The inclusion of outpatient treatment medicines in compulsory health insurance coverage was approved in the final reading of Milli Majlis (Parliament) on 29 November 2024. Thus, the project reflects issues such as the conditions for reimbursement of outpatient medications under compulsory health insurance, the determination of outpatient medications provided under compulsory health insurance by the service envelope, and the provision of outpatient medications at the expense of the compulsory health insurance fund.

Sources:

- Official web-site of the President of the Republic of Azerbaijan: https://president.az/en/
- The Milli Majlis of the Republic of Azerbaijan: https://meclis.gov.az/index.php?lang=en
- COP29 Official website: https://cop29.az/en/home
- WHO official website: https://www.who.int/teams/environment-climate-change-and-health/climate-change-and-health/advocacy-partnerships/talks/health-at-cop29

Date of submission: 29 November 2024

Current issues in the field of health law in Denmark

Prof. Caroline Adolphsen

NCP for Denmark

Professor at Aarhus University (updated on 5 November 2024)

Introduction

In Denmark, the public hospitals are run by 5 regions that each cover a part of Denmark. Some regions cover bigger cities while others are less populated, and the vulnerability of the patients differ quite a bit. In order to level out the services and to make sure that there are sufficiently educated healthcare professionals all over Denmark, the Danish government has presented a plan to (among other things) cut the number of regions down to four and to make sure that the system will be closer to the patient and not the other way around.

New legislation

Treatment for children and adolescents who are showing signs of mental illness or mental distress

The diagnosing of mental illness is done by the regional psychiatric entities or specialized doctors. However, in order to amend for the very long waiting lists for such evaluations, it is now mandatory for the municipalities to offer free and accessible evaluations and treatment for children and adolescents who are not thriving. The idea is to shorten the waiting lists for access to the psychiatric entities by mandating the municipalities to handle the less serious cases.

Rules on the right not to be resuscitated

Euthanasia is not legal in Denmark, but the government has asked a committee to look into the possibility of making it legal. It is, however, legal for the medical professional to discontinue life-sustaining treatment of a patient who is imminently dying, and if a patient withdraws his or her consent, treatment can only be carried out after rules about treatment with force. The patient can also make a decision in advance ("treatment will") to refuse treatment under future circumstances where the patient is no longer, and will never be, capable of giving an informed consent. Parliament has adapted but not yet set into force a wider access to make such advanced declarations for patients aged 60 and above in cases of cardiac arrest.

Brand new judgement from the European Court of Human Rights – Case of Lindholm and the Estate after Leif Lindholm v. Denmark

On 5 November the Strasbourg Court made a long-awaited judgement in a case about treatment with blood of a (now deceased) patient belonging to the faith of Jehovah's Witnesses. The patient had carried with him an advanced medical directive stating that he didn't want to be treated with blood but has been treated anyway. The ECHR ruled that there had been no violation of articles 8 and 9 as the advanced directive had been taken

into account when deciding on the treatment and as the Danish rules (section 24 of the Health Act) clearly stated that refusals to receive blood should be given based on information from a medical professional and could only be valid in connection with a current treatment.

Date of submission: 7 November 2024

France launches its national committee on digital ethics: the “CCNE du Numérique”.

Éloïse Gennet

NCP for France

According to the decree of 23 February 1983, the CCNE’s mission was to ‘give its opinion on the moral problems raised by research in the fields of biology, medicine and health’. But this mission has now evolved in 2021 to ‘give its opinion on the ethical problems and social issues raised by advances in knowledge’.

After more than 40 years of existence, the CCNE continues to explore a wide variety of topics, including on key issues such as research ethics (notably with its 2024 opinion 145 on “The framework for ethical evaluation of clinical research. Encouraging clinical research without undermining the protection of individuals”).

Yet CCNE has also adapted to modern health challenges and is for instance working on issues at the interface between health and the environment, or on digital health ethics. In fact in December 2019, the French government and the CCNE had formally established the National Pilot Committee for Digital Ethics (CNPEN), embedding it within the CCNE to leverage its long-standing role in bioethics. The aim was to create a specialized body that could analyze, deliberate, and provide guidance on ethical concerns specifically related to digital transformation.

Over a few years of activity, CNPEN has issued several opinions on topics such as ethical issues surrounding autonomous vehicles, telemedicine, digital applications for pandemic control, facial recognition technologies, or ethical issues around the use of AI in medical diagnostic.

Following this pilot phase during which the CNPEN operated under the guidance of the CCNE, it has now become a new independent consultative institution, the “CCNE du Numérique”, tasked with issuing ‘opinions on ethical issues raised by advances in science, technology, uses and innovations in the digital field, and their potential impacts, particularly social, economic, environmental or educational’.

This Digital CCNE represents a significant development in the response to the ethical challenges posed by advances in the field of digital technology. According the CCNE, it makes France the first nation to have such a national committee dedicated to digital technology, in a similar way to the creation 41 years ago of the CCNE for life sciences and health.

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000049591295

https://www.ccne-ethique.fr/sites/default/files/2024-05/CCNE%20CP%20cr%C3%A9ation.pdf

https://www.ccne-ethique.fr/sites/default/files/2024-04/Communiqu%C3%A9%20de%20presse%20avis%20145.pdf

https://www.ccne-ethique.fr/sites/default/files/2024-04/Avis%20145_0.pdf

https://www.ccne-ethique.fr/sites/default/files/2023-02/Dossier%20de%20presse%2040%20ans.pdf

Date of submission: 25 November 2024

EAHL Country Report: Ireland

Dr Brenda Daly

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EAHL National Contact Point for Ireland

Assisted Dying in Ireland

Since publication of the Joint Oireachtas Committee on Assisted Dying Report in March 2024,[1] the Voluntary Assisted Dying Bill 2024 (a private member's bill[2]), was introduced to An Dáil Éireann (the Irish parliament) on 25th June 2024.[3] The aim of this Bill was to establish a legal framework for assisted dying in Ireland. However, this bill has lapsed due to the dissolution of An Dáil Éireann and Seanad Éireann,[4] as a general election was called for 29th November 2024.[5]

The recommendations set out in the Joint Oireachtas Committee on Assisted Dying Report 2024 were subject of a debate by the members of An Dáil Éireann on Thursday, 17th October 2024.[6] Members of An Dáil Éireann acknowledged that there are equally strong held public opinions both in favour of, and in opposition to, legalising assisted dying in Ireland. One notable point raised during the Dáil debate highlighted the need to improve funding for palliative care and end of life care, irrespective of any changes to the current legal framework to legalise assisted dying. Pursuant to this debate, members of An Dáil Éireann voted on the motion "That Dáil Éireann shall take note of the Report of the Joint Committee on Assisted Dying entitled Final Report of the Joint Committee on Assisted Dying, copies of which were laid before Dáil Éireann on 21st March, 2024". This motion passed with 76 votes in favour, and 53 votes against the motion.[7] However, dissolution of An Dáil Éireann on 8th November 2024 and the subsequent general election held on 29th November 2024 means that no further action will be taken at this juncture to act on the Joint Committee on Assisted Dying's report. At the time of writing, following the general election, Fianna Fáil are seemingly in position to lead the next government. It is worth noting that there is no apparent commitment in the Fianna Fáil 2024 election manifesto to legislate for assisted dying. Furthermore, prior to the vote on the Joint Committee on Assisted Dying Report, the Fianna Fáil TD, Michéal Martin (who has been re-elected and is likely to be the next Taoiseach of Ireland) indicated that "…he had serious reservations about what was

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[1] Houses of the Oireachtas. Joint Committee on Assisted Dying: Final Report of the Joint Committee on Assisted Dying. March 2024. Available at https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_assisted_dying/reports/2024/2024-03-20_final-report-of-the-joint-committee-on-assisted-dying_en.pdf

[2] Any member of An Dáil Éireann can introduce a private member's bill, however such bills rarely become law as they require the support of the government. https://www.citizensinformation.ie/en/government-in-ireland/houses-of-the-oireachtas/private-members-bills/

[3] Voluntary Assisted Dying Bill 2024 (Bill 50 of 2024). Available at https://data.oireachtas.ie/ie/oireachtas/bill/2024/50/eng/initiated/b5024d.pdf

[4] Seanad Éireann is the upper house of the Irish parliament

[5] https://www.oireachtas.ie/en/bills/bill/2024/50/

[6] An Dáil Éireann debate - Thursday, 17th October 2024 - https://www.oireachtas.ie/en/debates/debate/dail/2024-10-17/37/

[7] Report of the Joint Committee on Assisted Dying: Motion (Resumed) Dáil Éireann - 23 October 2024. Available at https://www.oireachtas.ie/en/debates/vote/dail/33/2024-10-23/153/

proposed by the majority of the Assisted Dying Committee."[8] It remains to be seen whether the next coalition government will include a commitment to legislate for assisted dying in Ireland.

Assisted Dying – Northern Ireland

While geographically Northern Ireland is on the same island as Ireland, and politically and constitutionally part of the United Kingdom, it is acknowledged that it would be in an unusual position should legalisation of assisted dying occur in the Republic of Ireland, England and Wales, and Scotland. As noted above, there has been extensive debate in the Republic of Ireland on legalising assisted dying. In March 2024, a member's bill, Assisted Dying for Terminally Ill Adults (Scotland) Bill, was introduced.[9] On 29th November 2024, a majority of ministers in the United Kingdom's House of Commons approved the second reading of the Terminally Ill Adults (End of Life) Bill 2024-25.[10]

Because of devolution in the United Kingdom, the responsibility for legislating on assisted dying is that of the Northern Irish Assembly.[11] Assisted dying is currently illegal in Northern Ireland.[12] Two of the political parties (Sinn Féin and the SDLP) have expressed some support to introduce changes to the law on assisted dying for persons with terminal illness. Only one of the 18 elected Northern Irish MPs,[13] Colum Eastwood (SDLP), voted in support of legalising assisted dying at the recent vote in the House of Commons on the Terminally Ill Adults (End of Life) Bill 2024-25. The majority view is that this legislation ought to be dealt with by the UK government rather than the Northern Irish devolved administration.

Assisted Human Reproduction

The Health (Assisted Human Reproduction) Act 2024 was signed into law on 2nd July 2024 however this Act was not commenced before the November 2024 general election in Ireland. There is a commitment by two of the main political parties (Fianna Fáil and Fine Gael) who are likely to form part of the new coalition government to ensure the commencement of this legislation, and to set up the Assisted Human Reproduction Regulatory Authority.

In the most recent Budget published by the government, €37 million in funding has been allocated for a number of women's health initiatives, including a new scheme to provide access to free hormone replacement

[8] "Dáil to vote on final Oireachtas report on assisted dying" (Friday 18th October 2024) – available at https://www.rte.ie/news/politics/2024/1018/1476120-assisted-dying/

[9] Scottish Government, Bill debate on euthanasia, assisted death and suicide: FOI release (4 September 2024) https://www.gov.scot/publications/foi-202400412911/

[10] This vote was held on 29th November 2024. There were 330 votes in favour, and 275 votes against this bill. https://votes.parliament.uk/votes/commons/division/1877

[11] Northern Ireland also elects 18 members of parliament to represent the 18 constituencies of Northern Ireland in the UK House of Commons.

[12] Suicide Act 1961, section 2

[13] One MP, Clare Hanna (SDLP) abstained from this vote. MPs representing Northern Ireland's Alliance Party, Democratic Unionist Party (DUP), Ulster Unionist Party (UUP) all voted against legalising assisted dying. The 7 elected Sinn Féin MPs did not vote as members of Sinn Féin do not take their seats in Westminster due to the party's abstention policy.

therapy (HRT) for women with symptoms of menopause; funding to enable the provision of post-mastectomy products; and an extension of the scheme for publicly funded assisted human reproduction.[14]

Patient safety

Commencement legislation, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (Commencement) Order 2024 (SI No. 482 of 2024) stipulates that all sections of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (No.10 of 2023), other than section 68 (Review of specified incident by chief inspector), commence into operation on the 26th September 2024. The purpose of this legislation is to "to strengthen openness and transparency throughout the Irish health care system." This legislation applies to both the public and private health care settings.

Recent case law

Health Service Executive v H.H. [2024] IEHC 564

This case concerned a young person suffering an eating disorder who had been admitted as an emergency patient to a specialist eating disorder unit in September 2023. She had been detained involuntarily in accordance with section 23 of the Mental Health Act 2001.

Following diagnosis with an acute eating disorder, this patient was then treated as an outpatient on a weekly basis. This patient was identified as falling into the high-risk category for a life-threatening event as per the "*Medical Emergencies in Eating Disorder Guidance*". The patient wanted to discharge herself from the relevant treatment. The medical team treating this patient believed that she lacked capacity, and could not understand that she was at high risk. Consequently, the Health Service Executive (HSE) sought a court order granting detention of the patient in the approved centre/hospital for the purposes of providing the requisite medical and therapeutic care. Furthermore, the HSE sought permission to administer treatment which would include nasogastric feeding, and permission to sedate or restrain the patient if necessary to do so. The HSE deemed nasogastric feeding an essential part of this patient's treatment plan.

The High Court found that nasogastric feeding does constitute treatment for the purposes of section 2, Mental Health Act 2001. However, the High Court ruled that nasogastric feeding could not be administered under restraint as this is not explicitly provided for in the Mental Health Act 2001.

Date of submission: 02 December 2024

[14] Government of Ireland, Budget 2025 Expenditure Report. (1st October 2024) p.106. Available at https://www.gov.ie/en/publication/cb193-your-guide-to-budget-2025/

A preliminary (critical) overview of Italy's institutional reform towards an effective implementation of the One Health approach

Prof. Dr. Stefania Negri

NCP for Italy

In Italy, the year 2024 was marked by profound changes in the structural organisation and governance of key government health authorities including the Ministry of Health and the Italian Medicines Agency (Agenzia Italiana per il Farmaco - AIFA). In particular, by Decree of the Prime Minister no. 196 of 30 October 2023 – *Regolamento di organizzazione del Ministero della salute* – in force as of 3 January 2024, the Ministry of Health underwent a significant re-organisation which completely redesigned its institutional architecture.

Pursuant to this reform, the Ministry's administrative structure is now composed of four major Departments, each one articulated into three Directorates-General (DGs):

a) Department of General Administration, Human Resources and Budget;

b) Department of Prevention, Research and Health Emergencies;

c) Department of Planning, Medical Devices, Drugs and Policies in Favour of the National Health Service; and

d) Department of Human Health, Animal Health and Ecosystem (One Health), and International Relations.

The most interesting and striking innovation is the establishment of the One Health Department, which comprises the following DGs: Healthy lifestyles and relationships with the ecosystem; Hygiene and safety of food; and Animal health. This structural reform is the precondition for a true paradigm shift towards a better and more effective implementation of the One Health approach at national level, in line with global and regional efforts aimed at improving prevention, preparedness and response to public health emergencies of international concern, including pandemics.

The One Health approach has gained increasing momentum in the aftermath of the Covid-19 pandemic and is nowadays unquestionably recognised as the best possible model to enhance preparedness face to multidimensional health emergencies. From a conceptual point of view, One Health embodies a holistic and integrated approach to public health and promotes multisectoral responses to complex health risks emerging at the human-animal-ecosystem interface, including food safety hazards, zoonoses, antimicrobial resistance (AMR), environmental contamination and other major risks connecting public health, animal health, plant health and environmental protection. From an operational point of view, One Health encourages and supports synergic actions between the human, veterinary, food and environmental sectors, the integration of

surveillance and control systems and the convergence of efforts aimed at achieving common global health objectives. From an institutional point of view, the One Health model requires interinstitutional, multisectoral and multilevel involvement (*whole-of-government approach*) and the establishment of specific governance mechanisms at global, regional and national levels.

At the international level, a successful implementation of this approach relies on the action of the Quadripartite Coalition gathering the World Health Organization (WHO), the World Organization for Animal Health (WOAH), the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP). This international partnership successfully operates on the basis of common objectives and converging expertise, creating joint governance structures, consultation and coordination mechanisms and joint operational tools. It was formalised on 17 March 2022 with the signature of a Memorandum of understanding which provided a legal and formal framework for the four organizations to adopt a more integrated and coordinated approach in collaborative efforts, guided by the Joint Action Plan (2022-2026) which integrates other existing coordination initiatives at global and regional level.

At the European Union level, interinstitutional collaboration in support of the One Health agenda was strengthened with the establishment of the Cross-agency One Health Task Force in 2023, involving the European Center for Disease Prevention and Control (ECDC), the European Agency for Chemicals (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). In line with the Joint Framework for Action (2024-2026) which identifies priority strategic objectives, the Task Force aims to make cooperation between EU agencies permanent and structured, based on the principles of coordination, collaboration, communication and capacity building.

The Italian One Health Department is meant to provide the same multisectoral and interinstitutional collaborative framework guaranteeing the successful implementation of the One Health approach at the domestic level. The innovation is undoubtedly significant, albeit Decree 196/2023 raises some concerns with regard to the internal organisation of the Department, its competences and the required coordination with other Departments, ministries and relevant public administrations and bodies.

First of all, the division of competences between the three One Health DGs seems to contravene to some extent the rationale underlying the holistic vision of One Health, since the sectors of human, animal and environmental health are not fully integrated but are entrusted to the three separate DGs, which could mean still operating in silos.

Secondly, as far as the scope and competence of the One Health Department are concerned, there are two major gaps that may turn into major criticalities: 1. lack of competence on infectious diseases, which are

exclusively entrusted to the DG Prevention included within the Department of Prevention, Research and Health Emergencies; 2. no competence on the management of health emergencies, conferred on the DG Health emergencies within the Department of Prevention, Research and Health Emergencies; 3. no reference at all to the "silent pandemic" of antimicrobial resistance (never mentioned in Decree 196/2023). On the other hand, "correct lifestyles" seem to have been inappropriately included within the One Health paradigm and strangely associated with the protection of the environment. In principle, health problems related to unhealthy lifestyles (i.e. chronic non-communicable diseases caused by known and preventable risk factors such as alcoholism, tabagism, unhealthy diets etc.) would be better placed among those falling under the purview of the DG Prevention and appear much less relevant to the One Health discourse.

Thirdly, moving to the necessary interinstitutional cooperation required by the One Health model, the four Departments should "ensure the organic and integrated exercise of the functions actually carried out by the Directorates-General" (art. 2, paragraph 2. b of Decree 196/2023), while the Heads of Department should coordinate the work of their own DGs and "the development of operational collaboration between departmental structures and other administrations and public sector bodies" (art. 4, paragraph 2.b). However, nothing else is added beyond such very general provisions and the Decree falls short of creating any connecting structure or any intra- and inter-ministerial coordination mechanisms. This notable gap suggests that the concrete operational methods of concertation and consultation will be hopefully set by way of future additional regulatory acts complementing the Decree 196/2023.

This latter issue is of the utmost importance, given that intra- and inter-departmental cooperation is compelling in more than one respects. In the first place, it is essential that the DG for animal health strictly interacts with the DG on hygiene and safety of food, which is responsible for risk management, the alert system and emergencies linked to food and feed safety as well as food-borne zoonoses, as well as with the DG on the relationship with the ecosystem, which also carries out physical, chemical and biological risk assessment functions regarding food safety. Inter-departmental cooperation is equally important. The same DG for animal health, which is entrusted with the epidemiological surveillance of infectious and diffusive animal diseases and the control of zoonoses, should closely cooperate with the DG for public health emergencies (operating within the Department of Prevention, Research and Health Emergencies) which deals with epidemiological surveillance, prevention and control of infectious and diffusive diseases, as well as with surveillance, prevention and control of health emergencies.

Cooperation with administrations outside the Ministry of Health is another key concern, since effective implementation of the One Health approach requires collaboration across multiple sectors, including agriculture, environment, and trade (just to mention a few), which often fall outside the purview of health ministries.

In conclusion, despite some identifiable grey areas, it is somewhat premature to express a final judgment on the effectiveness of the reform, which is still work in progress. What appears clear from now is that the success of the One Health Department will depend on the ability to achieve an optimal level of systematic, integrated and inclusive cooperation that concretely achieves the desired paradigm shift towards a more effective application of the One Health model at all levels. It is to be hoped that future integrative acts will provide the necessary operational tools to achieve this ambitious goal.

Date of submission: 20 December 2024

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

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1. Amendments of the Law on the Rights of Patients in the context of non-initiation of futile medical treatment.

Futile medical treatment is the initiation or continuation of medical treatment for a patient in a situation where there is no reason to believe that the medical treatment will lead to an improvement in the patient's health, prolongation of life or other benefit, or where the medical treatment may lead to prolongation of life but the suffering and burden caused by the medical treatment outweigh the potential benefit. In such cases, if the legal framework so provides, there may be a necessity to consider non-initiation of futile medical treatment, which raises fundamental issues that affect the end of a person's life and presents a fundamental issue of human rights.

To ensure the right of a person to make a conscious choice to refuse futile medical treatment and to die with dignity, receiving pain and suffering alleviating therapy, psychological and spiritual support appropriate to the state of health, as well as to ensure humane treatment of the patient at the end of life, the legislative process of the Republic of Latvia intends to provide a mechanism for the realisation of the right of patients at the end of life. In particular, the Law on the Rights of Patients of the Republic of Latvia is to be amended to allow the patient to express his or her will not to initiate or to discontinue futile medical treatment in a future situation and to provide a mechanism for the exercise and protection of the patients' right to autonomy at the end of life, when the patient is no longer able to express his or her will.

See here for more information: https://tapportals.mk.gov.lv/public_participation/aaf20fd4-0754-4cc8-a717-3540613c139d

2. A new law has been developed and submitted for public consultation: the Law on the Secondary Use of Electronic Health Data.

Health data is very valuable for scientific research and the development of new medical technologies. Secondary use of health data allows us to use data already held by healthcare institutions to drive innovation and improve healthcare. Currently, there is no regulatory framework in the Republic of Latvia to determine the procedure for the secondary use of electronic health data. To ensure this for the common good of society,

while strictly protecting the privacy of individuals' health data, the draft law "The Law on the Secondary Use of Electronic Health Data" has been developed and it aims to create a legal framework for the secondary use of electronic health data to ensure the availability of data for research, innovation, policy making, education, patient safety, and personalised medicine for every patient. The draft law will provide a legal framework and will also contribute to the wider implementation of innovation in healthcare in the Republic of Latvia.
See here for more information: https://tapportals.mk.gov.lv/legal_acts/04d31a1d-3630-4198-905e-623662f9cd98

3. The amendments to the Cabinet of Ministers of the Republic of Latvia Regulation No. 60 of 20 January 2009, titled "Regulations on Minimum Requirements for Medical Institutions and Their Departments", have been developed and submitted for public consultation.

Cabinet of Ministers of the Republic of Latvia Regulation No.60 of 20 January 2009, titled "Regulations on Minimum Requirements for Medical Institutions and their Departments" stipulates requirements for outpatient medical institutions, including that the medical institution, be in a building designed or adapted for its operation (Sub-paragraph 3.1 of Regulation No.60).
According to the Medical Treatment Law of the Republic of Latvia, an optometrist is a functional specialist (medical person) who is entitled to provide medical services in a medical institution. For an optometrist's retail shop to be registered as a medical institution and for an optometrist to provide their services, the premises must comply with a specific type of use or classification. However, an optometrist's retail shop offers both the sale of medical devices and the services of an optometrist.
The aim of the amendments of the Cabinet of Ministers of the Republic of Latvia Regulation No 60 of 20 January 2009, titled "Regulations on Minimum Requirements for Medical Institutions and their Departments" is to establish minimum requirements for an optometrist's office to ensure the provision of high-quality and safe services, considering the specificities of the optical field.
See here for more information: https://tapportals.mk.gov.lv/public_participation/751e94ee-63fd-4717-8b78-48c99ece7ef0

4. Refusal of vaccination for minors: challenges within the national legal framework and the legal consequences of parental decisions in the Republic of Latvia. Solutions for improving the legal framework are being explored in the health policy planning process in the Republic of Latvia.

In the Republic of Latvia, the rights of minor patients are strictly regulated by national legal framework including the Law on the Rights of Patients of the Republic of Latvia. Despite the seemingly clear legal framework on the protection of the rights of minor patients in the Republic of Latvia, practice shows that legal

challenges to balancing the rights of minor patients, legal representatives of minor patients and the public to health protection do arise in various practical situations. These legal challenges arise mainly when the legal representatives of minor patients implement their right to refuse the mandatory vaccination of minor patients. For example, in the Republic of Latvia in 2024, there was a public case of the death of a minor patient whose legal representatives had decided not to vaccinate him against diphtheria or a disease for which vaccination is mandatory under national legal acts. Following this case, several questions have been raised about possible amendments to the national legal framework, including potential educational issues for the legal representatives of minor patients, possible liability issues for waiving compulsory vaccination of minor patients, possible exclusion from educational institutions and other issues.

See here for more information: https://www.vm.gov.lv/lv/jaunums/vienojas-par-atbalstu-vecakiem-un-gimenes-arstiem-bernu-vakcinacijas-nodrosinasanai-tiesibu-ekspertiem-javerte-vecaku-atbildiba-par-lemuma-sekam

5. The amendments to the Cabinet of Ministers of the Republic of Latvia Regulation No. 803 of 25 October 2005, titled "Rules on the Principles Governing the Pricing of Medicinal Products," have been developed and will enter into force on 1 January 2025.

On 1 January 2025, amendments to the Cabinet of Ministers of the Republic of Latvia Regulation No. 803 of 25 October 2005, titled "Rules on the Principles Governing the Pricing of Medicinal Products," will enter into force. The main objective is to provide more affordable prescription medicines to patients with more affordable prescription medicines by modifying the current mark-up model, which has also been highlighted by the Competition Council, the World Health Organization, and the World Bank. The revision of the pricing model for medicines is one of the ways to enhance the affordability of medicines, as outlined in the Informative Report on measures to reduce the cost of medicines in the Republic of Latvia, adopted by the Government of the Republic of Latvia.

See here for more information: https://tapportals.mk.gov.lv/legal_acts/92e4d3d8-e80b-4784-bdd6-c2b9071221e4;
https://likumi.lv/ta/id/353805-grozijumi-ministru-kabineta-2005-gada-25-oktobra-noteikumos-nr-803-noteikumi-par-zalu-cenu-veidosanas-principiem-

6. In the Republic of Latvia, a publication has been developed in the field of digital transformation in healthcare, which is significant for the development process in the healthcare sector.

Publication: Balode, A., & Bikava, I. (2024). Balancing Expectations for Digital Transformation in the Healthcare: Development of the New Cancer Registry in Latvia. In K. Kang, & L. Li (Eds.), *E-government Digital Frontiers - Transforming Public Administration Through Technology*

In the publication, the authors indicate that the healthcare sector has been slower to embrace digital transformation compared to other industries. However, it is evident that digitalization offers significant growth and innovation potential, particularly in ensuring patient-centric healthcare. Despite this potential, implementing digital solutions often involves a disproportionately lengthy and challenging process. As a European Union member state, the Republic of Latvia has achieved considerable progress in digitalization, especially in cancer treatment and related data processing. A modern, population-based cancer registry can serve several crucial purposes from both the patient's perspective and in analysing healthcare quality, cost-effectiveness, service demand, supply, and policy development. Even though digital transformation began over a decade ago, the first phase of national level oncology data management was only implemented in 2024. The key takeaway here is that "Digital Transformation is not merely an IT project!" In the observed case, critical factors influencing success included industry professionals' readiness for change and the active impact of European Union initiatives, combining both bottom-up and top-down approaches.

See here for more information: https://doi.org/10.5772/intechopen.1007352

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Spotlights on recent changes in health law in Lithuania

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Here is the overview of some legal changes in health law that took place in Lithuania in the last few months of 2024.

- The Constitutional Court has accepted in June the request of a group of members of the Parliament (*Seimas*) to investigate whether the Law on Assisted Reproduction, which currently entitles only persons who have entered into a marriage or a registered partnership agreement to receive assisted reproduction services in the country, is compatible with the Constitution of Lithuania. The members of the Seimas who have taken the case to the Court point out that, according to the legal regulation laid down in the Law, single women and unmarried couples are not entitled to receive assisted reproduction services, and access to such services depends solely on the form of the family (couple) relationship. According to the applicants, such a legal regulation is not in line with the practice of many European countries and is possibly contrary to the Constitution. The decision of the Constitutional Court of the Republic of Lithuania is still pending.
- As of 1 July 2025, amendments to the Law on Health Insurance will enter into force in the country, which will benefit patients, and will give the State Patient Funds the right to impose punitive measures on medical institutions, pharmacies and other undertakings for breaches of the legal requirements. Patients will be able to recover more quickly and easily the money illegally taken from them for a personal healthcare service, medicine or medical aid that should have been provided free of charge. Violations of the law are most common in outpatient home care (providing services that have not been provided), in prosthetic dental care (providing prosthetic dental work that has not been provided and sometimes has not even been started, prosthetic services provided by non-physicians, etc.), in charging extra for services that should be free to patients, etc.
- The Ministry of Health (MoH) sets the general qualification requirements for nursing administrators. The new qualification requirements, which will enter into force on 1 January 2025, will apply only to newly recruited nursing administrators, and all nursing administrators will have to meet higher qualification requirements from 1 January 2031. The highest general qualification requirements for the administrator responsible for the institution's nursing policy are a master's degree or equivalent higher education qualification in the relevant science subject group, 3 years' experience in nursing and 3 years' experience in a managerial role. For the lowest level (ward) nursing administrator, a bachelor's degree in nursing and midwifery from a higher education nursing program or equivalent higher education qualification and 3 years' experience in nursing will be sufficient. The changes in health care facilities

will enhance the quality of services provided by nurses, and allow for the expansion of services and responsibilities through the redistribution of functions within the health care facility.

- Since 2020, the State Medicines Control Service carries out assessment of applications for reimbursed medicines. Over the last couple of years, the Service has been heavily criticised for the long queue of applications awaiting evaluation and the excessively slow evaluation process. This situation has now changed significantly. As a result of consistent work, the time taken to evaluate an application has been reduced year by year and this autumn of 2024 the previous queue of applications awaiting evaluation was eliminated. This means that important decisions for patients will be made faster.
- As of 1 November 2024, the rules for determining the extent of the impairment have changed. The previous rules have been in force for 20 years, despite changes in both the diagnosis and treatment of diseases, as well as different interpretations of the medical criteria. The new rules on the determination of the degree of impairment of health of victims will not only help to redress the injustice suffered by victims, and enable the courts to ensure proportionate sentencing, but will also have a preventive effect on offenders, which will contribute to a safer society. For example, one of the innovations of the amended rules is that fractures of the jaw and loss of parts of the face, among other injuries, will now be considered as serious bodily harm. Loss of 30% of 'participation' will also be considered a serious impairment. 'Participation' is the ability of disabled or elderly people to participate in social life.

Sources:

The Parliament of Lithuania: https://www.lrs.lt/

The Ministry of Health of Lithuania: https://sam.lrv.lt/

State Drug Control Service: https://vvkt.lrv.lt/

Constitutional Court of the Republic of Lithuania: https://lrkt.lt

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Malta: The duty of medical practitioners to provide emergency assistance

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The Medical Council of Malta issued a circular in November 2024 addressed to all medical practitioners. The scope of the circular is to cover "instances wherein medical practitioners who are not on duty act as first responders, in an unofficial capacity, in a scenario involving an emergency, accident or a tragic event, including but not limited to instances of sudden illness or medical complication, traffic collisions, building collapse, fire emergencies, natural disasters and similar events".[15] The Medical Council then stipulates in the November 2024 Circular that medical practitioners "who are not on duty but who encounter such an emergency, accident or tragic event, *have a moral and ethical responsibility to assist individuals whose life or personal safety is at risk*. It is important for such medical practitioners to apply their knowledge and skill to the best of their abilities to try to safeguard the life and health of the individual in question".[16] A medical practitioner whose skills are, for whatever reason, limited is not *ipso jure* excused from the ethical and moral responsibility to assist inasmuch as it is specified in the November 2024 Circular that "such medical practitioner has a moral and ethical duty to assist according to their level of care and skill as a first responder, even it is limited to basic first aid and outside the scope of their primary expertise".[17] It is furthermore clarified in the November 2024 Circular that in "these scenarios, the medical practitioner in question shall, as far as reasonably possible, ensure that official emergency services have been alerted" and, as soon as an official emergency service provider or a healthcare professional serving in an official capacity, though not necessarily a medical practitioner, arrives on the scene, "the medical practitioner shall retire in their favour". The Medical Council also specifies the circumstances when medical practitioners would be ethically and morally justified not to provide assistance in the scenario at hand involving an emergency, accident or a tragic event: "There is another emergency service provider on the scene; or [a] more appropriate emergency service provider can attend to such an emergency, accident or tragic event; or [t]he medical practitioner's judgement is impaired in view of alcohol, substance and/or medication; or [t]he life or personal safety of the medical practitioner would be placed in jeopardy; or [b]y providing assistance, the medical practitioner would put at risk the life or personal safety of third parties; or [t]here is an impediment to assist appropriately for health reasons, or the skills or lack thereof of the medical practitioner in question may compromise further the health of the individual requiring assistance".[18]

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[15] Medical Council Malta, *Ethical and Moral Duty to Provide Emergency Assistance* (Circular No. 01/2024 – 12th November 2024) p 1.
[16] *Ibid.* Emphasis added.
[17] *Ibid.*
[18] *Ibid.*, pp 1 – 2.

Even setting aside the substance of the November 2024 Circular, which alone arguably raises some valid questions, there are at least three broader juridical considerations worthwhile highlighting here:

The Medical Council of Malta is the regulatory body in relation to medical practitioners in Malta. It *inter alia* has the function "to prescribe and maintain professional and ethical standards"[19] for the medical profession. It can consequently at least plausibly be the case that the November 2024 Circular is now relevant to the professional and ethical standards of the medical profession.

Although it has been ruled in an unrelated case that the ordinary law in relation to the Medical Council's investigative and disciplinary powers is not in conformity with the State's obligations arising from the right to a fair trial,[20] the law as it stands today still provides that the Medical Council can exercise disciplinary measures if it finds, after due inquiry, that a medical practitioner "failed to abide by the professional and ethical standards applicable to him".[21] Subject to changes to the latter domestic law so as to align with the right to a fair trial, it is at this stage tenable that the Medical Council could in principle enforce the duty arising from the November 2024 Circular by imposing disciplinary measures if it transpires that a medical practitioner failed to abide by the moral and ethical duty to provide emergency medical assistance.

The November 2024 Circular additionally refers to the civil law whereby, all else being equal, "any person who causes damages in the performance of a rescue or in the course of assisting another person whose life or personal safety is in clear danger, shall not be liable for any damage caused in the course of the rescue or of giving assistance to the person who he rescued or assisted or tried to rescue or assist, to that person's property or to third parties or third party property".[22] The November 2024 Circular also refers to the criminal law whereby, all else being equal, "a person will not be criminally liable if, confronted with a present or imminent danger to another person, he performs an act necessary to ensure the safety of that person, whether or not the act actually ensures the safety of the person".[23] Yet, it was made clear in the House of Representatives when the latter civil law and criminal law were being introduced into the statute book in the 2017 – 2022 Legislature that there was no obligation on an off-duty professional to provide emergency assistance.[24] In spite of this, the Medical Council has now arguably used its authority arising from the Health Care Professions Act to introduce an ethical and moral responsibility on off-duty medical practitioners to provide emergency medical assistance. In that case, it is also tenable that the Medical Council has effectively shifted the onus of proof on medical practitioners, when they do not fulfil their ethical and moral duty to provide emergency medical assistance, to justify why they were ethically and morally justified in not intervening to provide emergency medical assistance.

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[19] Health Care Professions Act, Chapter 464 of the Laws of Malta, Article 10 (1)(d).
[20] *Spiteri Dottor Stephen v Kunsill Mediku et.*, Civil Court First Hall (Constitutional Jurisdiction) – 13/06/2023 [Ref: 175/2020].
[21] Health Care Professions Act, Chapter 464 of the Laws of Malta, Article 32 (1)(c).
[22] Civil Code, Chapter 16 of the Laws of Malta, Article 1033A.
[23] Criminal Code, Chapter 9 of the Laws of Malta, Article 226C.
[24] House of Representatives Malta – Office of the Clerk, *Dibattiti tal-Kamra tad-Deputati (Rapport Ufficjali u Rivedut)*, 13th Legislature: Sitting No 137 (4 July 2018) Hon. Therese Comodini Cachia, p 739.

Country update – Norway

Andrea J. Mietle and Karl Harald Sovig

Norwegian health law is constantly developing.[25] In the following, we will limit our focus to the proposal for a new abortion act and three recent Supreme Court decisions concerning the COVID-19 pandemic.

Through Prop. 117 L (2023-2024), the government has proposed a new abortion act, intending to extend the right to self-determined abortion from week 12 until week 18.[26]
Despite desiring extended self-determination, the consideration is not absolute, in which abortion after week 18 will continue to be made by a tribunal, with the viability of the fetus being the absolute limit for allowing abortion.[27] The government further proposes to remove the current requirement for tribunal proceedings when performing a fetal reduction in order to create equal rights to all interventions before week 18.[28]

The proposal further addresses several other issues, including cementing the current practice of healthcare personnel's right to refrain from partaking in abortions into law. The proposal was made with dissent from one of the two parties in the coalition government. Despite the dissent, the act will come up for a parliamentary vote in December. If self-determination is extended to week 18, Norway will be placed in group with Sweden and Denmark (recently amended). Compared to other Nordic countries, Iceland has self-determination until week 22, while Finland has until the 12th week (recently amended).

During the COVID-19 pandemic, Norway introduced strict restrictions on freedom of movement to combat the spread of infection.[29] In the following, this post will discuss the Supreme Court´s argumentation on the legality of the restrictions, focusing on ECHR and EEA law throughout the cases HR-2024-1107-A, HR-2024-1109-A, and HR-2024-1110-A.

HR-2024-1107-A addresses the return of a Swedish citizen residing in Norway after visiting family. After refusing to check in to a quarantine hotel, he was reported for breaching the COVID-19 regulations. In court, he argued that the legal requirement in ECHR art. 7 had not been met by the conditions being too vague. The Supreme Court rejected his argument due to the terms being clearly communicated by the legislature and that the ECtHR has ruled that the requirement of clarity does not obstruct provisions with a certain scope for interpretation (para. 81).

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[25] For an overview, see Karl Harald Sovig, Medical Law in Norway, Wolters Kluwer, 2 edn. 2022.
[26] Helse- og omsorgsdepartementet. (2024). *Regjeringen legger frem forslag til ny abortlov*. https://www.regjeringen.no/no/aktuelt/regjeringen-legger-fram-forslag-til-ny-abortlov/id3051033/. Downloaded 20.10.2024
[27] Prop. 117 L (2023-2024) p. 46
[28] Prop. 117 L (2023-2024) p. 55
[29] See for instance regulation 2020-03-27-470 which were amended on a weekly basis during the pandemic.

When assessing ECHR Article 8, the Supreme Court concluded that the requirements for suitability, necessity, and proportionality were met through the legislator assessing the conflicting interests. The implementation was therefore within the state's margin of appreciation. The Supreme Court then made a supplementary assessment under EEA law. The same arguments were largely used to establish that the assessment of necessity, suitability, and proportionality had been met. The court thereby determined that the margin of appreciation could not be stricter under EEA law than under the ECHR. The state had thereby acted within its authority when requiring the defendant to check in at the quarantine hotel.

The cases assessed through HR-2024-1109-A and HR-2024-1110-A largely coincide and will thereby be assessed together. In the first case, the defendant refused to be tested for COVID-19 at the border, whilst in the second the defendant could not provide a negative test upon entering the country. The defendants argued that the test obligations entailed border control, which the state did not have grounds for under regulation (EU) 2016/399 (Schengen Borders Code) art. 22, 23 and 25. When assessing the question, the Supreme Court evaluated the control´s intensity, frequency, and selectivity. Based on the evaluation, the court stated that despite having similarities with border control, the control was less intense and more selective as it only applied to people arriving from areas with compulsory quarantine. As a consequence, The Supreme Court concluded that the requirements did not breach the Schengen regulation.

Date of submission: 25 November 2024

Slovakia: Recent developments in health legislation (Jun – November 2024)

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Decree No. 115/2024 Coll. Decree of the Ministry of Health of the Slovak Republic (hereinafter „MH SR"), amending and supplementing Decree of the MH SR No. 321/2005 Coll. on the scope of practice in certain health professions, as amended. The decree introduced small changes related to administration of intravenous medications. In force: Jun 15, 2024

URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/115/

Act No. 120/2024 Coll. Act amending and supplementing Act No. 355/2007 Coll. on the protection, promotion and development of public health and on the amendment and supplementing of certain acts, as amended, and amending and supplementing certain acts. It transposes Directive (EU) 2022/431 of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16. 3. 2022). In force: Jun 1, 2024. URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/120/

Act No. 125/2024 Coll. Act amending and supplementing Act No. 578/2004 Coll. on healthcare providers, healthcare workers, professional organizations in healthcare and on amending and supplementing certain acts, as amended by later regulations, and amending and supplementing certain acts. In force: July 1, 2024. This act introduces changes in various areas., e.g. changes that modify professional work activities in the healthcare profession of dental assistant, in the healthcare profession of practical nurse - assistant and in the healthcare profession of paramedic, persons who are in an employment relationship with a healthcare provider and are students in higher grades of specified types of healthcare study programs at secondary and higher education institutions. Also modifies the conditions of accreditation for institutions offering postgraduate healthcare education and the accrptance of healthcare workers coming from abroad, shortens office hours in which emergency medical services are provided as part of primary care and other. URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/158/

Act No. 158/2024 Coll. Act amending and supplementing Act No. 2/2005 Coll. on the assessment and control of noise in the outdoor environment and amending Act No. 272/1994 Coll. on the protection of human health, as amended, as amended In force: 15 July 2024.

Transposition of Directive 2002/49/EC of 25 June 2002 relating to the - assessment and management of environmental noise (OJ L 189, 18. 7. 2002) as amended, and Regulation (EU) 2019/1010 of 5 June 2019 on

the harmonisation of reporting obligations in the field of environmental law and amending Regulations (EC) No 166/2006 and (EU) No 166/2006 of the European Parliament and of the Council 995/2010, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU, Council Regulations (EC) No. 338/97 and (EC) No. 2173/2005 and Council Directive 86/278/EEC (OJ L 170, 25. 6. 2019). URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/158/

Act No. 175/2024 Coll. Act amending and supplementing Act No. 581/2004 Coll. on health insurance companies, healthcare supervision and on amending and supplementing certain acts, as amended, and amending and supplementing Act No. 358/2021 Coll. on the National Institute for Value and Technology in Healthcare and on amending and supplementing certain acts, as amended. In force: August 1, 2024.
The main task of the Institute is the assessment of health technologies for the purpose of categorising medicinal products, medical devices and dietary foods, except for generic medicinal products and biosimilar medicinal products. The Institute carries out scientific and advisory activities based on the methods of evidence-based medicine and standardized internationally accepted procedures.
URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/175/

Decree No. 208/2024 Coll. Decree of the MH SR, which determines the scope of nursing practice provided by a nurse independently, independently based on a doctor's indication and in cooperation with a doctor and the scope of midwifery practice provided by a midwife independently, independently based on a doctor's indication and in cooperation with a doctor. In force: August 1, 2024. URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/208/
Decree No. 210/2024 Coll. Decree of the MH SR, which amends the Decree of the MH SR No. 531/2023 Coll. on the categorization of institutional health care. In force: August 1, 2024. URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/210/
Decree No. 223/2024 Coll. Decree of the Government of the Slovak Republic, which amends the Regulation of the Government of the Slovak Republic No. 200/2019 Coll. on the provision of assistance for the supply and distribution of fruit, vegetables, milk and products thereof for children and pupils in schools, as amended. In force: September 1, 2024.
URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/223/20240901
Resolution of the Government of the Slovak Republic No. 682 on granting amnesty in cases of offenses committed in connection with anti-pandemic measures. In force: November 8, 2024. URL: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2024/286/20241108
Act No. 309/2024 Coll. Act amending and supplementing Act No. 578/2004 Coll. on healthcare providers, healthcare professionals, professional organisations in the healthcare sector and on amending and supplementing certain acts, as amended, and supplementing Act No. 580/2004 Coll. on health insurance and

amending Act No. 95/2002 Coll. on insurance and amending certain acts, as amended. In force: December 12, 2024. URL: https://static.slov-lex.sk/static/SK/ZZ/2024/309/20241201.html

Decree No. 314/2024 Coll. Decree of the MH SR amending Decree of the MH SR No. 22/2018 Coll., establishing districts areas and fixed points for outpatient clinics of the fixed outpatient emergency service, as amended In force: December 2024.

URL: https://static.slov-lex.sk/static/SK/ZZ/2024/314/vyhlasene_znenie.html

Act No 321/2024 Coll. Act amending Act of the National Council of the SR No. 219/1996 Coll. on protection against abuse of alcoholic beverages and on the establishment and operation of anti-alcohol detention rooms, as amended. In force: January 1. 2025. URL: https://static.slov-lex.sk/static/SK/ZZ/2024/321/20250101.html

Date of submission: 25 November 2024

Slovenian healthcare at a crossroads: How to solve problems with accessibility to healthcare services, healthcare staff and management of healthcare institutions?

(Report on the state of affairs in the Slovenian healthcare system in the period 2022-2024)

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Beginning of the 2025 will mark two and a half years since the beginning of the term of the Prime Minister Robert Golob. His party – *Gibanje Svoboda* (eng. *Freedom movement*) won 41 parliamentary seats, the most in the history of independent Slovenia. The current 15th government of the Republic of Slovenia is in a coalition of three political parties, the Gibanje Svoboda, the Social Democrats (SD) and the Left party, which together have 53 parliamentary seats in the 90-member National Assembly. A stable and comfortable coalition enabled the Prime Minister to draw up an ambitious coalition agreement, which placed a reform of the healthcare system among the highest political priorities. The implementation of this task was entrusted to the Minister of Health, orthopaedic surgeon Danijel Bešič Loredan who was a vocal critic of the situation in Slovenian healthcare and often involved in various personal and institutional disputes. The first major changes to the healthcare system implemented by Minister Bešič during his term were the intervention law in healthcare[30] and the abolition of complementary (voluntary) health insurance and its transfer to obligatory health insurance in the form of payments of a mandatory health contribution in a single amount[31].

The basic purpose of the intervention law, which the minister called a stress test in health care, was to improve accessibility to health services. The key measure for the realization of this purpose was a payment for all health services carried out by providers in the public health network, without a ceiling, provided that the providers first complete their regular program of health services financed by public funds. The intervention law was worth around 200 million euros in total in 2022, 2023 and 2024, according to the explanatory memorandum. The biggest part in amount of 160 million euros was dedicated for payment of services carried out above the regular programs financed by the public funds. After the first year of implementing these measures and spending around 137 million euros, it was determined that instead of shortening of waiting times and improving accessibility, the adopted intervention law extended them in many areas. Less than a year after the measures were adopted, there were more patients on waiting lists than when they were adopted. Since the "health experiment", in which the state financed all health services, did not bring concrete changes, it was

[30] Zakon o nujnih ukrepih za zagotovitev stabilnosti zdravstvenega sistema (ZNUZSZS) Uradni list RS, št. 100/22, 141/22 – ZNUNBZ, 76/23 in 136/23 – ZIUZDS.

[31]

discontinued. It is worth noting that even before the adoption of the intervention law, the profession loudly warned about the ineffectiveness of such measures, but the minister ignored them.

The abolition of complementary health insurance and its transfer to obligatory health insurance in the form of payments of additional mandatory health contribution in a single amount of 35 euros was second major change of Slovenian health system. The complementary health insurance was abolished on 31st December 2023. The abolition of the complementary health insurance was the minister's response to the announced increase in the premium for insurance by the health insurance companies. The insurance companies justified the increase with rise of medical inflation and the fact that the increase had not been made for a long time. The ministry did not consider the announced increase justified, so it first froze the amount of the monthly premium for insurance with a legally controversial measure (the adoption of a regulation), and then abolished the insurance altogether. By introducing a mandatory health contribution in a single amount, the government pursued a fairer contribution for health insurance. Although the exact implications of the new mandatory health contribution are not yet known, the current single premium seems to be unfair, as it does not take into account the financial situation of citizens and thus affects those with lower incomes more, which is contrary to the government's efforts to create a more solidary health insurance system. In addition, in the first year after the abolition of insurance, major consequences are already being felt in the area of rapid growth of private health insurance and the increasing number of insured persons of this type of insurance, which further worsens the regressive nature of the health insurance system.

Minister Bešič resigned on 7th July 2023, amid accusations of inefficiency and inactivity regarding the realization of coalition commitments, among which the separation of private and public healthcare stands out. He was replaced by dr. Valentina Prevolnik Rupel, who committed to the realization of coalition promises. Increasing rumours about the complete separation of private and public healthcare, which prohibits doctors employed in public healthcare institutions from practicing healthcare in private healthcare providers, and great dissatisfaction with the salary system, led to the longest strike of Slovenian doctors in history. Doctors began the strike on 15th January 2024, and the strike, although most doctors have already started working normally, is still ongoing today. In mid-November 2024, the government reached an agreement with representative trade unions regarding the reform of the salary system. The reform is not a true reform in technical meaning, because it is not based on a value-based classification of various professions, but rather the classification depends on the bargaining power of various interest groups, so that new dissatisfactions about the agreement of various interest structures in the public sector can be expected in the future. However, the government has not yet found a suitable solution regarding the demarcation between private and public healthcare. The Health Care Act, which proposed a solution regarding the demarcation, was withdrawn from public discussion due to the great dissatisfaction of the medical profession and is now secretly devising new solutions without the knowledge of key stakeholders in healthcare such as academic and healthcare community. Such an approach

raises serious doubts about the appropriateness and quality of the proposed solutions and measures, which the government is expected to present in 2024.

In addition to the above measures, which have visibly changed the structure of the Slovenian healthcare system, it is also worth mentioning tackling the issue of accessibility of primary care physicians, which the government addressed with clinics for unspecified patients (patients who do not have a personal doctor); the adoption of new legislation in the field of quality in healthcare; and the planned digitalization of healthcare, which is in the process of drafting the legislation. The only area in which there is no activity, even though it is a key area of Slovenian healthcare, is the reform of the supervision and management of public healthcare institutions. It is expected that this will be the next area addressed by the Ministry of Health. Despite numerous measures in the last two years, it is difficult to reasonably assess that the measures have achieved the desired goals or their purpose.

Date of submission: 16 December 2024

Report from Spain

Updates on Spanish health law in 2024

Juan-Ignacio Ochagavías-Colás

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NCP for Spain

First of all, this report outlines a concise analysis of key healthcare regulations enacted or currently under parliamentary consideration in the latter half of this year, followed by a second section focused on the new case law of the Spanish Constitutional Court concerning legal competences of state and regional health authorities throughout a public health crisis.

1. New healthcare regulations

Law 3/2024, of 30 October, regulates the improvement of the quality of life of people with amyotrophic lateral sclerosis and other diseases or highly complex and irreversible processes. This law addresses cases of patients with a significant reduction in life expectancy, who have not responded to treatment or who have no therapeutic alternatives that could improve their functional status or prognosis. Other requirements include the need for complex social and healthcare focused on the home environment, which has a high impact on the immediate surroundings of the affected individuals.

Regarding healthcare measures, the law includes the training and specialization of healthcare professionals in these types of highly complex and irreversible diseases or conditions, as well as the guarantee of a maximum time frame for receiving benefits. In this regard, Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, is amended to adapt the provision of specialised care and social healthcare to these purposes. The regulatory framework is complemented by measures that streamline the procedures related to the disability status and degree of dependency of these patients.

On the other hand, the following legislative initiatives are currently under parliamentary consideration: firstly, a Bill to amend Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, as well as Law 41/2002, of 14 November, which regulates patient autonomy and rights and obligations regarding information and clinical documentation. Secondly, the Bill on the universality of the National Health System.

Finally, in this section, it is essential to highlight the entry into force of the following regulations:

a) Royal Decree 568/2024, of 18 June, which creates the State Public Health Surveillance Network, regulating it in accordance with provisions of Article 13.3 of Law 33/2011, of 4 October, General Public Health Law (coordination different surveillance systems with continuous and uninterrupted operation 24 hours a day). This regulation also creates and regulates the Early Warning and Rapid Response System, addresses the regulation of the National Reference Laboratories for the aforementioned state network, and establishes the principles of public health surveillance: a multidisciplinary and "one health" approach, as well as information for action and universality, along with the general principles established in Article 3 of Law 33/2011, of 4 October (e.g. evaluation, transparency and equity) and in Article 140 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector (regarding inter-administrative relations).

b) Royal Decree 922/2024, of 17 September, amending Royal Decree 183/2004, of 30 January, which regulates the individual health card, allows health administrations to issue the health card with the same validity in both physical and virtual formats. The latter option may replace the physical health card provided that the holder expresses their consent.

Citizens will be able to use their new health card at all centres and health services of the National Health System and at any pharmacy in Spain. The autonomous communities have 18 months to adapt the current cards. The aim of the regulation is to adapt the health card of the National Health System to technological advances and to enhance people's access to health services: particularly, when citizens travel outside their autonomous community, in emergency situations, or due to the loss of the physical card.

c) Royal Decree 610/2024, of 2 July, which establishes the title of Specialist Doctor in Emergency and Urgent Care Medicine and updates various aspects of the training for the title of Specialist Doctor in Family and Community Medicine.

It is worth noting that the training will have a minimum duration of four years, with the first two years being common to the specialty of Family and Community Medicine. The regulation establishes a procedure for professionals in one of the two specialties to obtain the qualification of the other through an evaluation test and a training period.

2. Case law of the Spanish Constitutional Court

On 5 November 2024, the Spanish Constitutional Court issued a ruling stating that the state of alarm is sufficient to impose measures such as those used by the Spanish Government during the coronavirus crisis. Thus, "high-intensity" restrictions can be imposed without resorting to states of emergency or siege: the state

of alarm can establish high-intensity limitations on fundamental rights as long as it complies with the necessary constitutional requirements and, in particular, as long as it respects the principle of proportionality.

Accordingly, the Spanish Constitutional Court holds that the suspension of fundamental rights is contingent not on the severity of the measures taken, but on the presence of a specific enabling circumstance (such as the declaration of a state of emergency or siege).

In this context, the Court has declared null and void the "preventive measures" introduced by a regional law in Galicia for health crisis contexts, such as the isolation of sick people, home isolation, hospitalisation, or mandatory vaccination.

With regard to these measures, the court asserts that, as they restrict fundamental rights, their regulation can only be effected by the National Parliament through an organic law.

Date of submission: 30 November 2024

Sweden

Titti Mattsson

NCP for Sweden

New Legislative Acts and Regulations

A regulation on the contributions for assistive work tools became effective on the 1st of July 2024. The revised regulation (1991:1046) on Contributions for Assistive Work Tools[32] allows funding for updates and upgrades of computer-based assistive devices, along with training. The possibility of settling a repayment obligation to the Swedish Social Insurance Agency through the transfer of assistive work tools is being removed. Individuals who become unable to work will only be required to repay the grant if the assistive work tool has never been used. These changes aim to make assistive tools more accessible and equitable for those in need.

There have been changes for employers in the area as the provision for compensation for high sick pay costs has been abolished through amendments to the Sick Pay Act. [33],[34] Effective from 1st of July 2024 employers may only apply for compensation for costs that incurred before mid 2024, with final payments expected in 2025. However, compensation for employees under the special high-risk protection remains unaffected. The special high-risk protection covers employees with frequent or long-term illnesses, allowing compensation for employers and exemption from the waiting day for the employee.[35]

The Swedish Work Environment Authority is preparing major changes of its regulatory framework, expected to take effect on January 1st 2025. The goal is to improve clarity on how the regulations are interconnected, specify which regulations apply to different groups, enhance consistency, and to simplify the regulation. Of relevance to medical law is the updated guidance on medical controls in the workplace which are outlined in the Swedish Work Environment Authority´s regulations and general advice (AFS 2023:15).[36]

During 2024, Chapter 114 of the Swedish Social Security ACT (SFS 2010:110) was replaced with a new chapter concerning the processing of personal data. The aim is to modernize and enhance the social insurance system. The new chapter outlines guidelines for the process of personal data by the Swedish Social Insurance Agency (Försäkringskassan) and the Swedish Pensions Agency (Pensionsmyndigheten). It is complemented by SFS 2024:14[37], a regulation detailing the procedures for personal data processed by the same agencies. The

[32] SFS 2024:389 Förordning om ändring i förordningen (1991:1046) om bidrag till arbetshjälpmedel
[33] Lagen (1991:1047) om sjuklön, förordningen (2010:425) om ersättning för kostnader för sjuklön m.fl. lagar och förordningar.
[34] Prop. 2023/24:83 Ersättning för höga sjuklönekostnader upphör SFS: 2024:400–402, 405 och 409.
[35] https://www.forsakringskassan.se/privatperson/sjuk/anstalld/sarskilt-hogriskskydd?utm_source=chatgpt.com
[36] Arbetsmiljöverkets föreskrifter och allmänna råd (AFS 2023:15) om medicinska kontroller i arbetslivet.
[37] https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/forordning-202414-om-behandling-av_sfs-2024-14/?utm_source=chatgpt.com

regulation emphasizes the establishment of routines for granting, modifying, and revoking access rights to personal data, as well as regular monitoring of data access. It also outlines conditions under which direct access to personal data is permitted for specific authorities and individuals, ensuring that such access is granted only when necessary and with appropriate safeguards.

National court rulings and decisions

AD 2023 nr 75: In December 2023, the Swedish Labour Court decided to uphold the legality of a private geratric centre´s Covid-19 vaccination policy. The Court ruled that withholding salaries from unvaccinated employees who refused vaccination was permissible.

HFD 2024 not. 25: The general rule in Swedish law is that information obtained within healthcare information is confidential; however, the decision about admitting a person to compulsory psychiatric care is public. In this case, the Supreme Administrative Court ruled that decisions as to releasing a person from compulsory psychiatric care are also public.

NJA 2024 s. 277: The Supreme Court clarified the standard of proof in cases concerning damages in healthcare. It ruled that there must be a reasonable probability that the damage suffered could have been avoided by carrying out the chosen procedure in a different way or by choosing another available procedure which, according to a retrospective assessment from a medical point of view, would have met the need for care in a less risky way.

The Administrative Court in Växjö, case nr 578-24: The Administrative Court decided on 18 October 2024 that it is unlawful for a County Council to demand that persons residing in Sweden for longer than two years have to pay a fee for interpreters in healthcare. According to the Court, such rules violate the constitution.

AD 2024 nr 66: The Swedish Labour Court: AD 2024 nr 66. This case concerns a person with disabilities who applied for a job as an assistant nurse at the neonatal ward. When the person, before the interview, notified that she was a wheelchair user, the interview was cancelled. The Labour Court ruled that no discrimination had taken place.

JO 2024-06-05 Dnr 4763-2023. In this decision, the Parliamentary Ombudsman criticizes the County Council and a psychiatrist working there, who, for several years, provided information about the wrong patient for the courts in the case of compulsory psychiatric care.

The Parliamentary Ombudsman criticizes psychiatric healthcare for introducing a requirement to undergo routine drug tests for persons requiring ADHD medication, see **JO 2023 s. 127**. It is argued that the imposition of such routines is not reconcilable with the prohibition of forced bodily interventions in the Swedish constitution. In 2024, several other agencies, such as the Health and Social Service Inspectorate and Discrimination Ombudsman, has taken a similar standing as the Parliamentary Ombudsman.

Date of submission: 21 November 2024

Legislative news in the field of health care of Ukraine

Khrystyna Tereshko

NCP for Ukraine

On November 20, 2024, the Verkhovna Rada of Ukraine adopted the draft law "On the Protection of Personal Data" as a basis.

The document was developed to fulfill Ukraine's obligation stipulated in Article 15 of the Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their Member States, on the other hand, and task 11 of the Action Plan for the Implementation of the Association Agreement between Ukraine and the EU, approved by the Resolution of the Cabinet of Ministers of Ukraine dated October 25, 2017 No. 1106.

The draft law aims to increase the level of protection of the constitutional right to respect for privacy by strengthening the standards of personal data processing and providing more rights to the subject of personal data to ensure the possibility of exercising full control by the subject over the processing of his personal data.

The draft law provides for:

- bringing the terminology of the field of personal data protection in line with new international standards;
- detailing and more understandable formulation of the principles of personal data processing;
- clearer formulation of the grounds for personal data processing;
- detailed and transparent requirements for consent to the processing of personal data, which will avoid abuse and manipulation;
- expansion of the rights of personal data subjects and the mechanism for their implementation;
- clear definition of the responsibilities of the controller and the operator of personal data;
- the procedure for reporting a personal data leak; the institution of the person responsible for personal data protection, its functional responsibilities, requirements and procedure for appointment;
- regulation of the transfer of personal data to the territory of foreign states and international organizations;
- financial liability, administrative and economic sanctions applied to the controller and/or operator for violating the right to personal data protection, which will ensure the effectiveness of the law and compliance with its requirements.

The draft law defines special requirements for:

processing of personal data (sensitive personal data), processing of personal data related to criminal prosecution, processing of biometric data by public authorities, and processing of personal data for the purpose of direct marketing, election campaigning, and political advertising.

📌 More details at the link:

https://itd.rada.gov.ua/billInfo/Bills/Card/40707

On November 20, 2024, the Verkhovna Rada of Ukraine adopted as a basis the draft law “On Amendments to Certain Legislative Acts of Ukraine on the Implementation of the Assessment of Daily Functioning of a Person”

The draft law of Ukraine “On Amendments to Certain Legislative Acts of Ukraine on the Implementation of the Assessment of Daily Functioning of a Person” was developed with the aim of creating regulatory and legal principles for changing approaches to assessing the needs and the mechanism for their provision for persons with limitations in daily functioning and reforming the system of medical and social expertise in Ukraine.

The main objectives of the draft law are to simplify the processes of establishing disability by formalizing the relevant criteria and regulating procedures; digitalizing the examination process; introducing transparent appeal mechanisms; changing the mechanism for financing medical and social expertise. The draft law introduces a change in approaches to determining the needs of people with functional limitations and simplifying their receipt of services and other types of assistance that they need.

📌 More details at the link:

https://itd.rada.gov.ua/billInfo/Bills/Card/45179

On November 20, 2024, the Verkhovna Rada of Ukraine adopted the draft law "On the Mental Health Care System in Ukraine" as a basis.

The draft law was developed with the aim of creating a holistic, separate legislative act that, based on the principles of the WHO and the European Union, as well as on the basis of strict observance of human rights, the principle of human orientation, intersectoralism and the biopsychosocial model, will regulate the mental health care system in Ukraine.

The developed draft law covers a wide range of issues regarding the organization and functioning of the mental health care system in Ukraine, emphasizing the protection of the rights and support of persons with mental disorders and their integration into society, in particular:

1) terminology in the field of mental health care is introduced, which includes definitions of such concepts as “mental health”, “mental health service”, “mental health service provider”, “mental health professionals” and other terms necessary to ensure the completeness and quality of legal regulation of this area;

2) the principles of mental health care are clarified, such as focusing on the needs of the individual, combating discrimination and stigmatization;

3) the legal, organizational, economic and social foundations of the mental health care system are regulated;

4) the rights and obligations of individuals in the field of mental health care are determined, including the right to timely, high-quality services, choice of service providers, access to information;

5) the obligations of service providers to maintain confidentiality and protect the personal data of service recipients are established;

6) a system of management and coordination of activities in the field of mental health between various entities is introduced - from public bodies to the non-state sector, the role of the state in ensuring conditions for people's mental health is determined, the powers of central executive bodies, in particular the Ministry of Health, the Ministry of Social Policy, the Ministry of Education and Science, the Ministry of Defense, the Ministry of Internal Affairs, the Ministry of Veterans Affairs, and other bodies related to this area are determined.

📌 More details at the link:
https://itd.rada.gov.ua/billInfo/Bills/Card/44876

Date of submission: 27 November 2024

November 2024 EAHL Newsletter: Updates on UK health-related law

Mary Guy

NCP for United Kingdom

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Over the course of 2024, a number of health-related law developments have emerged across the UK. The aim here is to highlight selected developments across the UK and its countries. The HFMA introductory guide to NHS finance provides overviews of the different healthcare structures in operation across England, Northern Ireland, Scotland, and Wales.

Case law:

The UK Supreme Court (UKSC) has handed down two health-related judgments in 2024. Firstly, the conjoined appeals of *Paul*, *Polmear*, *and Purchase* [2024 UKSC 1] addressed questions of whether/when a duty of care is owed in respect of psychiatric harm caused by witnessing the death or medical crisis of a relative arising from a condition which a doctor negligently failed to diagnose or treat. The UKSC concluded that, while doctors owe a duty of care to protect the health of their patients, they do not owe a duty of care to members of the patient's close family to protect them against the risk of illness from the experience of witnessing the death or medical crisis of their relative from a condition which the doctor has negligently failed to diagnose or treat. This conclusion was reached by a majority of six to one, with acknowledgements, inter alia, of the distinction between medical treatment and accidents, and despite historical differences in this area of law, the same result would be reached under Scots law.

Secondly, *RM* [2024] UKSC 7 addressed the question of whether the Review Tribunal was entitled to conclude that RM's mental disorder continued to be of a nature/degree warranting his continued detention in hospital for medical treatment. More specifically, whether the test for discharge from a Restriction Order under Article 78 of The Mental Health (Northern Ireland) Order 1986 was met. The UKSC concluded unanimously that RM's continued detention remained lawful, and addressed questions about differences in the wording of the 1986 Order as compared to the Mental Health Act 1983 in England and Wales, finding that cases from England and Wales can be followed in Northern Ireland where it is appropriate to do so.

Legislation:

The *Abortion Services (Safe Access Zones) (Scotland) Act 2024* was enacted in September 2024 in response to increasing anti-abortion demonstrations outside premises in Scotland where abortion services are provided. (Equivalent legislation had been passed in 2022 by the UK parliament and the Northern Ireland Assembly). For early commentary, see article by Emily Ottley.

The Health Service Procurement (Wales) Act 2024 received Royal Assent on 5 February 2024. It enables Welsh Ministers to disapply provisions of the (UK-wide) Procurement Act 2023 and to create a new procurement regime for services used by the Welsh NHS.

Secondary legislation included amendment regulations in Scotland for managing cross-border access to prescriptions with England (where prescription charges remain), and regulations in Wales amending charges to overseas visitors.

Other 2024 developments:

The UK election of the Labour government in July 2024 saw the appointment of a new Secretary of State for Health and Social Care, Wes Streeting MP, after a period of uncertainty with 5 Conservative MPs in this role between 2022 and 2024. Current action taken by the new government includes a review of the role of Physician Associates, and a wide-ranging consultation about the future of the NHS.

New appointments were made in Scotland to the roles of Cabinet Secretary of Health and Social Care and supporting Ministers in May 2024, in Northern Ireland for Health Minister in May 2024, and in Wales in September 2024.

At the time of writing (24 November 2024), the Terminally Ill Adults (End of Life) Bill for England and Wales is scheduled to receive its first parliamentary debate on 29 November. It has been introduced as a Private Members' Bill (as distinct from a Government Bill), which has contributed to the controversy about government neutrality on this issue. The Assisted Dying for Terminally Ill Adults (Scotland) Bill was introduced in March 2024, and consultations are ongoing.

Date of submission: 24 November 2024

The EAHL IG "Supranational biolaw" activities on the EU health policy platform: new opportunities for EAHL members to interact with the European Commission and health stakeholders

Éloïse Gennet, Pin Lin Lau, Aurélie Mahalatchimy

What is the EU health Policy Platform?

The EU Health Policy Platform is an online collaborative forum established by the European Commission in 2016 to promote dialogue and cooperation among a wide range of stakeholders in the health sector, including public authorities, non-governmental organizations, healthcare providers, patient organizations, industry representatives, and academic experts. This platform plays a critical role in shaping and implementing EU health policy by allowing diverse health-related stakeholders to share ideas, best practices, and knowledge to improve health outcomes across the European Union.

Involvement of the EAHL IG Supranational Biolaw

The EAHL IG Supranational Biolaw selected by the European Commission to launch a thematic network on the EUHPP platform in September 2021, entitled 'Health as a fundamental value. Towards an inclusive and equitable pharmaceutical strategy in the European Union'.

The topics addressed by this network were highly topical, as they came at a time when the European Commission was starting public consultations and in-depth assessment in view of the upcoming reform of the pharmaceutical legislation (which was finally published in April 2023).

During the academic year 2021-2022, the EAHL IG Biolaw, under the coordination of Aurélie Mahalatchimy and Éloïse Gennet, led the development of the thematic network. This mainly materialised through the organisation of three webinars on the EUHPP platform. All the scientific exchanges during webinars served as a basis for drawing up the joint declaration and increasing its impact, the main achievements of the thematic network for an inclusive pharmaceutical strategy.

The Joint Statement, the main output of the network's work, was developed through the webinars, the drafting of partial versions and consultations with both webinar speakers and network participants. It thus combines a theoretical approach derived from university research with a more applied approach, thanks to exchanges with other stakeholders in the healthcare field. This original configuration has provided the joint declaration with both background information and identification of the legal issues involved, as well as concrete, operational recommendations relating to pharmaceutical legislation and related health policies.

The joint statement was presented to the European Commission and broadcast live to platform members at the EUHPP annual meeting on 5 May 2022. The purpose of this meeting was to present the work carried out

during the year, including presenting the content of the joint statement in order to invite organisations to formally support its content, and to share experiences of coordinating thematic networks.

A similar work has been led by Dr Pin Lean Lau entitled "Navigating Health Inequalities in the EU through Artificial Intelligence".In fact in the academic year of 2022-2023, the EAHL IG Biolaw, under the coordination of Pin Lean Lau, joined the Brunel University of London Centre for AI: Social & Digital Innovations, and Health Action International, in the thematic network for navigating health inequalities in the EU through artificial intelligence, and its impact on key populations. The Joint Statement, in a similar way to the thematic network of its predecessor, was presented to the European Commission and broadcast live to stakeholders at the EUHPP annual meeting in Luxembourg on 19 April 2023. The Thematic Network on Navigating Health Inequalities in the EU was transformed into a permanent Stakeholder Network in June 2023.

Continued benefits for EAHL members

While the joint declarations are in themselves the main achievements of the thematic networks, their preparation involves the creation of links of trust and collaboration between the various stakeholders in the network, but also with the European Commission, in particular DG Health, which can be of benefit of any EAHL member.

The final achievement of these temporary thematic network is their transformation into a permanent network. Their continuation makes it possible to continue the work on the review of pharmaceutical or AI legislations, to promote the dissemination of the recommendations set out in the joint declaration and to monitor their implementation, in particular by organising new webinars on the EUHPP platform.

EAHL members can thus use these permanent networks to communicate on their research or policy work to health stakeholders and to DG santé directly, as the EUHPP continues to provide technical assistance for the organization of webinars. It can also be used to contact relevant health stakeholders working on similar topics, and of course, the registration on the EUHPP also gives access to all webinars and other scientific organized by all different stakeholders represented on the platform beyond EAHL IG Supranational Biolaw's networks. If you are interested in the networks, please contact

Éloïse Gennet, eloise.gennet@univ-amu.fr or Aurélie Mahalatchimy, aurelie.MAHALATCHIMY@univ-amu.fr (Stakeholder Network on the pharmaceutical legislation)

Pin Lin Lau, PinLean.Lau@brunel.ac.uk (Stakeholder Network on artificial intelligence)

Access to the EU HPP requires a registration.

In addition to a website that is freely accessible but limited to the dissemination of general information, only registered users can access the content of the EUHPP platform. Registration on the EUHPP platform is not open to everyone in order to ensure the security of its debates and transparency in the dialogue on health policies'.

Website: https://webgate.ec.europa.eu/hpf/.

To be able to register on the EUHPP (EU Health Policy Platform), an organisation must:

Be represented by an individual with a valid institutional email address.

Be a European, national, regional or local entity registered in an EU Member State, an EEA country or a country participating in the Health Programme.

Be listed in the European Union's transparency register, representing only its own interests. Universities, educational establishments, hospitals and public academic institutions are exempt from this obligation, as are staff of the European institutions and representatives of national ministries.

Belong to a category of organisations eligible under the platform's rules of procedure, including public health bodies, NGOs, patient or healthcare professional associations, educational establishments, academic institutions and companies involved in evidence-based health promotion in Europe.

Date of submission: 25 November 2024

Health and Technology Law LLM offered by the University of Groningen, Faculty of Law

Healthcare increasingly relies on technology to reduce costs and improve the quality of care, yet the use of technology in these settings means we must devote adequate attention to any potential security and privacy risks. Consequently, many global health challenges raise complex legal questions that require the shared expertise from both health law and technology law. That's why the University of Groningen, Faculty of Law has created it's new specialized Health and Technology Law LLM programme, to give students the opportunity to obtain a profound knowledge of health law, technology law, as well as the interface between both regimes. The LLM is led by Prof. Brigit Toebes, and taught by leading experts within the Groningen Centre for Health Law (GCHL) and the Security, Technology, and e-Privacy (STeP) Research Group.

If you'd like to know more about this unique LLM programme, you are welcome to watch their comprehensive presentation about the LLM on YouTube, or visit the programme webpages. You can also ask questions through their Faculty information request form.

EJHL Announcement

Dear colleagues and experts in health law across Europe,

As the editors of the *European Journal of Health Law*, we personally invite you to deepen your engagement with the Journal and the vibrant community it represents.

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https://forms.office.com/e/vE2wsfH4aU

Your engagement as both authors and reviewers is vital for maintaining the high standards and impact of the *European Journal of Health Law*. Together, we can continue to build a community of excellence in health law research and practice.

Thank you for your commitment to advancing health law in Europe. We look forward to your contributions to the Journal, whether as an author, a reviewer, or both.

With best regards,

Herman Nys (editor-in-chief)

Mette Hartlev (editor)

Titti Mattsson (editor)

Henriette Roscam-Abbing (editor)

Tom Goffin (managing editor)

European Journal of Health Law

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