EUROPEAN ASSOCIATION of HEALTH LAW

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Message from the President

Dear members, dear colleagues,

Summer has started, hopefully offering you time to take some distance from everyday concerns and find new inspiration. It is also the time to look forward to the 9th EAHL conference in Warsaw from 18 to 20 September, where we will once again meet and exchange knowledge and experiences on important health law developments at national and at European level.

Following good tradition, the conference will be preceded by the young researchers workshop, organised in close cooperation with the rapidly growing Young Scholars Interest Group. The tried-and-tested format allows them to get to know each other and each other's research better, see cross-links and get feedback.

2024 has already been an intense year for our association. The first months of the year saw the Strategic Writing School for young scholars, a series of webinars with high-level guest speakers on writing and publishing research. In early June, there was the first Jean Monnet (EU4GH) summer school in Salerno on "The European Union and global health". The summer school was organised by Prof. Stefania Negri, director of the Jean Monnet Centre of Excellence “New visions of the European Union’s role in global health”, in collaboration with the EAHL, the Global Health Law Consortium (GHLC) and the Observatory on Human Rights: Bioethics, Health, Environment.

You will find reports on both successful events in this newsletter, as well as an update on the various activities of the members of the Interest Group on Supranational Biolaw. This highly active interest group illustrates how our association can provide a boost to new initatives and strengthen the connections between

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experts in Europe. Thanks to the efforts of our national contact points, after reading this newsletter you are also once again informed about important legal developments in several European countries.

The central theme of our biennial congress is "Health and Fundamental rights". The large number of abstracts submitted shows that this overarching topic is at the heart of health law. Unfortunately, the theme is also more pertinent now than ever, given the flagrant violations of human rights within and near European borders. The horrible developments in Ukraine, in Israel and Palestine make us realise every day how fragile peace is, as well as access to quality healthcare. It is and remains more crucial than ever to put respect for integrity, human rights and fundamental freedoms at the top of the agenda.

With the entire board, we wish you much reading pleasure and look forward to meeting you in good health in Warsaw.

Steven Lierman

Spotlights on recent changes in the Austrian legislation and jurisdiction

Caroline Voithofer (NCP for Austria) and Raphael Wibmer

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

1. Public Health Care: the Act on Implementing Agreements between the Federal Government and the Federal States (Vereinbarungsumgesetzungsgesetz 2024 - VUG 2024)

A key provision affecting medical and health law is the law with the unwieldly title "Act Implementing Agreements between the Federal Government and the Federal States of Austria (Vereinbarungsumgesetzungsgesetz 2024 - VUG 2024)". It was published in the Federal Law Gazette I 191/2023. We briefly present some of the key changes of the VUG 2024 which have been in force since 1 January 2024.

Based on the planning requirements at federal level (for details see the Health Target Control Act; Gesundheits-Zielsteuerungsgesetz, Federal Law Gazette I 3/2024) planning at provincial level will in future determine the capacities and regional allocation of healthcare facilities in the area of non-monetary benefits as well as their specific and binding care mandates in both the intramural and extramural areas. Thus, Regional Structure Plans for Health (RSG) and the relevant ordinances need to include additional information addressing capacity planning. The Health Target Control Act also requires the establishment of a data evaluation platform for the joint use of secondary data from the healthcare sector available at federal, state and social insurance level. This platform aims to enable comprehensive and necessary analyses for the management, planning, quality assurance and financing of the healthcare system.

The Austrian Health Insurance Fund (Österreichische Gesundheitskasse) must conclude a uniform nationwide overall contract with the Austrian Medical Association with a uniform catalogue of services and harmonised fees throughout Austria; the possibility of overall (regional) fee agreements will no longer apply. Until such an overall agreement is concluded, the existing regional overall agreements and their further development, including the possibility of fee adjustments, will remain in place.

In future, the implementation of the binding RSG staffing plan – determined between the health insurance institution and the respective local medical association – will only relate to the specific local distribution of posts. In case that no agreement can be reached with the medical association on the specific local distribution within six months of the respective RSG regulation coming into force, this local distribution can be determined by the health insurance institution itself. The selection procedure for advertising a physician position is accelerated by no longer requiring the agreement of the respective medical association. If a position has been advertised unsuccessfully at least twice, health insurance providers can conclude contracts for temporary care based on contracts with physicians authorised to practise the profession on a freelance basis until an individual

contract is concluded. Supplementary or deviating regulations can also be agreed on opening hours and professional domicile.

Furthermore, the VUG 2024 allows the conclusion of special individual contracts with group practices and primary care units without the consent of the respective medical association if there is no overall contract.

2. Amendments of the Austrian Physicians Act (ÄrzteG)

From December 2023 to the end of March 2024, the Austrian Physicians Act was amended three times (Federal Law Gazette I 195/2023, I 191/2023, I 21/2024), focusing on occupational language requirements, training for general practitioners and staff requirements of medical training centers. The language exam for proof of adequate language qualifications in § 4 (3a) ÄrzteG for independently practising physicians now specifies that a minimum language proficiency of CEFR-B2 is necessary.

Training for general practitioners was completely revised in § 7 ÄrzteG. Not only are general practitioners now named specialists in general practice and family medicine, their training now fairly matches those of other specialists. Instead of a 33-month mostly practical training, trainees now have to complete a 51-month training. This includes a 33-month basic (speciality) training and an 18-month speciality training, which both have to take place in the context of employment. Basic Training includes training of at least six months in the field of general and family medicine and six months in the field of internal medicine. For the 21 remaining months, trainees can choose a number of subjects specified by the Austrian medical association. Speciality training includes practical training via employment in the field of general medicine and family medicine.

Amendments in §§ 9, 10 and 13 ÄrzteG revise the current 1+1 system, in which medical training centres are required to have at least two medical specialists plus an additional specialist for each additional training position. Consequently, medical training centres for specialist training focusing both on basic training and speciality training as well as training clinics (“Lehrambulatorien”) according to § 13 ÄrzteG only require one specialist per training position.

On 16 March 2023 the Austrian Constitutional Court annulled passages of § 140 (3) of the ÄrzteG, Federal Law Gazette I 169/1998, I 140/2003 as unconstitutional (G 237/2022). The provision stated that the chairperson of the disciplinary commission (§ 140 (3) first sentence ÄrzteG) and the deputy (§ 140 (3) second sentence ÄrzteG) would be appointed by the (then) Federal Minister for Health and Women’s Affairs on the recommendation of the Austrian Medical Association. It also provided for an obligation to reach agreement with the Federal Minister of Justice (§ 140 (3) third sentence ÄrzteG). The involvement of a federal minister in the appointment of a member of the disciplinary commission was seen in contradiction to Art. 120c (1) of the Federal Constitutional Act (B-VG), Federal Law Gazette 1/1930. With the Amendments published in the Federal Law Gazette I 195/2023 the provisions relating to the formation of disciplinary commissions for physicians, dentists and veterinarians were adopted so that they comply with the constitutional requirements.

3. Changes in pharmacy legislation

Two amendments relevant to pharmacy legislation were passed at the end of 2023: One within the VUG 2024 and the other within a newly introduced specialized Act on Veterinary Pharmaceuticals (Federal Law Gazette I 186/2023).

The VUG 2024 introduced a nationwide evaluation board which aims at standardizing the procurement of medicinal products in hospitals and enhancing the more efficient use of scarce healthcare resources of the public insurance system. Potentially this might lead to the restriction of the freedom of the drug commissions and hospital pharmacies.

With the VUG 2024, the competences of hospital pharmacies have been expanded through extended dispensing options of hospital pharmacies to inpatient care and nursing facilities as well as to patients in the hospital and persons "whose treatment is related to the hospital, provided that the medicinal products are covered by a cross-sectoral care and/or financing model for rare diseases" (§ 36 (1) no. 3 lit b) Pharmarcy Act - ApoG). This might change prescribing and dispensing practices in the hospitals.

The introduction of a specialised Act on Veterinary Pharmaceuticals (Tierarzneimittelgesetz – TAMG) does not entail any major changes for pharmacies. Only § 49 TAMG, which provides authorization for dispensing small quantities of medical products by veterinary in-house pharmacies to another veterinary in-house pharmacy, can be mentioned as a real innovation. The introduction of a separate law for veterinary medicinal products may also serve to improve legal certainty, even though the corresponding provisions of the Medical Products Act (Arzneimittelgesetz - AMG) were probably already well-known.

4. Civil High Court Decision on "wrongful birth" and "wrongful conception"

The Austrian Civil High Court clarified in its decision from 21.11.2023 (3 Ob 9/23) that:

1. Both in the case of a medical intervention aimed at contraception (e.g. vasectomy or tubal ligation) and in the case of prenatal diagnostics, the financial interests of the mother/parents in preventing conception or - if there is an embryopathic indication - the birth of a (further) child are covered by the protective purpose of the treatment contract.

2. If the child had not been conceived or born if the mother/the parents had been properly informed, the physician is liable (irrespective of any disability of the child) in particular for the maintenance costs to be borne by the parents for the child.

The Civil High Court deviated in this ruling from its previous case law, according to which "wrongful birth" and "wrongful conception" were two non-comparable groups of cases, and now explained that from the point of view of tort law, both situations must necessarily be assessed in the same way, because if the doctor had acted without negligence (and additionally, in the case of "wrongful birth", a termination of pregnancy requested by the mother or the parents), the child would not have been born.

In addition, it expressly upheld its previous case law that the parents, who would have decided in favor of a (lawful) termination of pregnancy in view of the child's severe disability if they had been properly informed by the physician, must be reimbursed in particular for the entire maintenance costs, i.e. not just for the additional needs caused by a disability.

Date of submission: 27 May 2024

News from Azerbaijan

Lala Jafarova

NCP for Azerbaijan

In November 2024 Azerbaijan will host the 29th session of the Conference of the Parties to the United Nations Framework Convention on Climate Change - COP29.

2024 was declared the **"**Year of Solidarity for a Green World**"** in Azerbaijan**.** The country has set targets, aiming to reduce greenhouse gas emissions by 35 percent by 2030 and 40 percent by 2050, relative to the 1990 baseline year.

- *The "Electronic Prescription" system has been launched on the official website of the Ministry of Health*

An electronic prescription is a digital analogue of a paper prescription. The "Electronic Prescription" system has the function of electronic registration of prescriptions issued to citizens in public and private medical institutions of Azerbaijan. At the same time, the Electronic Prescription system will provide prescription management for doctors, patients and pharmacists through a single platform.

Now, after an examination by a doctor or a medical consultation, citizens can receive prescribed medications using an electronic prescription from any pharmacy operating in our country. To do this, one must present the registration number of the electronic prescription or the QR code on the electronic prescription to the pharmacist. An electronic prescription can be presented to the pharmacist either by the patient or by the person to whom this document was entrusted.

- *Medical certificates required during recruitment and for obtaining a driver's license are now in electronic format*

From May 1, it will be possible to obtain both medical certificates in electronic form from medical institutions.

Health certificate for recruits and applicants entering universities, colleges, high schools, submitted for obtaining a driver's license now can be submitted electronically.

Electronic certificates have the same legal force as paper ones.

- *The process of issuing referrals for planned examination and treatment to private medical institutions that have a contract with the State Agency for Compulsory Medical Insurance (Agency) has been made electronic for citizens.*

It will be possible to choose the institution from "e-Tabib" mobile application to receive medical services that cannot be provided in state medical institutions on the basis of referral in contracted medical institutions of the Agency.

- *Updates on prescription rules effective starting from 1 January 2024*

Thus, persons arriving in the Republic of Azerbaijan or traveling abroad will be able to freely import and export medicines for personal use according to a prescription approved by the body (structure) determined by the relevant executive authority.

According to the law, a prescription may contain a drug that, based on clinical protocols, is considered necessary for the treatment of a patient, but does not have state registration under its international nonproprietary name (name of the active substance).

- *In the end of 2023 The State Agency for Compulsory Medical Insurance has transferred its information systems to the "Government Cloud".*

Sources:

- The Milli Majlis of the Republic of Azerbaijan: https://www.meclis.gov.az/index.php?lang=en
- Ministry of Health of the Republic of Azerbaijan: https://sehiyye.gov.az/en/media/xeberler-ve-yenilikler/
- The State Agency on Mandatory Health Insurance: https://its.gov.az/
- TABIB: https://tabib.gov.az/
- AZƏRTAC news: https://azertag.az/en

Date of submission: 27 April 2024

A new legal framework for psychology practice in Federation of Bosnia and Herzegovina

Ervin Mujkic

NCP for Bosnia and Herzegovina

The House of Representatives of the Parliament of the Federation of Bosnia and Herzegovina recently accepted the draft Law on Psychology Practice. Of course, the path to the final version, its enactment, and the commencement of the implementation of this law is still long, as the draft will be considered in the House of Peoples, followed by a public debate, then reconsideration in both houses of Parliament, this time in the form of a proposal, and finally, voting on the proposal.

In the explanation of the draft law, the proponent states, among other things, that currently there is no legal framework for the activities of psychologists in the Federation of Bosnia and Herzegovina, which results in a completely chaotic state in this field, causing the entire society to face serious and long-term harmful consequences, which are reflected in the following:

- use of psychological measurement instruments by unqualified individuals;
- questionable reliability and validity of the psychological instruments used;
- abuse of psychological instruments and violation of intellectual property rights;
- internships, employment, and the organization of psychology practice in general.

Psychological assessment (diagnostics) is the foundation of psychological activity, upon which the determination of individuals' and groups' psychological (intellectual, cognitive, emotional, psychomotor, psychosocial, and other) potentials rests, for the purpose of explaining and predicting their behavior, finding the causes of inefficiency or disorders, and planning and implementing psychological treatments. Currently, this activity is not legally regulated in the Federation, which results in unqualified individuals conducting diagnostics without possessing the psychological tests and techniques to draw professionally responsible conclusions. The availability of psychological measurement instruments to unqualified individuals endangers those in need of professional psychological, psychiatric, and psychotherapeutic treatment (potentially suicidal and psychotic individuals, individuals with developmental difficulties, individuals with occupational diseases, etc.).

In other countries, the use of psychological instruments is regulated by laws and other legal acts under strict control, especially in terms of limiting the availability of tests to unqualified individuals. Due to the frequent abuse and availability of tests to unqualified and inadequately educated individuals without the possibility of their legally controlled use in Bosnia and Herzegovina, test publishers from the region have started refusing to sell tests to psychologists from Bosnia and Herzegovina to protect intellectual property rights, based on

knowledge of violations of legal and ethical provisions and misuse of tests and their distribution by individuals without an undergraduate education in psychology.

Due to the lack of a legal framework for the activities of psychologists, there was no possibility of securing funds for test calibration, i.e., preparing tests for the Bosnian population. As a result, psychologists in Bosnia and Herzegovina do not possess profession-verified psychological tests for the activities they perform. The Law on Psychology Practice is the legal basis for initiating further activities for the preparation, distribution, and control of the use of adequate psychological instruments. In this regard, it should be emphasized that psychologists in the Federation of Bosnia and Herzegovina obtain psychological instruments from Croatia and Serbia, where these tests are calibrated for the populations of neighboring countries and created in languages that may not necessarily be the language of testing in Bosnia and Herzegovina. Many tests are translated from foreign languages without proof of their usability, seriously questioning the quality of the findings, as there is a dilemma about whether the person has a problem or simply did not understand the terms in the test.

In Bosnia and Herzegovina, psychological tests are copied and distributed without any control, which is punishable worldwide. This is one reason why psychologists from Bosnia and Herzegovina have ended up on the "blacklist" of psychological instrument publishers. Abuse also manifests as familiarizing third parties with the content of test materials and providing instructions on how to fake responses to gain various rights (pensions, disability benefits, etc.). One of the greatest dangers of misuse and unprofessional work with psychological measurement instruments is present in issuing assessments for weapon carrying permits, assessing the ability to perform highly risky and demanding professions, and in forensic psychological expertise and evaluations for the needs of courts and prosecutors' offices.

Furthermore, to publish a research article in scientific journals, psychologists must prove they have not violated the legal framework for the use of tests. Without the Law on Psychology Practice, this has become impossible, and therefore the publication of scientific papers in psychology is significantly hindered.

Additionally, psychology students face a problem immediately after graduation because there is no regulation for conducting psychology internships. They are often left to act independently, without mentors, without collegial support, and without taking a professional exam, which is entirely contrary to the practice prescribed by the European Diploma in Psychology (EuroPsy).

Also, private psychological practice in the Federation of Bosnia and Herzegovina is not regulated, so psychologists who want to conduct their activities privately register them as "craft and related activities." A profession that directly affects the lives of citizens cannot conduct professional supervision of private practice to ensure high-quality service and client protection without a legal framework. It should also be added that there is no unified register of psychologists in the Federation of Bosnia and Herzegovina, which prevents planning society's needs for psychologists and optimally utilizing the existing potential of psychologists.

Given the current state in this area, which can be described as quite chaotic due to being burdened with numerous problems, it can be stated with certainty that the adoption of this law is urgently needed and should not be delayed any further. The proposed draft law, with potential additional improvements, can fully meet the objectives set by the proponents themselves, which relate to ensuring the quality of psychological services, protecting public social care policies, protecting children, safeguarding public health, and ensuring the safety of users. This means providing accessible, timely, safe, and quality psychological services to all categories of citizens in need.

Date of submission: 29 May 2024

Current issues in the field of health law in Denmark

Caroline Adolphsen,

Full professor at Aarhus University

NCP for Denmark

Introduction

Over the last year, national focus has been on reforms and laying the groundwork for a better and more robust healthcare system. Very little new legislation has been passed, but the government has decided on a 10-year plan to improve the treatment of children and adolescents who need psychiatric care. Together with other parties from the parliament, the government has made an agreement to strengthen the coherence in the individual treatment of patients who need to consult different healthcare professionals.

New legislation

Abortion

Though not yet entered into force one of the biggest developments in Danish healthcare legislation is that it will now be possible for a woman above the age of 15 to get an abortion without parental consent. Furthermore, the legal limit for abortion without approval from a board will be moved from week 12 to week 18. It should be added that the Faroe Islands (a part of the Danish Realm) still does not have a right to abortion and that their parliament just voted against a bill making free abortion legal.

New rules about nurses, midwifes and specialized nurses

In Denmark, nurses and midwifes are authorized and can therefore act on their own under certain circumstances, and in these cases, they are responsible for the treatments. In other cases, they act under the responsibility of other medical professionals. In two new amendments to the authorization act, nurses and midwifes are given a broader area for acting on their own (sections 54 and 55, respectively) and a new category of specialized nurses is introduced (section 54 a).

Societal focus

On a national level there has been some focus on a number of less positive stories regarding access to healthcare in Denmark.

- Last summer, it was discovered that one of the biggest hospitals in Denmark (Aarhus Universitetshospital/Aarhus University Hospital) had neglected to inform patients suffering from gastrointestinal cancer about their right to be referred to treatment abroad.
- This winter it was discovered that a company operating a large number of general practitioners' clinics in scarcely populated areas did not provide the correct information to the regions when reporting which treatments their patients had received.

- This spring it turned out that patients from Region Sjælland/Region Zealand had to wait several years to have their jaws operated because they were only referred to treatment within Region Zealand, which is not in accordance with Danish law

Date of submission: 21 May 2024

France to legalize an "active assistance in dying"?

Éloïse Gennet

NCP for France

For almost two years now, the question of changing the legal framework on the end of life in France has been the object of heated social debate. More specifically, it is the potential legalization of an "active assistance in dying" that is at the heart of the controversy.

The legislative proposal

President Macron presents the "active assistance in dying" as a *sui generis* French model that departs from euthanasia or assisted suicide.

Active assistance in dying is defined in the proposal as "the prescription to a person by a doctor, at that person's express request, of a lethal product and the assistance in administering this product by a doctor, in a public or private health establishment, at home accompanied by a team of specialist carers, or in an establishment of a legally approved association" (Article 3).

Such assistance is reserved for people who have reached the age of majority, are capable of expressing their free and informed preferences/wishes, and suffer from a serious and incurable condition with a short- or medium-term life-threatening prognosis, in particular when this condition causes physical or psychological suffering that cannot be relieved or is unbearable (Article 6 of the proposal). The expression "short or medium term" is to be assessed by the medical teams, but could refer to a few weeks or a few months. No precise list of the illnesses concerned will be drawn up, but when they impair discernment, psychiatric or neurodegenerative illnesses will not be included in the list of incurable illnesses opening the possibility of a request for assisted dying.

When all these conditions are fulfilled, the individual may request assistance in dying. Subsequently, it is the responsibility of a medical team to collectively and openly deliberate on the appropriate course of action in response to this request. Healthcare professionals may invoke a conscience clause and refuse to prescribe the lethal treatment, but a healthcare establishment must be able to redirect patients to a team likely to consider their request.

One of the polarizing aspect of the proposal is that persons making the request will administer the lethal product themselves, yet if they are not physically able to do so, they can designate another person (a doctor, nurse, carer, etc.).

The previous context

The law of 2 February 2016, the "Claeys-Leonetti" law, establishes the principle that everyone has the right to a dignified and peaceful end of life. In particular, the law authorises the administration, at the patient's

request (in particular through advance directives), of deep and continuous sedation until death. Such sedation may only be requested by patients suffering from a serious and incurable condition with a short-term life-threatening prognosis, “presenting suffering that is refractory to treatment, if the cessation of treatment is likely to result in unbearable suffering”. However, in this case, the aim is to relieve the suffering of a person whose death is imminent and inevitable: sedation does not cause death, the latter is simply the result of the progression of the illness.

However, the implementation of this law has not proved very successful. It remains largely unknown to patients and healthcare professionals alike. Recourse to deep sedation remains very rare and is difficult to implement outside hospital. Lastly, the law does not allow to respond to all end-of-life situations, since it is limited to cases where the prognosis for survival is very short-term.

Since 2017, no fewer than six bills introducing the possibility of euthanasia or assisted suicide had already been presented in the National Assembly, without success. However, these proposals highlighted the need for a societal debate to provide an appropriate response to patients at the end of life.

The steps leading to the proposal

On 13 September 2022, the Comité Consultatif National d'Éthique, the French National Consultative Ethics Committee, published its opinion 139 on the end of life, stating that it was in favour of an “active assistance in dying”, provided that palliative care was strengthened at the same time (which the 2024 legislative proposal also does).

On the same day, the President of the Republic announced the creation of a Citizens’ Convention on the end of life, led by the Economic, Social and Environmental Council (CESE), which brought together 184 citizens between December 2022 and March 2023. A large majority of these citizens were in favour of opening up assisted dying, either in the form of assisted suicide or euthanasia, or in the form of assisted suicide with the exception of euthanasia.

In addition, the Macron Government has conducted a wide-ranging consultation of healthcare professionals; besides, a working group was set up at parliamentary level to exchange the points of view of all different political groups.

The legislative proposal was finally presented a year later to the Council of Ministers on 10 April 2024.

Next steps

It will now be debated in Parliament, which comprises two chambers: the National Assembly and the Senate. It will be discussed in the Assembly from 27 May, before being sent to the Senate. The government has announced that it will not initiate the fast-track procedure for this legislative proposal. Such a procedure allows a joint committee to be convened to reach a compromise text after a single reading by both chambers.

For further information

Find here the legal proposal, its explanatory memorandum, impact assessment, and the opinion of the Conseil d'État: https://www.legifrance.gouv.fr/dossierlegislatif/JORFDOLE000049401821/.

Find here the Opinion 139 of the French National Consultative Ethics Committee (CCNE) on Ethical issues relating to end-of-life situations: https://www.ccne-ethique.fr/en/publications/opinion-139-ethical-issues-relating-end-life-situations-autonomy-and-solidarity?taxo=0.

Find here the Citizen's Convention on the end-of-life: https://www.lecese.fr/convention-citoyenne-sur-la-fin-de-vie.

Acknowledgments

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Date of submission: 7 May 2024

Ireland: recent developments in health law

Dr Brenda Daly, Associate Professor of Law,

Dublin City University,

NCP for Ireland

1. Assisted Dying

Assisted dying and euthanasia is currently prohibited in Ireland. Subsequent to the first ever Irish Supreme Court judgment, *Fleming v Ireland*,[1] which upheld the prohibition on assisted dying, there have been calls from various organisations including End of Life Ireland and Irish Doctors Supporting MAiD (Medical Assistance in Dying) to legalise assisted dying. A private members' bill was introduced in 2020, Dying with Dignity Bill;[2] the purpose of this proposed Dying with Dignity Bill is to permit assisted dying for qualified persons, such as those who have been diagnosed with a terminal illness.[3]

Pursuant to this, a decision was made by the Government to establish an Oireachtas Special Committee on Assisted Dying in January 2023 "to consider and make recommendations for legislative and policy change relating to a statutory right to assist a person to end his or her life (assisted dying) and a statutory right to receive such assistance."[4] This remit also included the option of concluding that no change to the current legal position should occur.[5] The Committee's terms of reference included how provision for assisted dying might operate in Ireland; an examination of safeguards relating to the provision for assisted dying; an examination of the constitutional, legal and ethical issues relating to such a provision; and identification of possible unintended consequences of such a provision. The Committee convened public meetings between June 2023 and January 2024 with submissions from relevant stakeholders to examine the spectrum of Constitutional, legal and ethical issues concerning dying, assisted dying, and end of life care. On 6th March 2024, the Joint Oireachtas Committee published its determination that legislation should be introduced to legalise assisted dying in limited circumstances. The final report contains 38 specific recommendations setting out details of eligibility criteria, safeguards to protect against coercion, recommended changes to current criminal law provisions, role of medical professionals, protection of medical professionals' right to conscientious objection,[6] and the need to set up an independent body responsible for assisted dying services, as well as reviewing assisted dying applications and other research and investigatory functions.[7] The Joint Oireachtas

[1] *Fleming v Ireland* [2013] IESC 19
[2] https://data.oireachtas.ie/ie/oireachtas/bill/2020/24/eng/initiated/b2420d.pdf
[3] https://www.oireachtas.ie/en/bills/bill/2020/24/
[4] https://www.oireachtas.ie/en/committees/33/assisted-dying/
[5] Houses of the Oireachtas. Joint Committee on Assisted Dying: Final Report of the Joint Committee on Assisted Dying. March 2024. Page 3.
[6] Recommendation 17
[7] See pages 8-18 for details
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

Committee on Assisted Dying recommendations provide that eligible persons must be an Irish resident,[8] over the age of 18,[9] and in particular, Recommendation #27 states that:

> "The Committee recommends that only a person diagnosed with a disease, illness or medical condition that is: a) both incurable and irreversible; b) advanced, progressive and will cause death; c) expected to cause death within six months (or, in the case of a person with a neurodegenerative disease, illness or condition, within 12 months); and d) causing suffering to the person that cannot be relieved in a manner that the person finds tolerable, is eligible to be assessed for assisted dying."[10]

It is unclear at this juncture if the government will act upon the recommendation to legalise assisted dying.[11]

2. Surrogacy and Assisted Human Reproduction

The Health (Assisted Human Reproduction) Bill 2022 was passed by An Dáil Éireann (the main chamber of the Irish legislature) on 31st May 2024 and will now progress to An Seanad Éireann (the upper house of the Irish parliament).[12] The purpose of this Bill is to regulate surrogacy and the provision of assisted human reproduction, including the regulation of storage and research involving embryos, embryonic stem cells or stem cell lines in Ireland. The proposed Bill sets out a regulatory framework for both domestic and international altruistic surrogacy arrangements.[13] Altruistic surrogacy arrangements will be subject to approval by the Assisted Human Reproduction Regulatory Authority (this independent regulatory board will be established upon passing of this Bill). A prohibition on commercial surrogacy arrangements remains in place.

3. Assisted Decision Making

The Assisted Decision Making (Capacity) Act 2015 commenced on 26th April 2023,[14] heralding a momentous change to the legal framework regarding the rights of those who may lack full capacity to make decisions for themselves at present, and also in the future (for example, persons with intellectual disabilities, individuals living with dementia or with mental illness, elderly persons). The scope of this legislation extends to any decisions that may be made about the individual's personal welfare, as well as decisions about property and other affairs. The Act repeals the Lunacy Regulation (Ireland) Act 1871 thus abolishing the ward of court system and marking a shift towards a more human rights approach empowering those who may experience challenges to their capacity to make decisions about their welfare, property, finances etc rather than the traditional paternalistic approach of decision making by persons in authority to determine what is in the best

[8] Recommendation #25
[9] Recommendation #26
[10] See pages 14-15 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
[11] https://www.independent.ie/irish-news/government-to-be-asked-to-respond-to-report-calling-for-assisted-dying-laws/a819438778.html
[12] https://data.oireachtas.ie/ie/oireachtas/bill/2022/29/eng/ver_b/b29b22d.pdf
[13] For further information see Part 7 Domestic Surrogacy and Part 8 International Surrogacy, Health (Assisted Human Reproduction Bill) 2022
[14] https://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/html

interests of those individuals deemed to lack capacity. This Act will also be applicable to any decisions made in the context of healthcare, so will have to be taken into consideration by healthcare professionals regarding any medical treatment or provision of health services. The Act automatically presumes that the person has capacity. The Act provides for five different types of assistance to facilitate those individuals who may need help to make their own decisions. The type of assistance varies depending on the specific needs and capacity of the individual concerned.

4. Access to termination of pregnancy

The law in Ireland regarding access to termination of pregnancy has significantly changed since the constitutional referendum in May 2018 resulted in a vote in favour of repealing the Eighth Amendment of the Irish Constitution (removing the equal constitutional right to life of the mother and the unborn) and replacing it with the Thirty-sixth Amendment of the Constitution Act 2018 so that "[p]rovision may be made by law for the regulation of termination of pregnancy". The Thirty-sixth Constitutional amendment and the subsequent, Health (Regulation of Termination of Pregnancy) Act 2018, provides women with the right to access lawful termination of pregnancy in Ireland.

In compliance with the requirements of section 7 Health (Regulation of Termination of Pregnancy) Act 2018 to conduct a review of the operation of the legislation every three years, the report of the Independent Review of the Operation of the Health (Regulation of Termination of Pregnancy) Act was published on 26th April 2023.[15] The objectives of this independent review included an evaluation of the extent to which the objectives of Health (Regulation of Termination of Pregnancy) Act 2018 had been achieved or not, as well as conducting an assessment of the impact of the 2018 Act on access to termination of pregnancy services in Ireland since its introduction, taking into consideration the level of services available previously, including the impact on the number of Irish women accessing termination of pregnancy services in both Ireland and other jurisdictions. The Independent Review highlights a number of challenges arising in respect of implementation of the legislation and access to services, including concerns regarding geographical access to services, lack of clear guidelines on the interpretation of sections 9, 10 and 11 of the Act, delays due to the mandatory 3 day waiting period, and the impact of conscientious objection on the provision of services.[16]

In June 2023, proposals to amend the Health (Regulation of Termination of Pregnancy) Act 2018 were approved at the second stage of An Dáil Éireann.[17] Among the proposals contained in the Health (Regulation of Termination of Pregnancy) (Amendment) Bill 2023 are recommendations: "to provide for abortion on request prior to foetal viability; to abolish the 3 day waiting period for abortion on request; to allow for abortion

[15] https://www.gov.ie/en/publication/13fe5-the-independent-review-of-the-operation-of-the-health-regulation-of-termination-of-pregnancy-act-2018/
[16] O'Shea, M. The Independent Review of the Operation of the Health (Regulation of Termination of Pregnancy) Act 2018. 28th February 2023. Available at: https://www.gov.ie/pdf/?file=https://assets.gov.ie/255442/bda412d4-9538-47a5-8abc-ce22826bbae6.pdf#page=null
[17] https://data.oireachtas.ie/ie/oireachtas/bill/2023/10/eng/initiated/b1023d.pdf

on grounds of fatal foetal abnormality that are likely to lead to the death of the foetus either before or within a year of birth; to allow for abortion where there is a risk to the life, or of serious harm to the health, of the pregnant woman; and to decriminalise the provision of abortion." Review of the Health (Regulation of Termination of Pregnancy) (Amendment) Bill 2023 was delayed to facilitate the Joint Committee on Health's review of the Report on the Independent Review of the Operation of the Health (Regulation of Termination of Pregnancy) Act 2018. In December 2023, the Joint Committee on Health review concluded that "work should be advanced to give effect to the recommendations.." [18] as advised by the Independent Review report.

The Health (Termination of Pregnancy Services) (Safe Access Zones) Act 2024 came into legal effect on 7th May 2024. The purpose of this Act is to provide safe access zones for service providers, healthcare professionals and those individuals seeking to access termination of pregnancy services. This legislation prohibits conduct including obstruction or impeding access to relevant healthcare premises, and prohibits the communication of material that is likely to influence the decision of an individual providing or seeking access to termination of pregnancy services.

5. The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 was signed into law on 2nd May 2023. This legislation provides for the mandatory open disclosure of notifiable incidents which occur in the provision of a health service to a person.

Date of submission: 31 May 2024

[18] Houses of the Oireachtas. Joint Committee on Health Report on the Independent Review of the Operation of the Health (Regulation of Termination of Pregnancy) Act 2018. December 2023. Available at: https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_health/reports/2023/2023-12-15_report-on-the-independent-review-of-the-operation-of-the-health-regulation-of-termination-of-pregnancy-act-2018_en.pdf

Malta: Enforced Sterilization and Virginity Testing

Dr Daniel Bianchi,

Lecturer in Health Care Law, University of Malta

NCP for Malta

A. Enforced Sterilization

There have been two recent changes to Title VIII of Malta's Criminal Code on crimes against the person under its sub-title IX concerning threats, private violence and harassment. The first change occurred by way of Act X of 2024.[19] Article 2 of the latter Act introduces a new version of Article 251F of the Criminal Code thereby substituting the preceding version of that same provision addressing the criminal offence of enforced sterilization. The preceding version of Article 251F of the Criminal Code, which has now been substituted, read as follows: "Any person who for non-medical reasons, by force, deceit, bribery or threats surgically removes or disables a person's reproductive organs without that person's full and informed consent, leading to sterilization, shall be guilty of enforced sterilization …".[20] The new version of Article 251F (1) of the Criminal Code now reads as follows: "Whosoever surgically removes or disables a minor person's reproductive organs, or an adult person's reproductive organs without that adult person's free and informed consent, leading to sterilization, shall be guilty of enforced sterilization …". Furthermore, Article 251F (3) now provides that whosoever is an accomplice to the latter offence "by aiding, abetting or procuring the enforced sterilization of any minor person or adult person shall, unless the act constitutes a more serious offence under any other law or any other provision of this Code, be liable, on conviction, to the punishments laid down in sub-articles (1) and (4) of" Article 251F. The new version of the offence of enforced sterilization in the Maltese Criminal Code arguably then has five characteristics that distinguish it from the preceding version of Article 251F.

First, whereas the preceding version of Article 251F of the Criminal Code meant that sterilization for medical reasons fell beyond the scope of the criminal offence of enforced sterilization, the new version of Article 251F instead engages with a medical intervention as a possible, but not evident, exception to the general rule that enforced sterilization is a criminal offence. Thus, it is not the case that any sterilization for medical reasons is exempt from criminal liability. It is instead now provided in Article 251F (2) that "no offence under this article shall be committed when sterilization shall result as a consequence of a medical intervention" but only if that intervention satisfies, as a minimum, all three conditions listed in the proviso of that sub-article. Any medical intervention that does not satisfy all three conditions listed in Article 251F (2) is not otherwise, all else being equal, exempted from the purview of the offence of enforced sterilization under Article 251F. The first condition arising from the proviso to Article 251F (2) then is that the medical

[19] Act X of 2024 – Criminal Code (Amendment No. 4) Act, 2024 [Government Gazette of Malta No 21,197 – 23/02/2024].
[20] Act I of 2014 – Criminal Code (Amendment) Act, 2014 [Government Gazette of Malta No 19,204 – 31/01/2014], Art 2.

intervention "is not performed with the purpose of achieving enforced sterilization" in terms of Article 251F. The second condition for the exception to apply as it was originally indicated in the Bill preceding Act X of 2024 simply provided that the medical intervention "would have been otherwise deemed medically necessary by a medical professional".[21] Following comments made in the House of Representatives over the course of the Bill's second reading,[22] that second mandatory condition for the exception in relation to medical interventions to apply was amended within the Adjunct Committee for Consideration of Bills,[23] before the third reading, so that Article 251F (2) now provides that the medical intervention:

> would have been otherwise deemed medically necessary by one (1) or more medical professionals, in accordance with the applicable standard of care, with such standard following established medical practice, and with such medical intervention consisting of one (1) or more procedures, and which has the aim of saving or preserving the life of an adult person or of a minor person, in the immediate or longer term.

As such, for instance, absent the latter aim of saving or preserving life, it will be an offence to perform enforced sterilization even for medical reasons. Furthermore, the third condition so that, when accompanied by the other two conditions, the exception to the general rule that enforced sterilization is a criminal offence may apply is that the medical intervention "follows established medical practice with regard to the granting of informed consent by the patient in terms of other legislation".[24] The latter condition then furnishes reason to consider other legislation. By way of example, the Health Act outlines if, when and how a person who has attained the age of sixteen years, but not eighteen years,[25] would have the right to consent to or refuse, medical attention, care or treatment.[26]

The second distinctive characteristic of the new version of Article 251F of the Criminal Code when compared to its preceding version is that, other than the exception that I outlined in the previous paragraph, it will be a criminal offence to remove or disable "a minor person's reproductive organs"[27] and it will also be a criminal offence to remove or disable the reproductive organs of an adult person who "is unable to give free and informed consent in accordance with this article, whether due to a cause that is either temporary or long-term".[28] It is thus clarified in the new version of Article 251F (2) that "no other person shall be able to substitute said adult person's free and informed consent for the purposes of this article". It is furthermore provided that, other than in the circumstances outlined in the preceding paragraph of this report, "any surgical

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[21] Bill No 86, Criminal Code (Amendment No. 4) Bill [Government Gazette of Malta No 21,167 – 19/12/2023] clause 2.
[22] House of Representatives Malta, Plenary Session, 14th Legislature: Sitting No. 193 (10th January 2024). See, for instance: Hon Graziella Galea and Hon Rebecca Buttigieg.
[23] House of Representatives Malta, *Kumitat Permanenti ghall-Konsiderazzjoni ta' Abbozzi ta' Ligi Aggunt (Rapport Ufficjali u Rivedut)*, 14th Legislature: Sitting No. 22 (7th February 2024).
[24] Criminal Code, Chapter 9 of the Laws of Malta, Art 251F (2).
[25] Daniel Bianchi, *Medical Law in Malta* (Alphen aan den Rijn: Kluwer Law International – 2023) 162 – 163.
[26] Health Act, Chapter 528 of the Laws of Malta, Art 27 (2).
[27] Criminal Code, Chapter 9 of the Laws of Malta, Art 251F (1).
[28] *Ibid.*, Art 251F (2).

procedure performed on a minor person, and that leads to sterilization, shall be deemed to be enforced sterilization for the purposes of this article … and no other person, including a parent or legal guardian, shall be able to provide consent for such a procedure in the name of the minor person, other than when the exception mentioned would be applicable".[29] With the exception of medical interventions as indicated in the preceding paragraph of this report, the new version of Article 251F does not therefore furnish an exception to the offence of enforced sterilization were a substitute decision-maker to furnish consent on behalf of another person to undergo a procedure that surgically removes or disables reproductive organs.

The third distinctive characteristic of the new version of Article 251F of the Criminal Code is that, while all else being equal an adult person may elect to undergo surgery to remove or disable one's own reproductive organs, that surgery must be done in accordance with the adult person's free and informed consent as defined in that provision so as not to incur criminal sanction. Article 251F (2) thus now clarifies that, for the purpose that article, free and informed consent shall:

> (i) mean consent reflecting the will and preferences of an adult person, freely given directly by said adult person, in respect of a surgical procedure the adult person might undergo which may lead to sterilization; and (ii) be given after said adult person would have been provided with prior information, in respect of the purpose and nature of the procedure, as well as of its consequences, risks and alternative options thereto, in a manner that is appropriate, accessible and easy to understand for that adult person, including, as necessary, through non-conventional methods of communication and access to independent support from third parties; and (iii) be able to be withdrawn at any moment prior to the procedure following its initially having been given, with said possibility having been likewise communicated to the adult person alongside the information indicated above.

Whosoever surgically removes or disables an adult person's reproductive organs without the subject's free and informed consent in accordance with all three of the above characteristics listed in Article 251F (2) of the Criminal Code may be open to being found guilty of enforced sterilization in terms of Article 251F (1) even if the adult person ostensibly consented to the procedure but not in line with the requirements of "free and informed consent" as defined Article 251F (2).

The fourth distinctive characteristic of the new version of Article 251F of the Criminal Code is that, while in the preceding version of Article 251F at least one between "force, deceit, bribery or threats"[30] had to be present in order for enforced sterilization to qualify as a criminal offence, those criteria of force, deceit, bribery or threats are now no longer required under the new version of Article 251F for enforced sterilization to qualify as a criminal offence in terms of that provision. Instead, the punishment prescribed for any of the

[29] *Ibid.*
[30] Act I of 2014 – Criminal Code (Amendment) Act, 2014 [Government Gazette of Malta No 19,204 – 31/01/2014], Art 2.

offences in Article 251F (1) to (3) shall now "be increased by one (1) degree, when the commission of such crimes involves also the use of force, deceit, fraud, bribery, false pretences, coercion or threats".[31]

The fifth distinctive characteristic of the new version of Article 251F of the Criminal Code when compared to its predecessor is that the victim of the offence is now taken into account as an injured party. As such, that injured party may benefit from compensation from the person convicted of the offence of enforced sterilization under Article 251F for the harm that was occasioned in its performance. It is thus now provided in Article 251F (5) that, in addition to any other punishment "to which the person convicted of such an offence may be sentenced, the Court may also order such person to pay the injured party such sum of money as may be determined by the said Court … as compensation for the harm, including moral and, or psychological harm caused to such party by, or by means of the offence". That order by the court would then constitute an executive title for all intents and purposes of the Code of Organization and Civil Procedure, Chapter 12 of the Laws of Malta.

B. Virginity Testing

A second recent change to Malta's Criminal Code occurred as a consequence of Act XI of 2024.[32] This Act added Article 251EA to the Criminal Code, which provides for the offence of virginity testing. It was clarified over the course of the pertinent Bill's second reading within the House of Representatives that it was being introduced as a precautionary measure,[33] meaning that there was no evidence per se of virginity testing being regularly practiced in Malta. Article 251EA (1) of the Criminal Code thus now provides that whosoever "carries out virginity testing upon another person by examining the female genitalia of that person shall be guilty of an offence…". It is furthermore provided in Article 251EA (2) that whosoever "aids, abets, counsels, incites, procures, coerces or advertises virginity testing" shall also be guilty of an offence and liable to the same offence as the person who may be found guilty of carrying out virginity testing.

To be clear, for the purposes of Article 251EA, virginity testing is defined in Article 251EA (3) as the examination of female genitalia, meaning "vagina or vulva", for the purpose or purported purpose of determining virginity. The offence will subsist "with or without consent" [34] of the person being examined. As such, the subject's consent will not exonerate a person from criminal liability for virginity testing in terms of Article 251EA.

There is however a proviso in respect of medical examinations carried out by a medical professional. Thus, a proviso to Article 251EA (3) of the Criminal Code excludes from the ambit of virginity testing for the purpose of Article 251EA "any medical examination of the female genitalia which may be carried out by a medical professional during a medical intervention, in accordance with established medical practices". In this

[31] Criminal Code, Chapter 9 of the Laws of Malta, Art 251F (4).
[32] Act XI of 2024 – Criminal Code (Amendment No. 5) Act, 2024 [Government Gazette of Malta No 21,208 – 15/03/2024].
[33] House of Representatives Malta, Plenary Session, 14th Legislature: Sitting No. 192 (9th January 2024), Hon Rebecca Buttigieg.
[34] Criminal Code, Chapter 9 of the Laws of Malta, Art 251EA (3).

respect, it is the latter “established medical practices”, rather than defined parameters at law, that are the basis upon which to establish whether the actions of a “medical professional” fall within the scope of the offence in Article 251EA of the Criminal Code.

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Poland: latest updates in health law

Maria Sokalska

NCP for Poland

The parliamentary elections held in 2023 and the subsequent change of government brought the promise of major changes in the organization of the Polish healthcare system. However, the war across the country's Eastern border continues to affect the situation in the country in a significant way. Hence, 2024 will likely be a very challenging year and the new Minister of Health has begun her term in very exigent circumstances.

The National Transformation Plan for 2022-26, based on health maps, presents a diagnosis of the country's health situation and the challenges to be faced by the Polish healthcare system in the upcoming years[35].

Cardiovascular diseases, rapidly increasing cancer rates, tobacco smoking and alcohol abuse, high BMI and untreated high blood pressure are responsible for the majority of premature deaths. In terms of health indicators, Poland continues to rank below the EU average.

In the current situation the discussion on public health is taking on particular importance.

As many diseases are diagnosed late, emphasis must be put on their earlier detection and, first of all, on prevention. In response to the problem, the Ministry of Health has announced preventive health checkup packages for different groups of patients.

From 1 September 2025 a health education program will start being implemented in primary and secondary schools where students will have the possibility to learn about disease risk factors and how to live a healthy lifestyle on a practical basis.

It is encouraging that the European Commission has given the green light to the National Recovery and Resilience Plan (REPowerEU Plan), the fifth part of which is allocated for improvement of the quality of healthcare and better access to it.

Poland has been implementing national strategic programs in cardiology, oncology, and psychiatry which can be compared to roadmaps with defined implementation goals. Their aim is to ensure high standards of treatment and guarantee safety to each and every patient from diagnosis through all the stages of treatment to its end. The central idea of those programs is that every patient, regardless of his or her home address, should be offered the same quality of diagnosis and treatment.

[35] Minister of Health Announcement of 15.10.2021, Journal of Laws of the Ministry of Health of 15.10.2021, item 80. Pursuant to art. 95b of the Act on Healthcare Services Financed from Public Funds of 27.07.2004

All those programs are effective thanks to a dedicated and well-educated doctors and nurses. What has been hindering their effective operation for several years is a significant shortage of medical professionals in Poland which ranks below the EU average in terms of the number of physicians and nurses.

Intensive efforts have been made to increase the number of medical students in Poland. Currently 32 academic and 7 vocational studies are offered at Polish universities.

The reform of the system also implements a set of incentives for medical, nursing, and physiotherapy courses. The process itself is monitored at different stages and it has been expected that educated doctors will be given all the means and tools needed to provide safe and effective treatment.

In 2019, the Ministry of Health introduced a simplified recruitment and employment procedure for doctors educated in non-EU countries, which so far has resulted in as many as 4000 medical professionals from Ukraine and Belarus working for the Polish healthcare system. Many of them have demonstrated to be highly qualified experts, strongly committed to their work despite the enormous trauma suffered as a result of the war.

Technological progress

Access to IT systems provides new opportunities for improvement of healthcare quality. E-prescriptions have already proven to be useful and convenient for patients undergoing treatment and cross-border e-prescriptions can already be used in 8 European countries. Meanwhile, preparations are underway for a central e-registration system for patients seeking specialized healthcare services.

The top priority task is to further increase the reach and range of e-services and to build a central depository of medical data. The associated challenge which must be faced is to increase the protection of personal data, ensure the protection against cyberattacks and improve the operational continuity of IT systems.

Criteria for standardizing data in healthcare centers are being prepared at the regional level to prevent the inconsistency between systems provided by different IT companies from impeding exchange of medical records.

Technological development calls for specialists who will enable healthcare workers to use technology in their everyday work.

At the same time, health information technology should become an element of medical and nursing university courses.

The role of scanning in diagnosis is increasing year over year with as much as 80% of diagnoses being currently made on the basis of such tests. Radiology is the first field of medicine to apply AI algorithms, which accelerate diagnostic processes, improve the performance of medical staff or even generate financial benefits for healthcare facilities. Their goal is not to replace, but rather to support humans in the diagnostic and

decision-making processes. Augmented Intelligence, which is discussed herein, expands the capabilities of doctors instead of replacing them.

Mental health

In the contemporary world, where the pace of life is fast and everyday challenges – overwhelming, mental health has become a priority.

Mental disorders have reached epidemic proportions with as much as 26% of Poles at risk of developing them. The problems of people struggling with anxiety, schizophrenia, or post-traumatic disorder pose a new kind of challenge for our healthcare system.

An epidemic of mental disorders in children and youth can be observed as well. Within the last three years, the number of pediatric mental health hospitalizations has increased by 100%. Mental health issues experienced by young people include among others developmental disorders such as autism and ADHD, as well as emotional, anxiety and mixed disorders.

The Resolution on Guaranteed Psychiatric Care and Addiction Therapy[36] Services adopted by the Minister of Health on 19 June 2019 introduced a three-level assistance system based on community care centers employing psychologists, psychotherapists and community therapists.

Specialists working at other reference levels can provide their assistance to such centers whenever such a need arises. The second level corresponds to community mental health centers, and the third one is based on inpatient psychiatric wards. The Ministry of Health announces further reform of child psychiatry, in which the cooperation between the Ministry of Social Policy, the Ministry of Justice and family courts will play an important role.

Long-term care

Poland's population is shrinking and structurally ageing.

The population of seniors, whose number is rapidly growing, cannot be replaced by young people as the birth rates are low.

The impending „demographic tsunami" has already entailed a burden for the Polish healthcare system.

The newly appointed Senior Policy Council consists of 30 representatives of various professions. It promotes the opinion backed up by the current state of medical knowledge, according to which hospitalizations should be limited to most serious cases. To make seniors life easier, Senior Care Teams have already started working. These are multidisciplinary groups of nurses, physiotherapists, psychologists and social workers whose assistance can in many cases provide an alternative to hospital treatment.

[36] Journal of Laws of 2019 item 1285, as amended

An important decision was the establishment of personal assistance for people with disabilities. It is a service of personalized support in handling matters which a disabled person cannot handle on their own.

A personal assistant can be a person who is willing to act as such and who undergoes the respective training. The service, which will be available in every district, will include from 40 to 200 hours of assistance per disabled person, financed by the Polish National Health Service (NFZ). It is estimated that in the nearest future 20-25 thousand caregivers will be needed.

The hospice movement which was initiated in the 1970s has experienced dynamic growth in Poland. It allows for patients with potentially life-threatening illnesses to receive special care.

Currently in our country there are a couple of hundreds palliative care facilities, including home hospices, inpatient care units and outpatient palliative care centers integrated with formal healthcare system.

Even in the most challenging clinical conditions appropriate medication and care provided by a team composed of a psychologist, physiotherapist and nurse can improve the quality of life of patients.

In rural areas it is necessary to implement a coordinated, flexible system of care adapted to the specific needs of every patient which would be provided at home with the assistance of home-based caregivers.

The latest decision of the Minister of Health to abolish limits of patient intake indicates that palliative care is becoming a matter of growing importance for the organization of the healthcare system.

Women are changing healthcare in Poland

The role of women in healthcare cannot be overstated. They comprise 75% of all medical students, take on the hardest of tasks and become leaders and authorities on various areas of medicine.

Actions taken by women against the Polish Constitutional Court's decision to restrict access to abortion not only resulted in social mobilization, but also demonstrated the increasing impact Polish women have on the country's healthcare system.

My Health, My Rights is the notion under which a debate is currently held in the Sejm committee on 4 bills which propose to facilitate access to abortion to varying extents.

"Day-after pills" - emergency contraceptive pills have been available on prescription since July 2017. The government proposal enabling access to them without a prescription for women over 15 years of age is still under intense discussion.

The women have managed to secure that the in vitro fertilisation method which is already financed by the State.

The State Budget will also cover the costs of fertility preservation in cancer patients.

Transform today – change tomorrow

On 1 January 2025 Poland will take over the presidency of the European Council. The country will preside over the EU body in a very interesting period with a new European Commission and a new European Parliament already in office. Health care issues will have important part in deliberations and for the Polish representatives subjects prevention, demography, telemedicine and mental health problems will be of special importance.

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Slovakia. Latest updates in health legislation (September 2023 – May 2024)

Silvia Capikova

Faculty of Medicine, Comenius University in Bratislava

NCP for the Slovak Republic

1/ Heated tobacco products.

Amended law: Act no. 89/2016 Coll. on the production, labeling and sale of tobacco products and related products and on the amendment of certain laws as amended“.

Act no. 89/2016 Coll. regulates:

- requirements for ingredients and emissions of tobacco products and related reporting obligations, including maximum levels of tar, nicotine and carbon monoxide emissions in cigarettes,
- the conditions of labeling and packaging of tobacco products, including health warnings, which must appear on consumer packaging of tobacco products and every outer packaging,
- ban on marketing tobacco for oral use,
-long-distance cross-border sale of tobacco products,
- conditions for introducing new categories of tobacco products to the market,
- conditions for placing products related to tobacco products on the market, their labeling, including health warnings.

COMMISSION DELEGATED DIRECTIVE (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products (Available from: https://eur-lex.europa.eu/eli/dir_del/2022/2100/oj) resulted in an amendment to Act No. 89/2016 Coll.

Amending Act: Act No. 44/2024 Coll. of 13 February 2024, „amending Act no. 89/2016 Coll. on the production, labeling and sale of tobacco products and related products and on the amendment of certain laws as amended“. (Available from: URL: https://www.slov-lex.sk/pravnepredpisy/SK/ZZ/2024/44/vyhlasene_znenie.html)

Summary of substantial changes to Act No.89/2004 Coll.:

-Definition of a new legal term: „a heated tobacco product is a smokeless tobacco product or a tobacco product for smoking, from which emissions containing nicotine and other chemical substances are released by heating, which are subsequently inhaled by the user, belonging to a new category of tobacco products."! (§2, para 3, s)).

- "A manufacturer, importer or distributor may not place on the market such cigarettes, roll-your-own tobacco and heated tobacco products that contain a characteristic aroma.". (§ 5 par. 1).

-In § 5 par. 3 the first sentence reads: "The manufacturer, importer or distributor may not market such cigarettes, roll-your-own tobacco and heated tobacco products that contain aromas in any of their components, especially in filters, papers, packages, capsules, or any technical elements enabling the change of smell or taste of the tobacco products concerned or their smoke intensity.".

Amendments will come into force on January 1, 2025, amended law available from: https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2016/89/

2/ Transsexualism.

Guidelines of the Ministry of Health of the Slovak Republic No. S 09953 - 2022 – OZS "on the unification of procedures for the provision of health care for gender change before issuing a medical opinion on the change of gender of a person administratively registered in the registry" had been based on 1CD version 10 and approved on March 2022 by a then minister of health, and published in the Vestník - Journal of the Ministry of Health of the Slovak Republic, part 18-20, April 6, 2022, Vol. 70, p. 98-104. Available from: https://www.health.gov.sk/?vestniky-mz-sr. Upon its approval, the effectiveness was defined as day of its publication (April 6, 2022) until April 4, 2024. However, its effectiveness had been suspended on May 18, 2022 by a new Minister of Health.

Effective from April 3, 2024, the recent Ministry of Health of the Slovak Republic cancels the above guidelines about standard procedure for the diagnosis and comprehensive management of health care for an adult person with transsexualism and declares to prepare complex legislation based on ICD version 11. (Press release: https://www.health.gov.sk/Clanok?zrusenie-standard-transsexualizmus).

Summary of changes: Surgery (castration) required, besides other legal requirements, for legal gender recognition.

3/ Professional competences of healthcare professionals.

Amended legislation: Decree No. 3231/2005 Coll. of the Ministry of Health of the Slovak Republic of June 30, 2005 „on the scope of practice in some health professions".

Amending decree: MH SR decree No. 115/2024 Coll.

Summary of changes: As of Jun 15, 2024, amendment decree is modifying professional competences of Paramedic in the military medical service, Practical nurse - an assistant with professional qualifications for the performance of specialized work activities and Practical nurse - assistant with professional competence to perform certified work activities.

Amended MH SR decree No. 3231/2005 Coll. available from: https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2005/321/

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Latest updates in Spanish health law (September 2023-May 2024)

Juan-Ignacio Ochagavías-Colás
IDIVAL- University of Cantabria
NCP for Spain

In this report on Spanish health law concerning developments over the last months, I will highlight a draft law recently adopted by the Spanish government and a new development in the field of medicine price regulation. Consequently, this report includes a first part for the analysis of the new regulation and a second section in which I consider noteworthy the new jurisprudence of the Spanish Constitutional Court on a controversial issue concerning the vaccination of minors.

1. Regulatory developments

In Spain, a draft law on the universality of the National Health System is currently going through parliament. Given this legislative novelty, in this section I will analyse its most important novelties, although the definitive legal text will be known in a few months' time.

Firstly, the bill regulates the right to be attended in the National Health System, modifying articles 3 and 3 bis of Law 16/2003, of 28 May, on the cohesion and quality of the National Health System. Regarding universal access to the National Health System, the following objectives must be underlined:

a) Extend the right to health protection at public expense to Spanish nationals living abroad during their temporary movements to Spanish national territory and their accompanying family members when this coverage is not provided for, in accordance with terms of Community regulations on the coordination of Social Security systems or bilateral agreements that include the provision of health care.

b) Extend the right to health protection at public expense to ascendants who are reunited with their son or daughter who is entitled to health care and are dependent on him or her. In such cases it is required that there is no third party liable to pay for their health care. Consequently, the competent authorities will not require health insurance for authorisation of residence in Spain or registration in the central register of foreigners when they ascertain that the ascendant person is dependent on the person entitled to the right.

c) Guarantee homogeneity in the effectiveness of the right to health protection for people who are not registered or authorised as residents in Spain. Additionally, it includes applicants for international protection, displaced persons seeking and benefiting from temporary protection and victims of human trafficking or sexual exploitation. All of them when they are identified in these terms in accordance with current legislation during their stay in Spain and for as long as they remain in this situation.

Secondly, the bill amends article 8 of Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, in order to regulate the single common portfolio of health services. In this way, the basic common portfolio of care services, the supplementary common portfolio and the common portfolio of

additional services would be consolidated. It also clarifies that public health services constitute part of the common portfolio of services of the National Health System and that they must be provided in a joint and coordinated framework.

Concerning the provision of specialised care, the bill includes precision, personalised, predictive, preventive, participative and population-based medicine. In other words, the aim is to address the characteristics of each patient in order to adapt the diagnosis and therapeutic or preventive measures in a more individualised manner.

Thirdly, articles 13 and 14 of Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, are amended. This new development in the provision of specialised and socio-health care aims to clarify that the rehabilitation of patients with functional deficits is aimed at facilitating, maintaining or restoring the highest possible degree of functional capacity and independence.

Fourthly, in financial terms, the draft law provides that health care will be financed from public funds as long as there is no third party required to pay under national legislation, European Union law, bilateral agreements and other applicable legislation.

Likewise, the draft law stipulates that no new health co-payments may be established, maintaining the economic contribution in the cases of pharmaceutical benefits, orthopaedic and orthoprosthetic benefits and ancillary services. The latter cases will be subject to a contribution by the user and are regulated by their specific rules.

Fifthly, the second article of the bill modifies the Law on guarantees and rational use of medicines and health products, approved by Royal Legislative Decree 1/2015, of 24 July, to include the percentages of contributions by users in the outpatient pharmaceutical provision through pharmacies, adjusting to the new cases included in the aforementioned legal reform.

Finally in this section, the second new regulatory development in Spanish healthcare regulations in recent months is Order SND/1186/2023 of 20 October, which updates the system of reference prices for medicines in the National Health System in 2023, an essential tool for controlling pharmaceutical spending.

This regulatory amendment sets the current reference groups of medicines according to the provisions of article 98 of the Law on guarantees and rational use of medicines and health products in accordance with Royal Decree 177/2014, of 21 March, which regulates the system of reference prices and homogeneous groups in the National Health System and certain information systems on financing and prices of medicines and health products.

2. Case law of the Spanish Constitutional Court

Constitutional Court Ruling 148/2023, of 6 November 2023, analyses a case in which the parents disagree on the need and advisability of vaccinating their minor daughter against covid-19. This ruling is subsequent to

STC 38/2023, of 20 April, which analysed for the first time the impact of vaccination on the fundamental right to physical integrity, albeit referring to a person with a disability.

In the case of Judgment 148/2023 the claim for constitutional protection asserts that there has been a breach of the daughter's fundamental right to physical and moral integrity on two grounds:

a) Courts authorised her vaccination against covid-19 without having previously obtained the informed consent of parents and of the minor herself in writing and with all the guarantees required by Law 41/2002, of 14 November, the basic law regulating patient autonomy and the rights and obligations regarding clinical information and documentation.

In particular, there is no professional report or data that would allow us to affirm that the minor had the maturity referred to in article 9.3 c) of Law 41/2002, for the purposes of taking responsibility for the act of consenting to the exclusion of her parents.

b) Courts have not justified the need for the vaccine, nor the direct benefits it would bring to the child within the meaning of article 6.1 of the Oviedo Convention.

In any case, the Spanish Constitutional Court in its rulings on vaccinations prioritises the interests of minors and people with disabilities regarding the protection of their health. For this purpose, the court considers that the recommendations of health authorities and a risk-benefit weighing of the specific vaccine must be taken into account.

Date of submission: 31 May 2024

Sweden: new legislation and regulations for the transition into 2024

Titti Mattsson

NCP for Sweden

1. Government grants to regions for healthcare preparedness

The Regulation (2023:489) on State Grants to Regions for Healthcare Preparedness

Effective Date: January, 1, 2024

Summary:

The regulation contains provisions on state grants to regions for healthcare preparedness. The purpose of the grant is to enable regions to implement measures to strengthen healthcare preparedness so that healthcare activities can be maintained during heightened readiness. The National Board of Health and Welfare (Socialstyrelsen) adjudicates matters concerning state grants under the regulation.

SFS: 2023:489 https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/forordning-2023489-om-statsbidrag-till-regioner_sfs-2023-489/

2. State Grants to Municipalities for the Preparedness of Social Services and Healthcare

New Regulation: Regulation (2023:490) on State Grants to Municipalities for the Preparedness of Social Services and Healthcare

Effective Date: January 1, 2024

Summary:

The regulation contains provisions on state grants to municipalities for the preparedness of social services and healthcare. The purpose of the grant is to enable municipalities to implement measures to strengthen the preparedness of social services and healthcare so that operations within social services and healthcare can be maintained during heightened readiness. The National Board of Health and Welfare (Socialstyrelsen) adjudicates matters concerning state grants under the regulation.

SFS: 2023:490 https://svenskforfattningssamling.se/sites/default/files/sfs/2023-06/SFS2023-490.pdf

3. Clarification of Primary Care's Responsibility for Rehabilitation

Amendments: Healthcare Act (2017:30)

Effective Date: January 1, 2024

Summary:

As part of primary care's core mission, it also includes providing rehabilitative interventions based on the patient's individual needs and circumstances.

SFS: 2023:37 https://svenskforfattningssamling.se/sites/default/files/sfs/2023-02/SFS2023-37.pdf

4. **Clarified opportunities to use digital technology in elderly care.**

Change in law: The Social Services Act (2001:453) and the Act (2001:454) on the processing of personal data within social services.

Effective Date: March 1, 2024

Summary:

The Social Services' possibilities to use digital technology (e.g., safety alarms or cameras) within home care or in special housing for the elderly are clarified.

SFS: 2023:000 och 2023:000 (inget SFS nummer ännu?)

5. Product notification and reporting obligation for tobacco-free nicotine products

New Law: The Law (2022:1257) on Tobacco-Free Nicotine Products

Effective Date: January 1, 2024

Summary:

Manufacturers and importers of tobacco-free nicotine products must notify the Public Health Authority of all such products they intend to provide to consumers on the market. Furthermore, manufacturers and importers of tobacco-free nicotine products must submit complete information to the Public Health Authority each year on sales volumes and information on the preferences of different consumer groups, including children or young people under 25 years of age. Tobacco-free nicotine products may not be provided to consumers if the notification or reporting obligation is not fulfilled. Provisions on fees for product notification, reporting obligations, and the Public Health Authority supervision of tobacco-free nicotine products are introduced in the Regulation (2022:1263) on Tobacco-Free Nicotine Products.

SFS: 2022:1257 https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-20221257-om-tobaksfria-nikotinprodukter_sfs-2022-1257/

Sources:

https://www.regeringen.se/contentassets/4074740fc0d240b6b5080ecb24c4c5d0/viktigare-lagar-och-forordningar-infor-halvarsskiftet-2023.pdf

https://www.regeringen.se/contentassets/9a76c50d1688481ab78f2c6094f7f1f6/viktigare-lagar-och-forordningar-infor-arsskiftet-2023-2024.pdf

Date of submission: 6 March 2024

Legislative news in the field of health care of Ukraine

Khrystyna Tereshko,

NCP for Ukraine

On February 07, 2024, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Preservation of the Gene Pool of the Ukrainian People"

The law was developed with the aim of preserving the gene pool of the Ukrainian people, as well as regulating the issue of social protection of military personnel in terms of ensuring their right to biological parentage (maternity).

The law provides:

1) that in the event of the death or declaration of death of a person whose reproductive cells are stored, their free storage in accordance with this Law is carried out within 3 years from the moment of the death of this person, and after the expiration of this period, further storage of such cells can be extended at the expense of another person, defined in the person's order regarding own reproductive cells;

2) that a natural person, whose reproductive cells are stored in accordance with the law, has the right to dispose of them in the event of his death. At the same time, the disposition, as well as the use of auxiliary reproductive technologies using the appropriate reproductive cells, is carried out in accordance with the procedure and conditions established by law;

3) that in the case of using the reproductive cells of a person who made the appropriate order in the event of his death for the conception of a child, this natural person is recognized as the father or mother of the child born in this way;

4) that a person's declaration of will, made and notarized before the entry into force of this Law regarding his own reproductive cells, is the basis for the use of assisted reproductive technologies using these reproductive cells.

📌 More details at the link:

https://itd.rada.gov.ua/billInfo/Bills/Card/43590

On February 07, 2024, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On the Organization of the Appropriate Level of Medical Support of the Armed Forces of Ukraine"

The law was developed in order to consolidate the powers of the Ministry of Defense of Ukraine to approve protocols and standards for the provision of pre-medical and medical care at the pre-hospital level for the security forces and defense forces based on (among) NATO standards and/or standards approved by individual NATO member states, to determine the procedure for compliance specified standards (recommendations) and supervise their compliance. And also, to approve, in agreement with the central

executive body, which ensures the formation and implementation of state policy in the field of health care, minimum requirements and/or quality standards for specialized medical products, as well as their list, which are used by security forces and defense forces in tactical conditions (during hostilities).

The law provides for amendments to Article 10 of the Law of Ukraine "On the Defense of Ukraine" and Article 14-1 of the Law of Ukraine "Basics of the Legislation of Ukraine on Health Care", which provide for the Ministry of Defense of Ukraine to be empowered to approve clinical protocols for the security forces and the defense forces. reports of material and technical equipment, standards for providing pre-medical and medical care at the pre-hospital level during hostilities and training of security forces and defense forces as assigned (in tactical conditions) based on (among) NATO standards and/or standards approved by individual states - members of NATO.

It is also envisaged to give the Ministry of Defense of Ukraine the right to determine the procedure for compliance with the specified standards (recommendations) and to supervise their compliance.

📌 More details at the link:

https://itd.rada.gov.ua/billInfo/Bills/Card/43371

On May 22, 2024, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine on Strengthening the Capacity of Supervisory Boards of Healthcare Institutions and Extending the Simplified Period of Reorganization into State Non-Commercial Enterprises"

The law was developed with the aim of strengthening the capacity of supervisory boards of health care institutions and stimulating the reorganization of such state institutions into state non-commercial enterprises.

The law proposes to set out in a new edition the fourth and fifth parts of Article 24 of the Fundamentals of Ukrainian legislation on health care, which will provide that foreigners or persons may be members of the supervisory board of a state or communal health care institution by decision of the owner or authorized management body without citizenship, except for citizens of the Russian Federation or the Republic of Belarus. Independent members of the supervisory board are included in the composition of the supervisory boards, the number of which must be the majority of the members of the supervisory board. The order of formation, requirements for members of the supervisory board of a health care institution, rights, duties of the supervisory board of a health care institution, and a standard provision for it are approved by the Cabinet of Ministers of Ukraine.

📌 More details at the link:

https://itd.rada.gov.ua/billInfo/Bills/Card/42869

Date of submission: 29 May 2024

Updates on UK health-related legislation

Edward S. Dove[1]

[1] *Reader in Health Law and Regulation, School of Law, University of Edinburgh, United Kingdom.*

NCP for UK

For the purpose of this EAHL newsletter, it is not possible to highlight every legislative change in the past year or so that impacts the provision of healthcare or health research, particularly given the number of statutory instruments (secondary legislation) passed in each of the legislative chambers across the UK every year. Nor is it particularly sensible to discuss bills that may or may not become law; this incudes, in the UK Parliament, the Data Protection and Digital Information Bill; and in the Scottish Parliament, the Abortion Services Safe Access Zones (Scotland) Bill and the Learning Disabilities, Autism and Neurodivergence Bill. Instead, I focus on several updates that are in my view 'significant', meaning they have direct impact on the organisation of healthcare or health research in the UK or the provision of health care and health research.

Since my last note was published in 2023, which covered (*inter alia*) the Health and Social Care Act 2022 and Medicines and Medical Devices Act 2021, there have been a few minor health-related legislative changes in the UK (from both the UK Government and the Devolved Administrations). In terms of 'significant' updates, I would flag only the Patient Safety Commissioner for Scotland Act 2023, which is discussed below.

As of the time of writing (15 February 2024), I highlight the few legislative developments across the UK.

UK Statutory Instruments

The Medical Devices (Amendment) (Great Britain) Regulations 2023

These Regulations, made under section 15(1) of the Medicines and Medical Devices Act 2021, amend the Medical Devices Regulations 2002, which were made under section 2(2) of the European Communities Act 1972 (among other powers). They provide the UK medical devices sector with additional time to transition to the post-Brexit "UK Conformity Assessed" (UKCA) marking regime for medical devices (which has been operational since 1 January 2021), specifically by extending the periods during which manufacturers and importers can place CE-marked medical devices on the market in Great Britain, which covers England, Wales, and Scotland. This will help ensure continuity of supply and availability of medical devices so that patients have continued access to safe and high-quality medical devices in Great Britain.

CE-marked devices compliant with the EU Medical Devices Regulation 2017/745 or EU In Vitro Diagnostic Medical Device Regulation 2017/746 will be accepted on the Great Britain market until 30 June 2030, which should provide the necessary time for the UK medical devices sector as a whole to prepare for the future UK regulatory regime. On expiry of the transitionary window, all devices will need to comply with the UK Medical Devices Regulations 2002 in full in order to be placed on the Great Britain market.

The Immigration (Health Charge) (Amendment) Order 2024

This Order updates the Immigration (Health Charge) Order 2015, and specifically the amount that certain migrants who are subject to immigration control must pay for the Immigration Health Charge to access NHS services free of charge (subject to those charges UK residents must pay, such as for prescriptions and dental treatment in England).

The Order increases the full rate of annual Immigration Health Charge from £470 to £776 per year for students, their dependents, applicants for the Youth Mobility Scheme, and children under 18. In respect to all other applications liable to pay the Immigration Health Charge, the charge will be increased from £624 to £1,035 per year.

The territorial application of this instrument is the whole of the United Kingdom.

Acts of the Scottish Parliament

Patient Safety Commissioner for Scotland Act 2023

This Act, passed unanimously by the Scottish Parliament, establishes an independent Commissioner to advocate for systemic improvement in the safety of health care (which includes forensic medical examinations) in Scotland, and promote the importance of the views of patients and other members of the public in relation to the safety of health care.

The Commissioner is independent of the Scottish Government and the NHS and will be accountable to the Scottish Parliament. The Commissioner is empowered to consider or investigate any issue they believe to have a significant bearing on patient safety in healthcare, and they are empowered to hear from patients and their families as well as gather information from healthcare providers, to inform their work.

The Commissioner must produce a Patient Safety Charter which sets out what the Commissioner expects of health care providers in terms of standards and good practice in relation to patient safety, including how providers engage with patients and their families.

The Commission also must produce a strategic plan (the period of which must not exceed 4 years), which is publicly available, setting out the Commissioner's strategy for involving the public, and patients in particular, in the Commissioner's work, as well as objectives, proposals for achieving the objectives, a timetable for doing so, and an estimate of the costs for doing so.

United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024

Although not purely health-related, it is worth noting that this Act was passed unanimously in the Scottish Parliament in December 2023, and domesticates the United Nations Convention on the Rights of the Child (UNRC) into the law in Scotland.

The Act places public authorities under a duty not to act incompatibly with the UNCRC requirements, and provides legal remedies should they fail to do so. The Act also places an obligation on the Scottish Government to conduct a "child rights and wellbeing impact assessment" on new primary and secondary legislation to assess the likely effects (if any) it would have on the rights and wellbeing of children.

Most of the Act's provisions will come into force in July 2024.

Article 24(1) of the UNRC states that "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services."

Scottish Statutory Instruments

The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (Commencement No. 6) Regulations 2024

These Regulations, made in exercise of the powers conferred by section 36(2) of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, commences as of 31 January 2024 section 17 (Advertising and brandsharing), section 18 (Free distribution and nominal pricing), and section 19 (Sponsorship) of the Health (Tobacco, Nicotine etc. and Care (Scotland) Act 2016, to enable the Scottish Government to introduce further restrictions in 2024 in relation to restricting advertising and promotion of vaping products in Scotland.

Wales Statutory Instruments

The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Commencement No. 3) Order 2023, The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Commencement No. 4) Order 2023, The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Commencement No. 4) Order 2023

These series of instruments brought into force a number of provisions of the Health and Social Care (Quality and Engagement) (Wales) Act 2020. This Act came into force on 1 April 2023, and aims to (*inter alia*) strengthen the existing Duty of Quality on NHS bodies and extend it to the Welsh ministers for their health service functions; create a Duty of Candour on NHS service providers for openness and honesty with patients and service users harmed during care; and amplify voices by replacing community health councils with Llais, an all-Wales citizen body for health and social care.[37]

Date of submission: 15 February 2024

[37] Welsh Government, "Health and Social Care (Quality and Engagement) (Wales) Act: summary", available at: https://www.gov.wales/health-and-social-care-quality-and-engagement-wales-act-summary.

Updates from EAHL Interest Group on supranational biolaw

Jean Monnet Chair on EUBioethics (2023-…)

M. Fartunova-Michel (PI) has organised her first annual colloquium entitled "What model for the European Union's biolaw?" on 14-15 March 2024 at the Law Faculty of Nancy, in French, with the following other IG members: E. Brosset, N. Coghlan, E. Gennet, A. Mahalatchimy.

"European Union Health Law and Policy" UK-FR partnership (2024)

M. Flear (PI), T. Hervey, A. Mahalatchimy, E. Gennet, E. Brosset, M. Glinel have been successful in obtaining a grant from the UK Springboard for UK-FR exchanges.

I-BioLex research project (2021-2025)

- The I-BioLex Workshop "Definitions and regulatory concepts in Biolaw" (at the Law Faculty, 9 April 2024, Aix-en-Provence, France) has involved several IG members under the scientific coordination of A. Mahalatchimy and M. Glinel: A. Bottacci, E. Brosset, G. Chassang, N. Dubruel, E. Gennet, M. Guerriaud, L. Feriol, E. Rial-Sebbag.
- The 3rd I-Biolex project meeting took place on 10 and 11 April at the Law Faculty, in Aix-en-Provence, France. IG members involved in are: E. Brosset, M. Flear, E. Gennet, M. Glinel, T. Hervey, A. Mahalatchimy (PI), E. Rial-Sebbag, V. Roby

EuroGCT H2020 research project (2021-2025)

Following the production of previous EuroGCT website's contents in English involving several IG members, two new contents have been provided in 2024 by IG members for the activity led by A. Mahalatchimy:

§ G. Chassang and L. Feriol, Collecte, traitement et contrôle des données, April 2024.

§ G. Chassang and L. Feriol, Partage des données / Ouverture des données, April 2024.

Law in Science podcast (Permanent)

I. Fausch who has created the « Law in Science » multidisciplinary podcast on Spotify has interviewed A. Mahalatchimy on advanced therapy medicinal products, 6 May 2024.

Seminar on "European Union Health Law. Scope and Methodologies"

E. Brosset, E. Gennet, M. Glinel and A. Mahalatchimy have invited Prof. T. Hervey for a seminar in person and online on 30 May 2024 at the law Faculty in Aix-en-Provence, France.

OUP Online Encyclopedia of European Union Law (Ongoing and open-ended)

Many members of the IG on Supranational Biolaw participate in the Oxford Encyclopedia of European Union Law published online by Oxford University Press. The General Editors of the Encyclopaedia are Professors

Sacha Garben and Laurence Gormley. The Commissioning Editor for entries on EU Health Law is Professor Tamara Hervey. Recent entries have been published by Markus Frischhut, Eloïse Gennet and Aurélie Mahalachimy and work is ongoing by Estelle Brosset (France); Joaquin Cayon (Spain); Nathalie De Grove-Valdeyron (France); Mirko Dukovic (Hungary); Inesa Fausch (Switzerland); Mark Flear (United Kingdom); Markus Frischhut (Austria); Eloïse Gennet (France); Mary Guy (United Kingdom); Tamara Hervey (United Kingdom); Pin Lean Lau (United Kingdom); Aurélie Mahalatchimy (France); Olly Bartlett (Ireland); Vera Lucia Raposo (Portugal); and Santa Slokenberga (Sweden).

Workshop on Framing EU Health Law through connectivity, Université Aix-Marseille, 31 May 2024.

This one-day workshop focuses on the collective framing of the (sub)discipline of EU health law. It will consider how we conceptualise EU health law, as a transversal topic of EU law more generally. In this, we both continually constitute our field of enquiry, and offer challenge to the orthodoxy of EU law scholarship and practice, and its organising structures.

Estelle Brosset (France); Joaquin Cayon (Spain); Nathalie De Grove-Valdeyron (France);; Mirko Dukovic (Hungary); Inesa Fausch (Switzerland); Mark Flear (United Kingdom); Markus Frischhut (Austria); Eloïse Gennet (France); Marie Glinel (France); Tamara Hervey (United Kingdom); Pin Lean Lau (United Kingdom); Aurélie Mahalatchimy (France); Santa Slokenberga (Sweden); Olly Bartlett (Ireland); Vera Lucia Raposo (Portugal). The workshop is a collaboration between I-Biolex, Aurelie Mahalachimy, Eloise Gennet, and the British Council Springboard fund (Mark Flear), co-hosted by Aurélie Mahalachimy, Eloise Gennet and Mark Flear, and organised by Tamara Hervey.

Workshop on THE CONTOURS OF PHARMACEUTICAL REGULATION IN THE EU (11 June 2024)

Sponsored by the Jean Monnet European Centre of Excellence at Dalhousie University and the Office of the VPRI at Dalhousie University through the Next Wave Fund, with support from the Institute for the Study of European Laws (ISEL), City Law School, City University of London. Tomislav Sokol; Marie Glinel; Tamara Hervey

Colloque international « espace européen des données de santé et ia, enjeux juridiques et défis de mise en œuvre », 3 & 4 june 2024

Sponsored by the Jean Monnet EDIHL/IRDEIC. Nathalie De Grove-Valdeyron, Titti Mattson et Giacomo di Federico.

Date of submission: 27 May 2024

Young Scholars Research Group – supporting members to shape their research output

***Dr Mirko Đuković**, Post-doc fellow Department of Law, European University Institute*
***Dr Andrea Martani**, Post-doc Fellow University of Basel*
***Sofia Palmieri**, PhD Candidate Ghent University*
***Denniz Sabo**, PhD Candidate Stockholm University*
***Noemi Conidit**, PhD Candidate University of Bologna*

During last year's highly successful Medical Law School hosted by the University of Göttingen and the EAHL, we had a fruitful discussion with PhD candidates and post-doc fellows who hinted about the need to engage in activities to keep our network connected between conferences. As a result, with the kind support of the EAHL Board, we organized the equally successful Strategic Writing School. This was our first online series of lectures and discussions with guest speakers who shared invaluable insights, eager to help our students understand the process of writing and the planning and publishing research we engage with. Their wisdom and experience have been a source of inspiration for our young scholars.

The series of webinars focused on carefully selected topics that addressed uncertainties about publishing prospects in medical and health law, biomedical law and ethics, and overall European jurisprudence on law and technology. Starting in January with the first session and ending in May with our last session, we hosted six scholars over five sessions, lasting around an hour. Although initially created for the EAHL membership, the school managed to attract new members among young researchers, who have since seen a significant improvement in their research output. This achievement is a testament to their hard work and dedication. Overall each session was attended by 20-25 participants. The speakers presented between 30 and 40 minutes, after which we engaged in discussions that, to our satisfaction, sometimes lasted more than the promised hour of their time.

The first session was opened with a welcome note by Professor Steven Lierman. The guest speaker, Dr Patrick Allo, a Researcher and Research Policy Officer at KU Leuven, presented in a live interview format. The main topic of discussion was how to get started with a research proposal, how to decide (and deal) with the different typologies of (Ph.D. projects (cumulative thesis vs. book), how to structure a research proposal, and also how to deal with amending the initial (PhD) project proposal.

The second session focused on different research outputs, where Professor Tamara Hervey, a Professor at the City, University of London, invigorated participants by giving bountiful examples from her career. With over 250 publications to her name, she specifically addressed the "niche" research interests and variety of topics we cover in the interdisciplinary field of health law, advising that there is no such thing as a niche topic, as

every topic is nested in larger, more established topics, with all the benefits that come from that. Professor Hervey made a comprehensive comparison between types of publications, giving her views on the pros and cons of each finishing with her method of picking her projects, reminding us that we should always try to enjoy and have fun with our writing projects.

Professor Tom Goffin of Ghent University led the third session. Professor Goffin is also the Managing Editor of the European Journal of Health Law, so it was more than suitable to have him share his expertise on navigating the publication landscape, particularly in health law. The focus of his presentation remained on the process of selecting appropriate publication venues for our research. Professor Goffin kindly introduced health law journals with insights on choosing the right journal and how to craft an effective cover letter for article submission. Particular emphasis was placed on the importance of publishing in various jurisdictional areas, particularly the US, UK, and EU, and discussed the differences in requirements and styles across these regions.

During the fourth session, we hosted a Professor at the Faculty of Medicine, KU Leuven, Dr. Kris Dierickx. As a Professor of medical ethics, he reflected on several topics related to research ethics and integrity, including plagiarism, self-plagiarism, and the novel conundrums pertinent to the use of chat GPT and other similar AI tools for research and writing. He mainly discussed transparency in the research process and sound ethical practices and guidelines concerning authorship. During this session, participants were particularly interested in the importance of sufficient processes for ethical review in light of recent incidents of research misconduct in different contexts.

The final session was dedicated to “Surviving thesis writing.” For this session, we were lucky to have two brilliant young scholars with us: Dr. Inesa Fausch, Legal Researcher at the University of Basel, and Professor Pin Lean Lau from Brunel University and each presented 20-minute tips for handling the end of the PhD journey and how to transform the thesis into a book proposal, respectively. Dr. Fausch provided valuable insights on ensuring the project's excellent quality towards the end and dealing with deadlines and the stress that may come from the PhD journey. Professor Lean Lau presented selected reasons for transforming one’s PhD thesis into a book. She thoroughly explained the different stages of such a process, providing concrete tips throughout her speech. Participants were interested in their views on how far writers should go in presenting their points of view and perspectives in the thesis, given that the thesis is such a different format from others, and how to compromise with the editor’s requests.

The participants' feedback shows they were delighted with the selected topics, the content, and the invited speakers, with the expectation that we would continue with similar activities.

Jean Monnet EU4GH Summer school "The European Union and global health"

University of Salerno, 3-7 June 2024

The School of Law of the University of Salerno (Italy) hosted from 3 to 7 June 2024 the first edition of the Jean Monnet Summer School “The European Union and Global Health”, offered by the Jean Monnet Centre of Excellence “New Visions of the European Union’s Role in Global Health” (EU4GH) (co-funded by the European Union under the Erasmus + Programme).

The Summer School was organised by Prof. Stefania Negri, EAHL National Contact Point for Italy, in collaboration with the Board of the European Association of Health Law (EAHL), the Global Health Law Consortium (GHLC) and the Observatory on Human Rights: Bioethics, Health, Environment.

The summer course consisted of 24 hours of lectures taught by internationally renowned scholars with a recognised expertise in the fields of European Union health law and global health law. The faculty included EAHL President and Vice-President, Professors Steven Lierman (University of KU Leuven) and Joaquín Cayon de Las Cuevas (University of Cantabria) and Board member Dr. Mirko Duković (European University Institute); GHLC members Professors Benjamin Mason Meier (University of North Carolina at Chapel Hill), Lisa Forman (University of Toronto), Mark Eccleston-Turner (King’s College London) and Katharina O’ Cathoir (University of Copenhagen); as well as key staff members from the EU4GH Centre, Professor Pia Acconci (University of Teramo), Dr. Sandro Bonfigli (Italian Ministry of Health), Dr. Emanuele Cesta (Italian Medicines Agency) and members from the Centre’s Expert Advisory Board, Professors Gabriela Oanta (University of La Coruña) and Maria Isabel Torres Cazorla (University of Malaga).

In line with the EU4GH Centre’s focus, the course addressed the pillars of EU health law and its interactions with global health law, major legal issues related to the establishment of the European Health Union and the EU role as global health actor, with emphasis on the management and response to cross-border health threats and public health emergencies of international concern.

The main target audience was represented by LLM, PH.D. and postgraduate students but the course was also open to other categories of interested participants from other fields of study and research. The course reported 102 registered participants from Italy, Germany, Poland, Romania, Spain, Ukrania, Armenia, Bangladesh, China, Egypt, Philippines, India, Morocco, Nigeria, Turkey, Uganda, and to allow the widest possible attendance it was offered in hybrid form, with most international students attending remotely.

New 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.

University of Groningen

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.

EAHL

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EAHL secretariat organizes decision on admission and informs applicants about further procedure.

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