EUROPEAN ASSOCIATION of HEALTH LAW

December 2021

EAHL Newsletter

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EAHL
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Message from the President

Dear EAHL members,

This year is almost coming to its end, and I hope that you all will have a peaceful Christmas celebration. As most other, I hoped that 2021 would be the final year of the pandemic, although I knew that this could be wishful thinking. We know for sure that Europe and the rest of the world will have to live with the pandemic also in 2022. The pandemic reminds us of how unequal the access to health care is, both when it comes to vaccination and intensive treatment. In this matter, legal remedies are an essential feature and health lawyers are needed!

The pandemic affected also the EAHL activities, but partly in a positive way. We have been able to meet digitally, and academic events can be held with short notice and on contemporary issues, e.g. the seminar that we had in the spring regarding vaccination passports.

Still, it is a different experience to meet in person then online and I am looking forward to the EAHL conference in Ghent in April. The organizers are planning for alternatives if it cannot be held as scheduled. Please register and follow update on the website: https://healthlaw2022.eu

All the best for 2022!

Karl Harald Søvig

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The EAHL Interest Group (IG) on Supranational Biolaw

Updates

Since the last EAHL newsletter and update in July 2021, the EAHL Interest Group on Supranational Biolaw has conducted the following activities, thanks to the involvement of several of its members.

Publications:

Aurelie Mahalatchimy, Pin Lean Lau, Phoebe Li & Mark Flear (Paper), Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of An Imaginary, (2021) Journal of Law & Biosciences Vol. 8 Issue 2: July to December 2021

Sue Tansey, Siobhán O'Sullivan, & Mark Flear, What might Brexit mean for UK and international bioethics?, https://www.nuffieldbioethics.org/blog/what-might-brexit-mean-for-uk-and-international-bioethics
29 September 2021

Conferences:

Critical Legal Conference 2021 on "Frankenlaw", organized by University of Dundee (Scotland) and University of Victoria, British Columbia (Canada), 3- 4 September 2021

- Panelists from EAHL IG

Pin Lean Lau & Mirko Dukovic, Contemporary Iliad's Chimeras: Cognition Commodification of Monstrous Frankensteinian Entities, Human Stewardship and the Law's Dilemmic Response

Nordic Permed Law Symposium on Genome Editing, Health Innovations and Responsible Regulation, organized by Nordic Permed Law (EAHL IG member Santa Slokenberga is a Board Member), Uppsala (Sweden), 3 – 4 November 2021

- Panelists from EAHL IG

1) Vera Lúcia Raposo, A Room with a View (and with a Genetically Engineered Drug): Advanced Therapy Medicinal Products and Genetic Tourism in Europe
2) Pin Lean Lau, Addressing Cognitive Vulnerabilities through Genome Editing: Techno-Legal Adaptations for Persons with Cognitive Disabilities
3) Judit Sándor, The Past and Future of Genome Editing

4) Michal Koscik & Eliška Vladíková, The Object – Based and Process – Based Regulation of Genome Editing
5) Santa Slokenberga, What Would it Take to Enable Germline Editing in Europe for Medical Purposes?

Projects:

Developing and Piloting a Tripartite One-Health Assessment Tool for Antimicrobial Resistant Relevant Legislation, WHO (completed October 2021)

- Project Lead: **Phoebe Li** (University of Sussex)
- Other EAHL IG members involved are Dobrochna Bach-Golecka, Joaquin Cayon-De las Cuevas, Brenda Daly, Mirko Dukovic, Mathieu Guerriaud, Michal Koscik, Pin Lean Lau, Aurelie Mahalatchimy
- The final chapter on Human Health and Antimicrobial Resistant Relevant Legislation was drafted by Phoebe Li and Pin Lean Lau, and submitted to the WHO at the end of September 2021.
- Further information on the results and publication will be communicated by the WHO.

EU Health Policy Platform, European (EU HPP) Commission; EU Thematic Networks 2021, Proposal titled Health as a Fundamental Value: Towards an Inclusive and Equitable Pharmaceutical Strategy for the EU (September 2021 – September 2022)

- Project Leads: **Eloïse Gennet and Aurélie Mahalatchimy** (University of Aix-Marseille, UMR 7318 DICE CERIC)
- Other EAHL IG members involved are mainly: Estelle Brosset, Joaquin Cayon-De las Cuevas, Brenda Daly, Anne-Marie Duguet, Inesa Fausch, Mark Flear, Clotilde Jourdain-Fortier, Markus Frischhut, Mary Guy, Nathalie de Grove Valdeyron, Mirko Dukovic, Mathieu Guerriaud, Tamara Hervey, Michal Koscik, Pin Lean Lau, Isabelle Moine-Dupuis, Sabrina Röttger-Wirtz and Santa Slokenberga.
- The Proposal has been successful and selected by the European Commission as one of the EU Thematic Networks 2021 and by the persons registered on the EU HPP after a presentation at a Pitch webinar on 7 July 2021.
- The proposal has been presented by E. Gennet and A. Mahalatchimy on behalf of the EAHL IG on Supranational Biolaw at a kick off meeting organized by the European Commission on 24 September 2021, and on 20 October 2021 at one of the Health in Europe's webinar organized by Mary Guy.
- The first webinar on EU Values and Health Digitalization: The Inclusion of Vulnerable Groups will be held on the EU Health Policy Platform on 22 November 2021, 11am to 12.30pm (CET).

Date of submission: 15 November 2021

Czech Republic report

Michal Koščík, Ph.D.,
Masaryk University

Legislation: Reform of health insurance act

The parliament of the Czech Republic has approved one of the most notable changes in Health insurance policy in the past decade. The health insurance system is traditionally based on compulsory participation, broad coverage of health services and very low (or completely absent) out of pocket payments. The scope of health services that have to be covered by an insurance company is not defined by the contract but by the law. The law sets forth that the cost-effectiveness of each treatment or medicine needs to be assessed by the State Institute of Drug control before it is considered to be reimbursed by public health insurance. The process of assessing cost-effectiveness is notoriously slow, and some drugs are not even included in the assessment for various reasons. This leads to a structural problem, where critically ill patients try to apply for the reimbursement of expensive innovative treatments, claiming that the officially designated "cost-efficient" treatment is not suitable for their medical condition. The Act on Public health insurance sets forth that the patient has a right to treatment that is otherwise not covered by health insurance if the provision of such health services is the only option of treatment. The number of requests for exception spiralled to tens of thousands of requests per month.

The amendment to the Act on Public Health Insurance, which will become efficient in 2022, addresses the abovementioned issues by:

- Updating an administrative procedure that deals with requests for exceptional reimbursement of medicines and treatments that are not covered under usual circumstances. If the health insurance provider decides not to approve the request it shall decide in administrative proceedings. The party to the proceedings shall be the insured person (patient). The provider of healthcare is not a party to the proceedings but is obliged to cooperate with the insured person and the health insurer. The proceedings shall be decided by a semi-independent *"review board"* which consists of four members appointed by the director of the health insurance company and one member appointed by the Minister of Health. No more than two review board members may be employees of the health insurance company concerned. At least one member of the board must be a lawyer, and at least one member must be a physician. Administrative courts can review the decision of the board.
- Introducing new principles for the reimbursement of medicinal products for the treatment of orphan diseases in a simplified administrative proceeding that recognises relevant patient organisations as the parties to the proceedings.

Case law: Constitutional court brings the loss of chance doctrine back to contention.

The ruling of the Constitutional Court no IV.ÚS 3416/20 involved a case of a young woman who died after her pregnancy was terminated by caesarean section. The lower courts concluded that, although the hospital had breached its legal duty and that the provided medical care was *non lege artis*, there was no causal link between the unlawful conduct and the damage to the patient's health, since the main cause of death could have occurred even without any malpractice.

The case reached the Supreme Court, which refused arguments of complainants based on the loss chance doctrine. The constitutional court subsequently annulled the judgment of the Supreme Court due to a procedural mistake. However, in the form of an obiter dictum, the Constitutional court emphasised that the "loss of chance" for life and health is a good protected by the Charter of human rights of the Czech Republic. The constitutional court suggested that the loss of chance doctrine should be included into consideration but left for the Supreme court to decide how. In the words of the Constitutional court, it "does not feel called upon to dictate to the Supreme Court that it should apply the doctrine of loss of chance". However, the Constitutional court sends a message that this doctrine "appears to be very appropriate" and that the eventual rejection of this doctrine must be based on substantial grounds.

COVID – 19 pandemic: Case-law and recent developments

The summer of 2021 brought dozens of cases where administrative courts cancelled most of the epidemiological restrictions on services, restaurants, hotels and leisure facilities, mainly on formal grounds. The administrative courts often held the reasoning behind these measures not convincing, not sufficiently reasoned, and without assessing the proportionality of the interference with the rights of the persons concerned.

In the recent judgement no. 10 As 229/2021 – 31 the Supreme Administrative Court ruled that it is not possible to order a quarantine simply by phoning a person suspected of being infected; an individual decision is required under the Administrative Code.

On the 1st of November 2021, the Czechia formally switched off the nationwide tracing app *"e-rouska"* because it was "no longer necessary". It can be observed that the performance of the tracing app was very disappointing as the Ministry switched it off despite being in the middle of the fourth wave of covid-19 infections.

Date of submission: 15 November 2021

The 2021 French Bioethics Law

Éloïse Gennet

NCP for France

The 4th French bioethics law came into force on 4 August 2021 and will be revised again in seven years. Some of its main points are summarized here.

Access to **Assisted Reproductive Technology** has been opened to non-medical necessity. It will now be accessible (and reimbursed by social security) not only to heterosexual couples, but also to any couple of two women, or to a woman who is not married. Women couples wanting to benefit from ART will have to give a notarized joint consent to be affiliated to the child before its birth. Post-mortem insemination will remain forbidden in France.

Children who were born from gamete donation will have the **right to know their origin** once they reach the age of majority. Gamete donation will thus be conditioned to the consent that non-identifying information is kept (age, physical traits, familial situation…) and potentially disclosed to the child in the future, together with the actual identity of the donor. During a transition period, former donors will be given the chance to consent to this new system and if they don't, the use of their gamete will be prohibited.

Another novelty of this 4th bioethics law is that there is no need anymore to demonstrate a medical necessity in order for men and women to preserve their gametes (in order to benefit from ART at a later stage). There also is no need anymore for the consent of the donor's spouse. It is forbidden for a person to whom the donor is economically dependent (*e.g.* the employer) to pay for the fees related to **gamete preservation**.

Surrogacy will remain prohibited, even though the highest French civil court, the Cour de cassation, had given authorization to integrally transcribe the birth certificate of a child born abroad from a surrogacy arrangement in compliance with local laws. In contrast, only the biological parent will be able to have the filiation to the child transcribed, whereas the other parent who is not a biological parent will have to adopt the child as had been done in French law in the past.

Organ donation has been facilitated. The possibility to match several donors and recipients together for cross-allocation is extended from 2 pairs to 6 pairs, including post-mortem organ donation. Consent to post-mortem organ donation is presumed for all adults (unless they explicit refused in the past), including for incapacitated adults. The possibility for minors and incapacitated adults to donate bone marrow to their parents is made easier provided that there is an *ad hoc* external legal representation to avoid conflict of interest.

The selection methods for **blood donors** will be modified in order to avoid discrimination on sex or sexual orientation.

Following a scandal in France on the conditions under which **donated human bodies** were kept, health establishments will now have to obtain a specific authorization from the ministry and commit to respect the dignity of the donated bodies.

When necessary for decisions about their healthcare and treatment, family members of a deceased person can get access to information on his/her **genetic characteristics** and can even have supplementary genetic tests made (but only if the person had not explicitly refused and the member is directly related, i.e. a parent or a child).

It is now possible for a patient doing a genetic test (be it in the clinical or in the research settings) to be informed about **incidental findings** unrelated to the initial test when these findings allow the patient (and when relevant his/her family) to receive curative or preventive care. The patient can also refuse to be informed about incidental findings.

Advertisement on **recreative genetic tests** is forbidden in France.

The new law distinguishes between two cases regarding **scientific research with embryos**: research on human embryos requires the obtention of an authorization whereas research on human embryonic stem cells or on human induced pluripotent stem cells only requires a declaration. Most importantly, it authorizes embryo research even without a therapeutic goal when such research aims to improve the knowledge on human biology and research on genome editing on the human embryo. Other types of research remain prohibited, notably the creation of hybrid embryos with animal cells, the creation of embryos for research purposes or the cloning of embryos.

The law has created a new category in the medically necessary abortions, the **multifetal pregnancy reduction** which can be implemented up until 12 weeks of pregnancy if such a reduction can reduce the health risks either for the woman or the embryos.

Regarding **intersex children**, the law foresees slightly longer timeframes to declare the sex of the newborn child, which remain extremely short (three months instead of a few days). The modification of sex in the civil statutes in these cases should be made easier. Parents of an intersex newborn will be directed to one of the four national reference centers for rare diseases in genital development for better information and care.

The mandate of the French **National Consultative Committee on Ethics (CCNE)** has been widened to include questions related to artificial intelligence or the environment. The CCNE will organize public debates every year on ethical questions.

The use of **neuroimaging technology** to measure an aspect of brain function is prohibited in judicial expertise. The French Ministry of health will be able to prohibit neuro-modulation technologies**,** like deep brain stimulations, when they pose risks for human health.

The law gives a normative frame for data processing through **artificial intelligence** in the field of health care and notably requires that patients are informed of such algorithmic processing.

Sources:

LOI n° 2021-1017 du 2 août 2021 relative à la bioéthique

Supiot E., « Loi de bioéthique : les grandes lignes d'une réforme attendue », *Dalloz Actualités*, 7 septembre 2021.

Bioy X., « La loi de bioéthique 2021, plus sociétale que jamais », AJDA, 2012 :1826.

Date of submission: 15 November 2021

Report from Spain.
Contemporary issues in the pandemic context and health law.

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

1. Covid-19 and vaccination process in Spain.

Currently, Spain has one of the lowest incidence rates in Europe (52 cases per 100,000 inhabitants this week) and, at this moment, most of population has been fully vaccinated (88%). Taking into account this figures, experts do not consider that hospital saturation will occur like previous epidemic waves, but the truth is that there is an upward trend, especially in cases of infected people. Consequently, and officially, according to latest reports from Ministry of Health, Spain has started a new expansionary phase of the pandemic. without its full scope being determined at this time, given the uncertain trend of epidemic data in the country.

Regarding vaccination of booster dose, in Spain it is being administered to those over 70 years of age and to people with certain immunodeficiencies.

Official data and different updated documentation about vaccination strategy can be consulted at the following web link of Ministry of Health:

https://www.mscbs.gob.es/en/profesionales/saludPublica/ccayes/alertasActual/nCov/vacunaCovid19.htm

2. Other information about vaccination process: Report from the Ministry of Health on the effectiveness of Covid vaccines in Spain.

The Spanish Ministry of Health has published the first technical report on the effectiveness of vaccines, confirming the data already advanced by clinical trials. The document, called "Analysis of the effectiveness of vaccination against covid-19 in Spain", indicates that different (4) vaccines supplied (Pfizer, AZ, Moderna and Janssen) have slowed the spread of covid-19 and, above all, its most dramatic consequences.

Thus, deaths have fallen more than 90% and infections, between 70% and 90%, according to this official report. It also indicates that the mRNA and AstraZeneca vaccines provide more protection than the Janssen single-dose.

Moreover, it is ensured that vaccines are effective among young and old people, maintain immunity over time, although it is progressively reduced, and work against variants of SARS-CoV-2 virus known so far.

This report can be consulted at the following website:

https://www.mscbs.gob.es/en/profesionales/saludPublica/prevPromocion/vacunaciones/covid19/Efectividad_vacunaCOVID-19.htm

3. Restrictions in Spain.

Since mid-September, most of restrictions have been lifted. However, the national Public Health Commission has considered to maintain the mandatory use of face masks (technically known as "mechanical protection") indoors or outdoors when the safety distance (1,5 meters) cannot be kept.

Thus, there is a context of tense calm or “wait-and-see” regarding the next evolution of data (autumn and winter): about not only the incidence of covid-19, but also the common seasonal flu (influenza) among other respiratory diseases, such as respiratory syncytial virus (RSV), which causes most bronchiolitis in minors.

Likewise, the Spanish Alerts and Emergencies Coordination Center (CCAES) is cautious about the behavior of the Delta variant, its possible interaction with others, the evolution of the epidemic in countries with strong links with Spain, such as United Kingdom, and the impact of potential rebounds.

In other words, Law 2/2021, of March 29, on urgent prevention, containment and coordination measures to face the health crisis caused by COVID-19, will continue in force for a while.

In addition to this, authorities of Autonomous Communities maintain their capacity at the local level to use weekly control mechanisms against covid-19 virus, for instance, in order to regulate capacities in specific areas.

Finally, the mandatory use of covid passports depend on authorizations at the regional level, both temporarily and with respect to each situation (limited to specific events or entry into nightlife venues, for example). This kind of authorizations and their extensions must be ratified by Superior Courts of the Autonomous Community, in addition to the subsequent judicial control by the Spanish Supreme Court, which has endorsed covid passports in some limited contexts.

4. The Spanish Supreme Court regarding the measures limiting fundamental rights during the pandemic.

The Fourth Section of the Administrative Chamber of the Supreme Court has issued two judgments this year on the limitation of fundamental rights by ordinary legislation (STS 719/2021 and STS 788/2021). This Chamber of the Supreme Court said that restrictions of fundamental rights in the framework of the fight against the pandemic does not always and necessarily require coverage of the state of alarm. Thus, health law may provide normative coverage to the restrictions of fundamental rights - of movement, of assembly, to family privacy, ...- (that is, through Organic Law 3/1986 on Special Measures in Public Health Matters, Law 14/1986 General of Health and Law 33/2011 General of Public Health).

However, the substantive justification of health measures must be commensurate with the intensity and extent of a restriction of fundamental rights. Therefore, mere considerations of convenience, prudence or precaution are not enough.

5. Resolutions of the Spanish Constitutional Court.

- Regarding a hypothetical mandatory vaccination.

An unconstitutionality appeal against a law of the Autonomous Community of Galicia that raises the possibility of compulsory vaccination in situations of serious risk to public health by the regional health authorities is pending judgment. So far, the Constitutional Court has only issued a resolution that temporarily suspends this regional regulation, although it has advanced that it is not possible to impose mandatory vaccination because, nowadays, there is no legal coverage because this is not included among preventive measures in Organic Law 3/1986 on Special Measures in Public Health Matters.

- Regarding the Alarm State.

At the beginning of October 2021, the Constitutional Court declared against the national government being able to interrupt the operation of the Spanish Parliament in the pandemic context. And a few days ago, the Constitutional Court declared unconstitutional both the six-month extension (from October 25, 2020 to May 9, 2021) and the appointment of delegated competent authorities established by Royal Decree 926/2020 of the second State of alarm. They are added to another previous sentence that declared unconstitutional the first State of Alarm in relation to the general confinement of the population, which required the declaration of the State of Exception.

In the sentence of the second State of Alarm, it should be noted that what is unconstitutional is not the duration of the extension, by itself, but the unreasonable or unfounded nature, considering the agreement adopted by the Congress of Deputies, of the decision for which that term was set. Likewise, it is indicated that the extension was authorized when the limiting measures of rights included in the request were not going to be applied immediately by the Government. Its practical application depended on the future decisions of the presidents of the Autonomous Communities.

Regarding designation of delegated competent authorities, the court considers that, among other reasons, this decision is against the organic law.

6. Assisted human reproduction.

The Ministry of Health has drawn up a Ministerial Order that has been published in recent days with new criteria for access to assisted human reproduction techniques contained in the portfolio of common services of the National Health System.

Until now, these techniques were aimed at a therapeutic purpose for people with fertility disorders, to prevent the transmission of diseases or serious disorders, or to preserve fertility in situations associated with special pathological processes.

Now, with this new regulation, the reproductive right in the public health system is guaranteed to women without a partner, lesbian women and transgender people with the ability to carry a child.

7. New bill of health law.

Finally, note that the Government of Spain has approved this week a bill of equity, universality and health cohesion. Some of these measures are already in force by decree law or by the general budget laws of the State. In any case, it must be debated in the Spanish Parliament. The legal aspects to take into account in the coming weeks are universality, co-payments or the forms of health center management.

GHENT 20-22 April 2022

After a too long period of social distancing, webinars, online-conferences and absence of real academic and social events, we are looking forward to see each other from 20 until 22 April 2022 in the lovely city of Ghent, Belgium, one of Europe's best hidden secrets! It offers a combination of the history offered by Belgium's Bruges and the vibrant livelihood of Belgium's Antwerp. Or in other words: the perfect setting to once again meet in person and discuss the future of health law!

One of the most important lessons learned from the COVID-19-crisis is that we need to be able to trust on our healthcare to be patient-centered, effective, safe, efficient, equitable and timely, or in other words that we need to be able to trust on the quality of our healthcare. Health law plays a vital role with regard to quality of healthcare, not only through liability and sanctioning mechanisms when the quality and safety in healthcare was not enough, but also and foremost in creating frameworks through which the quality of healthcare can be guaranteed.

This conference will therefore offer a unique programme of distinguished keynote speakers, workshops and oral and poster presentations on broad scientific issues covering the conference theme: "Quality in healthcare. Can the law help to guarantee safe and reliable care for the patient?" This conference theme will be divided in 4 subthemes:

1. Quality and safety (Right to quality of care; Liability & compensation; Alternative mechanisms for liability & compensation; Standard of care, …)
2. Quality of healthcare professionals & practices (Recognition, accreditation & certification; Quality measurement; Inspection mechanisms, deontology & disciplinary sanctions; Free movement of healthcare professionals, …)
3. Quality and new technology (Artificial Intelligence, Enhancement of healthcare , Personalized medicine, …)
4. Quality of health data governance (Health data governance; Quality of data; Quality of care and GDPR; Research with health data, …)

It is with great joy and enormous pleasure that we invite you, researchers, clinicians, educators, policy makers in health law to present your work on the 8th European Conference on Health Law, "Quality in healthcare. Can the law help to guarantee safe and reliable care for the patient?", from 20-22 April 2022! Welcome in Ghent!

Prof. dr. Tom Balthazar & Prof. dr. Tom Goffin

Early bird registration and abstract submission before 31 December 2021.

Conference website: www.healthlaw2022.eu

Contact: eahl2022@ugent.be

The Clinical Trial Regulation is coming into effect in January 2022

The Clinical Trial Regulation (Regulation EU No 536/2014) will finally come into effect in the EU on 31 January 2022, replacing the Clinical Trials Directive (2001/20/EC). The Regulation will bring about a greater level of harmonization of the rules for conducting clinical trials throughout the EU. This is a change from the current Clinical Trials Directive, which allow for national rules concerning clinical trials to vary from one member state to another.

The Regulation will enter into force at the same date as the go-live of the Clinical Trials Information System (CTIS), the new centralized EU portal and database for clinical trials. Via the CTIS, the Regulation will harmonize the registration, assessment and supervision processes for clinical trials throughout the EU. Among other things, this will make it easier to conduct multinational clinical trials. By harmonizing the rules and procedures for clinical trials, the Regulation aims to increase both the number and the efficiency of clinical trial studies conducted within the EU. The Regulation also aims to make information on clinical trials more transparent, by requiring information on the authorization, conduct and results of all clinical trials carried out in the EU to be publicly available.

Read more:

https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation

Evaluation of the Cross-Border Healthcare Directive

As the Cross-Border Healthcare Directive (Directive 2011/24/EU) turned 10 years this year,
The Cross-Border Healthcare Directive (Directive 2011/24/EU), giving EU nationals the right to seek planned healthcare in another EU country, was adapted ten years ago this year. As the Directive turns ten, the Commission is evaluating the performance of it. The aim of the evaluation is to “assess how the Directive’s objective to facilitate access to safe and high quality cross-border healthcare in another Member State has been met and to what extent the Directive has promoted patient rights and cross-border cooperation between Member States for the benefit of EU citizens”.

The Commission have already carried out a public consultation, where citizens, as well as NGO’s, companies and others were asked to evaluate the functioning of the Directive. The results of this public consultation have been published on the Commission’s website.
(Commission adaption planned for Q2 2022)

Read more:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights_en

https://ec.europa.eu/health/cross_border_care/consultations/cbhcdir_evaluation_en

Austrian government announce plans to make Covid-19 vaccine compulsory

The Austrian government recently announced its plans to make vaccination against Covid-19 mandatory, with exemptions for those unable to be vaccinated on medical grounds. This will make Austria the first European country to make Covid vaccination mandatory for society at large, with similar mandates (policies?) until now being limited to certain sectors. The planned policy raises several legal questions, including whether such policies are compatible with ECHR law.

The ECtHR have not yet ruled on compulsory vaccine policies related to Covid-19. The Court's existing case law does, however, indicate that such measures could be compatible with the ECHR. Earlier this year, the ECtHR held that compulsory vaccination of children for certain diseases did not violate Article 8 of the Convention.

The case concerned a pre-Covid policy in the Czech Republic, requiring that school children be vaccinated against certain diseases. The Court held that compulsory vaccination represents an interference with the right to respect for private life within the meaning of Article 8 of the Convention but found that the interference at question was justified. The interference pursued the legitimate aim of protecting the health of both those vaccinated and others and was considered necessary in a democratic society.

Notably, the Court afforded the State a wide margin of appreciation and emphasized that there is a consensus among European states that vaccination is "one of the most successful and cost-effective health interventions and that each state should aim to achieve the highest possible vaccination level among its population". The judgment has been commented by Anna Nilsson, see European Journal of Health Law 28 (2021) 323–340.

Read more:

https://www.theguardian.com/world/2021/nov/19/austria-plans-compulsory-covid-vaccination-for-all

https://brill.com/view/journals/ejhl/28/3/article-p323_7.xml?ebody=full%20html-copy1

The ECtHR notifies Poland of 12 cases related to abortion ban

Earlier this year, a near-total ban on abortions came into effect in Poland. This was the result of a decision by the Polish Constitutional Court finding a provision in the Family Planning Act of 1993, allowing for legal abortion in cases of fetal abnormalities, unconstitutional. The decision has led to Poland's already extremely restrictive abortion legislation becoming even more restrictive.

The near-total ban prompted an interim resolution from the Committee of Ministers of the Council of Europe (Interim Resolution CM/ResDH(2021)44), calling on Poland to "adopt clear and effective procedures for women to access lawful abortion".

The Polish Constitutional Court's decision was also highly controversial within Poland, sparking large-scale protests and leading to the European Court of Human Rights receiving more than 1000 applications relating to abortion rights in Poland. Now, the ECtHR have notified Poland of 12 individual cases related to the

abortion ban. Relying on Article 8 and 3 of the Convention, the applicants complain that they are potential victims of a violation of their rights, citing that if they become pregnant, they would be obliged to carry the foetus to term.

In *A, B and C v Ireland* the ECtHR held that the Convention does not confer a right to abortion, but that legislation regulating the interruption of pregnancy touches upon the sphere of the private life of the woman. The Court have therefore regarded restrictions on abortion sought for reasons of health or well-being as an interference with Article 8, requiring justification. In that case, the Court determined that the State's margin of appreciation was broad, even though a substantial majority of European states allowed abortion on broader grounds than Ireland. In the decade since *A, B and C*, this European consensus have widened even further, with Ireland being among the countries that have liberalized their legislation. One would expect the Court's view on this broadening consensus to be decisive for the breadth of the margin of appreciation, and thereby possibly the outcome, in these upcoming cases against Poland.

Read more:

https://www.hhrjournal.org/2021/11/the-scales-of-the-european-court-of-human-rights-abortion-restriction-in-poland-the-european-consensus-and-the-states-margin-of-appreciation/#_edn35

https://hudoc.echr.coe.int/app/conversion/pdf/?library=ECHR&id=003-7074470-9562874&filename=Notification%20of%20applications%20concerning%20abortion%20rights%20involving%20Poland.pdf

EAHL

Membership of the EAHL is open to health lawyers in Europe and health lawyers from other countries can become associate members.

To become a member of the EAHL, please, send your electronic application to

eurohealthlaw@gmail.com

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

EAHL membership prices:

- Regular one year membership – 76 EUR;
- Regular two-year membership – reduced fee of 130 EUR!
- Student/PhD student membership – 38 EUR;
- Associate (for non-Europe resident only) – 38 EUR.

For more information, please, visit:

http://www.eahl.eu/membership

Next EAHL Conference

Early bird registration and abstract submission – before **31 December 2021**.

Conference website: www.healthlaw2022.eu
Contact: eahl2022@ugent.be

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