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Vaccination against
COVID-19

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Message from the President



EAHL President
Prof. JD. Karl Harald Søvig

Dear EAHL members,

The first part of this issue is dedicated to vaccination against Covid-19. I would like to thank all the national contact points (NCPs) for contributing. Although not all European countries are represented, the survey covers various parts of our continent.

Supply of vaccines differs, and it seems like the countries within the EU/-EEA (and UK) are in a more favorable position than others. In all countries, vaccines are offered for free.

The legal foundation varies. Some countries have regulated the vaccination regime by legislation, while others have used various forms of soft law. When it comes to the content, the overall impression is that the priority guidelines are rather similar. Elderly, health personnel and citizens with underlying diseases are given priority. Vaccines are evenly distributed in the countries and none seem to prioritize areas with high infection rate. Still, there are many differences when it comes to the details.

None of the countries in the survey have introduced mandatory vaccination. Still, vaccination can be required for travelling, access to certain events, etc., which indeed can be an incitement to vaccination. In practice, citizens will often be faced with an offer they cannot refuse.

In most countries, citizens are not able to choose between approved vaccines from different producers. Some countries are aiming at introducing a possibility to choose when supplies are better, while Serbia has already introduced this.

These country reports regarding vaccination demonstrate the strength of our association when we join efforts. I hope that the newsletter will also fertilize to further research. If we receive more country reports, we will also make a second edition.

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Last but not least, we also have a new section in this newsletter with a brief introduction to health law in Hungary and Lithuania. A warm welcome to Orsolya Varga and Aiste Gerybaite as new NCPs and thank you for your contributions.

Enjoy reading, keep your distance and stay healthy!

Karl Harald Søvig



Annagrazia ALTAVILLA, EAHL Member of the Board of Directors

The new initiative of the Council of Europe on children participation in decision-process regarding their health

Editorial

The UN Convention on the Rights of the Child and other human rights instruments, recognising that children are rights-holders with a progressively evolving ability to make their own decisions, endorsed changes in the general perception of the autonomy and protection of children regarding their capacity to participate in decision-making. However, on matters concerning their health, there is uncertainty as to how the increased recognition of their decision-making capacity should be addressed.

The Council of Europe (COE) Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) recognises as priority to strengthening children's participation in the decision-making process in biomedical field. To this aim, the COE - Committee on Bioethics (DH-BIO) released a new initiative to explore provisions and experiences across Council of Europe Member States and develop common considerations and positions.

A survey has been set up, with the support of TEDDY European Network of Excellence for Paediatric Research, to identify national provisions, guidelines and practices aimed at increasing children participation in decision making process in health care, research and more in general in biomedical field. Some questions focused on identifying practices in areas that need specific considerations (such as emerging technologies, rare diseases, advanced therapies, COVID-19...) have also been included. Results of this survey will be used for outlining best standards and practices and determining the roadmap for developing a specific COE "Guide".

As it is well underlined by the Council of Europe Strategy for the Rights of the Child (2016-2021): "Children have the right to be heard and participate in decisions affecting them, both as individuals and as a group [...]". Making it possible is also one of the main scopes of TEDDY Network that is always proactive in the achievement of this goal.

As consultant and expert of the Council of Europe within the Strategic Action Plan on Human Rights and technologies in biomedicine, and TEDDY Chair, I am very pleased and honoured to oversee this new initiative.

This edition of the EAHL Newsletter intends to provide an overview of the COE initiative and its rationale. I really hope that EAHL partners and main stakeholders will actively participate in this initiative and in the

survey (available until 31 March 2021). They will thus contribute to the implementation of the children rights in the biomedical field.



The Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025): an important achievement and a starting point

In June 2020, the Committee on Bioethics (DH-BIO) of the Council of Europe adopted its new Strategic Action Plan on Human Rights and Biomedical Technologies in Biomedicine (2020-2025) based on the COE Convention on Human Rights and Biomedicine (Oviedo Convention), which since 1997 has been the only legally binding international instrument dedicated to human rights in biomedicine. Designed to contribute to protecting human dignity, human rights and individual freedoms with regard to the applications of biology and medicine, this Strategic Action Plan puts particular emphasis on addressing the challenges posed by new technological developments and by the evolution of established practices in the field of biomedicine also in children perspective.

Four thematic pillars are at the heart of this five-year strategy:

1. "Governance of technology" aimed at embedding human rights in the development of technologies which have an application in biomedicine, and at fostering public dialogue to ensure greater transparency in the biomedical field. To steer the innovation process in a way which connects innovation and technologies with social goals and values and to assess the relevance and sufficiency of the existing human rights framework, addressing issues raised by the applications of new technologies (e.g. gene editing, neurotechnologies, AI...), are also considered important objectives.

2. "Equity in health care" aimed at promoting equitable and timely access to appropriate innovative treatments and technologies in healthcare. The plan provides to draw up a specific recommendation to promote equitable access to innovative treatments and appropriate technologies, taking into account the fundamental principles such as justice and beneficence, and to promote a harmonised framework across member States to combat inequities between them and to empower them.

3. "Physical and mental integrity": new scientific developments and the evolution of existing practices (such as the collection and sharing of genomic and health data), raise novel questions relating to autonomy, privacy, and even freedom of thought. They also change societal perceptions in how to balance the protection and respect for autonomy of vulnerable populations (e.g. children, persons with mental health difficulties, older persons...). Specific actions are foreseen to increase recognition of their decision-making capacities.

4. "Co-operation and communication" aimed at increasing communication strategies and dissemination of the outputs of the Committee on Bioethics to internal and external stakeholders to maximise their uptake and utility. To improve a long-term strategic co-operation with Council of Europe committees and other

intergovernmental bodies working in the field of bioethics is also a priority. In a children perspective, the Strategic Action Plan provides specific consideration on children and paediatric population, underlining that important and specific human rights challenges are also emerging through established practices in the field of biomedicine. It considers of paramount importance to bring the voice of European youth into bioethics discussions at the Council of Europe. Furthermore, the Strategic Plan calls for strengthening children's participation through concrete actions such as the delivery of a "Guide to good practice concerning the participation of children in the decision-making process on matters regarding their health". To achieve this objective, the first step has been to develop a survey to explore provisions, guidelines, experiences, and practices across the Council of Europe Member States.



Participation of children
in the decision-making process
on matters regarding their health

Survey on national provisions, guidelines and practices
aimed at increasing children participation in decision
making process in the biomedical sector

The Survey on national provisions, guidelines and practices aimed at increasing children participation in decision making process in the biomedical sector.

To identify national provisions, guidelines and practices aimed at increasing children participation in decision making process in health care, research and more in general in biomedical field, a survey has been developed by the Committee on Bioethics of the COE and Annagrazia Altavilla TEDDY Chair and member of the EAHL Board of Directors.

The on-line survey will be submitted to the COE Committee on Bioethics (DH-BIO) and Steering Committee for the Rights of the Child (CDENF) representatives and the main stakeholders (healthcare professionals, patients' associations, investigators, companies, charities, regulators, ethics committees...). Results of this survey will be used for outlining best standards and practices and determining roadmap for developing the "Guide to good practice concerning the participation of children in the decision-making process on matters regarding their health". This Guide will be developed by the DH-BIO in co-operation with the CDENF and will be aimed at implementing children rights (their evolving capacities and autonomy, conceptualised as "the child's right to an open future"). It will target healthcare professionals and will also be accessible to the children's parents and/or legal representatives.

For more details, please refer to the rationale of this initiative. The survey is composed of 8 main questions and some sub-questions that are both closed and opened to leave the possibility to provide with more detailed information. Taking into account the heterogeneity of legal contexts, one of the main objectives is to verify how the principles included in the UN Convention of the rights of the child have been implemented and if a right of minors to participate in treatment and research decisions is recognised in national laws. Firstly, questions aim at identifying if specific provisions related to the participation in decision making process in healthcare and research are included both in national legislations and in national/local guidelines.

Secondly, it is asked to provide more details about eventual initiatives, experiences and procedures aimed at increasing children participation in decision making process within both healthcare and biomedical research (including specific therapeutic areas), focusing also on eventual initiatives aimed at fostering children advisory and advocacy role. To safeguard children's rights in relation to medical practices which have future or long-term implications for them being of paramount importance, questions regarding initiatives aimed at increasing awareness of children and at including them in decision process related to emerging technologies (such as gene editing, advanced therapies... information society technologies, nanotechnology,) are also included. Finally, to stick to current pandemic situation and relative issues, it is asked to detail eventual initiatives aimed at increasing awareness of children about COVID-19 pandemic situation in terms of prevention, healthcare, and research.

The survey is available at this link

(<https://forms.office.com/Pages/ResponsePage.aspx?id=grBJPtViSUilsIbtUZKH0jiNS65PNzVioDGUGTDoK3dUME1LQ0s4RFhRVFFDOEJKTjZSOE1BWUlaTS4u>) and will be opened until 31 March 2021

By participating in this survey, you will sustain the COE initiative promoting children rights and their participation in decision making in health.



Publication on Lancet Child & Adolescent Health

For the further details on this initiative, please also refer to the article that the Annagrazia Altavilla published with colleagues of the Council of Europe DH-BIO and CDENF on Lancet Child & Adolescent Health.

Altavilla A, Halila R, Kostopoulou M-A, Lwoff L, Uerpmann K, Strengthening children's participation in their health: the new initiative of the Council of Europe, Lancet Child Adolesc Health 2021 Feb 10. Doi: 10.1016/S2352-4642(21)00019-5.

COVID-19 Vaccination in Azerbaijan

*Prof. Dr. Vugar Mammadov, MD, JD, FCLM
Lala Jafarova, NCP*

As of 6 February 2021, there are 231022 total coronavirus cases in the country with 224961 – healed, 3156 – deaths.

The Cabinet of Ministers of the Republic of Azerbaijan approved the “Strategy of vaccination against COVID-19 in the Republic of Azerbaijan for 2021-2022” on 16 January 2021 by the Order No. 48s. Azerbaijan was the first in the South Caucasus to launch vaccination. The country is a member of the COVAX initiative, through which various vaccines to be delivered to our country. Delivery of 4 million doses of vaccines made in China has been already ensured. To the date of 6 February 2021, 848 thousand doses of COVID-19 vaccine have been already delivered to Azerbaijan.

The State Agency for Compulsory Medical Insurance has launched a new electronic service called "COVID-19 vaccine appointment"⁶. Citizens can select the time and place to book an appointment for vaccination on the webpage of the service.

The vaccination is carried out at the expense of the state and is voluntarily to all population. There are no restrictions or discrimination against persons who have not been vaccinated yet. Therefore, this does not represent any legal obligation. The only obligation to travel abroad/visit the country is negative coronavirus test done within 72 hours before departure.

The strategy approved phased vaccination with the priority to healthcare workers and their immunization has started on 18 January 2021. Stage 1B covers persons over 65 years. Stage 1C - staff involved in the anti-epidemic measures conducted by the law enforcement agencies. The second stage includes:

- A. high-risk from medical view group (those with chronic diseases such as respiratory system, diabetes, hemodialysis, obesity);
- B. 50 years and older people with at least one chronic illness;
- C. employees of the education and social sectors, permanent residents of social institutions, employees of the ASAN Service and DOST centers, of public transport sector, telecommunications operators and providers, bank workers that are in direct contact with the population, workers in the postal area that are in direct contact with the population;
- D. individuals involved in the high-risk work (working in the areas vital for society and those that are under significantly higher risk working in areas - national and regional security, justice, finance and other).

To the moment, there is only one type of vaccine available in the country. However, it is expected other vaccines to be brought in the near future.

According to the national legislation⁷⁸⁹¹⁰ vaccinated person has the right to get the allowance in case of complications after vaccination. In case of death, a one-time allowance is assigned to the relatives.

Information regarding postponement of non-essential medical care because of Covid-19: at the moment, the healthcare system is working as planned as the number of infected per day is declining. The health care system in the country is undergoing reformation, as compulsory health insurance was introduced this year. It was supposed to come into effect last year. However, it was postponed due to the coronavirus pandemic. Therefore, there is some branching of the health care structure in the country between the Ministry of Health and the State Agency for Compulsory Medical Insurance So, some legal issues have not been settled yet.

Reference:

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2. “News” *Task Force under the Cabinet of Ministers of the Azerbaijan Republic*, 6 Feb. 2021, nk.gov.az/az/category/10/.
3. *State Agency on Mandatory Health Insurance*, 6 Feb. 2021, its.gov.az/.
4. *APA news*, 6 Feb. 2021, <https://apa.az/en>.
5. *Trend news agency*, 6 Feb. 2021, <https://en.trend.az/>.
6. “COVID-19 vaccination appointment” *The State Agency on Mandatory Health Insurance*, 6 Feb. 2021, <https://randevu.its.gov.az/> (in Azerbaijani).
7. Law on immunoprophylaxis of infectious diseases: <http://www.e-qanun.az/framework/752> (in Azerbaijani).
8. Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No. 163 of October 12, 2001 “On the List of family members entitled to a one-time allowance for post-vaccine complications leading to death and approval of the amount of this allowance”: <http://e-qanun.az/framework/2749> (in Aze.)
9. Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No. 208 of November 28, 2000 “On approval of the list of post-vaccination complications entitling to temporary disability allowance”: <http://www.e-qanun.az/framework/452> (in Aze.)

Date of submission: 9 February 2021

Vaccination strategy in Belgium

*Tom Balthazar
NCP for Belgium*

Vaccination is not compulsory. Not for the general public. Not for health-care workers nor for any other specific group.

At this moment the vaccination is not a prerequisite for the access to any event.

Employers must respect the freedom of their employees and cannot require to be informed about their vaccination status. The vaccination in the workplace has to be organised by the occupational physician and by the “service for prevention and protection on the workplace”. They must respect the professional secrecy and may not inform the employer about the vaccination status of the employees. As a consequence of the collective organisation of the vaccination and the public campaign to promote vaccination, it is impossible to protect completely the privacy of the employees concerning the vaccination. As every employer has the right to inform his colleagues and the general public (by social media) about the fact that he has been vaccinated, it is possible that it becomes visible who is *not* vaccinated.

In the healthcare sector, the hospitals and other health care institutions are asked by the Government Agencies responsible for the organisation of the vaccination to give information about the vaccination rates.

The vaccination will be offered free of charge. There will be no possibility to choose between the available vaccines. There is no exceptional legal provision about the liability for the vaccines or their administration.

The priority guidelines are elaborated on the basis of an advice of the superior Health Council (<https://www.health.belgium.be/en/report-9618-prioritization-risk-groups-sars-cov-2-vaccination-phase-1b>) and were confirmed by decisions of the ‘federated entities’: the communities responsible for the organisation of the vaccination.

The priority guidelines divide the population in three groups (1a, 1b and 2):

GROUP 1a

In the first instance, the most vulnerable and exposed people will receive the vaccine.

- Residents and employees in residential care centres and collective care institutions. They will be vaccinated first, then the corresponding staff (including volunteers), followed by collective care institutions.

- Medical personnel from first-line care and hospitals: they are in close contact with COVID-19 patients every day. To protect them, they will be prioritised for vaccination.
- The other staff in hospitals and healthcare centres will be vaccinated, including organisations which work in prevention activities, such as vaccination centres and cancer screening centres, Child and Family and ONE.

GROUP 1b : vulnerable people without acute medical issues, but at high risk

Priority will be given to people outside hospitals, who are at the highest risk. It concerns the following groups:

- People over the age of 65 : people older than 65 will be a priority in this phase. If there is sufficient vaccine available, these people will be vaccinated simultaneously. Otherwise, we will start with the oldest people and then go down through the age groups.
- People with an increased risk: People aged between 45 and 65 with risk factors such as:
 - Diabetes,
 - Hypertension,
 - Chronic cardiovascular, lung, kidney and liver disease, haematological cancers up to 5 years after diagnosis,
 - All recent cancers (or recent treatments against cancer)
 - Obesity (Body Mass Index ≥ 30).

The phase 1b will also include people who fulfil essential social and/or economic roles (such as police-staff).

GROUP 2 - broader population

Thirdly, the vaccine will be available in sufficient quantities to provide it to the rest of the population.

The organisation of the vaccination has led to an intense debate about the privacy protection and to several conflicts between the Government Agencies and the Data Protection Authority. The priorities to people with increased health risks in the age between 18 and 65 can only be executed by consulting data bases with health information. The “agreement of cooperation” between the federal state and the communities and regions responsible for the organisation of the vaccination of 5 February 2021 proposes a system of data processing for the organisation of the invitation for the vaccination and the registration of the people who received a vaccine. The advice of the DPA about this agreement was very critical: according to the DPA several principles of the GDPR were not respected. It is unclear at this moment (26 February) if the agreement will be changed before the final approval by the parliaments of the different entities.

Country report for Bosnia & Herzegovina on vaccination against the COVID-19

Ervin Mujkic
NCP for Bosnia & Herzegovina

With almost 5,000 deaths with a population of about 3.5 million, Bosnia and Herzegovina has one of the highest COVID-19 related mortality rates in Europe and hopes to start immunisation of its population as soon as possible.

Although Bosnia and Herzegovina was one of the first countries to apply for the COVAX mechanism led by the World Health Organization and GAVI vaccine alliance, and sign a contract with COVAX, this country has not yet received a single vaccine and is among the few countries that have not yet started immunizing the population. Bosnia has ordered 1.2 million vaccines under the COVAX scheme and nearly 900,000 vaccines from the EU, and is still waiting for the first shipments, so the authorities are trying to establish contact with other suppliers and producers of vaccines as well, and trying to obtain vaccines from other sources, mainly from Russia and China. A small batch of Russia's Sputnik V vaccine arrived in February in Republic of Srpska, enabling it to start inoculating only the medical staff working in COVID-19 hospitals and departments, after The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina approved its use.

In the Federation of Bosnia and Herzegovina, the Ministry of Health has recently adopted amendments to the Rulebook on the Methods of Immunization, Immunoprophylaxis and Chemoprophylaxis of Infectious Diseases and Persons Subject to This Obligation, adding a new chapter on immunization against the COVID-19 in the conditions of a declared epidemics.

According to medical and epidemiological indications, immunization with the appropriate vaccine against the COVID-19, following the manufacturer's instructions, is recommended (non-compulsory) for:

- a) health workers and support staff working in health facilities, especially those working in departments caring for patients at high risk for complications; medical staff and carers in institutions for the accommodation of the elderly;
- b) persons in institutions for the accommodation of the elderly;
- c) persons over 60 years of age;
- d) persons (age according to the manufacturer's instructions) with chronic diseases of the respiratory and cardiovascular system, chronic kidney and liver diseases, diabetes, chronic neurological diseases and various types of immunosuppression, asplenia or splenic dysfunction, morbidly obese;
- e) persons employed in public services relevant to the response to the COVID-19 epidemic (police, education, etc.).

Given the current state of vaccine availability in Bosnia and Herzegovina, it is illusory to expect that patients will be able to choose which vaccine they will get.

The current regulations on the issues of health care, health insurance and protection of the population from infectious diseases in Bosnia and Herzegovina, do not regulate a separate regime of liability neither for vaccination in general, or vaccination against COVID-19 in particular, so the general principles of civil liability are to be applied in such cases.

Date of submission: 22 February 2021

REPORT ON VACCINATION AGAINST COVID – 19 IN BULGARIA

*Prof. Mariela Deliverska, LL.M, Ph.D., DSc.
NCP for Bulgaria*

In March 2020 the Bulgarian National Assembly has adopted Law on Measures and Actions During the State Emergency¹, where anti-epidemic measures were introduced on the entire territory of the country. In May 2020, with an amendment of the legislation, additional measures have been introduced focusing on overcoming the consequences after the end of State of Emergency.

On December 7th, 2020 the Council of Ministers of the Republic of Bulgaria adopted National Vaccination Plan against COVID – 19², aiming to counteract the spread of the virus and reduce the potential health consequences of COVID-19.

The immunization campaign against COVID - 19 was launched on December 23rd, 2020³. Special executive body (National Executive Board on Vaccination) was established, as responsible for the coordination of vaccination activities at national level and for providing control over the implementation of the National Vaccination Plan. Further on, according to article 63a, para. 1 of the Bulgarian Health Act - in case of epidemic spread of infectious diseases [such as COVID – 19] the Minister of Health may order anti-epidemic measures. The duration of such measures is limited to certain period of time, as measures could apply for the entire territory of the country or for a specific region or territory of the country. Although the COVID – 19 vaccination campaign covers the entire territory of the country, at regional level the organizational activities have been carried out by the Regional Health Inspectorates.

According to the National Vaccination Plan against COVID – 19 the vaccination process has been scheduled to be performed in 5 (five) phases. Phase 1 of the Plan targets individuals who are at high risk of getting infected with COVID – 19, including medical staff and personnel at inpatient and outpatient care facilities, healthcare professionals, dentists, pharmacists. Phase 2 of the Plan targets vaccination of staff and inmates at social institutions, pedagogical specialists and employees at mink farms. Phase 3 of the vaccination plan targets people involved in maintaining the functioning of essential public life activities. Phase 4 of the plan covers vaccination of elderly people and people over 65 years of age and those with concomitant chronic diseases. The final 5th phase of the plan focuses on vulnerable groups of the population who are at high epidemiological risk of infection, related to their living conditions and lifestyle.

¹ The law has been promulgated in the State Gazette on 24th March 2020, Issue 28

² The National Vaccination Plan against COVID – 19 has been adopted by the Council of Ministers of the Republic of Bulgaria according to Decision № 896 of December 7th, 2020.

³ The start of the immunization campaign against COVID – 19 was launched with Order № ПД-01-726 of the Minister of Health issued on December 23rd, 2020. The content of the Order (in Bulgarian) is available on: https://www.mh.government.bg/media/filer_public/2020/12/25/zapowed_rd-01-726-23122020.pdf

The use of vaccine against COVID-19 in Bulgaria complies with the authorization issued by the European Commission on the recommendation of the European Medicines Agency.⁴

The immunization against COVID – 19 in Bulgaria is not compulsory. The population has been recommended to undergo vaccination. The application of vaccine against COVID – 19 is carried out on voluntary bases and is free of charge. Currently, whoever wants to undergo vaccination is not allowed to choose for himself which of the authorized vaccine against COVID – 19 to be applied.

Vaccination of target groups of the population, prioritized according to the National Vaccination Plan against COVID – 19 has been performed in compliance with requirements established by Ordinance № 15 of 12.05.2005 on immunizations in the Republic of Bulgaria. According to Bulgarian legislation⁵ medical activities are carried out after the expressed informed consent of the patient. ⁶ The person who wants to undergo vaccination has to sign an informed consent prior to the act of vaccination. In order to make an informed decision on whether to be vaccinated or not, and before signing the informed consent form, the person becomes acquainted with the indications of the vaccine, its contraindications, as well as possible side effects and side effects.

There is no separate liability regime for vaccination in Bulgaria. According to the general rule, the marketing authorization holder and manufacturer are liable for the medical product on the Bulgarian market. In cases of claim for compensation for damages caused by a defective vaccine, according to the Bulgarian Consumer Protection Act, for claims regarding damages caused by a defective product, the liability of the manufacturer, distributor and traders shall be engaged. In other cases, when claims do not regard damages caused by a defective product, the common liability for damages goes under the regulation of the Bulgarian Obligations and Contracts Act. The common liability under the Bulgarian Obligations and Contracts Act could also apply in cases of physical and/or moral damages caused.

Date of submission: 22 February 2021

⁴ Currently vaccination in Bulgaria has been performed using the three vaccines which have been authorized across the EU – the vaccine against COVID - 19 of BioNTech-Pfizer, the vaccine of Moderna pharmaceutical company, as well as the vaccine against COVID-19 of AstraZeneca.

⁵ According to article 87 of the Bulgarian Health Act

⁶ When the patient is a minor or has been placed under limited guardianship, in order to perform medical activities it is necessary (in addition to his informed consent) and the consent of his parent or guardian.

Special report on COVID-19 vaccination, Estonia.

*Tiina Titma
NCP for Estonia*

The European Union's joint vaccine portfolio includes vaccines and vaccine candidates from seven vaccine manufacturers and the preliminary purchase contracts have been entered with the following vaccine manufacturers: AstraZeneca, Sanofi, Janssen Pharmaceutica NV, Pfizer/BioNTech, Curevac, and Moderna. For February 22, the European Commission has approved conditional marketing authorisation of the three first vaccines to prevent COVID-19 in the EU: Comirnaty (Pfizer/BioNTech), COVID-19 Vaccine Moderna and COVID-19 Vaccine AstraZeneca.

Estonia is participating in a European Union joint procurement. On 26 December, Estonia received the first shipment of COVID-19 vaccine which consisted of 9,750 doses. On 27 December, the process of vaccination against COVID-19 was launched. At first, the vaccination of health care workers was prioritised, followed by nursing care units in hospitals, as well as to the workers and residents of care facilities in January 2021. For today, the target group includes also individuals who are over seventy years of age and who are included in a risk group based on their diagnosis. Estonia's national COVID-19 vaccination plan (not enacted in law) states the next vaccination target group to be the employees of educational institutions and frontline workers who are responsible for ensuring internal security (such as employees of the Rescue Board and the Police and Border Guard Board, plus volunteer rescuers and assistant police officers). A second injection will be administered to recipients after a period of time which has been prescribed by the manufacturer and it is considered the recipient to develop the required level of immunity, both doses must be administered. The process of vaccinating children will commence as soon as a vaccine has become available which is suitable for children.

On February 22, Estonia has received altogether 121 470 doses of COVID-19 vaccines from three manufacturers. According to the plan of the Government, until the end of 2021, the vaccination against the coronavirus will be free of charge for all Estonian residents, including people who do not have health insurance. The patient has yet no right to choose the vaccine but the choice between the vaccines of different manufacturers will become possible after enough quantities of vaccines have reached Estonia. It is decided to use AstraZeneca vaccine for individuals under 70 years of age. There has been noticeable demand of Russian vaccine Sputnik V, especially among the residents near the Russian border.

Vaccinations are voluntary in Estonia. Currently, there is no proof of vaccination provided for travelling. It is possible to prove vaccination with an immunization passport, that can be issued on paper by the provider of health care services. However, the argumentation has arisen whether the employer may fire the employee in the case of refusing to get the vaccine. And some propose the interpretation that it could be possible in some

cases where the vaccination is a prerequisite to get a particular position. No legal cases have yet been filed in court.

Provision based on article 5 pp 2 and 3 of the Directive 2001/83/EC of the European Parliament and of the Council is currently under the consideration of the Estonian Parliament. According to that provision (i) Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm and (ii) ... Member States shall lay down provisions in order to ensure that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

The liability of providers of health care services is stated in the Law of Obligations Act as the use of generally unrecognised methods upon provision of health care services. According to this act (i) providers of health care services ... shall be liable only for the wrongful violation of their own obligations, particularly for errors in diagnosis and treatment and for violation of the obligation to inform patients and obtain their consent and (ii) the burden of proof regarding circumstances which are the bases for the liability of the provider of health care services ... shall lie with the patient unless the provision of health care services to the patient is not documented as required.

There is no mandatory liability insurance for health care service providers in Estonia. Permanent residents of Estonia and persons living in Estonia on the basis of a temporary residence permit for whom social tax is paid or who pay social tax on their behalf have the right to health insurance.

Date of submission: 22 February 2021

Covid-19 vaccinations in Germany

(by Hanna-Luisa Tippner, Susannah Vierke, Lia Noebel)

1. Is vaccination compulsory by law (directly or indirectly as a prerequisite for access to certain events, etc.)?

Vaccination is voluntary and will most likely remain so. There are discussions on granting certain privileges to those who have been vaccinated. The Ethics Council as well as the Minister of Health reject privileges to avoid a two-class society, especially since only a few Germans currently have the opportunity to be vaccinated. Nevertheless, some private companies, such as event agencies, are planning to restrict access to events to vaccinated guests.

2. Priority guidelines

a) What is the legal status of the guidelines (prescribed by law or as recommendations)?

The vaccination process is prescribed by law in form of a governmental ordinance issued by the Federal Ministry of Health. It is based on the recommendations of the Robert-Koch-Institute, a higher federal authority.

b) Which groups (elderly, health personnel, etc) or areas (rural/central) are given priority?

The population is divided into different groups according to priority:

– Group 1 (highest priority)

- Over 80-year-olds
- Residents of old people's and nursing homes and health staff working there
- nursing and assessment staff in outpatient care services
- workers in medical facilities with a high risk of exposure, especially in intensive care units, emergency rooms, rescue services and vaccination centres
- medical workers who care for people at high risk, in particular in oncology or transplantation medicine

– Group 2 (high priority)

- Over 70-year-olds
- People with dementia, mental disabilities, severely psychiatric patients (bipolar disorder, schizophrenia, major depression) and their nursing staff
- People with cancer, severe chronic lung diseases, severe diabetes or chronic liver/kidney disease
- Patients after an organ transplant
- People with a body mass index over 40
- Persons who, due to special circumstances in the individual case, are at high risk of a severe or fatal course of the disease
- Doctors and staff with regular patient contact

- 2 close contacts of certain persons in need of care
- 2 close contacts of pregnant women
- Police and law enforcement officers with a high risk of infection
- Workers and residents of refugee and homeless facilities
- **Group 3 (increased priority)**
 - Over 60-year-olds
 - Persons with pre-existing conditions (heart disease, diabetes, HIV, autoimmune diseases)
 - People with a body mass index over 30
 - Workers in medical facilities with low risk of exposure
 - Persons in relevant positions in state institutions
 - Persons working in a particularly relevant position in critical infrastructure facilities and companies (e.g., Pharmacy services, water and energy supply, transport and traffic services)
 - Educators and teachers, people who work in the food trade sector
 - People, with precarious working or living conditions
- **Group 4**
 - People for whom there is no increased risk of infection or a severe course of a Covid-19 disease

3. Is it up to the patient to choose between the vaccine(s) that are approved and available?

No, it is generally not possible to choose between the 3 different vaccines. Only in Berlin, the vaccination centres provide information in advance on which vaccine they use. In Berlin, therefore, one can choose a vaccine by choosing the respective vaccination centre.

4. Is there a separate liability regime for vaccination or more specifically, the covid-19 vaccine?

§ 60 of the Infection Protection Act regulates claims for compensation if government agencies have recommended a certain vaccine that caused the damage. Likewise, § 60 of the Infection Protection Act regulates claims if vaccination is compulsory. However, for the Covid-19 vaccination this is not the case in Germany. In all other cases, recourse must be had to the general liability for medicinal products pursuant to Art. 84 of the Medicinal Products Act.

Date of submission: 22 February 2021

Ireland

EAHL Country Report: Ireland

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(EAHL National Contact Point for Ireland)*

1. If vaccination is compulsory by law (directly or indirectly as a prerequisite for access to certain events, etc.)

In Ireland, vaccination is not compulsory by law. Vaccination against Covid-19 is strongly recommended and encouraged.⁷ Irish law recognises and upholds the Constitutional right to bodily integrity which means that valid and informed consent is required for any form of medical treatment. Informed consent is required for vaccination, and consent must be given voluntarily and not under duress. Patients retain the right to refuse consent to vaccination. The Health Service Executive has produced guidelines regarding the consent process for vaccination against Covid-19.⁸

The Tánaiste (deputy prime minister) Leo Varadkar has recently indicated that vaccine passports may be necessary in future for those travelling internationally as proof of vaccination and a negative Covid test.⁹

2. Priority guidelines

o What is the legal status of the guidelines (prescribed by law or as recommendations)?

The National Covid-19 Vaccination Strategy was published by the Department of Health on 15th December 2020.¹⁰ The Department of Health has published further guidelines identifying which groups are to be given priority in allocation of vaccines.¹¹ The priority guidelines are not prescribed by law and are recommendations.

• Which groups (elderly, health personnel, etc) or areas (rural/central) are given priority?

Distribution of vaccines is prioritised on the basis of risk.¹² The COVID-19 Vaccine Allocation Strategy prioritises the most vulnerable who are at risk of infection and those who work on the frontline providing health and social care.¹³ The following groups are given priority in the first stages of the vaccine rollout: those persons aged 85 or older; persons living in long-term care homes aged 65 or older; and frontline healthcare workers.¹⁴ The first vaccination was administered on 29th December 2020. By 19th February 2021, a total of 340,704 vaccine doses have been administered (214,384 people have been given their first vaccine; the second

⁷ <https://www2.hse.ie/screening-and-vaccinations/covid-19-vaccine/getting-covid-19-vaccine.html>

⁸ Health Service Executive. Consent for Vaccination for Covid-19: Guiding Principles. (06.01.2021). Available at <https://www.hse.ie/eng/services/news/newsfeatures/covid-19-nursing-home-resources/consent-for-vaccination-for-covid-19.pdf>

⁹ Tánaiste & Minister for Trade, Enterprise & Employment Leo Varadkar, 18th February 2021, Dáil Debates: Covid-19 (Enterprise, Trade and Employment): Statements. Available at: <https://www.oireachtas.ie/en/debates/debate/dail/2021-02-18/7/>

¹⁰ <https://www.gov.ie/en/publication/bf337-covid-19-vaccination-strategy-and-implementation-plan/>

¹¹ Further information is available at <https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/>

¹² <https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/>

¹³ <https://www.gov.ie/en/press-release/524dc-minister-for-health-announces-the-allocation-strategy-for-covid-19-vaccines/>

¹⁴ <https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/>

vaccine dose has been given to 126,320 people).¹⁵ Vaccination of those aged 85 or older (not living in long-term care homes) commenced in February 2021.¹⁶ Vaccinations will be distributed in various locations including GP surgeries, pharmacies and dedicated vaccination centres set up in each county of Ireland.¹⁷

3. If it is up to the patient to choose between the vaccine(s) that are approved and available?

Patients in Ireland do not have a right to choose between approved and available vaccines. The vaccines currently licensed for distribution in Ireland are the Pfizer/BioNTech, Moderna and AstraZeneca vaccines.¹⁸ Vaccinations are being provided free of charge and are not available privately. However the recommendation is that patients over the age of 70 should be given either the PfizerBioNTech or Moderna vaccine.¹⁹

4. Liability (Is there a separate liability regime for vaccination or more specifically, the covid-19 vaccine?)

Ireland is part of the European Union's vaccine advanced purchasing agreements therefore is required to provide State indemnity to the pharmaceutical companies. To date, Ireland has signed five of the six advanced purchasing agreements.²⁰ An expert group has also called for the establishment of a Vaccine Compensation Scheme to deal with any claims of liability.²¹ The Clinical Indemnity Scheme and General Indemnity Scheme extends indemnity cover for healthcare providers regarding provision of services during the Covid-19 pandemic.²²

Date of submission: 22 February 2021

¹⁵ <https://www.gov.ie/en/news/7e0924-latest-updates-on-covid-19-coronavirus/#the-latest-news-as-of-6pm-on-monday-22-february>

¹⁶ <https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/>

¹⁷ <https://www.gov.ie/en/publication/8a35f-irelands-covid-19-vaccination-centres/>

¹⁸ <https://www2.hse.ie/screening-and-vaccinations/covid-19-vaccine/rollout-covid-19-vaccines-ireland.html>

¹⁹ <https://www2.hse.ie/screening-and-vaccinations/covid-19-vaccine/immunity-covid-19-vaccine.html>;

<https://www.gov.ie/en/press-release/da62c-statement-on-the-approval-of-the-astrazeneca-covid-19-vaccine-in-the-irish-vaccination-programme/>

²⁰ <https://www.gov.ie/en/publication/bf337-covid-19-vaccination-strategy-and-implementation-plan/>

²¹ Department of Health. Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims. (published 19th December 2020). Available at: <https://www.gov.ie/en/publication/ffb23-expert-group-report-to-review-the-law-of-torts-and-the-current-systems-for-the-management-of-clinical-negligence-claims/>

²² https://stateclaims.ie/uploads/publications/State-Claims-Agency-Indemnity-Advices-COVID-19-Coronavirus_April-2020.pdf

Country report from Latvia

Santa Slokenberga
NCP for Latvia
Date: 22 February 2021

Vaccination in Latvia

This section gives an insight into the question of whether vaccination generally is voluntary in Latvia and whether that applies to COVID-19 vaccination, and as well as reviews the priority groups in regard to COVID-19 vaccination.

Central principles that steer the question of the voluntariness of vaccination are set out in the Epidemiological Safety Law²³ and detailed general requirements are set out in Cabinet Regulation No 330 of 26 September 2020 “Vaccination Regulations”.²⁴ From the outset, the law on whether or not vaccination is compulsory (mandatory) can appear to be rather ambiguous. However, a closer look reveals that the provisions on mandatoriness are focused on the state’s duty to secure availability and ensure accessibility of particular vaccines within the country, rather than subject persons to non-voluntary vaccination. Even if a particular vaccination falls under the “mandatory” scheme, there is a right to refuse vaccination.²⁵ Under the said regulation, the COVID-19 vaccination is not classified as mandatory.

Vaccination against COVID-19 is regulated under the Cabinet Regulation No.360 of 9 June 2020 “Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection” (COVID-19 Regulation).²⁶ The regulation establishes priority groups that determine the order in which persons are given access to vaccination. There are also certain limited possibilities to manoeuvre between these groups, should there be good reasons to do so (principles in that regard are reviewed below); there is, however, no priority ordering between persons belonging to the same group.²⁷ As of the time of writing, the priority groups are as follows:

- Group 1 covers various groups of workers in the field of medical care and pharmaceutical care, as well as persons, who have medical indications for vaccination.
- Group 2 covers clients and workers of social care institutions, as well as officials whose vaccination is necessary to ensure national security and continuity of state activities in accordance with the decision of the Cabinet.

²³ Epidemiological Safety Law, Latvijas Vēstnesis, 342/345, 30.12.1997.

²⁴ Cabinet regulation No 330 of 26 September 2020 “Vaccination Regulations”, Latvijas Vēstnesis, 341/343, 29.09.2000.

²⁵ See Section 30 Paragraph 1 of the Epidemiological Safety Law in correlation with Cabinet regulation No 330 of 26 September 2020 “Vaccination Regulations”, Paragraph 28.

²⁶ Cabinet Regulation No 360 of 9 June 2020 “Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection”, Latvijas Vēstnesis, 110B, 09.06.2020. OP: 2020/110B.1, Paragraph 1.17.

²⁷ See paragraph 62¹ 1. This priority list is recently revised (18 February 2021), and the healthcare institutions may continue to vaccinate the initiated priority group according to the previous priority list.

- Group 3 covers persons over 70 years of age, as well as persons with certain chronic diseases and persons living in the same household with children with certain chronic and immunosuppressive diseases, and persons caring for seriously ill persons at home.
- Group 4 covers persons of 60-70 years as well as teachers of pre-school, special education institutions as well as grade 1-6 teachers, and other staff who come into close contact with children in the course of their duties.
- Group 5 and 7 covers a range of workers of different listed areas, and their relative importance to particular interests determines the priority group.
- Group 6 covers persons staying in special institutions (e.g. shelter clients, persons in prisons).
- Group 8 covers employees of companies that come into contact with a large number of people and cannot observe distance (e.g. sales staff) as well as employees of companies where a large number of people come into contact with each other in the team and it is not possible to ensure distance (e.g. food production companies. It also covers employees of enterprises important to the national economy (e.g. communication enterprises)
- Group 9 covers all other members of the public who have not been vaccinated before.²⁸

Registration for COVID-19 vaccination is partially managed in a centralized way; there is a registration system www.manavakcina.lv or a possibility to call to a particular phone number in that regard,²⁹ or a possibility to call to a particular phone number in that regard, however, there is currently neither a duty to invite only those registered in the centralized system nor there is a prohibition to manage queues locally by vaccination centres. Thus, a parallel system exists, which has created room for confusion and uncertainty in the society.

COVID-19 vaccination is managed by several detailed principles set forth in the COVID-19 Regulation. The following are the main ones. To begin with, if the available vaccines and the vaccination capacity exceeds the number of persons who have applied for vaccination from the priority group that is being vaccinated at the relevant time, another member of the respective group shall be invited to vaccinate. If there are still places in the vaccination queue, people from the next priority group may be vaccinated.³⁰ It is also allowed to vaccinate several groups simultaneously with successive priority if there is a sufficient number of available vaccines and adequate vaccination capacity.³¹ However, it is not defined whether that applies to capacity within a particular vaccination centre, and thus, is of a decentralised application or within a state, and will thus be decided centrally. While it can be expected to be managed in a decentralised way that could risk causing confusion in the society, unless it is duly communicated. Moreover, persons from the next priority group may

²⁸ See annex 3 of Cabinet Regulation No.360 of 9 June 2020 "Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection", Latvijas Vēstnesis, 110B, 09.06.2020. OP: 2020/110B.1.

²⁹ Id., Paragraph 62¹⁷.

³⁰ Id., Paragraph 62¹ 3.

³¹ Id., Paragraph 62¹ 5.

also be vaccinated if it is related to the conditions of use and logistics of the particular vaccine.³² Finally, in order to reduce the risk of waste of vaccines, if at the end of the vaccination day or the weekend there is an open vial and there are other persons that are willing to be vaccinated at a given time, they may be vaccinated. In such a case, preference should be given to persons belonging to the next priority group or groups.³³

The law does not envisage a possibility to choose between various vaccines, but it does not preclude it either. Such situations can be managed under the general provisions set out in Law On the Rights of Patients that address patient's rights in medical treatment (prophylaxis is defined as medical treatment³⁴). Generally, in the case of several medical treatment alternatives, the choice lies with the patient, but the patient can also request the healthcare professional to make a choice for her. Although Section 5 paragraph 6 of the Law On the Rights of Patients³⁵ focuses on a physician that is competent to make the choice, the same principle should apply to the person doing vaccination if it is in the professional duties to make relevant independent decisions.

Finally, the law does not set up a particular liability or insurance scheme in relation COVID-19 vaccination.³⁶ The general rules on right to compensation apply. However, the COVID-19 Regulation envisages that all expenditures related to COVID-19 vaccination, including the treatment of complications (side effects) caused by vaccination are financed from the State basic budget.

³² Id., Paragraph 62¹ 6.

³³ Id., Paragraph 62¹ 7.

³⁴ Medical Treatment Law, Latvijas Vēstnesis, 167/168, 01.07.1997, Section 1 Clause 1.

³⁵ Law On the Rights of Patients, Latvijas Vēstnesis, 205, 30.12.2009.

³⁶ See R. Rožkalns, 16.pants. Tiesības uz atlīdzību, in: S. Slokenberga (ed.) Pacientu tiesību likuma komentāri, Latvijas Vēstnesis, 2019, pp.271-287.

EAHL COVID-19 COUNTRY REPORT – LUXEMBOURG

Luxembourg, 22 February 2021

Mike Schwebag (mike.schwebag@gmail.com)

Luxembourg Government declared the state of crisis on 17 March 2020 and Parliament conferred exceptional powers ending on 25 June 2020.

Two laws were voted to replace the regulations adopted with exceptional powers³⁷ and, after less than one month, replaced by one single law. The Law of 17 July 2020 introducing a series of measures to combat the COVID-19 pandemic³⁸ currently contains the main measures to fight the propagation of the virus. Initially valid until 20 September 2020, it has been already amended nine times to adapt the measures and extend the validity of the law.

This contribution focusses on vaccination issues and postponement of non-essential medical care.

1. Vaccination against SARS-COV2

1.1 Description of the national vaccination strategy

Luxembourg's vaccination strategy was first presented on 4 December 2020 by the Prime Minister and the Minister of Health, after its validation by the Government Council the same day³⁹. It was adapted and detailed on 25 January 2021⁴⁰. It is based on the recommendations of the WHO and the European Commission, was elaborated under the lead of the Ministry of Health. Both the High Council for Infectious Diseases⁴¹ and the National Ethics Commission⁴² were consulted, as well as representatives of the main actors implied.

Vaccination against Covid-19 is voluntary. Vaccination is so far not a prerequisite for access to any activity or service. Vaccines are made available free of charge, regardless of whether vaccination candidate has health insurance or not.

Given the limited availability of vaccines and the logistic challenges linked to it, vaccination is organized and controlled by State. Vaccinations take place in dedicated vaccination centers or as in-house vaccinations in hospitals or residential facilities for the elderly. At a later stage, vaccination should be available within medical practices.

³⁷ This contribution updates the two previous contributions to the EAHL newsletters, which contain further elements. For the period from 25/06 to 17/07/2020, two laws coexisted for less than a month: « Loi du 24 juin 2020 portant introduction d'une série de mesures concernant les personnes physiques dans le cadre de la lutte contre la pandémie Covid-19 et modifiant la loi modifiée du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des médicaments » and « Loi du 24 juin 2020 portant introduction d'une série de mesures concernant les activités sportives, les activités culturelles ainsi que les établissements recevant du public, dans le cadre de la lutte contre la pandémie Covid-19 ».

³⁸ Loi du 17 juillet 2020 portant introduction d'une série de mesures de lutte contre la pandémie Covid-19 et modifiant : 1° la loi modifiée du 25 novembre 1975 concernant la délivrance au public des médicaments ; 2° la loi modifiée du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des médicaments. (<http://legilux.public.lu/eli/etat/leg/loi/2020/07/17/a624/jo>)

³⁹ Press conference: <https://sante.public.lu/fr/actualites/2020/12/communiqu-e-strategie-vaccination/index.html>

⁴⁰ Press conference: https://gouvernement.lu/fr/actualites/toutes_actualites/articles/2021/01-janvier/25-briefing-bettel-lenert.html

⁴¹ Recommandations Covi-19 du Conseil supérieur des maladies infectieuses: <https://sante.public.lu/fr/espace-professionnel/recommandations/conseil-maladies-infectieuses/covid-19/index.html>

⁴² <https://cne.public.lu/fr/publications/avis.html>

Six vaccination phases have been defined, taking into account the necessity to protect the most vulnerable patients and to protect the capacity of the healthcare and social care system.

In a first phase, healthcare professionals and staff working in hospitals and residential facilities for the elderly, including cross border workers, as well as people living in residential facilities for the elderly, are vaccinated as a first priority. This phase started end of December 2020 and is currently ongoing.

The second vaccination phase is currently about to start. It concerns residents aged 75 and over, starting with the oldest (phase 2a), as well as people who are highly vulnerable due to a pre-existing health condition⁴³ (phase 2b).

In a third phase, people who are significantly vulnerable because of their age (70 and 74 years) and people who are significantly vulnerable due to a pre-existing health condition are foreseen to be vaccinated. Phases four and five are similarly organized based on age and precondition. In phase six the general population will be vaccinated, with a priority for people living in precarious condition. A timeline has not yet been announced for phases three to six and the planning is subject to adaptations based on availability and characteristics of the available vaccines.

Patients are currently not granted the choice of the vaccine. According to the guidelines issued, it is on the healthcare professional to choose the vaccine based on the information received from the patient during anamnesis.

1.2 Legal framework

The aforementioned amended law of 17 July 2020 contains the main measures to fight the propagation of the virus. When it comes to the vaccination strategy, it however solely addresses the issue of the processing of data within the vaccination program. Operational provisions relating to the national vaccination campaign are partially governed by the amended Grand-Ducal regulation of 22 October 2009 relating to treatment centers and vaccination centers as part of the management of a pandemic⁴⁴.

Standard product liability and civil law liability rules, as foreseen by ordinary law, apply to the vaccinations. This means that the manufacturer of a vaccine may be liable in the event of an adverse event due to a defective vaccine. A healthcare provider may be civilly liable for committing a fault in handling or administering the vaccine, if this fault causes a damage to the patient.

As the vaccination against SARS-COV2 is recommended and organized by the State, a specific liability regime for vaccinations is applicable pursuant to the Law of 4 July 2000 on the responsibility of the State for vaccinations⁴⁵. Thus, if the vaccination causes the death or results in permanent physical incapacity of the

⁴³ Concerned health conditions are: Trisomy 21; Solid organ transplants; Hematopoietic stem cell transplants within the first 6 months or under immunosuppressive treatment; Cancer or malignant homeopathy undergoing treatment (chemotherapy, radiotherapy, immunotherapy); Congenital immunodeficiency.

⁴⁴ Règlement grand-ducal modifié du 22 octobre 2009 relatif aux centres de traitement et aux centres de vaccination dans le cadre de la gestion d'une pandémie (<http://legilux.public.lu/eli/etat/leg/rgd/2009/10/22/n1/jo>)

⁴⁵ Loi du 4 juillet 2000 relative à la responsabilité de l'Etat en matière de vaccinations (<http://data.legilux.public.lu/eli/etat/leg/loi/2000/07/04/n1/jo>)

patient, the State is legally liable for the damage insofar as it is not compensable under the Social Insurance Code. This liability is without prejudice to any legal action that may be taken by the patient in accordance with ordinary law. Also, up to the amount of the compensation granted, the State is subrogated to the rights of the patient against those that might be responsible for the damage according to ordinary law.

Access to the vaccine may decide about the life of a vaccination candidate and the vaccination campaign is a key public health element to fight against the pandemic. The currently existing legal framework has the merit to address some of the key issues. At the same time, a more complete and a more consistent legal framework appears desirable.

2. Adaptation of the healthcare system and postponement of non-essential medical care

Major efforts were deployed to maintain activities as much as possible. Postponement of non-essential medical care had nevertheless to be decided, mainly during the period when Luxembourg hospitals were in “phase 4” of the hospital scale-up plan (17 November 2020 - 5 January 2021) declared by the health authorities.

When entering phase 4, hospitals are officially encouraged to deprogram surgical interventions that may be postponed without causing a loss of chance for the patient. Adaptation of the activities are decided at the level of the healthcare provider (hospital and physician in charge of the patient). No specific liability or insurance regime is in place.

REPORT OF COVID-19 STATUS IN NORWAY

*Harald Platou
NCP for Norway*

Norway has started the process of vaccination. The Norwegian Institute of Public Health (FHI) has made public the current order of priority. This is not regulated by law, but is passed on to the Health System and Municipalities as “orders” from the Directorate of Health.

The current order of priority are:

1. Residents in nursing homes and selected groups of healthcare personnel
2. Age 85 years and above and selected groups of healthcare personnel
3. Age 75-84 years
4. Age 65-74 years AND people between 18 and 64 years with these diseases/ conditions at high risk of a severe disease course
5. Age 55-64 years with underlying diseases/conditions
6. Age 45-54 years with underlying diseases/conditions
7. Age 18-44 years with underlying diseases/conditions
8. Age 55-64 years
9. Age 45-54 years

The patients cannot choose type of vaccine, nor where or when the vaccine is to be administered to the patient. Vaccination is not compulsory. All liability are regulated, as all other healthcare provided by the health system, through the Patient Injury Act.

Date of submission: 5 February 2021

Country report on legislative measures undertaken in Serbia for the purpose of combating the Corona virus outbreak – February 2021

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Is vaccination compulsory by law (directly or indirectly as a prerequisite for access to certain events, etc.)?

COVID 19 has been introduced into the Law on the Protection of Population from Communicable Diseases (hereinafter: Law) in 2020, as the disease transmitted by air. It belongs under the diseases over which the epidemiological surveillance has been conducted, and against which measures for prevention and suppression have been undertaken.

Article 32, provisions 2 and 3 of the Law have, broadly speaking, two criteria that provide the basis for obligatory vaccination – type of disease and some specificities related to the person: either he/she travels to the countries with the high prevalence of certain diseases, or he/she is vulnerable, or he/she performs the profession that makes him/her vulnerable to diseases, etc. Article 33 provides very broad possibility to the Minister of Health to enact the decision on obligatory immunization against some other communicable disease which is not explicitly listed in the Law, or obligatory immunization for certain categories of people, or where there is a danger for spreading of the communicable disease into the country, all in line with the plans for suppressing and eradicating of certain communicable diseases, in line with the recommendations of WHO, on the proposal of the Republic Institute of Public Health (hereinafter: RIPH).

So, the Law itself does not name COVID 19 as the disease subject of obligatory vaccination, but, through the different criteria, it opens the possibility that vaccination of COVID 19 or some other disease (which is recommended at the moment) becomes obligatory in some situations, and for some groups of population.

According to the Article 36, every three years Government enacts the Program of Immunization of the Population against Communicable Diseases, on the proposal of the Minister of Health. In 2020, this Program was adopted (Official gazette RS, no. 65/2020). Program does not mention vaccination against COVID 19 as obligatory. However, some chapters contain open lists of diseases subject of obligatory immunization (“other communicable diseases in line with the Law”).

So, vaccination against COVID 19 is, so far, recommended. But, the Law and the Program leave the open door to obligatory immunization against this or other diseases that could be treated as necessary for certain categories of people, according to epidemiological indications, or in line with the request of the destination country.

What is the legal status of the guidelines (prescribed by law or as recommendations)?

There are several guidelines for vaccination issued by the Republic Institute of Public Health.⁴⁶ Thus, they are not prescribed by the Law, but in the form of guidelines/recommendations of the RIPH, so not treated as legally obligatory. However, since the RIPH is one of the pillars of the health system in Serbia and planning body, the guidelines are being followed by the health institutions.

Which groups (elderly, health personnel, etc.) or areas (rural/central) are given priority?

Recommendations for vaccination against COVID 19 disease, prescribe the following priority groups for immunization, in the following phases:

➤ **First phase of vaccination: vaccine available for 1-10% population**

Phase 1a: Employees in health institutions with the highest risk of having or transmitting infection (coverage up to 3% of population); Employees in the elderly home care institutions and other institutions of social care.

Phase 1b: Elderly population.

➤ **Second phase of vaccination: Vaccine available for 11-20% of population**

The coverage of groups planned in the first phase will continue. In addition, for the second phase of vaccination it is recommended to include the following target groups: 1. Persons in the age group 65-74 years in the general population who are not included in the previous phase, 2. Persons under the age of 65 with comorbidities or health conditions presenting a high risk of severe illness or death, 3. Employees in services/institutions of vital importance (with an increased risk of disease occurrence or transmission or who cannot provide physical distance), 4. Employees in the state administration and local self-government who are especially exposed to infection (direct work with clients, field work, etc.) or who are especially endangered by the occurrence of severe forms of illness and death (presence of comorbidities), 5. Employees in utility and public companies, 6. Employees in the Ministry of Interior and Justice, 7. Employees in enterprises and institutions of special importance for the functioning of the company determined by the Government of the Republic of Serbia or an administrative body to which the Government of the Republic of Serbia entrusts the preparation of such a list of priorities, 8. Employees in education in institutions with a higher risk of virus transmission (colleges and high schools), 9. Employees in preschool institutions.

➤ **Third phase of vaccination: Vaccine available for 21-50% of population:** 1. Employees in educational institutions with a lower risk of virus transmission (primary schools), 2. Essential staff outside the medical and education sector not covered in the second phase, 3. Employees in the

⁴⁶ Recommendations for vaccination against COVID 10 disease (last version from 12. 01. 2021),

<http://www.batut.org.rs/download/aktuelno/preporukeZaVakcinacijuProtivCovid19oboljenja.pdf> ; Expert-methodological instruction for conduction of extraordinary recommended immunization against COVID-19 in Republic of Serbia by PFIZER-BIONTECH COVID-19 VACCINE (December, 2020),

<https://www.lkv.org.rs/Documents/News/StrucnoMetodoloskoUpustvoZaImunizaciju.pdf>; Guidebook for health employees for application of vaccine Pfizer-BioNTech COVID-19 Vaccine, Republic Institute for Public Health, Operational plan for immunization against COVID-19 in Republic of Serbia (2020), Ministry of Health RS, Republic Institute of Public Health, <http://www.batut.org.rs/download/aktuelno/operativniPlan.pdf>.

production of vaccines and in laboratories in places with a high risk of infection, 4. Persons who, due to their social status, are at increased risk of infection because they cannot provide physical distance: 4.1. Migrants and asylum seekers in collective accommodation, 4.2. Groups of persons living in unhygienic settlements, 4.3. Homeless people and people living in extreme poverty, and 4.4. Persons older than 50 years serving criminal sanctions.

Is it up to the patient to choose between the vaccine(s) that are approved and available?

Yes. There is a form on E-administration portal (<https://euprava.gov.rs/usluge/6224>) which should be filled in order to express the wish to be vaccinated. The form contains the multiple choice cluster. Person is invited to be vaccinated in line with the availability of the chosen vaccine.

*So far, there is no a separate liability regime for vaccination or more specifically, the Covid-19 vaccine, nor insurance. In the Covid 19 situation, regime of essential, non-essential, COVID-19 medical care is prescribed by the decisions of the Ministry of Health, on the proposal of Crisis Headquarters of the Government of RS.

Date of submission: 22 February 2021

COVID-19 Vaccination Programme in Slovak Republic: A Country Report

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Date: February 22, 2021*

Legal Framework for Vaccination in Slovak Republic

The legal basis for vaccination in the Slovak Republic (SR) is the Act No.355/2007 Collection of Laws of the Slovak Republic (hereinafter just “Coll.”) “On Public Health” and Decree of the Ministry of Health No. 595/2008 Coll., as amended. The Public Health Authority has powers to give order for compulsory vaccination of specific population groups or whole population, if reasoned by epidemiological situation, but this power was not used during COVID-19 pandemic. The Act distinguishes voluntary vaccination and mandatory vaccination. Child population should undergo compulsory vaccination against 10 most dangerous contagious diseases: diphtheria, Haemophilus influenzae „b“, hepatitis B, measles, parotitis, pertussis, poliomyelitis, rubella, tetanus and since 2009 also Streptococcus pneumoniae. For disobedience, parents can be sanctioned by a fine up to 331 Eur by a regional public health authority. Determined job holders with direct high risk of professional contagion (e.g. those who work in virologic laboratory), have mandatory duty to be vaccinated against: tuberculosis, rabies, influenza, hepatitis A,B and tick-borne encephalitis (for other professionals with higher risk of professional exposition, the vaccination is just recommended). Mandatory vaccination is paid from public health insurance, with no additional charges for people.

Before vaccination, health state of the patient has to be assessed and the health care professional authorised for vaccine delivery (a physician or a delegated nurse) has legal obligation to provide full information related to the vaccine applied. Vaccination delivery is regulated also under the Act No.576/2004 Coll. „On Health Care“.

Adverse effects of vaccination are subject of pharmacovigilance under Act No.362/2011 Coll. “On Medicines and Medical Aids”, as amended. The health care provider has a mandatory duty to report them on a special form to the State Institute for Drug Control. Also, a patient (or, a patient's legal representative) has right to report adverse effects of vaccination. There is no specific vaccination harm compensation scheme (legislation bills from 2014 and 2019 did not passed in the Parliament). In cases of vaccination-attributed harm, a general civil litigation shall apply and the claimant has to carry the burden of proof. Such litigation occurs rarely.

COVID-19 Vaccination Programme in Slovak Republic

Slovak Republic registered the first patient hospitalized with COVID-19 on March 6, 2020. Slovakia depends on the approval of vaccines by the European Medicines Agency (EMA) and vaccination strategy of the European Commission. Currently, the three EMA approved vaccines (by Pfizer/BioNTech, Moderna and Astra Zeneca) are in use. Vaccination started on December 27, 2020. A patient does not have right to register

for the particular vaccine from those that are approved and available, however, the right to refuse a particular vaccine is warranted under the section 6 of the Act No.576/2004 Coll. On Health Care. The Ministry of Health of the Slovak Republic (MHSR) had elaborated a template of informed consent form and had created a web portal concentrating information for the lay public related to COVID-19 vaccination⁴⁷, e.g. detailed information about vaccines currently in use, myth-busting, materials of the official national vaccination campaign, and many other.

There is no specific compensation scheme, following adverse events attributed to COVID-19 vaccination. Vaccination against COVID-19 is voluntary by law and free of any additional charges for people, paid from public health insurance. There are no direct or indirect prerequisites for access to certain events, areas or jobs enacted in the legislation. There is no mandatory duty even for essential workers such as healthcare workers or people who work in social care facilities to be vaccinated, however, they have priority under the current vaccination scheme. A negative antigen test or PCR test is no prerequisite for vaccination⁴⁸.

The „*National Vaccination Strategy against COVID-19 in the Conditions of the Slovak Republic*” had been elaborated by the MHSR and approved by the Government in December 2020⁴⁹. This document (available on web of the MH SR⁵⁰ and Public Health Authority⁵¹) plans vaccination in 4 „waves“. The first wave prioritizes healthcare workers and workers, students and volunteers who use to work with patients or clients in health or social care facilities or in social care field work, and essential workers such as soldiers (national Armed Forces perform a wide scope of operations to support health and social care facilities and municipalities since the pandemic outbreak). The second wave prioritizes vulnerable populations – clients in the social care facilities (elderly homes), people aged 65 or more, and patients with selected serious diagnoses such as oncological patients, people with multiple sclerosis, psychological disorders. Third wave prioritizes populations with higher risk of transmitting COVID-19: teachers, asylum seekers and homeless people. Other people, if aged 18+, are eligible in last wave.

The exact criteria for population prioritization that are basis for vaccination scheduling were developed by the MHSR. On February 11, 2021, new Decree of the MH SR No. 58/2021 Coll. “On Criteria for Determining the Order of Vaccination of Persons against COVID-19” passed and repealed the previous (MHSR Decree No.10/2021 Coll. of January 19, 2021). Also this document of February recognizes 11 phases of vaccination, based on prioritization of specific target groups. The phase starts with the opening of the application for the relevant population groups in the central registration system. Sector specific registration

⁴⁷ Accessed February 20, 2021, available from: <https://www.slovenskoproticovidu.sk/>

⁴⁸ Accessed February 20, 2021, available from: <https://www.slovenskoproticovidu.sk/vsetko-o-ockovani/ockovaci-proces/2-co-ak-pred-ockovanim-absolvujem-test-s-pozitivnym-vysledkom>

⁴⁹ Document No. S18864-2020-OMVZaEÚ-2. Accessed February 20, 2021, available from: <https://rokovania.gov.sk/RVL/Material/25588/1>

⁵⁰ Accessed February 20, 2021, available from: <https://www.health.gov.sk/Clanok?Hlavna-sprava-COVID-19>

⁵¹ Accessed February 20, 2021, available from: https://www.uvzs.sk/index.php?option=com_content&view=article&id=4568:narodna-strategia-okovania-proti-ochoreniu-covid-19-a-covid-automat&catid=250:koronavirus-2019-ncov&Itemid=153

systems are established by the Ministry of Education and Ministry of Interior. The document also defines criteria for vaccination use for substitutes of people who registered for vaccines on a certain day but did not attend – substitutes must meet the rigorous health criteria, but do not need to be registered. In the 1st phase, focus is on professional exposure. Prioritized are health and social care workers and supporting allied workers as outlined in the National Strategy above, including priests of registered churches delivering spiritual care in hospitals or social care facilities. In other phases, vulnerability and professional exposure is main focus, and vulnerability criteria are derived from higher age and health condition (risk factors stemming from chronic diseases). E.g., teachers of primary and secondary schools should be vaccinated during the 4th phase (currently running with Astra Zeneca vaccine). Vaccination is not planned for people aged under 18.

Ministry of Employment, Social Affairs and Family published together with MH SR a guidance about organization of vaccination for employees and clients of residential social services facilities – the vaccination is based on the registration and can be performed as 1) Individual vaccination based on previous individual registration via the online form, 2) Group vaccination in the premises of the vaccination centre or 3) Group vaccination via outpatient vaccination service delivered by trained vaccination teams.

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Covid-19 vaccinations in Sweden

Yana Litins'ka
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15th February 2020

Vaccinations and compulsion

Swedish constitutional law guarantees everyone freedom from forced bodily interventions, including vaccinations.⁵² This freedom can be limited only if prescribed by a law adopted by Parliament, with a purpose acceptable in a democratic society and confined to what is necessary for the purpose mentioned above. Currently, there are no such acts of Parliament that allow forced vaccinations. The absence of legislation on direct compulsion to be vaccinated means, in particular, that elderly patients with cognitive disabilities, such as dementia, need to be persuaded to get a vaccination, but cannot be forced to this medical procedure.⁵³

Priority guidelines

In December 2020, the Public Health Agency of Sweden adopted the National Plan for Vaccination Against Covid-19.⁵⁴ The National Plan has been revised several times since its adoption.⁵⁵ The latest version at the time of writing was adopted on 4th of February 2021. It suggests distributing vaccines in four phases and prioritising them as follows:

Phase 1. Persons who live in care homes for the elderly or receive social services at home; social, medical and other personnel who care for the elderly or for those who receive social services at home; close household contacts of persons who receive social services at home.

Phase 2. Persons who have received organ or bone marrow transplants, those who need dialysis, and members of the household of these groups; persons above the age of 60, with the most elderly given priority; persons above the age of 18 who receive disability-related social assistance; health and social care personnel.

Phase 3. Persons aged 60-64; persons aged 18-59 with health conditions that can increase the risk of being seriously ill due to Covid-19.

Phase 4. Other persons above the age of 18.

⁵² See e.g. Parliamentary Ombudsman decision of 27 February 2018 dnr 2089-2016; Prop. 2003/04:158 p. 48.

⁵³ Aftonbladet, Utmaning att få vaccinsamtycke från dementa (Challenge to get consent to vaccination of persons with dementia), 26 December 2020. Available at: <https://www.aftonbladet.se/nyheter/a/vA6Oa4/>

⁵⁴ Folkhälsomyndigheten (Public Health Agency of Sweden), Nationell plan för vaccination mot covid-19. Rekommendation för fortsatt vaccination av prioriterade grupper, med syfte att ge tidigt skydd till personer som har störst risk att bli allvarligt sjuka eller avlida i covid-19 (National Plan for Vaccination against Covid-19. Recommendation for Continued Vaccination of Priority Groups, with the Aim of Providing Early Protection to People Who are Most at Risk of Becoming Seriously Ill or Dying of Covid-19), 29 December 2020. Available at: <https://www.folkhalsomyndigheten.se/contentassets/d4c81c0ca7814f79a61bb457d4baab49/nationell-plan-vaccination-covid-19-rekommendation-prioritering.pdf>.

⁵⁵ Folkhälsomyndigheten (Public Health Agency of Sweden), Nationell plan för vaccination mot covid-19. Rekommendation för prioritering av vaccination mot covid-19 (National Plan for Vaccination against Covid-19. Recommendation for Prioritisation of Vaccines against Covid-19), 4 February 2021. Available at: <https://www.folkhalsomyndigheten.se/contentassets/43a1e203f7344a399367b816e2c7144c/nationell-plan-vaccination-covid-19-delrapport-3.pdf>.

The Public Health Agency of Sweden also states that if there is a shortage of vaccines, the age and socio-economic status of persons should be considered during prioritisation.

The guidelines in the National Plan are recommendations, which means that the 21 Swedish county councils may decide to derogate from them. For example, it has been reported that several county councils decided that certain health care personnel will be vaccinated during phase 1.⁵⁶

Choosing the vaccine

Three vaccines, namely Comirnaty (Pfizer/BioNTech), Covid-19 vaccine Moderna and Covid-19 vaccine AstraZeneca, are approved for use in Sweden. In accordance with the Patient Act (2014:821), in cases where there are several alternative treatments available, a patient should be offered a choice between them. The abovementioned provisions of the Patient Act do not contain justiciable rights. This means that although healthcare providers or staff have the obligation to offer alternatives, patients cannot, as of right, demand this from the authorities. The Public Health Agency of Sweden stated that persons will not be able to make such a choice due to the limited amount of vaccines available.⁵⁷

Liability

A separate liability regime for the Covid-19 vaccines has not been established. Instead, traditional compensation mechanisms are being used. As a general rule, if patients suffer certain adverse reactions to prescribed medication, they may receive compensation from the Swedish Pharmaceutical Insurance. However, not all medication is covered by this insurance. At the time of writing, all the vaccines against Covid-19 available in Sweden are covered by the Pharmaceutical Insurance. Other possibilities to obtain damages, in particular through tort proceedings, also exist.

⁵⁶ Region Skåne (Skåne County Council), Planeringen för pågående och kommande vaccinationer i Skåne (Planning for Ongoing and Upcoming Vaccinations in Skåne), 10 January 2021. Available at:

<https://vardgivare.skane.se/vardriktlinjer/vaccinationer/covid-19/>; Läkartidningen, Fler regioner vill prioritera vårdpersonal för vaccin (More County Councils will Prioritise Vaccination of Healthcare Personnel), 05 January 2021. Available at: <https://lakartidningen.se/aktuellt/nyheter/2021/01/flu-regioner-vill-prioritera-vardpersonal-for-vaccin/>.

⁵⁷ Folkhälsomyndigheten (Public Health Agency of Sweden), Frågor och svar om vaccination mot covid-19 (Questions and Answers about Vaccination against Covid-19), 28 January 2021. <https://www.folkhalsomyndigheten.se/smittskydd-beredskap/utbrott/aktuella-utbrott/covid-19/vaccination-mot-covid-19/fragor-och-svar-om-vaccination-mot-covid-19/>.

Report from Ukraine

*Khrystyna Tereshko,
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If vaccination is compulsory by law (directly or indirectly as a prerequisite for access to certain events, etc.)

According to the Roadmap for the introduction of the vaccine against acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2, and conduction of mass vaccination in response to the pandemic COVID-19 in Ukraine in 2021 – 2022, approved by the order of the Ministry of Health of Ukraine №3018 from 24.12.2020 (hereinafter - the Roadmap): «Vaccination against coronavirus COVID-19 in Ukraine will be voluntary for all groups of population and occupational groups».

Priority guidelines

What is the legal status of the guidelines (prescribed by law or as recommendations)?

Regulations:

Law of Ukraine «On protection of the population from infectious diseases» from June 06, 2000 (URL: https://ips.ligazakon.net/document/view/t001645?ed=2020_05_23);

The Roadmap for the introduction of the vaccine against acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2, and conduction of mass vaccination in response to the pandemic COVID-19 in Ukraine in 2021 – 2022, approved by the order of the Ministry of Health of Ukraine №3018 from December 24, 2020 (URL: <https://ips.ligazakon.net/document/MOZ32580?an=2>);

Immunization plan of the population against COVID-19, approved by the operational headquarters of the Ministry of Health of Ukraine for vaccine-controlled infections on December 22, 2020;

Calendar plan for vaccination of the population against COVID-19 in 2021, approved by the State Commission on Technogenic and Environmental Safety and Emergency Situations on January 29, 2021.

Which groups (elderly, health personnel, etc) or areas (rural/central) are given priority?

According to the Immunization plan of the population against COVID-19, vaccination should take place in 5 stages in the following priority:

- 1) January-April 2021 - people at critical risk of infection and development of COVID-19 and those who perform critical functions in the fight against the COVID-19 pandemic;
- 2) April-June 2021 - people with an extremely high risk of infection and development of COVID-19 and those who provide medical services;
- 3) June-September 2021 - people at high risk of infection and development of COVID-19 and those who perform functions to maintain the security and livelihood of the state;

4) September 2021 - March 2022 - people at increased risk of infection and development of COVID-19 and those who perform functions to support the security and livelihood of the state.

5) Vaccination of the rest of the adult population of Ukraine. If there is a sufficient amount of vaccine, it can be given at the same time as the previous steps.

According to the Roadmap, based on the recommendations of the WHO, SAGE and ETAGE, the Preliminary Framework Program on Fair Distribution of the vaccine against coronavirus disease COVID-19 (National Academies of Science, Engineering and Medicine; USA), the recommendations of the National Technical Group of Experts on Immunoprophylaxis of Ukraine, it is recommended to identify nine priority groups for vaccination against coronavirus disease COVID-19, which include (in order of priority access to vaccination):

- health professionals, including those directly involved in measures to combat the coronavirus disease COVID-19 pandemic;
- servicemen (including the Armed Forces of Ukraine and the National Guard of Ukraine) participating in the Joint Forces Operation;
- workers of the social sphere, including social workers;
- persons living in long-term care and support institutions and employees of such institutions;
- the elderly people (60 years of age and older), including those with comorbidities who are at risk for complications and death due to coronavirus disease COVID-19 (people diagnosed with endocrine system disease, cardiovascular diseases, chronic diseases of the respiratory tract, chronic diseases of the nervous system, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood);
- employees of critical state security structures, including the State Emergency Service of Ukraine, the National Police of Ukraine, the National Guard of Ukraine, the Security Service of Ukraine, servicemen of the Armed Forces of Ukraine, the Ministry of Internal Affairs of Ukraine;
- teachers and other education workers;
- adults (18 to 59 years of age) with comorbidities at risk for complications and death due to coronavirus disease COVID-19 (people diagnosed with endocrine, cardiovascular diseases, chronic diseases of the respiratory tract, chronic diseases of the nervous system, chronic diseases of the urinary system, cancer, chronic diseases of the hematopoietic organs and blood);
- people who are in places of detention and / or pre-trial detention facilities and employees of places of detention and / or pre-trial detention facilities.

If it is up to the patient to choose between the vaccine(s) that are approved and available?

The quality of vaccines imported into Ukraine is ensured in accordance with Article 9 of the Law of Ukraine «On Medicinal Products», according to which medicinal products are allowed for use in Ukraine after their state registration, except as provided by this Law.

The Law of Ukraine «On Amendments to the Law of Ukraine «On Medicinal Products» concerning state registration of Medicinal Products under Obligations» from January 29, 2021 provides permission to register vaccines from COVID-19 until the completion of clinical trials.

The Law of Ukraine «On Amendments to Certain Laws of Ukraine Concerning the Prevention of Coronavirus Disease (COVID-19)» from December 04, 2020 creates conditions for ensuring access of the population of Ukraine to safe, high-quality and effective vaccines against COVID-19. In particular, the terms of approval of clinical trials and state registration for vaccines or other medical immunobiological drugs for specific prevention of coronavirus disease are reduced.

According to the provisions of the Roadmap, the start and deployment of mass vaccination is possible if there are properly registered vaccines in Ukraine. Due to the limited number of vaccines available to Ukraine in the 4th quarter of 2020 - 1st quarter of 2021, vaccination at stage 1 may take up to three months.

Opportunity to choose between the vaccines that are approved and available is not provided by law.

Liability (Is there a separate liability regime for vaccination or more specifically, the covid-19 vaccine?)

The legislation does not provide liability for refusal of vaccination, in general, and of vaccination against COVID-19, in particular.

If you are able, we would also welcome information regarding postponement of non-essential medical care because of Covid-19.

According to the Resolution of the Cabinet of Ministers of Ukraine from December 09, 2020 № 1236 «On establishment of quarantine and introduction of restrictive anti-epidemic measures to prevent the spread on the territory of Ukraine of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2», on the territory of Ukraine for the period of quarantine restrictive anti-epidemic measures are introduced, namely it is forbidden:

- ✓ carrying out of planned hospitalization measures by state and municipal health care institutions, except:
 - provision of medical care due to the complicated course of pregnancy and childbirth;
 - providing medical care to pregnant women, mothers, postpartum women, newborns;
 - providing medical care in specialized departments of health care institutions to patients with oncological and pulmonary diseases;
 - providing palliative care in an inpatient setting;
 - provision of planned medical care by national health care institutions that provide tertiary (highly specialized) medical care, provided that appropriate sanitary and anti-epidemic measures are observed;

- carrying out other urgent and express measures for hospitalization, if as a result of their transfer (postponement) there is a significant risk to human life or health.

Who defines (non-)essential medical care (prescribed by law, who's responsibility, ...)

According to Art. 3 of the Law of Ukraine «Fundamentals of the legislation of Ukraine on health care», medical care - the activities of professionally trained medical workers aimed at prevention, diagnosis and treatment in connection with diseases, injuries, poisonings and pathological conditions, as well as in connection with pregnancy and childbirth;

The provision of emergency medical care is regulated by the Law of Ukraine «On Emergency Medical Care» and the Law of Ukraine «Fundamentals of the Legislation of Ukraine on Health Care». Emergency medical care - medical care, which consists in the implementation by employees of emergency medical care system emergency organizational, diagnostic and therapeutic measures, in accordance with this Law, aimed at saving and preserving the life of a person in an emergency and minimizing the impact of such a condition on his health. On the territory of Ukraine, every citizen of Ukraine and any other person has the right to free, accessible, timely and high-quality emergency medical care provided in accordance with this Law.

The provision of emergency medical care for the period of quarantine is not limited.

What about liability and insurance? Is there a specific regime?

There is no special regime of liability and insurance provided by national legislation.

United Kingdom – COVID-19 vaccination law

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1. Is vaccination compulsory by law (directly or indirectly as a prerequisite for access to certain events, etc.)?

No, in none of the four nations comprising the United Kingdom (England, Wales, Northern Ireland, Scotland) is vaccination for a disease compulsory by law, for any person or age group. In England and Wales, the Public Health (Control of Disease) Act 1984, as amended, stipulates at section 45E that while the relevant minister is empowered to make regulations to prevent danger to public health and prevent the spread of infection, such regulations *may not* include provision requiring a person to undergo medical treatment, and “medical treatment” includes vaccination and other prophylactic treatment.

The Coronavirus Act 2020 does not change this. Powers to make regulations in England and Wales are made under and subject to the restrictions in the Public Health (Control of Disease) Act 1984, discussed above. The Coronavirus Act 2020 introduces separate powers for Scotland and Northern Ireland to make health protection law under their devolved powers. They can be found at Schedule 18 for Northern Ireland – new section 25E inserted into the Public Health Act (Northern Ireland) 1967 – and Schedule 19 for Scotland (which permits Scottish Ministers to make Regulations in Scotland). Both the new section 25E of the Public Health Act (Northern Ireland) 1967 and paragraph 3 of Schedule 19 of the Coronavirus Act 2020 ensure the same prohibition as that in the 1984 Act, viz. that health protection regulations *may not* mandate vaccination.

There is no indication at this time that vaccination may become *de facto* compulsory, be it through private ordering or otherwise, as a prerequisite for access to certain events, access to public transportation, etc. Moreover, such schemes, were they to be implemented, would raise ethical concerns (e.g. interference with autonomy and bodily integrity, freedom of conscience) as well as concerns regarding human rights and compliance with the UK’s Equality Act 2010.

2. Vaccine priority guidelines

a. What is the legal status of the guidelines (prescribed by law or as recommendations)?

Each nation in the UK is following the Joint Committee on Vaccination and Immunisation (JCVI) advice, which are recommendations developed by an independent expert group. The advice/guidelines are only advisory; they are *not* prescribed by law.

b. Which groups (elderly, health personnel, etc) or areas (rural/central) are given priority?

This priority list is as follows:

1. residents in a care home for older adults and their carers
2. all those 80 years of age and over and frontline health and social care workers
3. all those 75 years of age and over
4. all those 70 years of age and over and clinically extremely vulnerable individuals
5. all those 65 years of age and over
6. all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7. all those 60 years of age and over
8. all those 55 years of age and over
9. all those 50 years of age and over
10. rest of the population (to be determined)

At the same time as the adults under 65 years with long term conditions, the vaccine will also be offered to adults who provide regular care for an elderly or disabled person.

3. If it is up to the patient to choose between the vaccine(s) that are approved and available?

So far, only the four UK national governments have access to the vaccine, and it is being offered on the NHS for free. Under such a distribution scheme, it is not possible to choose one vaccine over another (e.g. the Pfizer-BioNTech vaccine over the AstraZeneca-Oxford vaccine).

4. Liability: is there a separate liability regime for vaccination or more specifically, the COVID-19 vaccines?)

Yes. The UK operates a general “Vaccine Damage Payments Scheme”, as per the Vaccine Damage Payments Act 1979, whereby if a person is “severely disabled” as a result of a vaccination against certain diseases, they may receive a one-off tax-free payment of £120,000. COVID-19 is now one of the eligible diseases (along with 18 other enumerated diseases). Disablement is worked out as a percentage, and “severe disablement” means at least 60% disabled. This could be a mental or physical disablement and will be based on medical evidence from the doctors or hospitals involved in the person’s treatment. The vaccination must have been given in the UK or the Isle of Man, unless the person was vaccinated as part of their armed forces medical treatment. There are time limits on making such a claim.

Date of submission: 12 February 2021

Title: A short country report about the Hungarian healthcare system, with a focus on patient's rights

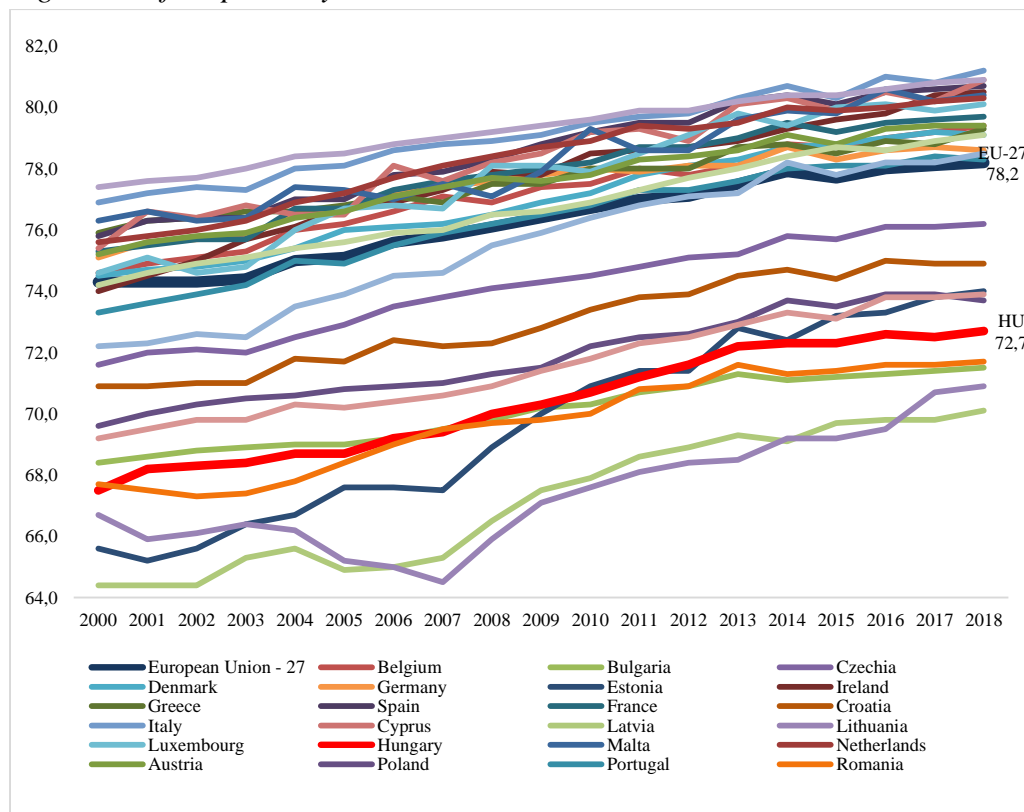
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Health status of the population in Hungary, in brief

According to the Eurostat database, in 2020, Hungary had a population of slightly under 10 million inhabitants. Hungary has a shrinking population since the 1980s due to low birth rate coupled with a relatively high mortality rate in the country. The proportion of people 65 years of age or older to population 15 to 64 years old is projected to be 56% in 2100, indicating a severely ageing population. [1] Since the 2000s, life expectancy at birth has significantly increased in all European Union 27 countries (EU-27), including Hungary. In 2018, life expectancy of the Hungarian population has reached 72.7 years, and considered low compared to other European countries such as Italy 81.2, Cyprus 80.9 and Sweden 80.9, and to the total EU-27 average of 78.2 (see Figure 1). [2] The expected life years in Hungary does not fully reflect the quality of healthy life of Hungarians. The number of years lived in healthy conditions and disable-free (Healthy life years (HLY)) from the total life expectancy years was estimated at 61.1 years in Hungary with 2.9 years gap from the EU-27 estimated average.[3]

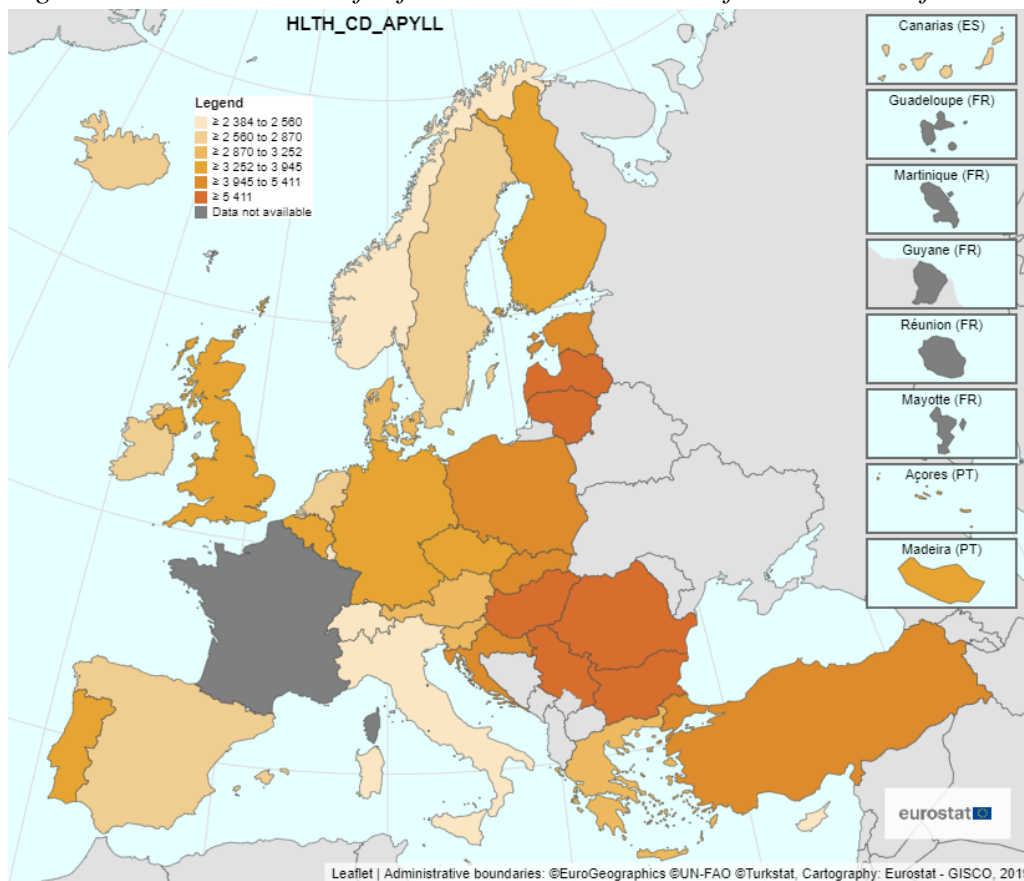
Figure 1. Life expectancy in EU-27 between 2000 and 2018



Source: Eurostat

Potential Years of Life Lost (PYLL) is a frequently used measure in public health focusing on the loss of life at young, adult and middle ages. [4] PYLL estimates the potential years lost due to premature death, namely death before 70. According to the Eurostat definition, the indicator is calculated by adding up the number of years between the age at death and 70 years for each premature death. As presented by Figure 2, there was a striking difference between PYLL of Central and Eastern European Member States and EU-15 the old EU-15 in 2017 [4].

Figure 2. Potential Years of Life Lost across the EU-27 for all causes of death



Source: Eurostat. Year: 2017 (latest available)

Constitution and right to health

The health status of the population requires attention and targeted interventions. The Fundamental Law of Hungary (Constitution) explicitly addresses the right to health. According to the Article XX

“(1) Everyone shall have the right to physical and mental health.

(2) Hungary shall promote the application of the right referred to in Paragraph (1) by an agriculture free of genetically modified organisms, by ensuring access to healthy food and drinking water, by organising safety at work and healthcare provision, by supporting sports and regular physical exercise, as well as by ensuring the protection of the environment.”

Detailed regulation is given by the Act CLIV of 1997 on health, healthcare services, and healthcare providers (on Healthcare). The coverage of the Act on Healthcare is broad, it provides a comprehensive framework of all aspects affecting human health. The purposes of the Act are to a) foster the improvement of health of the individual and the population by determining the system of conditions and means influencing health, as well as the

responsibilities of those involved in the establishment; b) contribute to ensuring equal access to health care services for all members of society; c) create the conditions whereby all patients may preserve their human dignity and identity, and their right of self-determination and all other rights may remain unimpaired; d) define the general professional requirements and guarantees of quality of health services regardless of the legal status of service providers and the funding of services; e) ensure the protection of health workers and healthcare institutions by defining their rights and obligations, and through safeguards arising from the peculiar nature of health services; f) enable that individual and community interests may be asserted in harmony, current public health objectives may be attained, the required funding may be available and deployed in an optimal way, and health sciences may continue to develop.

The English translation of the Act CLIV of 1997 on Healthcare is available on the website of the National Contact Point of Hungary, at www.patientsrights.hu.

Patients' rights

The Act CLIV of 1997 on Healthcare (Chapter 2) sets forth the rights and obligations of patients regarding healthcare, including:

- The Right to Healthcare
- The Right to Human Dignity
- The Right to Have Contact
- The Right to Leave the Facility
- The Right to Be Informed
- The Right to Self-Determination
- The Right to Refuse Healthcare
- The Right to Become Familiar with the Medical Record
- The Right to Professional Secrecy

Detailed explanation of each right is available on the above mentioned website at (<http://www.patientsrights.hu/patients-rights.html>), both in Hungarian and English. Since 2017 the Integrált Jogvédelmi Szolgálat (IJSZ) operates as an independent organizational unit of the Ministry of Human Resources for the integrated enforcement of citizens' rights related to patients', patients' and children's rights.[5] Patients have the right to file complaints, in relation to healthcare services and to treatment at the healthcare provider or at the financing organization. The healthcare provider and the financing organization will launch an investigation into all complaints filed, and inform the patients on the results within 30 business days. A summary report of patients' rights related cases is published on the IJSZ website, annually.

Although international comparison of the enforcement of patients' rights can be methodologically challenging, it is important to note that according to the Health Consumer Powerhouse report [6], Hungary is among the four worst performing countries among EU member states in terms of enforcing patients' rights. The field of patient rights covers 10 indicators in the Health Consumer Powerhouse report: Patient organisations involved in decision making, Right to second opinion, Access to own medical record, Registry of bona fide doctors, Web or 24/7 telephone HC info with interactivity, Cross-border care seeking financed from home, Provider catalogue with quality ranking, Patient records e-accessible, Patients' access to on-line booking of appointments?, and the use of e-prescriptions.

Implementation of the directive 2011/24/EU on patients' rights in cross-border healthcare

The IJSZ also serves as the national contact point for cross-border healthcare, and provides information to patients and healthcare professionals about their rights to cross-border care, complaints and redress procedures, and the availability of services. Additionally, the IJSZ provides information on the implementation of the directive (<http://www.patientsrights.hu/oep-2.html>) in Hungary.[7] Further explanation on cross-border healthcare is available at the website of the National Health Insurance Fund (Hungarian: Nemzeti Egészségbiztosítási Alapkezelő (NEAK)). [8]

The National Health Insurance Fund is responsible for carrying out the three major tasks related to cross-border healthcare since the entry into force of the laws on 25 October 2013 transposing Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, namely:

- Prior-authorization of cross-border healthcare.
- Reimbursement of domestic cost of cross-border healthcare.
- Registration of reports of cross-border healthcare.

Although Hungary accepts many patients (e.g. dental treatments) the number of outgoing patients is low or unknown. Such situation might be explained by the relatively low treatment costs in Hungary.[9]

Financing

Hungary has a long tradition of solidarity-financed public healthcare. The country has a tax-funded universal healthcare system, which is organized by the state-owned National Health Insurance Fund. Everyone is automatically affiliated to a health insurance scheme as soon they begin to work. Self-employed people have to register themselves, and employers register their employees, with help of the local bureau of the taxation and finance office and/or the local social insurance organisations.[10] Employers and employees pay contributions. Although the healthcare is considered universal, several reasons can prevent people in Hungary to benefit from healthcare. For example, since February 12, 2021, the social security number of a person who has failed to pay at least a half-year health care contribution is invalid. A person who does not have health insurance has to pay 8,000 HUF (approx. 22 EUR) a month, but socially deprived people can be exempted from this obligation. Due to the new regulation seventy thousand people may be left without a social security number, resulting in dropping out of the Social Security benefits.[11]

According to the Country Health Profile 2019, the health sector in Hungary is underfunded compared to most EU or OECD countries. Additionally, the public health expenditure accounts for only two-thirds of the total health expenditure (EU average is 79 %), while the level of out-of-pocket spending is high, 27 % (EU average is 16 %). [12]

Health system in Hungary, in brief

The Hungarian health system is highly centralized: the national government is responsible for setting strategies, issuing and enforcing regulations, controlling and also delivering care by outpatient clinics and inpatient care. [12] The Ministry of Human Capacities as top administrative body manages the health system via the Országos Kórházi Főigazgatóság (OKFŐ), which is responsible among others for coordination in healthcare, hospital planning and management, and medical licensing. [13]

According to the CXXIII/2015 Primary Health Care Act the patient has the right to receive long-term, personalized, continuous health care at the place of residence. The provision of primary health care services

is the obligation of the municipalities. The service of GPs is mainly carried out in the frame of an individual or social enterprise but a public servant relationship with a municipality or a health care institution is also possible. [14] Promising initiatives such the Swiss Hungarian Primary Health Care Development Model Programme to strengthen the primary healthcare services and prioritize prevention are to be mentioned.[12]

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Country Report: Lithuania

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NCP for Lithuania

Healthcare System Overview

Article 53 of the Constitution of Lithuania enshrines the obligation for the state to take of human health and guarantee medical assistance and services. It further enshrines that the law may establish a procedure for providing free medical assistance by public healthcare institutions.⁵⁸

The Ministry of Health (MoH) and the National Health Insurance Fund (NHIF) are the main central institutions, with local administrations playing an important role in the delivery of the healthcare services. The MoH supported by a handful of specialised agencies formulates health policy and regulations. Insurance coverage is provided to the population by the NHIF. In order to obtain coverage, persons resident in Lithuania must contribute to the NHIF, apart from children, students, pensioners and the unemployed, who are exempted from this requirement and are automatically covered by the NHIF.⁵⁹ Most actors in Lithuanian's healthcare system are public entities, nonetheless, private providers play an increasing role in the rapidly developing day care and day surgery segment as well as in diagnostic and interventional imaging services.

Lithuanian healthcare insurance system is based on two main principles: solidarity and universality. The first principle refers to the fact that the contributions paid by all employed persons, or persons otherwise engaged in active economy activities and the State itself contribute to the accumulation of Compulsory Health Insurance Fund. The second principle refers to an arrangement where all citizens of the Republic of Lithuania and foreign nationals permanently residing in Lithuania, as well as foreign nationals temporarily residing and legally employed in the country are obliged to pay compulsory health insurance contributions, and upon an occurrence of an insured event are entitled to receive healthcare services compensated from the budget.

Patient's rights in Lithuania and the implementation of the Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare

The rights of patients are regulated by the Constitution of the Republic of Lithuania, the Civil Code of the Republic of Lithuania, the Law on the Rights of Patients and Compensation for the Damage to Their Health (RPCDH). Further, Lithuania has ratified a number of international conventions with respect to patient's rights, including the Ljubljana Charter, the European Convention for the Protection of Human Rights and Fundamental Freedoms and so on.

Lithuania has also adopted and transposed into its national legislation the EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was adopted on 19th January 2011 and published in

⁵⁸ "Lietuvos Respublikos Konstitucija"

⁵⁹ "OECD Reviews of Health Systems Lithuania 2018 OECD Reviews of Health Systems Lithuania Assessment and Recommendations assessment."

the EU's Official Journal on 9th March 2011. It entered into application on 25th October 2013.⁶⁰ The National Contact Point (NCP) has been established in order to answer all the questions related to cross-border health care services for the Lithuanian residents and persons visiting our country. It was established specifically for this purpose. Expenses of the insured for cross-border health care shall be reimbursed to the extent and in accordance with the procedure that would be reimbursed for the respective health care expenses in the Republic of Lithuania in accordance with the provisions of legal acts of the Republic of Lithuania. The amount reimbursed may not exceed the actual costs of the insured person for cross-border healthcare. In accordance with the said directive, any European Health Insurance Card (EHIC) holder may apply for medical care directly to a GP who has an agreement with the Territorial Health Insurance Fund (THIF) in Lithuania. Visiting a GP is free of charge and, if necessary, the GP will refer a patient to a specialist and his consultation. The costs of treatment provided by private doctor who does not have an agreement with the THIF are not covered on the basis of EHIC. Admission to hospital takes place after referral by GP or specialist. In the case of an emergency a person may go directly to the hospital and provide his/her EHIC as well as proof of identity in order to access emergency healthcare services.

The the Law on the Rights of Patients and Compensation for the Damage to Their Health, instead, enshrines fundamental principles and rights for the patients. The said law specifies the protection of the following fundamental human rights: the protection of a person's life, health and wellbeing; Right to privacy and its protection (including, after one's death); The interests and well-being of the patient take precedence over the interests of society and science; and the interests of the minor are superior to the principles of government of his or her parents.⁶¹ The RPCDH also establishes principles related to the protection of patient's rights (informed consent for treatment; freedom of choice; conscious responsibility for yourself and your health the greatest possible involvement of a patient who is unable to fully express his will in all cases provided for by law). The said law also established principles of doctor's rights, and the principles of accountability, which include the principle of defending the weaker part of the legal relationship, principle of claiming (real) liability for the damage caused and the (real) possibilities of indemnification, and the principle of indemnification of non-pecuniary damage.

The RPCDH also enshrines the following patient's rights: right to high quality healthcare services; Right to choose a healthcare institution and professional; Right to Information; Right not to know; Right to decline healthcare services; Right of access of one's Medical Records; Right to Privacy and its specifics (also after one's death); Right to participate in research and teaching process; Right to complain; and right to compensation for the damages.⁶²

Date of submission: 5 February 2021

⁶⁰ "Cross-Border Healthcare in Lithuania."

⁶¹ Law on the Rights of Patients and Compensation of the Damage to their Health, Republic of Lithuania.

⁶² "Patient Rights | Ministry of Health of The Republic of Lithuania."

EAHL News

The EAHL Interest Group on Supranational Biolaw

The EAHL Interest Group on Supranational Biolaw has been launched. It aims to promote European health law, especially in its European-level dimension. ‘Supranational biolaw’ is understood as comprising the law of the European Union, the Council of Europe and the European Patent Organisation, regarding the law and the various legal issues arising from technological advances related to medicine and biotechnology.

While Supranational Biolaw in all its dimensions is often not understood as valuable in and of itself, it underpins or is inflected within national law, and is now so developed that it can no longer be ignored.

Through research, training and networking activities, the types of activities that correspond to the activities of EAHL, the EAHL Interest Group on Supranational Biolaw will help to effectively mobilise its Members to address demands from several groups within society, including legislators and regulators, scientists (researchers and clinicians), and patients regarding Supranational Biolaw. The Interest Group will also help to strengthen the position of academics within national level systems and political contexts that threaten their autonomy and role as facilitators of freedom of discussion.

The EAHL Interest Group on Supranational Biolaw is co-chaired by Aurélie Mahalatchimy (UMR 7318 DICE CERIC, CNRS, Aix Marseille University, Toulon University, Pau & Pays de l’Adour University, France) and Mark Flear (Queen’s University Belfast, UK), and managed by Pascal Gauttier (UMR 7318 DICE CERIC).

Current members include: Dobrochna Bach-Golecka (Poland); Estelle Brosset (France); Joaquin Cayon (Spain); Brenda Daly (Ireland); Anne-Marie Duguet (France); Inesa Fausch (Switzerland); Eloïse Gennet (France); Mary Guy (United Kingdom); Kaisa-Maria Kimmel (Finland); Phoebe Li (United Kingdom); PinLean Lau (Malaysia, Associate EAHL member); Jean McHale (United Kingdom); Isabelle Moine-Dupuis (France); Andrea Mulligan (Ireland); Stefania Negri (Italy); Emmanuelle Rial-Sebbag (France); Mike Schwebag (Luxembourg); Mirko Dukovic (Hungary); Nathalie De Grove-Valdeyron (France); Sabrina Roettger-Wirtz (The Netherlands); Judit Sandor (Hungary); Santa Slokenberga (Sweden); Tomislav Sokol (Croatia).

Further members from across Europe are in the process of joining. We will provide an update on the membership via the website in due course.



Extension of Deadline

The Max Planck Institute for Social Law and Social Policy in Munich is offering several

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We are looking for dissertation projects in the field of “Digital Health – Digitalisation in Health Law” for a new research group at our Institute. Possible topics include data protection and cybersecurity in healthcare, personalised medicine, and legal regulation of digital health.

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We offer attractive working conditions in a modern, well-equipped institute with a global network. Our institute holds the world’s largest social law library and is located close to LMU Munich, as well as the Bavarian State Library. Successful applicants receive a respective compensation in accordance with the TVöD to finance their PhD project.

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Your application should include a short project outline (5 pages max.), a curriculum vitae with a list of publications, and copies of your certificates and qualifications.

Please send your application stating **reference number 23-20** until **March 15th, 2021** to:

hr@mpisoc.mpg.de and **leber@mpisoc.mpg.de**

For further information please contact Dr. Christoffer Leber (Phone: +49-89-38602-501, or E-mail: leber@mpisoc.mpg.de).

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