EUROPEAN ASSOCIATION of HEALTH LAW

June 2021

EAHL Newsletter

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Special issue: Vaccination against COVID-19

EAHL
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Issue № 2

Message from the President

Dear EAHL members,

I hope that you are all fine, despite the pandemic. It is affecting us all, both as citizens of Europe and as health lawyers. This edition of the EAHL newsletter is also dedicated to legal issues in the wake of the pandemic.

For us, this is the first pandemic in our lifetime. The experience seems uniqies. Still, infectious diseases have treathened humans since we populated the globe. During one of the pandemics a couple of hundred years ago, it was prescribed by law to shoot travellers coming from Sweden to Norway! This measure would of course be unacceptable today but reminds us that we tend to look for exaggerated legal remedies when we feel defenseless. By this, I do not suggest that the EU digital COVID certificate is of such a character but we need an enlightened debate about this as well as other legal measures used as part of the strategy to combat the virus.

This newsletter contains country reports from several European states. The reports remind us that we are in the same boat, and the pandemic will not be over before it is ended in all countries. Even though we are facing the same disease, and are using the same basic remedies, there are differences when it comes to the details, cf. the divergent recommendations regarding vaccination of children in Austria and Germany. There are also substantial differences in Europe both when it comes to living conditions and the trust that we have to public authorities. There is no vaccination against distrust or medicine for in-equality, neither a legal remedy. Still, legislative measures can contribute to level the living and health conditions and rule of law can contribute to build trust between the citizens and the authorities. This is a work for health lawyers but under and after a pandemic.

Best wishes for the summer,

Karl Harald Søvig

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The EAHL Interest Group (IG) on Supranational Biolaw

News

The EAHL Interest Group on Supranational Biolaw has welcomed new members: Markus Frischhut (Austria), Matthieu Guerriaud (France), Edouard Habib (France); Tamara Hervey (United Kingdom), Clotilde Jourdain-Fortier (France), Michal Koscik (Czech Republic), Vera Lucia Raposo (Portugal), Claudia Seitz (Switzerland).

The EAHL Interest Group on Supranational Biolaw also has a new general manager, Dr Pin Lean Lau (Brunel University, UK) and two communication managers, Mirko Dukovic (Central European University, Hungary) and Edouard Habib (Aix-Marseille University, France).

Since its launch, the IG has conducted the following activities, thanks to the involvement of several of its members.

Conferences

- **Panel on "The Constitution of Biopolitics in the 21st Century"** selected for The Global Summit organized by The International Forum on the Future of Constitutionalism, Virtual Conference held on 12-16 January 2021 (https://law.utexas.edu/the-global-summit/virtual-schedule/day-4/concurrent-sessions-17/) involving

Chair: Mirko DUKOVIC (Central European University)

Panellists from the EAHL IG:

A. MAHALATCHIMY and M. FLEAR, Bioconstitutionalism in the European Union regulation of gene-editing technologies

P. L. LAU, 'Zombie' Apocalypses, the Black Death, and Virulent Gene-Edited Pathogens: Evolving Bio-Constitutional Legal Responses for Global Bio-Security,

M. DUKOVIC, Human Body as Crux: Covid19 challenges to Bioconstitutionalism

The Interest Group is very proud of M. DUKOVIC (PhD student) for his first selection and perfect chairing of a panel in a conference of this scale!

- **Virtual Symposium on "Law, Biomedical Technoscience and Imaginaries"**, Journal of Law and the Biosciences, 4 February 2021

Chair: Mark FLEAR (Queen's University Belfast)

Panellists from the EAHL IG:

M. FLEAR, Expectations as Techniques of Legitimation? Imaginaries in Global Bioethics Standards for the Regulation of Health Research

A. MAHALATCHIMY, P. L. LAU, P. LI, M. FLEAR, Framing and legitimating EU legal regulation of human gene-editing technologies: key facets and functions of an imaginary

Publications

- **Special issue on "Law, Biomedical Technoscience and Imaginaries"** in the Journal of Law and the Biosciences

Editor: Mark FLEAR (Queen's University Belfast) (with co-editor R. Ashcroft)

With papers from members of the IG:

M. FLEAR (with R. Ashcroft), Guest Editorial: Law, Biomedical Technoscience and Imaginaries

M. FLEAR, Expectations as Techniques of Legitimation? Imaginaries in Global Bioethics Standards for the Regulation of Health Research

A. MAHALATCHIMY, P. L. LAU, P. LI, M. FLEAR, Framing and legitimating EU legal regulation of human gene-editing technologies: key facets and functions of an imaginary

The Special Issue will be published soon, we will keep you posted and hope you will enjoy it!

- **The Oxford Handbook on Comparative Health Law**

Editor: Tamara K. HERVEY (City, University of London) (with co-editor D. Orentlicher)

With chapters from members of the IG:

J. CAYON-DE LAS CUEVAS, Organ Transplantation (with D. Orentlicher)

M. FRISCHHUT, Communicable and Other Infectious Diseases: The EU Perspective; and Introduction to Public Health Law (with W. E. Parmet, A. Garde, and B. Toebes)

T. K. HERVEY, Editors' Introduction to The Oxford Handbook of Comparative Health Law (with D. Orentlicher)

A.MAHALATCHIMY, Regulating Medicines in the European Union; Regulating Medical Devices in the European Union; and Introduction to Medical Products Law (with E. Lietzan and P. Zettler)

J. SANDOR, Decisions at the End of Life (with D. Orentlicher)

The Oxford Handbook on Comparative Health Law has been published online, and **the paper book will be published soon**. We will keep you posted and hope you will enjoy it!

- **Book "Innovation et Analyse des risques dans le domaine de la santé et des produits de santé dans l'Union Européenne : regards croisés"**, Cahiers Jean Monnet, Presses de l'Université Toulouse 1 Capitole

Editor: N. DE GROVE-VALDEYRON (University of Toulouse 1- Capitole)

With chapters from members of the IG:

N. DE GROVE-VALDEYRON, Dispositifs médicaux connectés et innovation technologique : quel rôle pour la normalisation européenne ?

A.MAHALATCHIMY and E. RIAL-SEBBAG, Le génome humain édité : risques et gouvernance

N. DUBRUEL & É. GENNET, « L'encadrement éthique et juridique des essais *in silico* en droit européen »
More information on this book here.

- The Health Law part of the OUP online encyclopaedia on EU Law

Editor: Tamara K. HERVEY (City, University of London)
With chapters from other members of the IG: J. CAYON-DE LAS CUEVAS, N. DE GROVE-VALDEYRON, M. FLEAR, E. GENNET, A.MAHALATCHIMY.
This work is ongoing!

Projects

- The common answer from several IG members to WHO call on **Anti- Microbial Resistance**.
  Lead: Phoebe LI (University of Sussex)

Other EAHL IG Members involved are: D. BACH-GOLECKA, J. CAYON, B. DALY, M. DUKOVIC, M. GUERRIAUD, M. KOSCIK, P. L. LAU, A. MAHALATCHIMY.
The project has been selected by WHO! It is running from May to October 2021, further information on the results will be communicated in accordance with WHO.

- The common answer from several IG members to the call for 2021 Thematic Networks under the EU Health Policy Platform, European Commission on **"Health as a fundamental value: Towards an inclusive and equitable pharmaceutical strategy for the EU"**

Leads: Eloïse GENNET and Aurélie MAHALATCHIMY (University of Aix-Marseille, UMR 7318 DICE CERIC)
Other EAHL IG Members involved are: J. CAYON-DE LAS CUEVAS, B. DALY, A.-M. DUGUET, C. FORTIER, M. FRISCHHUT, N. DE GROVE-VALDEYRON, SM. DUKOVIC, M. GUERRIAUD, M. KOSCIK, P. L. LAU, I. MOINE-DUPUIS, S. ROETTGER-WIRTZ.
The proposal has been shortlisted among the 5 semi-finalists by the European Commission. Please support us in voting for our proposal!

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 Pin Lean Lau (Brunel University), as well as by Mirko Dukovic (Central European University, Hungary) and Edouard Habib (Aix-Marseille University, France) for communication.
Current members include: Dobrochna Bach-Golecka (Poland); Estelle Brosset (France); Joaquin Cayon (Spain); Brenda Daly (Ireland); Nathalie De Grove-Valdeyron (France); Anne-Marie Duguet (France); Mirko Dukovic (Hungary); Inesa Fausch (Switzerland); Mark Flear (United Kingdom); Markus Frischhut (Austria);

Eloïse Gennet (France); Matthieu Guerriaud (France); Mary Guy (United Kingdom); Edouard Habib (France); Tamara Hervey (United Kingdom); Clotilde Jourdain-Fortier (France); Kaisa-Maria Kimmel (Finland); Michal Koscik (Czech Republic); Phoebe Li (United Kingdom); Pin Lean Lau (United Kingdom); Aurélie Mahalatchimy (France); Jean McHale (United Kingdom); Isabelle Moine-Dupuis (France); Andrea Mulligan (Ireland); Stefania Negri (Italy); Vera Lucia Raposo (Portugal); Emmanuelle Rial-Sebbag (France); Sabrina Roettger-Wirtz (The Netherlands); Judit Sandor (Hungary); Mike Schwebag (Luxembourg); Claudia Seitz (Switzerland); Santa Slokenberga (Sweden); Tomislav Sokol (Croatia).

Meesage from IG to the EAHL members

Dear EAHL colleagues,

The EAHL Interest Group on supranational biolaw has applied for the European Commission's 2021 Thematic Networks on the EU Health Policy Platform. Our proposal for an inclusive and equitable EU Pharmaceutical Strategy has been shortlisted among the 5 semi-finalists by the European Commission.

We would like to kindly ask you to support us in voting for our proposal on the EU Health Policy Platform and, in case of selection, in contributing to the discussion on the platform towards a finalized joint statement. Details can be found in the poster.

In addition to supporting our proposal, registering on the EU Health Policy Platform will give you access to wide information and to contribute to discussions in order to impact on the EU Health Policy.

In case you would like to disseminate this, please be aware that only health experts (mainly from Research organisations, universities and academic institutions; Public health non-governmental organisations; Organisations representing patients; Organisations representing health professionals; Health service providers; Health insurance bodies) are allowed to register on the EU Health Policy Platform, and consequently to vote and contribute to the discussions on this platform.

With Kind Regards,

The EAHL Interest Group on Supranational Biolaw.

The proposal from the EAHL Interest Group on Supranational BioLaw for the 2021 Thematic Network under the EU Health Policy Platform

Health as a fundamental value

Towards an inclusive and equitable pharmaceutical strategy for the EU

Bearing in mind the **principle of solidarity** in the EU, the Interest Group on Supranational Biolaw of the **European Association of Health Law** (**EAHL**) proposes to argue for the central role of the European Commission with the DG of Health and Food Safety in reaffirming **health as a fundamental value** in EU policies, and more particularly, in aiming at the **highest ethical standards** for the pharmaceutical strategy to be **inclusive and equitable** in the EU and beyond.

Relevance

The Covid-19 pandemic has highlighted many loopholes in how innovative pharmaceutical products are created, evaluated, produced and distributed in EU countries. One of the most visible issues brought into the spotlight has been **the lack of health equity**. Thus new Pharmaceutical Strategy for Europe may be the opportunity to address some of these loopholes and **strive** for even more **ambitious standards of equity** of access to therapies.

Objective

1) exploring how the **role** of the European Commission and Directorate-General for Health and Food Safety could **evolve**;
2) strengthening health equity through **inclusiveness and solidarity** in the Pharmaceutical Strategy.

Interest Group on Supranational BioLaw: https://eahl.eu/eahl-interest-group-supranational-biolaw

EUROPEAN ASSOCIATION of HEALTH LAW
THE EAHL INTEREST GROUP ON SUPRANATIONAL BIOLAW

HOW TO VOTE FOR OUR PROPOSAL

1. Using your **institutional email** register at: https://webgate.ec.europa.eu/hpf/
2. During the registration process: Use the **transparency number** of your institution. If your institution does not have one, type "NA" in the box.
3. You must select UK or an EU member state under "Country".
4. The approval of your account can take a few minutes (or up to one day).
5. Once your account is approved, use this link https://webgate.ec.europa.eu/hpf/item/item/40200 to enter the EU Health Policy Platform and vote for our proposal.
6. **Thank you for your support!** Only **three projects** will be selected and will have an impact on the EU Health Policy!
7. Should our proposal be selected, please **come back** on the EU Health Policy Platform and **contribute to the discussion** on our proposal for the evolution and finalization of the joint statement!

The voting ends on 26 July

EAHL full proposal is available on the EC Agora voting page:
EAHL_Inclusive Pharmaceutical Strategy for the EU

Different approaches in neighbouring countries: Vaccination recommendations for children and adolescents aged 12-17 years in Germany and Austria

Magdalena Flatscher-Thöni
NCP for Austria

Germany

In Germany the Standing Committee on Vaccination (Ständige Impfkommission, STIKO) recommends vaccination with the mRNA vaccine Comirnaty (BioNTech/Pfizer) in children and adolescents with pre-existing diseases due to an assumed increased risk of a severe course of COVID-19 disease. The use of Comirnaty in children and adolescents aged 12-17 years without pre-existing diseases is not generally recommended at present, but is possible after medical information and if the individual wishes and accepts the risk.

For further details see Robert- Koch Institut (RKI), Epidemiologische Bulletin 23/2021, https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/23_21.pdf?__blob=publicationFile

Austria

In Austria the National Vaccination Panel (Nationales Impfgremium, NIG) recommends vaccination against Covid-19 with the mRNA vaccine Comirnaty (BioNTech/Pfizer) in children and adolescents in the age group of 12-17 years without restrictions. With this, the National Vaccination Committee follows the recommendation of the European Medicines Agency and regulatory authority EMA. The COVID-19 Vaxzevria/AstraZeneca, COVID-19 Vaccine Moderna and COVID-19 Vaccine Janssen are currently not approved for people under 18 years in Austria.

For further details see Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (BMSGPK), COVID-19-Impfungen: Anwendungsempfehlungen des Nationalen Impfgremiums (24.6.2021), https://www.sozialministerium.at/Corona-Schutzimpfung/Corona-Schutzimpfung---Fachinformationen.html

Summary

The National Vaccination Panel (NIG) in Austria recommends vaccination for children and adolescents in the age group of 12-17 years without restrictions. The Standing Committee on Vaccination (STIKO) in Germany makes a different recommendation - namely to vaccinate children and adolescents between 12 and 17 only if they have an increased risk of a severe course of disease due to previous illnesses - or are in contact with persons from this risk group.

Date of submission: 30 June 2021

Bulgaria

EU Digital COVID Certificate and Human Rights

Information about author: ***Mariya Sharkova***, *Healthcare Attorney, Managing partner at Sharkova and partners and lecturer at the University for National and World Economic, Sofia. Member of EAHL.*

Introduction:

Since COVID-19 was declared a Public Health Emergency of International Concern (PHEIC) on January 30, 2020[1], the rapid response to this public health threat resulted in enormous social and economic costs all over the world. Since the pandemic was announced, there have been continuous discussions about how to ease the burden caused by public health measures on social and economic systems.

Scholars state that the rapid response to healthcare emergencies such as HIV/AIDS and EBOLA have historically led to restrictions of human rights and unfair treatment, especially of the most vulnerable.[2] The use of various public health measures for communicable disease containment such as quarantine and isolation, home confinement, public health surveillance, travel restrictions, and restrictions to public spaces reflects on the enjoyment of the right to respect for private life, right to free movement, right to assembly, and non-discrimination.

As is stated by Sekalala, public health responses to health emergencies should be guided by human rights and therefore requires an assessment of the necessity and fairness of public health measures.[3] In these circumstances, *the most challenging task for the states is to balance infectious disease control and human rights protection.*[4] The measures to protect public health in the context of an emergency should be *transparent, non-discriminatory, and proportionate to the legitimate public health circumstances.*[5]

The proposal of the European Commission to introduce the EU Digital COVID Certificate as a cross-border instrument to facilitate travel across the EU should also be assessed from a human rights perspective. In this regard, we should discuss if those certificates comply with the principle of non-discrimination and if they affect the right to respect for private life, and freedom of movement.

The context for EU Digital COVID Certificates:

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[1] COVID-19 Public Health Emergency of International Concern (PHEIC) Global research and innovation forum 12 February 2020. Retrieved on 5 May 2021, https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum.

[2] Sekalala, S. Harrington. J: Communicable Diseases, Health Security and Human Rights in Foundations of Global Health and Human Rights, in: Gostin. Lawrance and Benjamin Mason Meier. Oxford, 2020. pp. 221:242.

[3] Sekalala, S. Forman, L. Habibi. R et.al: Health and Human Rights are Inextricably linked in COVID-19 Response. BMJ Global Health 2020, pp. 1-7. doi:10.1136/ bmjgh-2020-003359

[4] McInnes, C. and Rushton. S. HIV/AIDS and Securization Theory, European Journal of International Relations 19 (1). January, 2012. pp. 115-138.

[5] Zidar. A. WHO International Health Regulations and Human Rights: From Allusions to Inclusion. International Journal of Human Rights 19(4): 505:526.

The assessment of the EU's Digital COVID Certificates compatibility with human rights should not be done without first discussing the current restrictions and their reflection on personal rights, such as the rights to liberty, privacy, freedom of movement, respect for private life, equity, and non-discrimination. Unarguably, the current travel restrictions across the EU limit the freedom of movement. They affect not only recreational travel, but also the lives of those who commute from one country to another due to their employment, or live away from their family, are studying abroad, or seek cross-border healthcare.

The current public health strategies include testing, quarantining travelers, surveillance, and data sharing. Therefore, the proposal of the EU Commission to introduce EU Digital COVID Certificates is aimed to restore the enjoyment of the freedom of movement during the pandemic and to release some of the restrictions on the right to respect for private life. However, the certificates themselves should be guided by human rights and should be non-discriminatory.

As stated in Council Recommendation amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic[6] the EU Digital COVID Certificate *aims to contribute to facilitating the gradual and coordinated lifting of restrictions to free movement put in place, following EU law, to limit the spread of SARS-CoV-2*. The EU Certificate will verify vaccination, negative tests, or recovery, and *will facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic.*[7]

EU Digital COVID Certificate and the right to respect for private life and freedom of movement

The right to respect for private life is guaranteed by Article 8 of the European Convention of Human Rights[8] and encompasses the right to privacy, the right to bodily integrity, and also the right to identity and autonomy.[9]

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[6] Proposal for a COUNCIL RECOMMENDATION amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic COM/2021/38 final. Retrieved on 13 June 2021.https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2021:38:FIN

[7] Ibid.

[8] *Everyone has the right to respect for their private and family life, their home, and their correspondence.*
There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety, or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

[9] *Although there are many aspects of the right to respect for private life, this article will concentrate only on those aspects relevant to the EU COVID-19 Certificates.*

The right to freedom of movement is guaranteed by Article 13 of the Universal Declaration of Human Rights[10], Article 12, para. 1 and 2 of the International Covenant on Civil and Political Rights (ICCPR)[11], and Article 45 of the European Charter of Fundamental Rights[12].

Those rights should be discussed together as they are interconnected in the context of the EU Digital COVID Certificate.

Testing and vaccination, although less invasive, can be considered as interference with the right to respect for private life, particularly the right to bodily integrity. Data sharing of healthcare status interferes with the right to privacy. This is especially true when providing proof of vaccination, a negative PCR test, or a certificate of COVID-19 recovery, all of which would be mandatory for cross-border travel. In theory, the EU Digital COVID Certificate is claimed to facilitate movement across countries; however, without alternatives, it can also be accepted as a pre-condition for travel and, therefore, limit the right to free movement and the right to respect for private life.

Nonetheless, these limitations can be justified when they pursue a legitimate aim, and the means to achieve that aim are proportionate.

Equity and Non-discrimination

The principle for equity and non-discrimination stipulates that the enjoyment of the abovementioned rights should be secured without discrimination. It is guaranteed by Article 14 of the European Convention of Human Rights[13], Article 21 of the European Charter of Fundamental Rights[14] and Article 1 of the Universal Declaration of Human Rights[15].

The assessment of the EU Digital COVID Certificates in the light of the non-discrimination principle requires determining if we find different treatment in a relevantly similar situation.[16] Is there a different

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[10] *Everyone has the right to freedom of movement and residence within the borders of each state. Everyone has the right to leave any country, including his own, and to return to his country.*

[11] *Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence.*
Everyone shall be free to leave any country, including his own.
The above-mentioned rights shall not be subject to any restrictions except those which are provided by law, are necessary to protect national security, public order (ordre public), public health or morals, or the rights and freedoms of others, and are consistent with the other rights recognized in the present Covenant.
No one shall be arbitrarily deprived of the right to enter his own country.

[12] *Every citizen of the Union has the right to move and reside freely within the territory of the Member States. Freedom of movement and residence may be granted, in accordance with the Treaties, to nationals of third countries legally resident in the territory of a Member State.*

[13] *The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.*

[14] *Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.*

[15] *All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.*

[16] Guide on Article 14 of the European Convention of Human Rights and on Article 1 of Protocol No 12 of the Convention. Retrieved on 13 June 2021. https://www.echr.coe.int/Documents/Guide_Art_14_Art_1_Protocol_12_ENG.pdf, last visited on 05/26/2121.

treatment of Digital COVID Certificate holders compared to those who are not eligible for a certificate? Are the three groups (vaccinated, PCR negative, or recovered from COVID-19) within the scope of the Digital COVID Certificate treated differently? Some may argue that the EU Digital COVID Certificate will put its holders in a privileged position as they will be able to travel across the EU without additional restrictions. It is true that, unlike the International Certificate of Vaccination or Prophylaxis, known also as yellow fever passport[17] which allows only those who are vaccinated to travel to designated countries, the Digital COVID Certificate provides three different alternatives: vaccines, PCR testing, or proof of infection-induced immunity. However, for those who do not have access either to vaccines nor to testing and have not yet suffered from COVID-19, their right to free movement will be limited. At the same time, it is also true that the current measures across EU member states also limit travel for those who do not hold a certificate of a negative PCR test. These measures can also include quarantine or follow-up testing.

It is also important to mention that some inequalities may occur between the three groups within the scope of the certificate, especially in countries where PCR testing is expensive or where other tests are accepted as proof of COVID-19 confirmed case. The holders of vaccination certificates will travel without the additional expenses connected to PCR testing, while those who have not been vaccinated may be overburdened with the cost of the tests. Additionally, many citizens representing specific vulnerable groups such as refugees and minorities, have limited or even no access to testing, while others have medical contraindications for vaccination.

Also, we need to be aware that not all people who have had COVID-19 have equal access to testing and diagnostic procedures and therefore, they do not hold proof of infection-induced immunity.
Notwithstanding, one may argue that those who are immunized are less likely to get infected and spread COVID-19 and to overburden healthcare facilities. In this regard, the groups of the vaccinated and the recovered from COVID-19 present little or even no threat to public health. Therefore, they should not be treated the same way as those who are not protected by immunity. Concerning different treatment, discrimination may also occur when the state fails to differently treat persons whose situations are significantly different.[18]

This argument provokes the question: Shall we ease the restrictions for the immunized or shall we invoke the principle of solidarity and treat everyone equally until vaccines and testing are available, accessible, and affordable for all?

Legitimate aim and proportionality test:

Once we establish interference or limitations of certain rights, we need to apply the legitimate aim and proportionality test to justify the (un)lawfulness of certain limitations or unequal treatment.

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[17] WHO International Health Regulations (2005). Annex 7.
[18] Guide on Article 14 of the European Convention of Human Rights and on Article 1 of Protocol No 12 of the Convention. Retrieved on 13 June 2021: https://www.echr.coe.int/Documents/Guide_Art_14_Art_1_Protocol_12_ENG.pdf, Retrieved on 03/26/2121.

The legitimate aim of the Digital COVID Certificate is to protect public health. COVID-19 is an airborne infectious disease, and its containment depends on public health measures, including travel control and restrictions. The need to prove your immunization status or provide a negative PCR test, therefore, is justified as vaccinated persons, persons with naturally obtained immunity, or those who have tested negative for COVID-19 are less likely to spread the disease.

The protection provided by the Digital COVID Certificate aims to safeguard the right to health. One of the priority obligations of the states under the International Covenant of Economic Social and Cultural Rights (ICESCR) in General comment No 14, para 44[19] includes the obligation to take measures to prevent, treat, and control epidemics and epidemic diseases. The right to health is interrelated with public health protection. States have a positive obligation to provide *the highest attainable standard of health*[20], including measures with regards to the spread of COVID-19. However, in a situation when public health measures limit individual rights, the states should make efforts to balance public and individual interests. The Digital COVID Certificates are promoted to restore freedom of movement and reduce the economic and social burden that also reflects on the enjoyment of certain rights and freedoms. As stated in the Council Recommendation amending the Council Recommendation (EU) 2020/1475 of 13 October 2020, otherwise *unilateral or uncoordinated measures is likely to lead to restrictions on free movement that are inconsistent and fragmented, resulting in uncertainty for Union citizens when exercising their EU rights*[21].

The determination of legitimate aim is not enough to justify the difference in treatment or limitations of certain rights. There should be a balance between the public interests that the measures protect and the rights and freedoms of the individuals.[22]

The ECHR requires *a reasonable relationship of proportionality between the means employed and the aim sought to be realized.*[23]

The principle of proportionality requires taking the least restrictive measures.[24] As we have already mentioned, current cross–border rules of different countries could be very restrictive by requiring PCR testing and even quarantine for travelers. The Digital COVID Certificates, therefore, offer alternatives for the immunized and thus facilitate travel across the EU.

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[19] Toebes. B. Forman. L. Bartolini. G. Towards Human Rights Consistent Response to Health Emergencies: What is the Overlap between Core Right to Health Obligations and Core International Obligations and Core International Health Regulation Capacities. Health and Human Rights Journal, 2020.

[20] The Preamble of the WHO Constitution.Retreieved on 13 June 2021 https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=7.

[21] Proposal for a COUNCIL RECOMMENDATION amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic COM/2021/38 final. Retrieved on 13 June 2021.https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2021:38:FIN

[22] Case "relating to certain aspects of the laws on the use of languages in education in Belgium" v.Belgium (merits) *(application no 1474/62; 1677/62; 1691/62; 1769/63; 1994/63; 2126/64)*

[23] *Molla Sali v. Greece* [GC], 2018, § 135; *Fabris v. France* [GC], 2013, § 56; *Mazurek v. France*, 2000, §§ 46 and 48; *Larkos v. Cyprus* [GC], 1999, § 29).

[24] *Enhorn v Sweden* [2005] E.C.H.R. 56529/00

One may also argue that the principle of proportionality *does not justify the application of the same measures over people at little or no risk of infection*[25] and therefore, the opportunity for the vaccinated to travel without further testing or quarantine meets the requirements of the proportionality test.

Nonetheless, some have voiced concerns about society segmentation caused by limited access to vaccines and testing. The distribution of vaccines among EU state members differs from state to state and is based on the domestic vaccination policies of each country. There are some examples of a lack of fairness in Bulgaria in the past few months where the now-former Prime Minister personally ordered the opening of green corridors, which undermined the Vaccination Plan introduced by the Council of Ministers of the Republic of Bulgaria.[26] Those corridors were open while the vaccination among the priority groups was still ongoing, and the vaccine supplies were very limited. As a result, the quicker, healthier, and those living in big cities with access to the green corridors were vaccinated, while the priority groups, including the elderly and chronically ill people, remained without a jab. Poor vaccine rationing can also be a result of corruption, fraud, and lack of capacity to organize the process of vaccination.

Since the tests and vaccines are not affordable, accessible, and available equally, obtaining a Digital COVID Certificate may depend on fair vaccine distribution; affordable and available testing; access to medical care to prove that one has had COVID-19. Additionally, there are specific groups of people with contraindications for vaccination. There is a legitimate concern about the marginalization and unfair treatment of those groups.

The principle of proportionality would require the States to take specific measures to compensate for the inequalities by offering social and healthcare support for vulnerable groups such as free testing and medical services and support fair vaccine distribution based on objective criteria. We also suggest that people with contraindications for vaccination should receive an exemption from the Digital COVID Certificate as has been done with the International Certificate of Vaccination or Prophylaxis[27], or should receive additional financial support for testing should a negative PCR test still be required for them.

What is next?

Digital COVID Certificates represent documents certifying specific facts of immunity or health status. The relevancy of those facts can be further determined by each country and could be used for different purposes, other than the ones proposed by the Commission. The next question is: Can we expect those certificates to be used for access to sporting and cultural events, public spaces (museums, religious places, schools), or workplaces? For example, many US universities[28] mandate vaccinations among on-campus

[25] Sevulescu. J. Are Immunity Passports a Human Rights Issue? Journal of Medical Ethics (2021).
[26] https://www.mh.government.bg/bg/novini/aktualno/nacionalen-plan-za-vaksinirane-sreshu-covid-19-v-r/, last visited on 05/26/2021.
[27] Annex 7 (i) of the IHR, WHO.
[28] Hundreds of colleges say COVID vaccines will be mandatory for Fall 2021. 11 May 2021. Retrieved on 13 June 2021. https://www.cnbc.com/2021/05/11/hundreds-of-colleges-to-require-covid-vaccines-for-fall-2021.html

students along with hospitals[29] that require proof of vaccination from their staff. Will there be "no jab, no job" or even "no jab, no pint[30]" conditions?

Date of submission: 14 June, 2021.

[29] 178 staffers at Houston Methodist hospital suspended for not complying with COVID-19 vaccine mandate. 10 June 2021. Retrieved on 13 June 2021. https://abcnews.go.com/US/178-staffers-houston-methodist-hospital-suspended-complying-covid/story?id=78195532

[30] Newspapers headlines: "No jab no pint" an EU vaccine "peace deal" with UK. 25 March 2021. Retrieved on 13 June 2021. https://www.bbc.co.uk/news/blogs-the-papers-56518557

Report from France

English summary of the opinion of the French National Ethics Committee on Covid-19 vaccination in children and adolescents of 9 June 2021.

For full text in French click here.

Éloïse Gennet,
NCP for France

1. Background

On 27 April 2021, the French Ministry of Health and Solidarities required the CCNE to formulate an opinion on the ethical issues related to Covid-19 vaccination of children and adolescents. Yet even before the CCNE could publish its opinion, the French government announced at the beginning of June that it would open the vaccination to minors aged from 12 to 18 years on 15th June 2021.

The CCNE issued its opinion on 9th June, covering several crucial aspects.

2. A vaccine strategy aiming at a collective benefit

Any vaccine strategy aims at both individual protection against severe forms of disease and long-term collective benefit through the decrease of the risks of disease transmission and collective immunity. To reach collective immunity, 80-85% of the total population should be immune, which France is unlikely to reach solely with adult vaccination because those only represent 78,5% of the population and at least 20% of them are against or reluctant towards vaccination.

Vaccinating minors could therefore help to reach collective immunity.

3. What direct individual benefit for healthy children and adolescents?

Research shows that half of diagnosed children are asymptomatic and that less than 1,5% of patients hospitalized in the intensive care units in France were under 18 years old. Severe forms of Covid-19 are extremely rare in the pediatric population and can usually be related to at least one of these two factors: being above 10 years old or having at least one comorbidity.

Individual benefit for children and adolescents to be vaccinated is very limited.

4. Consequences of lockdown measures on the physical and mental health of children and adolescents

Several publications warned against major and lasting consequences of the pandemic on minors' psychological health, especially in underprivileged social categories. Prevention policies could thus be seen as excessive for minors.

5. Is vaccination safe for children and adolescents?

Even with the Pfizer study from April 2021, the amount of data available on rare and serious adverse events in children is insufficient compared with adults, and all the more so as data should distinguish between infants, children and adolescents as they may have different immunological reactions to the vaccine.

Former vaccination campaigns in France targeting adolescents have suffered from suspicion of causing autoimmune diseases. This later demonstrated to be false, yet the distrust remained. The history could repeat as the safety of Covid-19 vaccines has not been sufficiently monitored and evaluated.

6. What are the benefits of vaccinating children and adolescents for society?

Not all the adult population will be vaccinated and the vaccine won't be efficient on all vaccinated adults. Hence the circulation of the virus in the pediatric population can increase the risk of repeated virus exposure and of the emergence of new variants. Still, more and more publications demonstrate that children below 12 years of age are not the most frequent source of infection. The potential to transmit the virus increases with age, especially above 12 years of age.

This could justify opening vaccination for minors between 12 and 18 years old.

7. The ethical issue of minors' consent

The validity of adolescents' consent is questionable if vaccination is presented as the only chance of returning to a "normal" social active life. Besides, it is always possible for the pandemic to evolve and for lockdown measures to be adopted again despite adolescents' vaccination. This would have long-term detrimental effects on their trust in public institutions.

It is ethically questionable for society to pressure minors in bearing the responsibility of collective immunity to compensate vaccine rejection by a part of the adult population and to avoid stigmatization in case of an epidemic rebound.

Consent of minors has to be taken into account in French law, which means that minors have to be adequately informed depending on their age and level of maturity. This should include the risk/benefit balance of getting vaccinated as well as alternatives to vaccination. Yet at the current rate of vaccination, there is not enough time dedicated for individual discussion with health professionals.

8. Conclusions

The recommendation for adults to get vaccinated should be renewed while avoiding stigmatizing those for whom it is contraindicated and while fostering access for those who did not get the chance to get vaccinated.

It is important to protect the specific vulnerability of children. The individual and collective responsibility of adults is to protect them from new restrictive measures.

Vaccinating children below 12yo is scientifically and ethically unacceptable.

It is indispensable to have specific pharmacovigilance monitoring long-term effects of vaccination in adolescents

It is crucial to inform adolescents who wish to get vaccinated on the uncertainties related to the disease, to the vaccine itself and its efficacy as well as on other alternatives to prevent infection.

They also need to be informed that other strategies are implemented, in case of an epidemic rebound, to safeguard their lifestyle, education, freedom and relations.

Date of submission: 18 June 2021

Romanian vaccination campaign

Cosmin Tarnovetchi

NCP for Romania

Although Romania is one of the European Union's poorest countries, it started coronavirus vaccination campaign faster than other countries. In the first months of the year, it regularly featured among the first nations in terms of the percentage of the population that received at least one vaccine dose. But in recent weeks, the number of administered daily vaccine doses in the eastern European nation has declined. By early June, only about 25% of the eligible population had received at least one shot, placing Romania at the bottom of the EU's ranking, with only Bulgaria faring worse. About 20% of the population, making up 3.8 million people, have so far been fully inoculated. The country heavily relied on its military and intelligence services to set up quickly the infrastructure needed to roll out the coronavirus shots throughout the country. Romania has probably one of the most militarised vaccine campaigns, the online platform used for vaccine registration is administered by one of our numerous intelligence services, the Special Transmission Service.

The problem is that Romania has the largest percentage of people leaving in rural areas in the EU, around 45%. This areas have big infrastructural problems, they don't have access to medical services, internet use and access is also a problem. This lack of medical infrastructure and personnel, has plagued the country's vaccination campaign. Problems that are related to the poor infrastructure were amplified by the Romanian state's low administrative capacity to handle the critical situation. Independent experts and academics have been largely ignored by those who have overseen this campaign. The country has had no less than four different ministers of health since the pandemic began. Another issue was that "politicians were too present" in promoting the country's vaccination campaign, being known that they are not really trusted by the population. Mass media was sending "mixed messages" about coronavirus vaccination, fueling vaccine hesitancy in the country. There are some influential TV news channels which on a daily basis promote on their talk shows various public figures such as actors, actresses, singers, even medical doctors who embrace conspiracy theories about COVID or vaccination. The experts pointed the role of the Romanian Orthodox Church in a country where religious authorities are still highly influential. According to the last census, which was more than 10 years ago, about 92% or so of Romania's population declared itself religious. Out of that 92%, 86% are Orthodox but the Romanian Orthodox Church wasn't fairly supportive of the vaccination campaign. Actually, some of its bishops and influential priests have sent mixed messages, questioning the reality of the pandemic and the need to get vaccinated.

Authorities are trying to boost their vaccination logistics, especially in rural areas, bringing the vaccine as close as possible to the end-user, developing the following concepts: vaccination in the general practitioner's cabinet; door to door vaccination teams; marathon vaccination events organised in public locations that meet all sanitary criteria; deploying mobile vaccination centres in areas that have no medical personnel, even getting the jabs at Dracula’s castle in Transylvania without an appointment.

Among all this measures, the expert think that usefull measures would be: the relaxation of rules to vaccination, involving experts to try to combat the conspiratorial views on these issues and allocating more money to do this.

Date of submission: 21 June 2021

Overview of the Covid-19 vaccination, Passports and new requirements.

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

1. The Covid-19 vaccination. Rate of progress.

The vaccination process is being developed in Autonomous Communities following the phases of the official strategy. Currently in Spain, 25 million people (52.7%) have received at least one dose of the vaccine, and 17 million people (36%) are already fully vaccinated.

Health services of Autonomous Communities have already administered almost 40 million doses, increasing the rhythm of vaccination during the month of June.

It is important to point out that vaccination figures varies among regions: all regions have more than 50 % of the population vaccinated with at least one dose, with the exception of Melilla. And with the full schedule, all regions have already exceeded 30 % of the vaccinated population.

Talking about next goals, health authorities estimate to have vaccinated approximately half of the population by 19 July, using health centres and other infrastructures prepared to carry out mass vaccinations.

Finnally in this section, it should be remarked that vaccination in people aged 12 years and older is estimated at 59.4 % with at least one dose and 40.6 % with full vaccination, according to official reports from the Ministry of Health.

2. The "Covid Passport".

The "Covid Passport" began to be implemented in Spain in June, being one of the first European countries to participate in the technical tests for its implementation. Tests on the use of the QR codes have been successfully completed, in addition to the use of its authenticity keys.

This document has a dual format, digital and paper, and is issued, stamped and delivered by Autonomous Communities. It is free of charge and its contents include, among other data, the number of doses and when they were administered to each traveller.

At this moment, this passport could be extended to non-EU countries, being discussed currently with the European Commission.

3. Current legal framework and restrictions.

Since last Saturday, Royal Decree Law 13/2021 has modified the regulation on the use of the mask contained in Law 2/2021. The evolution of the Covid-19 epidemic and vaccination in Spain have allowed to consider the beginning of a progressive reduction of social restrictions.

Thus, masks can be removed outdoors, but it is needed to maintain a distance of at least 1.5 metres from other people (unless they are cohabitants). However, the use of the mask remains indoors (shops and offices for instance), in any type of public transport or on streets in case of interact with people.

It will also be compulsory to wear a face mask on any kind of public transport: planes, trains, buses, taxis, boats... On boats or ships, it will not be compulsory to wear it on deck if there is an interpersonal distance of 1.5 metres, or in private cabins.

In addition, face masks are mandatory at large events, even in open spaces, when the audience is standing. For example, at an open-air concert, unless the audience is seated and the distance of one and a half metres is maintained.

Regarding to seating capacity at sporting events, the article of the New Normal Law that limited it has been removed. Thus, the public in football stadiums and basketball courts is restored, although the specific capacity will be determined by regional authorities.

In addition to this, masks are no longer mandatory in nursing homes or other institutionalised settings (except for visitors and workers who must continue to wear them), or indoor settings for essential workers where 80% of population is vaccinated.

Moreover, some Autonomous Communities are monitoring weekly the incidence of the virus at local level, in order to regulate capacity in specific public areas.

4. Requirements for travellers from United Kingdom.

At last, new requirements for travellers from the United Kingdom come into force in July. Consequently, british travellers need a negative PCR or antigen test carried out 48 hours before arrival, or being full vaccinated to cross borders. In any case, the last dose must be at least 14 days before travel.

Date of submission: 30 June, 2021.

9th World Sustainability Forum (WSF2021)

WSF2021 will be held from 13 to 15 September 2021: https://wsf-9.sciforum.net/.

WSF2021 is an international scientific conference coordinated by the MDPI Sustainability Foundation, under the patronage of the University of Basel. With this event, we hope to contribute to building a platform and network for a sustainability agenda that fosters partnerships among stakeholders beyond the boundaries of academic disciplines, narrow national agendas, and quarterly spreadsheets. We hope that this forum will contribute to the global debate as the world contemplates returning to a new normal and will contribute to establishing platforms and networks among stakeholders including lawmakers, commerce, the general public and academic disciplines. The aim is to bring structure to the vision of a sustainable world which deals fairly and transparently with the multifold issues of sovereignty, governance and society that have arisen in the pandemic.

NEXT EAHL conference – updated information!

The next EAHL conference to be held on **20-22 April 2022**!

EAHL will have a digital General Assembly in the autumn (tentative date 14 October).

EAHL

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

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

eurohealthlaw@gmail.com

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

EAHL membership prices:

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

For more information, please, visit:

http://www.eahl.eu/membership

IMPORTANT NEWS!

The next EAHL conference to be held on 20-22 April 2022!

Ghent University, Belgium.

More details to follow!

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