

## **LEGAL CHALLENGES OF COVID-19 VACCINE CERTIFICATES**

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### **Abstract**

*Even after more than a year since the declaration of the COVID-19 pandemics, the European Union tries to find means on how to loosen measures restricting free movement. After not such a successful start of mobile tracing applications and due to the gradual vaccination, the European Commission has decided to prepare a legislative proposal on „Digital green certificate“. Their aim is to safeguard free movement of persons within the EU via a coordinated activity. The article provides general information on the legislative proposals, legal challenges with regards to EU competencies, privacy and health in the EU and deals also with the aspect of proportionality and legitimacy. Its conclusion includes points for further discussion and recommendations.*

### **Key words**

COVID-19, human rights, competencies of the European Union, Digital green certificate, free movement of persons in the European Union, proportionality, legitimacy

### **Introduction**

As the pandemic situation linked with COVID-19 pertains, Member states are desperately trying to find ways to enable citizen's free movement right, provide with health safeguards and let the European Union citizens' lives back to normal. The European Commission submitted a proposal on Digital green certificates as a tool to facilitate free movement within the EU and potentially third countries. It shall include information about vaccination, testing or recovery from the COVID-19 infection. It is declared that it will not be discriminatory and that fundamental rights are one of the elements that would need to be in line with. On contrary, lack of sufficient assessment and scientific data only raise question marks whether such a system would not go beyond the limits of privacy rights of individuals.

In addition, the interlinked elements of health and free movement have been the center of debates with regards to the EU competencies due to its unclear and rather open provisions provided by the establishing Treaties. The fact that the Digital Green Certificates are established

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on the basis of a regulation leads to concerns whether such a legislative tool is not too excessive with regards to the EU competencies.

The article provides with legal challenges of the proposal on Digital Green Certificates. It focuses mainly on the question of EU competencies, however offers also information on more concrete legal aspects such as privacy issues from the point of view of vaccination and personal data protection. Throughout the text, a reader may find also general information on how the vaccination system works on a more global level and what are the competencies to require vaccination or to declare state of emergency.

## **1 Legal background on international vaccination system**

### **1.1 Declaration of state of emergency**

European Union, unlike WHO does not dispose of a competence to declare a state of emergency universally applicable for all Member States. Such powers lie with each Member State itself on the basis of their national legal framework or the WHO declaration as stated in part 1.2 of this article. Without any distinctive powers, the EU thus follows the rules of the WHO and aims its position within its sphere of competences, i.e. coordination in case of a cross-border health crises with regards to the internal market.

### **1.2 Legal aspects of cooperation between the European Union and WHO**

On the EU level, the cooperation with the International organizations is determined in Title VI of the Treaty of the Functioning of the European Union (hereinafter as “TFEU”). In addition, questions concerning public health shall be fostered by the cooperation with competent international organizations, providing the European Union with the shared competence.

It is important to study on what basis the cooperation between the two entities work. The clearest interlink is visible within the area of the internal market. What is necessary to verify is the coordination among the national competence of each Member State, the European Union as a separate entity and WHO as an international organization with its own legal stand. The definition of restriction of free movement as a part of the internal market can be seen also in the secondary legislation, i.e. Directive 2004/38/EC on the right of citizens of the Union and

their family members to move and reside freely. Its provisions concerning restriction of free movement on the basis of public health determine that a restriction can be justified only due to diseases of epidemic potential. Recognition or definition of a disease of epidemic potential is given to WHO or the Member State itself.

Observing the provisions, it is clear that the European Union, as a single entity, cannot declare a state of emergency due to the diseases of epidemiological character. It can be either a Member State itself or on the basis of WHO declarations. The WHO neither has a position whose decisions would become legally binding. Thus the WHO does not dispose of exclusive powers over the national Member States ones. Its declarations are either of a recommendation character or represent a tool of international law which is not enforceable within the same context as primary or secondary law of the Member State or the EU. As a result, the executive mechanism and a potential enforcement lies with a Member State after its prior verification comparing with their national legal framework.

Having a look into the secondary law of the European Union, the Regulation on establishment of the European Medicine Agency<sup>2</sup> provides it with a competence to participate in an international scientific dialogue with WHO. It neither does provide with competencies to declare state of emergency. Particularly, it provides with cooperation with WHO in matters concerning pharmacovigilance, as well as reporting any adverse reactions of medicinal products.

## **2 Digital Green Certificates proposals**

In March 2021, the European Commission adopted two Proposals for Regulations of the European Parliament and of the Council on Digital Green Certificates, one for the EU citizens<sup>3</sup>

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<sup>2</sup> European Medicine Agency (EMA) was established in 2004 with the aim to better coordinate the scientific evaluation of medicinal products within the European Union territory, to coordinate and monitor medicinal products, distribute information on pharmacovigilance, create a database of safe medicinal products, as well as to follow up on the existing medical products for the purposes of further use. In addition, it is the body responsible for the market authorization of medicinal products via its competent Committees. While the EMA has the competence to authorize a certain medical product to be placed on the market within the European Union and may equally impose penalties and sanctions on the Member States not complying with the rules, it does not have the exclusive competence over the market authorization process. A Member state has a full right and competence to authorize market authorization for medicinal products on the national level. In addition, when it comes to medicinal products imported from a third country, the exclusive competence to grant an authorization lies with the competent authorities of the Member State where the medical product was imported to unless an international agreement between the Union and the exporting state decides otherwise. It is however the role of the EMA to sort out possible conflicts between scientific opinions of Member States and the Agency.

<sup>3</sup> Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), COM/2021/130 final.

and one for third-country nationals wishing to or residing in the EU territory<sup>4</sup>. The aim is to create a coordinated and consistent mechanism to be approved and valid in all EU Member States in order to safeguard free movement of EU citizens as granted by Article 21 of the TFEU.

The proposed system, which seems to reflect the WHO system of vaccination passports, aims also to coordinate and unify the approach and mechanism of the PLF forms<sup>5</sup> within the EU. In addition, the explanatory memorandum of Proposal for Digital Green Certificate well includes the attempt to coordinate and cooperate with WHO on this matter. The WHO has designed a „Smart Vaccination Certificate Working Group“ (hereinafter as SVCWG) whose aim is to define the challenges and recommendations in order to provide common standards and governance for security, data exchange and privacy, as well as establishing a mechanism of vaccination certificate trusted worldwide. The cooperation with WHO and the EU's active inclusion in the SVCWG is thus crucial to be able to create a unified, well-coordinated, efficient and proportionate system.

Unlike previously with mobile tracing applications, when the system including cross-border threats was based on Decision 1082/2013/EU of the European Parliament and the Council, the Digital Green Certificates mechanism is reflected in the legal act of the Regulation of the European Parliament and the Council despite the fact that the technical safeguard somewhat shows signs of remarkable similarities with the mobile tracing applications. Both systems are to be based on the mechanism of a Digital Green Certificate Gateway, i.e. creation of technological interoperable patterns to enable various national systems to be compatible. Further, information about vaccination, COVID-19 test results or immunity followed by infection shall be portrayed on a backend of a mobile application (if not in paper format) to be submitted once travelling.

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<sup>4</sup> Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate), COM/2021/140 final.

<sup>5</sup> Passenger Locator Form.

### **3 Legal challenges of the proposals**

#### **3.1 EU competences in the field of health**

The competences of the European Union in the sphere of health are determined in the TFEU and it is mentioned in two areas of competence, i.e. shared on one hand and supporting and coordinating on the other. The notion of Article 4, paragraph 1 clearly indicates that shared competence is applied in the areas, which do not fall under the remit of exclusive or coordinative competences. The shared competence in the area of health concerns common safety in public health matters. With this regard, the Union's action in public health has primarily a coordinative competence unless it concerns, amongst others, fighting against the major health scourges, early warning and combating serious cross-border threats to health.

The provisions of the Treaty are however not that clear when determining the EU competence, mainly due to two main factors. Firstly, applying the principle laid down by the TFEU on shared competences, any scope concerning public health should primarily belong under the coordinative competence unless otherwise determined. Although TFEU explicitly mentions the spheres of action (e.g. cross-border health scourges and combating serious cross-border threats to health), the European Union must not provide with provisions harmonizing the regulations and laws of the Member States linked therewith. Secondly, the European Union is yet still obliged to respect the responsibilities of the Member States with regards to the definition of their health policy, its organization and management of health services. Such a division is often criticized defining it as exceeding of the EU's regulatory legitimacy.

It is important to clarify that even if TFEU determines that legislative acts of the European Parliament and the Council may be adopted within the ordinary legislative procedure in order to meet common safety concerns relating to standard of quality and safety of organs, human organ substances and blood, veterinary and phytosanitary fields and quality and safety of medicinal products, it does not mean that other areas may not enjoy to be regulated by a legal measure. With regards to the cross-border threats to health, the Council and the Parliament adopted a decision with the aim to tackle the issues stemming from a cross-border character of a threat to health, particularly by coordinating the Member States in order to adopt the most efficient approach.

It is obvious that the competence of the European Union in the public health sphere is questionable due to the character of two areas of competences. On the other hand, internal market area belongs explicitly under the shared competence of the EU. In addition, the latter is more clearly defined throughout the practice. Legal acts concerning health aspects in relation to free movement could be found on many occasions. Cases concerning health interlinked with an internal market element might trigger a notion of a clearer determination of competences given to the EU with regards to the internal market. The harmonization aspect has been confirmed also by the case-law of the European Court of Justice. However the harmonization of these two areas of competence seems to be the subject-matter of many important disputes, particularly with regards to tobacco.

Reflecting the interpretation of the EU competences above, the European Union does not envisage having a competence over the vaccination policies of Member States as such. It however may enter into the sphere of combating cross-border health threats unless harmonizing national laws of Member States.

Interestingly, concerning the legal basis empowering the European Union to intervene into the pandemic situation with the Digital Green Certificate proposal, the Commission preferred not to use the EU competences in the area of health, however its competences in the sphere of internal market and basic principles of subsidiarity and proportionality. It refers to the fact that the EU may act in case in order to facilitate the right to move and reside freely within the territory of the European Union. With regards to the basic principles, it bases itself on the statement that the uncoordinated and not unified approach of COVID-19 measures lead to restrictions of free movement and uncertainty for the EU citizens when exercising their EU rights. Last but not least, the EU is convinced that proposing and creating a vaccination certificate system is necessary to be done on the EU level, because only then a favorable outcome can be sufficiently achieved.

### **3.2 Intervention into privacy as a fundamental right**

#### **3.2.1 Personal data**

One of the main part of the Digital Green Certificate proposal is the establishment of a digital framework on the EU level, where the Member States shall each create its own digital

platform collecting personal data and then interlink its system with systems of other Member States in order to share more easily the relevant data on vaccination, testing or recovery. Thus a more facilitated movement of EU citizens shall be determined. According to Article 9 of the proposed Regulation, the personal data may be collected only for the purpose of issuance the certificates and accessible to national authorities or cross-border transport services authorized by national authorities. In its third paragraph, it also emphasizes that the personal data can be processed no longer than the period for which the certificates may be used to exercise the right to free movement.

Despite the will of the Member States to use the personal data also for other purposes, the Commissioner Didier Reynders explicitly remarked that the proposal was not to create a legal basis for other use by the Member States than the one of a free movement spelled out in the proposal<sup>6</sup>. On the other hand, the Digital Green Certificates may be used by Member States on their national level as well, if provided for in national law<sup>7</sup>. According to the text of the proposal, the processing of personal data among Member States will be held within a joint controllership.

Concerning the time of validity, the framework shall be suspended once the COVID-19 pandemic will be overcome. There is no particular definition of the time of suspension, but one may presume, on the basis of the relations of the WHO and the EU, that it would be only after the WHO will declare the status back to normal.

With regards to the creation of a digital framework and in spite of no political, nor decision-making power, it is important to mention the existence of the European Health and Digital Executive Agency (hereinafter as “HADEA”), an executive agency established in 2021. HADEA replaces the position of the previous agency called CHAFEA. It is entrusted to follow the implementation of the Union programs concerning health and digitalization. By means of delegation, apart from others, it specializes on Digital Europe program, program for single market and Horizon Europe project for research and innovation. Observing the structure and content of the legal framework, it seems that HADEA could play a key role in creation and implementation of the future vaccination passports.

It is undisputable that the system to be established will include processing of a vast amount of special categories of personal data, i.e. health data which, accessible to many national

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<sup>6</sup> <https://www.euractiv.com/section/coronavirus/news/council-ready-to-negotiate-on-covid-travel-certificate/>.

<sup>7</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_2593](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2593).

authorities and potentially other entities for a rather long period of time. In these instances, the Regulation 679/2016<sup>8</sup> (hereinafter as “GDPR”) envisages an impact assessment. Apart from a brief reference on the data protection subject and a reassurance of being in line with the GDPR rules, no thorough assessment has been undergone due to the time constraints.

In addition, it is also more than questionable how the system is to be suspended once the data will be already collected. Lacking sufficient scientific data and sound guarantees, it may not be excluded that it would lead to potential discrimination issues. On a broader aspect, it will only be interesting how the flow of the personal data in the form of the certificates will be established vis-a-vis third countries, particularly those that do not provide sufficient safeguards of fundamental rights. The rather recent case of Schrems II disabling a safe transfer of personal data to the US or Brexit could have a particular impact on these areas.

### **3.2.2 Vaccination and privacy matters**

On the basis of the case law of the European Court of Human Rights, vaccination is considered to be a serious intervention into the privacy of an individual. Protection of the privacy is anchored in many national and international documents. It is inevitable to mention that many EU countries do not even recognize an institute of obligatory vaccination. Those systems, when the obligation is required indirectly in order to profit from other fundamental rights keep struggling with the privacy aspect as a fundamental right.

In the recent case *Vavricka and others vs. Czech Republic*<sup>9</sup>, the Court deemed it proportionate that a child which was not vaccinated could not have attended kindergarten. It is only questionable how the Court would decide should we not have the pandemic situation. However, the crucial element in these terms is proportionality. The global system of vaccination within the COVID-19 pandemics without any sufficient scientific evidence raises a question on proportionality as well. There is not enough evidence on the vaccine behavior yet, nor the potential of getting infected even after vaccination. Linking the vaccination to free movement seems as an indirect obligation. Under the current conditions, the vaccination should not be used for the purposes of free movement, however only from the medical reasons.

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<sup>8</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), OJ L 119, 4.5.2016, p. 1–88.

<sup>9</sup> <https://hudoc.echr.coe.int/fre#%7B%22itemid%22:%5B%22001-209039%22%5D%7D>.



Concerning the privacy issue, the proposal includes provisions in its Article 10 that a Member State may require testing or a quarantine even after having been vaccinated. On one hand, such a system is established in order to prevent from discrimination on people who do not wish to get vaccinated, however, it can be only considered as disproportionate with regards to the intervention into the privacy to people already vaccinated. Having an individual vaccinated and potentially request testing or quarantine and thus restrict their rights is disproportionate.

Last but not least, the element of timing and the access to vaccines, as well as mutual recognition of vaccines by Member States is not yet uniformly established and could thus lead to disputes in the future.

### **3.2.2 Precautionary principle**

As defined by a Communication to the Commission on precautionary principle: “... the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty. The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty”.<sup>10</sup> The principle is based on proportionality, non-discrimination, consistency, examination of potential benefits, review and capability to assign responsibility for producing the scientific evidence. Despite the fact that this principle has been so far applied rather in the sphere of environment and world trade, there is no provision not allowing to apply it on the situation of the COVID-19 pandemics. Reading the definition, establishment of a global vaccination system imposes an intervention into fundamental rights yet not knowing all the scientific evidence of its efficiency. As a consequence, applying the precautionary principle, the lack of impact assessment, the consistency and even proportionality would serve as a precondition of not applying the precautionary principle and can be considered as a system intervening into the fundamental rights disproportionately.

In addition to the above, one may even question the factual necessity of global vaccination and digital certificates system. The mere existence of pandemics cannot establish

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<sup>10</sup> Communication from the Commission on the precautionary principle, COM(2000) 1 final, 2.2.2000.

necessity unless proportionate, efficient and based on evidence. In this case, it is evident that there are other, yet less intrusive, means to tackle the spreading of pandemics. The answer on necessity, i.e. legitimacy, was addressed in the proposal as a statement rather than a proper legal justification. However, it is probable that a thorough evaluation could lead us to a negative answering to the legitimacy and the question on precautionary principle would become irrelevant.

## **Conclusion**

The proposed Digital Green Certificates regulation somewhat escapes from the currently established mechanism. Even though historically, the European Union applied its powers to establish certain rules concerning free movement at the times of cross-border health crisis. Such measures have been so far formed on the basis of instruments not directly binding in the Member States or via recommendations in order to better coordinate the discrepancies caused by a specific situation on a short term basis.

However, proposing a regulation as the legal tool, the short term and indirect aspects are faded out. By means of such an act, one may be hesitant whether the already fragile limit of competencies in the public health area are not a materialized evidence of an extension of the EU competencies. Creation of a vaccination certificate mechanism could serve as a strong precedent easily leading to strengthening of the EU powers with regards to the Member States.

From the perspective of vaccination, the current regime seems not to answer to all the major privacy rights issues and its focus on the will to enable the life “back to normal” obscures a thorough assessment of the potential impacts. In addition, it lacks to address a more elaborated evaluation. Since the system is already rather developed, it will create a dangerous precedence for future cases. It will then lie with judicial powers to shape the limits of application.

To conclude, adoption of the Digital Green Certificates would lead to strengthening of the EU competences in case of pandemics and its role in reference to the relations with WHO. The “internal” relation of the EU and Member States will be subject to future debates. The interlink between the aspect of free movement and health matters could lead to discussions and follow-up actions with regards to the EU competences. The debates on vaccination will become a key topic as it stands on the crossroad on its future direction.

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