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# Committee on Legal Affairs and Human Rights

# Preventing vaccine discrimination

# **Report**<sup>\*</sup>

Rapporteur: Ms Thorhildur Sunna Ævarsdóttir (Iceland, Socialists, Democrats and Greens Group)

# A. Draft resolution

1. The Assembly recalls its work carried out in response to the Covid-19 pandemic and the measures taken to counter it, in particular its <u>Resolution 2329 (2020)</u> "Lessons for the future from an effective and rights-based response to the Covid-19 pandemic", <u>Resolution 2338 (2020)</u> "The impact of the Covid-19 pandemic on human rights and the rule of law", <u>Resolution 2383 (2021)</u> "Covid passes or certificates: protection of fundamental rights and legal implications", <u>Resolution 2361 (2021)</u> "Covid-19 vaccines: ethical, legal and practical considerations", <u>Resolution 2424 (2022)</u> "Beating Covid-19 with public health measures" and <u>Resolution 2455 (2022)</u> "Fighting vaccine-preventable diseases through quality services and anti-vaccine myth-busting".

2. The Assembly recalls that during the Covid-19 pandemic, Council of Europe member States have imposed various measures to restrict access to their territories (such as Covid passes, quarantine or self-isolation, bans on entering their territory, obligation to register or to carry out Covid-19 tests shortly before or after arrival, etc.). Some of them also decided to restrict access to public venues (such as bars, restaurants, sport, leisure, event and other venues) or even to some means of public transportation.

3. The Assembly recalls that, in accordance with the European Convention on Human Rights (ETS No. 5, "the Convention"), public health may constitute a legitimate purpose justifying restrictions on the rights to respect for private life (Article 8), freedom of assembly and association (Article 11) and freedom of movement (Article 2 of Protocol No. 4 to the Convention; ETS No. 46), any restrictions on the aforementioned rights must be "prescribed by law", "necessary in a democratic society" and proportionate to the legitimate aim pursued.

4. The Assembly notes that compulsory vaccination can raise issues under international human rights standards, in particular the right to respect for private life (Article 8 of the Convention) and the right to give free and informed consent to any intervention in the health field, which is enshrined in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Medicine ("Oviedo Convention", ETS No. 164). The Assembly notes that the starting position for a vaccine is that it should not automatically be generally mandatory, but notes that mandatory vaccination may sometimes be appropriate; for example for special professions such as those exposed to vulnerable populations. The Assembly also notes the cases pending before the European Court of Human Rights concerning mandatory vaccination for specific workers.

5. The Assembly recalls the information document "Protection of human rights and the 'vaccine pass'" issued by the Secretary General of the Council of Europe, the "Statement on human rights considerations relevant to 'vaccine pass' and similar documents" issued by the Council of Europe Committee on Bioethics (DH-BIO) and the statement "Covid-19 vaccination, attestations and data protection" issued by the Council of Europe Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD).

<sup>&</sup>lt;sup>\*</sup> Draft resolution and draft recommendation unanimously adopted by the committee on 5 September 2022.

6. It notes that the use of "Covid passes", and in particular of vaccine certificates, entails risks of infringements of human rights and fundamental freedoms. Those risks are further exacerbated when there are inequalities in access to vaccination against Covid-19. Moreover, the introduction and the use of Covid passes has in many instances led to distinct treatment of persons who have been vaccinated against Covid-19 and those who have not, as well as to possible discrimination between persons vaccinated with different vaccines. This may amount to unlawful discrimination within the meaning of Article 14 of the Convention if it does not have an objective and reasonable justification. The Assembly recalls that any inequality in treatment must pursue a legitimate aim and be proportionate; proportionality requires a fair balance between protecting the interests of the community (the legitimate aim) and respect for the rights and freedoms of the individual.

7. Referring to its <u>Resolution 2383 (2021)</u> "Covid passes or certificates: protection of fundamental rights and legal implications", the Assembly again stresses that measures such as the introduction of a Covid pass must be applied only in a context of fighting the pandemic and in compliance with the European Convention on Human Rights. There should also be clear and well-established scientific evidence showing that the adoption of such measures lowers the risk of transmission of SARS-CoV-2 to an acceptable level from a public health point of view. Any system of Covid passes should be limited in time according to the requirements of the public health emergency. Moreover, as stressed in Assembly's Resolution 2424 (2022) "Beating Covid-19 with public health measures", vaccination certificates should primarily be used for "their designated purpose of monitoring vaccine efficacy, potential side effects and adverse effects.

8. The Assembly recognises the introduction of the European Union Digital Covid Certificate (EUDCC), as an instrument for facilitating freedom of movement within the European Union within the context of the various travel restrictions during the Covid-19 pandemic and that that this type of system has also been used by numerous non-EU Council of Europe member States and other States.

9. The Assembly further notes that the EUDCC was also used for other domestic purposes such as limiting access to certain public venues and is concerned that such practices may lead to discrimination and other violations of human rights and fundamental freedoms.

10. The Assembly notes that although the European Medicines Agency (EMA) has granted conditional authorisation for the marketing of only six vaccines,<sup>1</sup> some member States of the Council of Europe administered other vaccines, including those listed only by the World Health Organisation (WHO) under its Emergency Use Listing (EUL) process or national authorities. The Assembly is worried that the use of Covid and vaccine passes may lead or might have led to discrimination in travelling and access to public venues between persons vaccinated with different vaccines, including those which have been approved only by the EMA, and those which have been listed only by the WHO.

11. The Assembly notes with satisfaction that the recognition of WHO-listed vaccines is now more and more widely accepted within the EU. However, while EU member States are free to limit access to public venues and to impose additional restrictions on non-EU citizens' access to their territory, which may lead to discrimination.

12. In the Assembly's view, vaccination against COVID-19 has made a major contribution to overcoming the pandemic. This has facilitated the lifting of various COVID-19 related restrictions and therefore indirectly restored the full enjoyment of many fundamental freedoms. Nevertheless, the pandemic is not yet over and new infringements on human rights and fundamental freedoms may still occur in the future. The Assembly therefore calls on all the member States to:

12.1. refrain from imposing further restrictions to individuals' human rights and fundamental freedoms, unless it is strictly necessary to achieve the legitimate purpose being pursued. All restrictions must be compliant with the requirements stemming from the Convention and the case law of the European Court of Human Rights;

- 12.1.1. they must be prescribed by law;
- 12.1.2. they should be in force for the shortest possible time;

<sup>&</sup>lt;sup>1</sup> Comirnaty (developed by Pfizer and BioNTech; BioNTech Manufacturing GmbH), Jcovden (previously Covid-19 Vaccine Janssen) (Janssen-Cilag International NV), Nuvaxovid (Novavax CZ, a.s.), Spikevax (previously COVID-19 Vaccine Moderna) (Moderna Biotech Spain S.L.)<sup>1</sup> and Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (AstraZeneca AB) and COVID-19 Vaccine (inactivated, adjuvanted) Valneva (Valneva Austria GmbH).

12.1.3. they must be proportionate to the pursued aim;

12.1.4. they must be effective.

12.2. take full account of the latest scientific evidence and expert knowledge, including that from the WHO, when deciding on restrictions to human rights and fundamental freedoms or on relaxation of such restrictions

12.3. treat equally all people vaccinated a against Covid-19 by a vaccine approved either by the EMA or by the WHO, whose evaluation under the EUL procedure enables a thorough assessment of the quality, safety and effectiveness of vaccines;

12.4. mutually recognise Covid passes issued by other Council of Europe member States;

12.5. refrain from preventing individuals from exercising their human rights and fundamental freedoms because they have not been vaccinated or because they have been vaccinated with a vaccine which is not approved by the EMA;

12.6. avoid discrimination between those who have been vaccinated against Covid-19 and those who have not or cannot be vaccinated, either for medical or other reasons;

12.7. avoid discrimination between people vaccinated against Covid-19 with different vaccines approved by different organisations;

12.8. discontinue the use of Covid passes for other uses than those which are strictly necessary to achieve a legitimate purpose.

13. The Assembly also calls on Council of Europe member States which have not yet ratified the Oviedo Convention (and/or Protocol No. 12 to the European Convention on Human Rights (ETS. No. 177) to do so without delay.

14. It also calls on Council of Europe member States which do not belong to the European Union to recognise the European Union Digital Covid Certificate.

15. The Assembly invites the European Union and its member States to:

15.1. refrain from imposing additional restrictions to free movement unless strictly necessary to achieve the legitimate aim pursued, including to that of EUDCC holders;

15.2. require the EUDCC only as a measure of last resort and to reassess its usefulness on a regular basis in the light of an epidemiological assessment,

15.3. elaborate common standards as regards the length of validity of the EUDCC;

15.4. respect the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union, when implementing Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, and other related EU legal acts.

16. Finally, the Assembly calls on all Council of Europe member States and other States to:

16.1. ensure proper funding to the WHO;

16.2. submit their national regulatory systems to the WHO Global Benchmarking Tool (GBT) in order to allow them to become WHO-listed authorities (WLAs).

#### B. Draft recommendation

1. Referring to its Resolution .... (2022) "Preventing vaccine discrimination", the Parliamentary Assembly recommends that the Committee of Ministers:

1.1. establish a list of human-rights compliant and effective practices as regards the use of Covid passes during the Covid-19 pandemic, with a special focus on the purposes for which they were used, the conditions under which they were issued and the period of their validity;

1.2. reflect on the impact of Covid passes, and in particular vaccine passes, on human rights and fundamental freedoms, and to consider how best to ensure that such measures do not constitute discriminatory practices in light of Article 14 of the European Convention on Human Rights (ETS No. 5);

1.3. exchange information on these issues with other international organisations such as the United Nations, the World Health Organisation and the European Union, and reflect, in co-operation with them, on the need to establish further common standards on measures to counter the Covid-19 pandemic.

1.4. provide input to the Intergovernmental negotiating body to draft and negotiate a WHO International Treaty on Pandemic Prevention, Preparedness and Response, with the aim of ensuring its compatibility with Council of Europe human rights standards.

# C. Explanatory memorandum by the rapporteur, Ms Thorhildur Sunna Ævarsdóttir

#### 1. Introduction

#### 1.1. Procedure

1. Following a motion for a resolution entitled "Preventing vaccine discrimination",<sup>2</sup> tabled on 10 September 2021 by Mr Ahmet Yildiz (Türkiye, NR) and others, at its meeting held in a hybrid manner in Paris on 7 December 2021, the Committee on Legal Affairs and Human Rights (the committee) appointed me as rapporteur on this subject. On 28 April 2022, the committee considered my introductory memorandum and authorised me to carry out a fact-finding visit to the headquarters of the World Health Organisation in Geneva (Switzerland), and to send out a questionnaire via the European Centre for Parliamentary Research and Documentation (ECPRD). On 23 May 2022, during its meeting in Paris, it held a hearing, which also covered the follow-up to Parliamentary Assembly's <u>Resolution 2383 (2021)</u> on "Covid passes or certificates: protection of fundamental rights and legal implications",<sup>3</sup> with the participation of Ms Karine Lefeuvre, Vice-President, National Ethical Consultative Committee for life sciences and health, Paris (France) and Mr Jan Rohde-Stadler, Team Leader on COVID-19 Free Movement issues, Directorate-General for Justice and Consumers, European Commission, Brussels (Belgium). On 22 August 2022, I carried out a fact-finding visit to the headquarters of the World Health Organisation (WHO) in Geneva, where I met Dr Rogério Gaspar, Director, Regulation and Prequalification Department, Access to Medicines and Health Products Division.

#### 1.2. Motion for a resolution

2. The motion for a resolution focuses on the issue of discriminatory treatment stemming from the use of different Covid-19 vaccines and recalls that some Council of Europe member States have restricted freedoms of persons who have not received vaccinations. Referring to the Assembly's Resolution 2383 (2021) "Covid passes or certificates: protection of fundamental rights and legal implications" and to Article 14 of the European Convention on Human Rights<sup>4</sup> ("the Convention" or "the ECHR"), the movers of the motion stress that the "preferential treatment" of persons who got vaccinated against Covid-19 should not lead to "unlawful discrimination" among vaccines listed by the World Health Organisation (WHO). They deplore the fact that some Council of Europe member States "(...) started to restrict the *freedom of movement* of people who received WHO-approved vaccines" and consider that "imposing restrictions on people vaccinated with vaccines approved by the WHO does not have an objective and reasonable justification within the meaning of Article 14 of the Convention". Such restrictions "(...) fail at striking a balance between protecting the interests of the community and the rights and freedoms of the individuals, as the individuals in question are vaccinated" approved vaccines pose significantly less risk than those who have not been vaccinated."

3. Referring to Assembly's Resolution 2338 (2020) "The impact of the Covid-19 pandemic on human rights and the rule of law",<sup>5</sup> the movers of the motion for a resolution recall that although Council of Europe member States have positive obligations to protect the health of their citizens, the measures they take in this respect "(...) should not contravene the Convention, *as well as the rights and freedoms of citizens of other countries.*" Therefore, it is proposed that the Assembly should examine "the disproportionate measures restricting the freedom of movement of people vaccinated with the WHO-approved vaccines and suggest measures to ensure that the rights of these people are not violated", in line with the Convention and other international legal instruments.

#### 2. Issues at stake

4. Within the Assembly, a number of reports, resolutions and recommendations on issues arising from the handling of the Covid-19 health crisis have been adopted but they do not focus specifically on the issue of discrimination based on different types of vaccines against Covid-19.<sup>6</sup> Most of them dealt with the general principles that had to be observed while handling the pandemic. For example, in <u>Resolution 2338 (2020)</u>, the Assembly called on member States of the Council of Europe to "ensure that all measures restricting human

<sup>&</sup>lt;sup>2</sup> Doc. 15361. Reference 4607 of 27 September 2021.

<sup>&</sup>lt;sup>3</sup> Adopted by the Assembly on 22 June 2021. On the basis of a report of this committee, rapporteur: Mr Damien Cottier (Switzerland, ALDE), <u>Doc. 15309</u> of 7 June 2021.

<sup>&</sup>lt;sup>4</sup> ETS No. 5.

<sup>&</sup>lt;sup>5</sup> Adopted by the Standing Committee on 13 October 2020, on the basis of a report of this committee, rapporteur: Mr Vladimir Vardanyan (Armenia, EPP/CD), <u>Doc. 15139</u> of 16 September 2020.

<sup>&</sup>lt;sup>6</sup> For the list of texts adopted by the Assembly in relation with the handling of the Covid-19 pandemic see: <u>https://pace.coe.int/en/pages/covid-19-special-page.</u>

rights that may be taken in response to a public health emergency are lawful, necessary, proportionate and non-discriminatory (...)".<sup>7</sup>

5. The motion for a resolution first mentions the issue of distinct treatment of persons who have been vaccinated against Covid-19 and those who have not. Then, it focuses on possible discrimination between persons vaccinated with different WHO-listed vaccines, without specifying the types of vaccines, and on restrictions in freedom of movement of citizens of other countries. Both types of differential treatment are closely related to the use of so-called "Covid passes" or, more precisely in this situation, to "vaccine passes".

6. As regards the first issue – that of discrimination between persons who have been vaccinated against Covid-19 and those who have not, it has already been considered at length in particular in Assembly's <u>Resolution 2383 (2021)</u> on "Covid passes or certificates: protection of fundamental rights and legal implications".<sup>8</sup> The Assembly has stressed that measures such as the introduction of a Covid pass or certificate must be applied in compliance with the positive obligations arising from the Convention and only when "clear and well-established scientific evidence" exists that they lower the risk of transmission of the SARS-CoV-2 virus "to an acceptable level from a public health point of view".<sup>9</sup> The Assembly has also stated that while "certification of vaccination status has legitimate and valuable medical uses", the use of Covid passes "(...) is fraught with legal and human rights complications (...)"<sup>10</sup>. Moreover, "if Covid passes are used as a basis for preferential treatment, they may have an impact on protected rights and freedoms" and such preferential treatment may constitute unlawful discrimination.<sup>11</sup>

7. As regards discrimination based on the fact of being vaccinated with different types of vaccines against Covid-19, the Assembly has not yet addressed this issue. This problem is aggravated by the European Union (EU) policies related to the handling of the Covid-19 pandemic and, in particular, its EU Digital Covid Certificate (EUDCC), which is supposed to facilitate freedom of movement within the EU but imposes on citizens of non-EU member States additional restrictions on travelling and in the enjoyment of some fundamental rights and freedoms. Since many EU countries (Germany, France, Italy and Latvia) introduced, at least temporarily, vaccination/recovery passes (without the possibility of submitting a negative Covid-19 test) and thus restricted access to many public spaces (such as bars, restaurants or event venues) or even public transportation (like long-distance public transportations, including TGV trains, in France), some persons travelling, staying for some time or living in those countries could not have access to such venues and/or means of transportation. This can raise several issues under the European Convention on Human Rights, and in particular as regards the enjoyment of the right to respect for private life (Article 8 of the ECHR), the right to freedom of assembly (Article 11 of the ECHR) or the right to freedom of movement (Article 2 of Protocol No. 4).

8. The motion for a resolution raises several complex – legal and scientific – issues. Therefore, as some of these problems are new, I will first focus on issues related to the WHO-listed vaccines and the EU policies concerning vaccine approval. Then, I will look at the vaccination coverage and the scope of the direct or indirect obligation to get vaccinated against Covid 19, on the issue of mandatory vaccination and the use of Covid/vaccination passes. In doing so, I will refer to the previous work of Assembly concerning the Covid-19 pandemic and to the information provided by parliamentary delegations in response to questionnaires sent through the ECPRD. Moreover, focus will also be given to restrictions of freedom of movement within the EU and entering the EU and the European Union Digital Covid Certificate. I will then refer to the concept of non-discrimination in international human rights law and the case law of the European Court of Human Rights concerning compulsory vaccination. Finally, I will have a look at the work of the WHO concerning a new international instrument on pandemic preparedness and response (announced by its Director-General in his speech of 12 April 2022).<sup>12</sup>

# 3. EMA-conditionally-authorised and WHO-listed vaccines against Covid-19

9. Issues related to developing Covid-19 vaccines have already been examined in the report of the Committee on Social Affairs, Health and Sustainable Development on "Covid-19 vaccines: ethical, legal and

<sup>&</sup>lt;sup>7</sup> Paragraph 12.1 of the resolution.

<sup>&</sup>lt;sup>8</sup> Paragraph 2 of the resolution defines a Covid pass or certificate as "official documentation of an individual's having been vaccinated against Covid-19, having recovered from Covid-19, and/ or of having tested negative for SARS-CoV-2 virus".

<sup>&</sup>lt;sup>9</sup> Paragraph 13.1. of the resolution.

<sup>&</sup>lt;sup>10</sup> Paragraph 2 of the resolution.

<sup>&</sup>lt;sup>11</sup> Paragraph 4 of the resolution.

<sup>&</sup>lt;sup>12</sup> WHO Director-General's opening remarks at the Public Hearing regarding a new international instrument on pandemic preparedness and response – 12 April 2022.

practical considerations" (which led to the adoption of <u>Resolution 2361 (2021)</u><sup>13</sup>).<sup>14</sup> As stressed in that report, before being approved, any vaccine has to undergo rigorous testing by its developer and then scientific evaluation by regulatory authorities. In case of member States that are part of the European Union (EU) and the European Economic Area (EEA), this may first include the European Medicines Agency (EMA) and other EU or EEA regulatory authorities before the competent national authorities decide on introduction of a newly approved vaccine in the national health care systems and vaccine policies.<sup>15</sup>

10. As regards Covid-19 vaccines being conditionally authorised in the EU, all of them have received from the European Commission, upon the scientific assessment of the EMA, a conditional marketing authorisation (CMA),<sup>16</sup> which is valid for one year and is renewable. The companies that market the vaccines must apply to have their authorisations renewed. The renewal process can take up to six months, including up to 90 days for EMA's evaluation.<sup>17</sup>

11. The following six vaccines have been conditionally authorised for use in the European Union: Comirnaty (developed by Pfizer and BioNTech; BioNTech Manufacturing GmbH), Jcovden (previously Covid-19 Vaccine Janssen) (Janssen-Cilag International NV), Nuvaxovid (Novavax CZ, a.s.), Spikevax (previously COVID-19 Vaccine Moderna) (Moderna Biotech Spain S.L.)<sup>18</sup> and Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (AstraZeneca AB) and COVID-19 Vaccine (inactivated, adjuvanted) Valneva (Valneva Austria GmbH) (which was conditionally authorised on 24 June 2022).<sup>19</sup> Vidprevtyn (Sanofi Pasteur) is currently under evaluation.

12. Marketing authorisation by the EMA is different from the WHO Emergency Use Listing (EUL) procedure, which is "a risk- based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics, with the ultimate aim of expediting the availability of these products to people affected by a public health emergency."20 It is a key tool for companies wishing to submit their products for use during health emergencies. The following criteria must be met (for vaccines): the disease for which the product is intended is serious or immediately life threatening, has the potential of causing an outbreak, epidemic or pandemic and it is reasonable to consider the product for an EUL assessment; existing products have not been successful in eradicating the disease or preventing outbreaks; the product is manufactured in compliance with current Good Manufacturing Practices (GMP) and the applicant company must undertake to complete the development of the product and apply for WHO prequalification once the product is licensed. An application for an EUL should follow the common technical format (CTD) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); the vaccine manufacturer has to submit to the WHO a number of data (manufacturing quality, non-clinical and clinical data, a plan to monitor quality, safety and efficacy and labelling details). A decision to issue an EUL is accompanied by a series of recommendations that must be addressed by the manufacturer. The WHO reserves the right to restrict or revoke the EUL of a vaccine product if a quality/safety issue has not been or cannot be resolved to its satisfaction.<sup>21</sup> An independent advisory group composed of six members - the Technical Advisory Group for Emergency Use Listing (TAG-EUL) – assists the WHO in the EUL process.

13. There are currently eleven Covid-19 vaccines recommended by the WHO under the EUL: Comirnaty (Pfizer-BioNTech), Vaxzevria (AstraZeneca), Covishield (Serum Institute of India Pvt. Ltd), Ad26.COV2.S (Janssen-Cilag International NV), mRNA-1273 (Moderna Biotech), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) (Sinopharm/Beijing Institute of Biological Products Co., Ltd), COVID-19 Vaccine (Vero Cell), Inactivated/CoronaVac (Sinovac, Life Sciences Co., Ltd.), SARS-CoV-2 Vaccine Inactivated (Vero Cell)/COVAXIN (Bharat Biotech, India) (however, its supply has been suspended), NVX-CoV2373/Covovax (Serum Institute of India Pvt. Ltd), NVX-CoV2373/Nuvaxovid (Novavax) and Ad5-nCoV (CanSinoBIO).<sup>22</sup>Five

<sup>&</sup>lt;sup>13</sup> Adopted on 27 January 2021.

<sup>&</sup>lt;sup>14</sup> <u>Doc. 15212</u>, 11 January 2021, rapporteur: Ms Jennifer de Temmerman (France, ALDE). See section 2 of the report. For more information, see also the minutes of the public hearing on "Towards a Covid-19 vaccine", held via videoconference, on Tuesday 1 December 2020, Committee on Social Affairs, Health and Sustainable Development, AS/Soc (2020) PV 09add declassified, 28 January 2021.

<sup>&</sup>lt;sup>15</sup> <u>Doc. 15212</u>, see above, paragraph 15.

<sup>&</sup>lt;sup>16</sup> The CMA is used in emergency situations such as a pandemic.

<sup>&</sup>lt;sup>17</sup> EMA, <u>Covid-19 vaccines: Key Facts.</u> See also <u>https://ec.europa.eu/commission/presscorner/detail/en/qanda\_20\_2390</u>

<sup>&</sup>lt;sup>18</sup> Previously COVID-19 Vaccine Moderna.

<sup>&</sup>lt;sup>19</sup> <u>https://vaccination-info.eu/en/covid-19/covid-19-vaccines (as of 1 August 2022).</u>

<sup>&</sup>lt;sup>20</sup> https://www.who.int/teams/regulation-prequalification/eul.

<sup>&</sup>lt;sup>21</sup> For more information, see WHO, <u>Considerations for the Assessment of COVID-19 Vaccines for Listing by WHO</u>, 25 November 2020, and <u>Emergency Use Listing Procedure | WHO – Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control).</u>

<sup>&</sup>lt;sup>22</sup> <u>https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued.</u>

of them have also been approved by the EMA. The Russian vaccine Sputnik V, the Sanofi and Valneva vaccines are still under assessment.  $^{\rm 23}$ 

14. The WHO recommendations made under the EUL are not marketing authorisations but are designed to support temporary availability and use in emergency situations. Each WHO Member State can allow the emergency use of a product under an EUL in their country.<sup>24</sup> An EU marketing authorisation offers a robust post-authorisation regulatory framework based on legally binding obligations, safeguards and controls.<sup>25</sup> Nevertheless, there is no objective justification for restricting within the European Union the freedom of movement of people vaccinated with vaccines listed only under the EUL. Both the EMA and the WHO approval processes are rigorous and ensure that the approved vaccines comply with international standards as regards their quality, safety and effectiveness.

# 4. Covid/vaccination passes

On many occasions, Council of Europe bodies and instances have expressed objections as to the use 15. of "vaccination certificates" or "passes". In her Information Document of 31 March 2021<sup>26</sup> the Council of Europe Secretary General Marija Pejčinović Burić highlighted the relevant human rights standards for addressing the issue of "vaccine certificates", i.e. documents that provide evidence of the administration of a vaccine to the person for whom it is issued. She stressed that although the use of such certificates for medical and travelling purposes was not new and supported the work undertaken in this context to harmonise these certificates at European and international level. However, she added that their use should be considered with "utmost caution" if they served purposes other than strictly medical, for example to give individuals exclusive access to rights, services or public places, and that they raised numerous human rights issues (risk of discrimination in relation to freedom of movement, right to respect for private and family life, the right to freedom of assembly or the right to freedom of religion). Their use for non-medical purposes also raises issues with regard to the protection of personal data,<sup>27</sup> such concerns were also raised by the Council of Europe Consultative Committee on the Data Protection Convention 108 (T-PD) in its "Statement on Covid-19 vaccination, attestations and data protection" of 3 May 2021<sup>28</sup> and the Council of Europe Committee on Bioethics (DH-BIO) in its "Statement on human rights considerations relevant to "vaccine pass" and similar documents" of 4 May 2021, which was also endorsed by the Conference of INGO<sup>29</sup>.

16. In its <u>Resolution 2383 (2021)</u>, the Assembly considered that the use of Covid passes may constitute "preferential treatment", which "(…) may amount to unlawful discrimination within the meaning of Article 14 of the Convention if it does not have an objective and reasonable justification. This requires that the relevant measure (i) pursues a legitimate aim, and (ii) is proportionate. Proportionality requires a fair balance between protecting the interests of the community (the legitimate aim) and respect for the rights and freedoms of the individual."<sup>30</sup> However, regardless the situation of others, restrictions on rights and freedoms are no longer justified for the individual concerned, if the risk of transmission of the SARS-CoV-2 virus is significantly lower.<sup>31</sup> The Assembly also stressed that "the extent to which a justification for differential treatment is objective and reasonable depends on the nature of the right or freedom in question and the severity of the interference".<sup>32</sup> Therefore, it called on member States of the Council of Europe to "(…) institute Covid pass regimes only when clear and well-established scientific evidence exists that such regimes lower the risk of transmission of the SARS-CoV-2 virus to an acceptable level from a public health point of view"<sup>33</sup> and to avoid discrimination, in case such a regime has been instituted, in particular by taking due account to the "relative effectiveness of different vaccines and vaccination regimes" in preventing the transmission of the disease.<sup>34</sup>

<sup>&</sup>lt;sup>23</sup> <u>https://extranet.who.int/pgweb/sites/default/files/documents/Status\_COVID\_VAX\_02April2022.pdf.</u>

<sup>&</sup>lt;sup>24</sup> EMA, <u>Covid-19 vaccines: Key Facts.</u>

<sup>&</sup>lt;sup>25</sup> Ibid.

<sup>&</sup>lt;sup>26</sup> SG/Inf(2021)11, Protection of human rights and the "vaccine pass", 31 March 2021, p. 3.

<sup>&</sup>lt;sup>27</sup> Ibid.

<sup>&</sup>lt;sup>28</sup> <u>T-PD-BUR(2021)6rev2</u>, 3 May 2021.

<sup>&</sup>lt;sup>29</sup> <u>https://rm.coe.int/dh-bio-2021-7-final-statement-vaccines-e/1680a259dd and Conference of INGOs, Recommendation on the COVID-19 pandemic: Call for ethical and human rights compliant management, CONF/PLE(2020)REC3, 16 December 2020.</u>

<sup>&</sup>lt;sup>30</sup> Paragraph 4 of the resolution.

<sup>&</sup>lt;sup>31</sup> Paragraph 5 of the resolution.

<sup>&</sup>lt;sup>32</sup> Paragraph 6 of the resolution.

<sup>&</sup>lt;sup>33</sup> Sub-paragraph 13.1 of the resolution.

<sup>&</sup>lt;sup>34</sup> Sub-paragraphs 13.3 and 13.3.6 of the resolution. Also, on the issue of differential treatment and discrimination, see Section 5.1 of the report by Mr Cottier, <u>doc. 15309</u>, see above.

17. Similarly, in its <u>Resolution 2424 (2022)</u> on "Beating Covid-19 with public health measures";<sup>35</sup> the Assembly called on member States of the Council of Europe to use "vaccination certificates only for their designated purpose of monitoring vaccine efficacy, potential side effects and adverse effects (...)".<sup>36</sup> It also called to avoid discrimination between and within countries with regard to ensuring global equitable distribution of vaccines and, in particular, to mutually recognise vaccination certificates issued by Council of Europe member States, as well as vaccination certificates of all WHO-listed vaccines.<sup>37</sup>

18. As regards national practices, I have not addressed the issue of COVID-19 passes in my questionnaire sent to the ECPRD, as this issue had been previously covered by two similar requests lodged by the Italian parliament and the Knesset (Israel) submitted respectively in July and September (ECPRD 4811 - Use of Green Pass to access public spaces and ECPRD 4843 - Covid-19 Green Passes to access specific venues). In reply to these two questionnaires, eleven out of thirty Council of Europe member States who replied between July and September 2021 (Austria, Cyprus, France, Germany, Greece, Ireland, Latvia, Luxembourg, Portugal and Slovenia)<sup>38</sup> indicated that access to certain venues such as gyms and sport facilities, restaurants and bars, indoor culture establishments, leisure facilities and other public spaces was subject to the requirement of presenting the EU Digital Covid Certificate. In Cyprus, this was also the case with public transportation. Some countries also required the EUDCC for tourism-related activities, such as hotels and other types of accommodation (Austria, Czech Republic, Germany, Slovenia and the Canary Islands in Spain) or transportation during excursions (Austria). Sixteen Council of Europe member States indicated that they did not require the EUDCC to access such venues (Albania, Belgium, Bulgaria, Croatia, Estonia, Finland, Georgia, Montenegro, the Netherlands, Norway, Poland, Romania, Spain, the Slovak Republic, Sweden and the United Kingdom). The restrictions related to the use of the Covid-19 passes are subject to time limits and have been re-evaluated by national parliaments on regular basis and on the basis of the epidemiological assessment and vaccination uptake.

19. As stressed by Ms Lefeuvre at the May hearing, the example of France is illustrative in the context of the fight against the Covid-19 pandemic. The Law of 5 August 2021 on the management of the health crisis had made it compulsory to have a health pass (pass sanitaire) in order to carry out certain activities. The French Ombudsman pointed out that this measure was discriminatory if there was no equality in access to vaccination. Furthermore, the National Ethical Consultative Committee had highlighted the need to ensure the proportionality of this measure, referring to the question of the existence of scientific evidence for the effectiveness of the pass, alternatives to vaccination and the question of transmission of SARS-CoV-2; it had also emphasised the gap in equality between those who had been vaccinated and those who had not. If the health pass was to be introduced, there had to be alternatives; otherwise, it would be a disguised form of mandatory vaccination, especially when Covid-19 tests were no longer reimbursed. The Conseil constitutionnel validated the health pass subject to certain conditions. It also validated the Law of 22 January 2022 on vaccine passes, while rejecting two of its provisions, concerning access to political meetings and measures taken by individuals checking the vaccine pass. The Ombudsman had criticised the proportionality of introducing vaccine passes as regards non-vaccinated children and because of possible violations of medical secrecy.

#### 5. Mandatory vaccination and the right to health

20. Ensuring good public health, and therefore, high immunisation coverage by the use of vaccines, falls in the scope of various international human rights instruments. Article 12 paragraph 1 of the <u>International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>39</sup></u> recognises that everyone has the right to enjoy the highest attainable standard of physical and mental health. More precisely, States have a responsibility to take necessary steps to achieve the full realisation of this right by the prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12.2c of the ICESCR). Similarly, Article 11 of the Revised European Social Charter (of 1996)<sup>40</sup> enshrines the right to protection of health and States Parties to this convention undertake, either directly or in cooperation with public or private organisations, "to prevent as far as possible epidemic, endemic and other diseases, (...)" (paragraph 3 of this provision).

<sup>&</sup>lt;sup>35</sup> Adopted by the Assembly on 27 January 2022, on the basis of a report by the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Stefan Schennach (Austria, SOC), <u>Doc. 15444</u> of 25 January 2022.

 <sup>&</sup>lt;sup>36</sup> Sub-paragraph 9.2.1.3. of the resolution.
 <sup>37</sup> Sub-paragraphs 9.3.2 and 9.3.2.1 of the resolution.

<sup>&</sup>lt;sup>38</sup> Twenty-nine member States of the Council of Europe replied to the first questionnaire (Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Georgia, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland and the United Kingdom) and nine to the second one (France and again Austria, Belgium, Germany, Hungary, Ireland, the Netherlands, Portugal and Spain).

<sup>&</sup>lt;sup>39</sup> Adopted by the United Nations General Assembly resolution 2200A (XXI) on 16 December 1966.

<sup>&</sup>lt;sup>40</sup> ETS No. 163.

21. Moreover, the 1997 Oviedo Convention (Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine),<sup>41</sup> the only international legally binding instrument on the protection of human rights in the biomedical field, enshrines the principle of "equitable access to health care of appropriate quality" (Article 3), taking into account health needs and available resources. It also clearly states that interventions in the health field may only be carried out with the free and informed consent of the person concerned, that "this person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks" and that he/she may freely withdraw consent at any time (Article 5). Moreover, "everyone has the right to respect for private life in relation to information about his or her health" (Article 10 paragraph 1) and "everyone is entitled to know any information collected about his or her health" (Article 10 paragraph 2). Nevertheless, these rights can be subject to restrictions "prescribed by law" and "necessary in a democratic society", in particular "for the protection of public health or for the protection of the rights and freedoms of others" (Article 26 paragraph 1).

22. Under the ECHR, States Parties to the Convention have a positive obligation to take appropriate measures to protect the life and health of those within their jurisdiction, especially under Article 2 of the Convention, enshrining the right to life, and its Article 8, enshrining the right to respect for private life.<sup>42</sup> Mandatory vaccination against Covid-19 poses a problem in terms of some human rights and fundamental freedoms, and in particular the right to respect for private life (Article 8 of the Convention).

The European Court of Human Rights (ECtHR or "the Court") has already examined cases concerning 23. compulsory vaccination, although not in context of the Covid-19 pandemic. It has stressed that compulsory vaccination - as an involuntary medical treatment - amounts to an interference with the right to respect for one's private life, which includes a person's physical and psychological integrity, as guaranteed by Article 8 § 1 of the Convention.<sup>43</sup> In its 2021 Grand Chamber judgment in the case of Vavřička and Others v. Czech Republic, the Court has confirmed that healthcare policy matters, including compulsory child vaccination, come within the wide margin of appreciation of national authorities.<sup>44</sup> It has found that the requirement that children be vaccinated against a range of diseases in order to attend nursery school did not violate the Convention, as it was not a disproportionate interference with the rights involved – the children were only unable to attend preschool, and the penalties imposed on parents were not excessive. The Court agreed with the argument of the Czech authorities that the aim of the legislation at stake, i.e. protecting against diseases which might pose a serious risk to health, was a "legitimate aim", as the legislation referred not only to those who received the vaccinations concerned but also those could not be vaccinated and were thus in a state of vulnerability.<sup>45</sup> Furthermore, the Court pointed out the value of social solidarity<sup>46</sup>, by giving weight to the interests of those who could only rely on herd immunity.

24. National vaccination schemes imposing mandatory vaccination may also infringe upon other rights enshrined in the Convention, such as the freedom of thought, conscience and religion (Article 9 of the Convention) – if the applicant has a critical opinion on mandatory vaccination on grounds of religious or other beliefs, the right to education (Article 2 of Protocol no. 1) – if vaccination is required for children to access school facilities, the right to property (Article 1 of Protocol No. 1) – if it is required for workers to continue their professional activities, or the right to respect for private life (Article 8 of the Convention), when data protection issues are involved<sup>47</sup>

25. In its <u>Resolution 2361 (2021)</u> the Assembly called on member States of the Council of Europe to ensure a high vaccine uptake, it initially called on them to "ensure that citizens are informed that the vaccination is not mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do so themselves"<sup>48</sup> and hence did not recommend a mandatory vaccination against Covid-

<sup>&</sup>lt;sup>41</sup> ETS No. 164. So far ratified by 29 Council of Europe member States (as of 1 August 2022).

<sup>&</sup>lt;sup>42</sup> For a list of cases see, for example, paragraph 282 of the Grand Chamber judgment *Vavřička and Others v. Czech Republic*, application No. 47621/13, judgment of 8 April 2021. Judge Wojtyczek expressed a dissenting opinion.

<sup>&</sup>lt;sup>43</sup> See, in particular, Solomakhin v. Ukraine, application No. 24429/03, judgment of 15 March 2012, paragraph 33.

<sup>&</sup>lt;sup>44</sup> Vavřička and Others v. Czech Republic, see above, paragraph 280.

<sup>&</sup>lt;sup>45</sup> Ibid, paragraph 272.

<sup>&</sup>lt;sup>46</sup> Ibid, paragraph 279.

<sup>&</sup>lt;sup>47</sup> Both the rights to freedom of thought, conscience and religion and the right to education were unsuccessfully invoked in the *Vavřička and Others v. Czech Republic* case; the Court considered them as inadmissible. Previously, in the *Boffa and 13 other v. San Marino*, application No. 26536/95, decision of 15 January 1998, the European Commission for Human Rights found that the application, in which the applicants complained about compulsory vaccination for children under Article 2,5, 8 and 9 of the Convention was inadmissible.

<sup>&</sup>lt;sup>48</sup> Paragraph 7.3.1. of the resolution.

19.<sup>49</sup> The Assembly also called on member States to "ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated".<sup>50</sup> In its <u>Resolution 2383 (2021)</u> on "Covid passes or certificates: protection of fundamental rights and legal implications", the Assembly stressed that although vaccination would be an essential public health measure for protecting the life and health of populations, it would be insufficient by itself.<sup>51</sup>

26. More recently, in its <u>Resolution 2424 (2022)</u> on "Beating Covid-19 with public health measures"<sup>52</sup>, the Assembly called on States to "encourage vaccinations", in "a human rights-compliant way".<sup>53</sup> It also called for "legislating for vaccination mandates for healthcare or social-care personnel" in contact with "highly vulnerable persons" and for "starting a public debate on possibly legislating for vaccination mandates for specific groups or the general population", however, without covering persons who for medical reasons should not get vaccinated or, for the time being, children.<sup>54</sup> In its most recent <u>Resolution 2455 (2022)</u> "Fighting vaccine-preventable diseases through quality services and anti-vaccine myth-busting", the Assembly has stated that "addressing suboptimal vaccination coverage is a matter of human rights protection and should be a priority for Council of Europe member States". Council of Europe member States should develop "comprehensive, forward-looking, pro-active and human-rights compliant vaccination strategies".<sup>55</sup> In doing so, they should ensure that "mandatory vaccination is only considered as a last resort, when this is necessary in order to fulfil a legitimate aim, is provided for by law, and is proportionate; its introduction is subject to public debate, parliamentary scrutiny and judicial oversight; and less constraining measures are given preference when

27. As regards national practices, I have not addressed the issue of mandatory vaccination against COVID-19 in my questionnaire sent to the ECPRD, as this issue had been previously covered by a similar request lodged by the parliament of the Czech Republic in December 2021 (ECPRD 4929 – Mandatory vaccination).<sup>57</sup> Out of the 24 Council of Europe member States whose parliaments replied to that questionnaire between October and December 2021,<sup>58</sup> no member State had introduced mandatory vaccination by legislation or decree. However, seven countries (Austria, France, Germany, Greece, Hungary, Latvia and Poland) have engaged in debates on this question generally (in particular Austria, which had adopted a law – not enforceable yet in this respect) or for certain professions (Poland). Five countries had already introduced mandatory vaccination for some professions (France, Germany, Greece, Hungary, and Latvia). Seventeen out of the twenty-four countries did not pass any legislation or decrees for this purpose.

28. At the May hearing, Ms Lefeuvre stressed that, according to comparative law studies, priority in vaccination against Covid-19 should be given to vulnerable people and that several member States of the Council of Europe, including France, had based their strategies in fighting against the pandemic on the very restrictive Italian approach. In December 2021, the French National Ethical Consultative Committee (CCNE) expressed its opposition to mandatory vaccination for the entire population, taking the view that there were too many uncertainties about its efficiency and the side effects of available vaccines. It stressed that any mandatory vaccination infringed upon individual freedoms and could only be imposed in very precise cases, taking into account the gravity of the infection, the advantages of the vaccination for the population and the risks related thereto. In the context of Covid-19 pandemic, it could only be a last resort measure in a situation

<sup>53</sup> Paragraph 9 and 9.1.3. of the resolution.

<sup>54</sup> Paragraphs 9.2.2.3. and 9.4.3. of the resolution.

<sup>&</sup>lt;sup>49</sup> This was also the position of the rapporteur of the Committee on Social Affairs, Health and Sustainable Development, Ms De Temmerman, see paragraph 62 of her report, <u>Doc. 15212</u>, see above: " (...) I would not recommend making these vaccines mandatory in any case – for the simple reason that mandatory vaccination has not been shown to work". <sup>50</sup> Paragraph 7.3.2. of the resolution.

<sup>&</sup>lt;sup>51</sup> Paragraph 1 of the resolution. However, in a declaration of 1 December 2021, the Assembly's Committee on Social Affairs, Health and Sustainable Development, stated that "the time has come to follow WHO advice, and not only invest in strong vaccine education campaigns, but also start the debate on mandatory vaccination". It also considered that Council of Europe member States should recognise all Covid-19 vaccines developed by them, as well as those which have been recognised by the WHO. See Declaration by the committee: The Covid-19 situation: "No-one is safe until everyone is safe", AS/Soc (2021) 54rev, 1 December 2021.

<sup>&</sup>lt;sup>52</sup> Adopted by the Assembly on 27 January 2022, on the basis of a report by the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Stefan Schennach (Austria, SOC), <u>Doc. 15444</u> of 25 January 2022.

<sup>&</sup>lt;sup>55</sup> Paragraphs 4 and 13 of <u>Resolution 2455 (2022)</u>, adopted on 24 June 2022, on the basis of the report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Ms Carmen Leyte (Spain, EPP/CD), <u>Doc. 15542</u> of 3 June 2022.

<sup>&</sup>lt;sup>56</sup> Paragraph 13.1.4. of the resolution.

<sup>&</sup>lt;sup>57</sup> A similar request at the same time was also lodged by the parliament of Slovakia (ECPRD 4928 – COVID-19 vaccination strategies).

<sup>&</sup>lt;sup>58</sup> These are: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain and Sweden.

of uncontrolled pandemic and with the use of vaccines with proven efficacy and whose side effects were wellknown. In March 2021, the CCNE had adopted a position in favour of mandatory vaccination for healthcare and medico-social staff, calling on them to show responsibility and solidarity in the exercise of their profession and replying on the principle of non-maleficence (i.e. that they should not put in danger other people). It stressed that such an obligation should be accompanied by an equal access to vaccines and non-contradictory data concerning their efficacy and side effects and that awareness-raising measures were still needed in this respect. If healthcare and medico-social staff showed a proactive approach, this could motivate the general population to get vaccinated and increase herd immunity.

# 6. EU Digital COVID Certificate

29. On 14 June 2021, the EU adopted Regulation 2021/953 establishing the EU Digital COVID Certificate during the pandemic.<sup>59</sup> The EU Digital COVID Certificate is issued free of charge by national authorities and is available in either digital or paper format containing a QR code. It certifies that a person has been vaccinated against COVID-19, has a recent negative test result or has recovered from the infection.

30. Regulation 2021/953 sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic (Articles 3-6)<sup>60</sup> and has been aimed at gradually lifting restrictions to free movement, in a coordinated manner.<sup>61</sup> At the same time, the regulation does not require EU member States to introduce limitations on the right to free movement. <sup>62</sup> The regulation also states that it cannot be interpreted as establishing a right or obligation to be vaccinated.<sup>63</sup> It is not a "vaccination passport", as it also covers test and recovery certificates. The regulation permits interested non-EU countries to be connected to the EU Digital COVID Certificate system, resulting in such certificates being treated as equivalent.<sup>64</sup> So far, 48 non-EU member States, including 17 member States of the Council of Europe (Albania, Andorra, Armenia, Georgia, Iceland, Liechtenstein, the Republic of Moldova, Monaco, Montenegro, North Macedonia, Norway, San Marino, Serbia, Switzerland, Türkiye, Ukraine and the United Kingdom and the Crown Dependencies), have done so<sup>65</sup>.

31. Where EU member States accept proof of vaccination in order to waive restrictions to free movement put in place to limit the spread of SARS-CoV-2, they are under an obligation to accept, under the same conditions, vaccination certificates issued by other member States for a vaccine centrally conditionally authorised at EU level (pursuant to Article 5 paragraph 5 of the regulation), given that the conditional marketing authorisations for this vaccine, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all EU member States.<sup>66</sup>

32. In addition, EU member States may, for the same purpose, accept certificates for a Covid-19 vaccine that has completed the WHO EUL procedure. As stressed in recital 34 of the regulation, EU member States are "in particular encouraged" to accept vaccination certificates issued for such vaccines, "in order to support the work of the WHO and to strive for better global interoperability". Moreover, if a vaccination certificate has been issued in a third country for such a WHO listed vaccine and the authorities of a member State have received all the necessary information, those authorities may upon request, issue a vaccination certificate, unless the vaccine is not authorised for use on its territory (Article 8 paragraph 1). Therefore, the acceptability criteria for free movement purposes are broad and can include the WHO listed vaccines that have not necessarily undergone the stringent EMA process of conditional authorisation. Information on which COVID-19 vaccines not authorised in the EU are accepted by EU member States for this purpose is published online, showing that many EU member States accept all or some WHO listed vaccines (such as Covishield, the

<sup>62</sup> Recital 14 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>59</sup> Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

<sup>&</sup>lt;sup>60</sup> The Regulation is accompanied by Regulation (EU) 2021/954, which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with EU law.

<sup>&</sup>lt;sup>61</sup> Under EU law, free movement is enshrined in Article 21 (1) of the Treaty on the Functioning of the EU and Article 45 of the Charter of Fundamental Rights. It is important to note that the right to free movement under EU law and the right to freedom of movement under Article 2 of Protocol No. 4 to the Convention are different in scope; only the former covers travel *between* countries. In addition, the concept of free movement in the EU goes beyond the mere travelling and its personal scope is limited to EU citizens and their family members.

<sup>&</sup>lt;sup>63</sup> Recital 36 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>64</sup> Article 8 paragraph 2 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>65</sup> Full list available at: <u>https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate\_en#recognition-by-the-eu-of-covid-certificates-issued-by-third-non-eu-countries</u>
<sup>66</sup> See also Recital 34 of Regulation (EU) 2021/953.

Sinopharm vaccine, CoronaVac, COVAXIN and COVOVAX).<sup>67</sup>This is also corroborated by the replies provided by some EU member States that have replied to the questionnaire I had send through the EPRDC and which are summarised in the Appendix to this report.<sup>68</sup>

33. EU member States also agreed to allow, as of 1 March 2022, non-essential travel to the EU for persons vaccinated with vaccines approved by the EU or having completed the WHO EUL procedure.<sup>69</sup> However, such persons may be subject to additional requirements such as tests, quarantine or the administration of an EU-conditionally authorised vaccine.

34. It should also be stressed that Article 11 paragraph 1 of the regulation still recognises the EU member States' competence to impose restrictions on free movement on grounds of public health. It states that member States can impose additional conditions on free movement (such as additional testing for SARS-CoV-2, quarantine or self-isolation), in addition to holding a valid Covid-19 certificate, if "they are necessary and proportionate for the purpose of safeguarding public health" in response to the pandemic, "also taking into account available scientific evidence". Such additional measures were taken, for example, in response to the emergence of the 'Omicron' variant of concern and included mainly pre-departure or post-arrival tests.<sup>70</sup>

35. The regulation covers the use of certificates for travel within the EU during the COVID-19 pandemic. It neither prescribes nor prohibits the use of COVID-19 certificates for domestic purposes, such as to regulate the access to events, restaurants, sport venues, public transport, or the workplace. If EU member States decide to use the EU Digital COVID Certificate for other purposes, this must be provided for in national law, which must comply in particular with data protection requirements.<sup>71</sup> It should then also ensure that the EUDCC can also be used.<sup>72</sup> Member States are free to set their own rules and conditions of acceptance of such certificates and there are divergences in their practices, in particular as regards acceptance periods for domestic use.<sup>73</sup>

36. Regulation 2021/953 states that it: "respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union ('the Charter'), including the right to respect for private and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the freedom of movement and the right to an effective remedy"; when implementing it, EU member States shall comply with the Charter.<sup>74</sup>

37. By 1 March 2022, EU member States issued more than 1.72 billion EUDCC, made up of 1.15 billion vaccination certificates, 511 million test certificates and 55 million certificates of recovery.<sup>75</sup> The EUDCC has been in use since 1 July 2021 and has been recently prolonged till the end of June 2023, following a decision taken jointly by the European Parliament and the Council of the EU; EU member States should refrain from imposing additional restrictions to free movement of EUDCC holders. As stressed in recital 58 of Regulation 2021/953, such restrictions imposed in relation with the COVID-19 pandemic should be lifted "as soon as the epidemiological situation allows". Moreover, the European Commission encourages EU member States to lift the obligation to present the EUDCC in the same circumstances.<sup>76</sup> It has also stressed that the EUDCC has had a "very positive impact on free movement at a time where Member States continue to restrict travel on grounds of public health" and has helped to avoid a "fragmented system of multiple national certificates".<sup>77</sup>

<sup>&</sup>lt;sup>67</sup> <u>https://reopen.europa.eu/en</u> (as of 29 July 2022).

<sup>&</sup>lt;sup>68</sup> A request concerning movement restrictions imposed during the COVID-19 pandemic had been submitted in June 2021 by the parliament of Georgia (ECPRD 4768). Twenty-eight member States of the Council of Europe had replied to it and the content of their replies correspond with that of the answers provided to my questionnaire.

<sup>&</sup>lt;sup>69</sup> Council Recommendation (EU) 2022/290 of 22 February 2022 amending Council Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction.

<sup>&</sup>lt;sup>70</sup> Report from the Commission to the European Parliament and the Council pursuant to Article 16(2) of Regulation (EU) 2021/953 of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (COM(2022) 123 final), 15 March 2022, Section 2.1.4.

<sup>&</sup>lt;sup>71</sup> Recital 48 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>72</sup> Recital 49 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>73</sup> Report from the Commission, see above, Section 2.5.

<sup>&</sup>lt;sup>74</sup> Recital 62 of Regulation (EU) 2021/953.

<sup>&</sup>lt;sup>75</sup> Report from the Commission, see above, Section 2.6.1.

<sup>&</sup>lt;sup>76</sup> Report from the Commission, see above, Section 3.

<sup>77</sup> Ibid.

# 7. Non-discrimination in international human rights protection law

38. Article 26 of the International Covenant on Civil and Political Rights<sup>78</sup> stipulates that "all persons are entitled without any discrimination to the equal protection of the law" and that "(...) the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination *on any ground*, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or *other status*."

39. The European Convention on Human Rights also contains a non-discrimination provision (Article 14)<sup>79</sup> but only with regard to enjoyment of rights and freedoms laid down in the Convention. The list of proscribed grounds of discrimination is open-ended, as Article 14 prohibits discrimination based on any "other status"<sup>80</sup> and may be developed further on a case-by-case basis. Under the Convention, protection against discrimination is offered to any person who is within the jurisdiction of a State party (Article 1).

40. The European Court of Human Rights is therefore limited to treating the right to non-discrimination only as an accessory right, namely only in conjunction with other substantive rights enshrined in the Convention (such as the right to life, the right to respect for private and family life or freedom of thought, conscience and religion). The Court is not competent to examine complaints concerning discrimination which concern rights that do not fall within the ambit of those protected by the Convention but it may find a violation of Article 14 of the Convention even when it does not find a violation of the substantive right.<sup>81</sup>

41. According to the ECtHR case law, the State may not, without any objective and reasonable justification, treat in different way persons in substantially similar situations. It enjoys a certain margin of appreciation in assessing whether and to what extent the existing differences justify different treatment; however, the inequality in treatment must pursue a legitimate aim and respect the criterion of reasonable proportionality.<sup>82</sup> Moreover, a failure, without an objective and reasonable justification, to treat differently persons whose situations are significantly different may also be contrary to the principle of non-discrimination.<sup>83</sup> The Court can also find a violation of Article 14 in cases of indirect discrimination (namely when an apparently neutral legislation or practice results in a disproportionate disadvantage for a particular group without reasonable justification).<sup>84</sup>

42. Moreover, Article 1 paragraph 1 of Protocol No 12 to the Convention introduces a general prohibition on discrimination in the enjoyment of "any right set forth by law " (and therefore not only those enshrined in the ECHR), also "*on any ground*, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or *other status.*" It applies to all acts of public authorities (paragraph 2). So far the application of this Protocol has been limited, as only it has been ratified by only 20 States Parties to the Convention.<sup>85</sup>

#### 8. Applications pending before the European Court of Human Rights

43. The question of potential violations of certain human rights and fundamental freedoms during the Covid-19 health crisis has already been raised before the Court, which has communicated a number of cases to States Parties to the Convention on this subject.<sup>86</sup> Nevertheless, the ECtHR has not yet pronounced itself on the issue of mandatory vaccination against Covid-19, the use of Covid passes or discriminatory treatment related to these two issues. An application by a French university lecturer who complained about the "health passes" introduced in France in 2021 and incited other people to lodge similar applications to the Court had

<sup>85</sup><u>https://www.coe.int/en/web/conventions/unknown-cets-number-/-abridged-title?module=signatures-by-treaty&treatynum=177</u> (as of 12 April 2022).

<sup>&</sup>lt;sup>78</sup> Adopted by the United Nations General Assembly resolution 2200A (XXI) on 16 December 1966.

<sup>&</sup>lt;sup>79</sup> "Article 14 – Prohibition of discrimination. 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."

<sup>&</sup>lt;sup>80</sup> Such as, for instance, fatherhood (*Weller v. Hungary*, application No 44399/05, judgment of 31 March 2009); marital status (*Petrov v. Bulgaria*, application No 15197/02, judgment of 22 May 2008) or membership in an organisation (*Danilenkov and Others v. Russia*, application No. 67336/01, judgment of 30 July 2009).

<sup>&</sup>lt;sup>81</sup> For instance *E.B. v. France*, application No 43546/02, judgment (Grand Chamber) of 22 January 2008. In this case, the Court only found a breach of Article 14 taken in conjunction with Article 8 (right to respect for private or family right).

<sup>&</sup>lt;sup>82</sup> Savez crkava "Riječ života" and others v. Croatia, application no. 7798/08, judgment of 9 December 2010, paragraphs 85-89.

<sup>&</sup>lt;sup>83</sup> Thlimmenos v. Greece, application no. 34329/97, judgment of 6 April 2000, para. 44.

<sup>&</sup>lt;sup>84</sup> See, for example, *D.H. and Others v. the Czech Republic,* application no. 57325/00, judgment of 13 November 2007 (Grand Chamber), in which the Court found a violation of Article 14 in conjunction with Article 2 of Protocol 1 (right to education) because of a practice of placing Roma children in special schools.

<sup>&</sup>lt;sup>86</sup> ECtHR, Press Unit, Fact-Sheet – Covid-19 health crisis, March 2022.

been declared inadmissible by the ECtHR, mainly for non-exhaustion of domestic remedies and abuse of the right of individual application (Article 35 paragraphs 1 and 3 of the Convention).<sup>87</sup> Therefore, the Court did not pronounce itself on the merits of the application. However, another application against France is pending and has been communicated to the French authorities; it concerns the mandatory Covid-19 vaccination imposed on firefighters.<sup>88</sup> The applicant complains that he is subject to occupation-based mandatory vaccination and also that his refusal to be vaccinated against Covid-19 has led, since 15 September 2021, to the suspension of his professional activity and the total stoppage of his salary. The Court has communicated this case to the French Government under Articles 8 (right to respect for private life) and 14 (prohibition of discrimination) of the Convention and under Article 1 (protection of property) of Protocol No. 1 to the Convention.

#### 9. Conclusions

44. The introduction of "vaccine passes" or, to a certain extent, of Covid passes (in particular, when access to Covid-19 tests is too costly) can be construed as an indirect compulsion for vaccination. As explained above, international legal instruments on the protection of human rights do not necessarily prohibit mandatory vaccination, but the latter can be very problematic in the context of the right to respect one's private life and the right to free and informed consent on interventions in the field of health. Furthermore, mandatory vaccinations are likely to erode trust in the government and have the potential to further alienate parts of society. Nevertheless, vaccinations should be widely encouraged and accepted as a socially responsible thing to do for the benefit of all.

45. The fact that the use of Covid-19 passes, and in particular vaccine passes used for restricting travelling and access to certain public venues, leads to different forms of discrimination in the enjoyment of the human rights and fundamental freedoms enshrined in the ECHR, especially as regards the right to respect for private life, the right to freedom of assembly and the right to freedom of movement. First of all, this may lead to discrimination between persons who are vaccinated and therefore possess a vaccine pass or another type of Covid pass, and non-vaccinated persons, as already stressed by the Assembly and other Council of Europe bodies. This type of discrimination may also occur between those who have been vaccinated and those cannot be vaccinated, either for medical reasons (including those who recovered from Covid-19 and cannot be immediately vaccinated) or because they have no access to vaccination for various reasons (including because of social origin, age or nationality). Moreover, as children are usually not required to be vaccinated, this circumstance may also raise an issue in case there is an obligation to present a 'green pass' to access certain venues. Although children were usually exempted from such an obligation, there are discrepancies as regards the maximum age for such an exemption and this may raise issues in case children travel or stay in different countries applying different restrictions. Another group which may be subject to discrimination is that of crossborder workers, who are required to undergo Covid-19 tests in case they were not vaccinated. The requirement to undergo such tests at very short intervals may also be considered as an indirect obligation to be vaccinated.

46. In this context, the introduction of the EUDCC has been a pragmatic and temporary solution, which facilitated to a great extent freedom of movement within the European Union in the time of pandemic. The EUDCC allows States to avoid further restrictions of fundamental freedoms and does not, in an of itself amount to an indirect obligation to be vaccinated, as it is also available to persons who present a negative COVID-19 test result or proof of recovery. Therefore, EU citizens and third-country nationals travelling to the EU from non-EU countries can enter the territory of the EU without being vaccinated. However, although the EUDCC has been a practical tool used to alleviate travel and other restrictions, it has also turned out to be a discriminatory measure in some situations, especially vis-à-vis non-EU citizens travelling to the EU.

47. Another form of discrimination – which so far has been examined to a lesser extent – is that between persons vaccinated with different vaccines (and therefore possessing a "vaccine pass"). The vaccine in question may be conditionally authorised by the EMA or listed by the WHO but not the EMA or by a national regulatory authority but not the WHO, nor the EMA, such as Sputnik V. The fact of being vaccinated with a non-EMA or non-WHO approved vaccine may also entail indirect discrimination on the basis of nationality in some situations (for example, in case of non-EU citizens travelling to an EU member State and being prevented from accessing certain public venues or using some means of transportation).

48. Although the EMA has granted conditional authorisation for the marketing of only six vaccines, some EU member States administered other vaccines, including those approved only by the WHO or national authorities. Moreover, although EU member States have been reluctant to grant marketing authorisation to all WHO-listed vaccines, the recognition of these vaccines is now more and more widely accepted within the EU and individuals vaccinated with such vaccines may enter the territory of EU member States. However,

<sup>&</sup>lt;sup>87</sup> ECtHR, Zambrano v. France, application no. 41994/21, decision on the admissibility of 7 October 2021.

<sup>&</sup>lt;sup>88</sup> ECtHR, *Thevenon v. France*, application no. 46061/21, communicated on 7 October 2021.

recognition remains at the discretion of each EU member State. Moreover, both Regulation 2021/953 and Regulation 2021/954, on which the use of the EUCDD is based, govern neither its use for domestic purposes nor the question of entry of third-country nationals to the European Union. Therefore, EU member States are free to limit access to public venues and to impose additional restrictions on non-EU citizens access to their territory, even though they accept Covid-passes issued on the basis of vaccination with a non-EMA approved vaccine.

49. So the use of the EU Digital Covid Certificate or other 'green passes' does leave a door open for vaccine discrimination, although some safeguards are included in the EU legal framework establishing the EUDCC and there have been some positive developments as regards the recognition of WHO-listed vaccines and the certificates based on them as well as the inclusion of 48 non-EU member States (including 17 Council of Europe member States) in the EU-Gateway system for the EUDCC.

50. It is too early to fully assess the necessity and the proportionality of the restrictive measures, such as the imposition of the Covid-19 passes, as one still lacks scientific data to assess their impact on the transmission of the SARS-CoV-2 and the development of the Covid-19. It should be noted that because of the lack of evidence available to fully assess the necessity and proportionality of these measures, the responsibility of States to use the least restrictive measures possible must be even higher that when ample evidence supports their implementation. Hopefully, the European Court of Human Rights will soon provide some guidance on this issue following the applications which have been lodged before it.

51. So far, vaccination against Covid-19 has made a major contribution to overcoming the pandemic and people have reclaimed many of their fundamental freedoms, as many Covid-19 restrictions have been lifted. However, this does not mean that the pandemic is over and that new restrictions will not be imposed. Several countries still carry out border controls and require Covid-19 certificates such as the EU Digital COVID Certificate or equivalent certificates to enter the national territory. Therefore, the risks of discrimination and violations of human rights and fundamental freedoms still persist.

52. To conclude, all people vaccinated by vaccines recognised by the EMA or the WHO should be treated equally and people should not be prevented from exercising their fundamental rights and freedoms because they have not been vaccinated or because they have been vaccinated with a vaccine that is not authorised for marketing or has not been recognised in a given country. The compulsory use of Covid passes, and in particular of vaccine certificates, entails risks of discrimination and risks of infringements of human rights and fundamental freedoms. Those risks are further exacerbated when inequalities persist in access to vaccination.

#### APPENDIX

#### A. Introduction

1. Parliaments of thirty-one Council of Europe member States have answered the questionnaire sent through the European Centre for Parliamentary Research and Documentation (ECPRD), providing details about the use of COVID-19 vaccines and the restrictions on travelling during the pandemic. The following countries have responded to the questionnaire: Albania, Armenia, Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Montenegro, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom. The information below reflects the situation in member States as at the time of responding to the questionnaire. Given the fast-moving nature of the covid situation and the response to the pandemic, the situation in the States mentioned may well have evolved and changes since this information was provided.

## B. Summary of replies provided in response to the questionnaire

## 1. Are all WHO-approved vaccines against COVID-19 authorised for marketing in your country?

2. None of the Council of Europe member States whose parliament answered the questionnaire had granted authorisations for marketing to all WHO-approved vaccines.

3. Most of the countries which replied to the questionnaire authorised the five EMA-approved vaccines (not included is the Valneva vaccine, which was authorised only recently). These are **EU member States**: **Austria**, **Bulgaria**, **Cyprus**, **Estonia**, **Finland<sup>89</sup>**, **France**, **Germany**, **Hungary**, **Ireland**, **Latvia**, **Lithuania**, **Luxembourg**, the **Netherlands**, **Poland**, **Portugal<sup>90</sup>**, **the Slovak Republic**, **Slovenia**, **Spain**, **Sweden** plus the **United Kingdom**.

4. Not all **European Union member States** that replied to the questionnaire have approved the abovementioned five vaccines. **Belgium, Denmark** and **Romania** have authorised four of them: all of them have approved Comirnaty (Pfizer-BioNTech), Covid-19 Vaccine Janssen (Janssen Cilag – International NV) and Spikevax (Moderna), while **Denmark** and **Romania** have also authorised Vaxzevria (AstraZeneca)<sup>91</sup> and **Belgium** – Nuvaxovid (Novavax) (but not yet as a booster vaccine).

5. In addition to the **five EMA-approved** vaccines, some **EU member States** have also authorised **some other WHO-listed vaccines**. Thus, **France** has authorised Covishield (Serum Institute of India Pvt., Ltd). **Hungary** has approved Sputnik-V (Gamaleya), SARS-Cov-2 Vaccine (Vero Cell), Inactivated (InCov) (Sinopharm, Beijing Institute of Biological Products Co., Ltd), CoronaVac (Sinovac Life, Sciences Co., Ltd) and has issued a provisional marketing authorisation for Covishield (Serum Institute of India Pvt. Ltd) vaccine. **Poland** authorised CoronaVac (Sinovac Life, Sciences Co., Ltd), Covovax (Serum Institute of India Pvt. Ltd), and Covishield (Serum Institute of India Pvt. Ltd). The **Slovak Republic** also used Sputnik-V (Gamaleya) from June to August 2021.

6. **Norway and Switzerland** also approved the four EMA-approved vaccines (Comirnaty (Pfizer-BioNTech), Covid-19 Vaccine Janssen (Janssen Cilag – International NV), Spikevax (Moderna) and Nuvaxovid (Novavax). **Norway** had also authorised Vaxzevria (AstraZeneca), but its marketing authorisation was put on hold in March 2021.<sup>92</sup>

7. The **United Kingdom** authorised in addition to the five EMA-approved vaccines the VLA2001 (Valneva) vaccine. However, only three of the six vaccines approved by the health authorities have been administered to the population: Spikevax (Moderna), Comirnaty (Pfizer-BioNTech) and Vaxzevria (AstraZeneca).

8. Other **Council of Europe member States** (which are not members of the European Economic Area) that replied to the questionnaire have approved Comirnaty (Pfizer-BioNTech) and Vaxzevria (AstraZeneca), namely **Albania, Armenia, Georgia, Montenegro and North Macedonia**. As regards the five EMA-approved vaccines, Türkiye only approved the use of Comirnaty (Pfizer-BioNTech) and **Armenia** also approved the use of Spikevax (Moderna) and Nuvaxovid (Novavax). Some of these Council of Europe member States have also

<sup>&</sup>lt;sup>89</sup> Vaxzevria (AstraZeneca) is no longer in use in Finland.

<sup>&</sup>lt;sup>90</sup> However, it does not administer Nuvaxovid.

<sup>&</sup>lt;sup>91</sup> However, only Comirnaty (Pfizer-BioNTech) and Spikevax (Moderna) are used in the vaccination programme.

<sup>&</sup>lt;sup>92</sup> It also suspended the roll-out of the Covid-19 Vaccine Janssen (Johnson & Johnson).

approved Sputnik-V (Gamaleya), namely Albania, Armenia, Montenegro and North Macedonia), CoronaVac (Sinovac Life, Sciences Co., Ltd) (Albania, Georgia and Türkiye), SARS-CoV-2-Vaccine (Vero Cell), Inactivated (InCov) (Sinopharm/Beijing Institute of Biological Products Co., Ltd) (Georgia, Montenegro and North Macedonia) and Sanofi/GSK COVID-19 (Armenia). Türkiye also approved Turkovac vaccine for emergency use.

#### 2. How does/did your country control the entry on your territory during the pandemic of COVID-19?

9. Types of border control have varied during the pandemic and depended on infection pressure, vaccination rates and the introduction of Covid-19 certificates. During the first wave of the pandemic (which started in March 2020), many countries closed their borders for several weeks and refused entry to their territory to non-nationals (for example, **Hungary, Poland, Romania** and **Türkiye**). Almost all Council of Europe member States imposed border controls and, if necessary, a temporary requirement to undergo self-isolation or quarantine.

10. Council of Europe member States also required travellers entering their territory to hold a EU Digital COVID certificate or an equivalent proof of vaccination, recovery or a negative test for Covid-19 (Albania, Armenia, Austria, Bulgaria, Cyprus, Denmark, Estonia, Finland, Georgia, Germany, Hungary, Ireland, Latvia, Lithuania, the Netherlands, North Macedonia, Montenegro, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom). Exceptions to this rule applied to some categories of persons such as cross-border commuters (for example, in Switzerland) or minors under a certain age limit (under 5 years in Poland since 15 December 2021; under 10 years in Georgia, under 12 years in Portugal and the Slovak Republic, and under 16 years in Finland). Post-arrival testing for Covid-19 was or could be required by some member States (France, Ireland, Lithuania, Norway and the Republic of Slovakia).

11. Some countries required travellers to fill a locator form (**Belgium, Cyprus**, **Ireland, Poland** and the **United Kingdom**) or a (digital) entry registration (in some cases, in **Germany**, and in **Norway**).

12. During the pandemic, some member States decided to impose temporary **bans** on border-crossing for all or certain non-nationals (Albania, Belgium, Denmark, Finland, Lithuania, the Netherlands, Spain, Sweden and the United Kingdom).

13. A system of categorisation of countries from which travellers were coming was also introduced in order to better assess the risk of contamination (for example, in **Belgium, Cyprus**, **Germany** and **Ireland**). In this respect, EU member States were assisted by the European Centre for Disease Prevention and Control (ECDC), which published a map of member States' regions, using a traffic light system based on the rate of reported cases. The **United Kingdom** adopted an equivalent system, with destinations classified as green, amber or red.

14. In certain States, different rules applied to different parts of the national territory. In **Portugal**, different rules were in force in the mainland, on the islands of the Azores and Madeira (see question No. 3). In the **United Kingdom**, each of the four constituent entities has the power to determine its own entry requirements at the border.

15. Many countries have already lifted all restrictions (Albania, Armenia, Montenegro, Norway, Switzerland, Türkiye and the United Kingdom; for the European Union member States see question No. 3). However, some other Council of Europe member States still maintain certain sanitary controls at their borders (France, Germany, Luxembourg, the Netherlands, Portugal and Spain). Portugal and Spain require travellers to hold a valid Covid-19 certificate proving vaccination, recovery or a negative test result. Germany, Luxembourg and the Netherlands have still restricted access to the country for people travelling from some countries (see below). In France, non-vaccinated travellers are obliged to present a negative test result in order to entry the country. If unvaccinated travellers come from a high-risk country, they must continue to present an urgent reason for coming to France and might be obliged to undergo a Covid-19 test upon arrival to France.

3. In case of EU member States – can a third-country national vaccinated with WHO-approved vaccine which has not been approved by the EMA enter the territory of your country and, if so, under what conditions?

16. Twenty-one European Union member States answered this question. Fourteen of them stressed that currently there were no restrictions on entering their territory (Austria, Belgium<sup>93</sup>, Bulgaria, Cyprus, Denmark, Hungary, Ireland, Latvia, Lithuania, Poland, Romania, Slovenia, the Slovak Republic and Sweden).

17. Before the restrictions were lifted in some of these States, third-country nationals vaccinated with any of WHO-approved vaccines were recognised as immunised when entering their territory (**Cyprus, Estonia, Finland, Latvia,** the **Netherlands**<sup>94</sup> and **Slovenia**). Others recognised some of them; for example, **Poland** allowed on its territory people vaccinated with CoronaVac (Sinovac Life, Sciences Co., Ltd), Covovax (Serum Institute of India Pvt. Ltd), and Covishield (Serum Institute of India Pvt. Ltd) and **Finland** (as of June 2022) – persons vaccinated with the same three vaccines, with SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinopharm), COVAXIN (Bharat Biotec, India) and Convidencia (CanSino Biologics Inc.) (Chinese, approved in May 2022). In **Lithuania**, individuals vaccinated with non-EMA-approved vaccines needed to submit a negative test for Covid-19. **Bulgaria, Denmark, Romania and Sweden** required "certificates of vaccination" but it is not clear which vaccines they referred to. The answers of parliaments of **Belgium, France** and **Ireland** do not contain any reply to the question at issue.

18. Moreover, as indicated above (question No. 2), some countries still require a valid Covid-19 vaccination certificate, a proof of recovery or a negative test result. **Portugal** allows persons vaccinated with CoronaVac (Sinovac Life, Sciences Co., Ltd.), SARS-CoV-2 Vaccine (Vero Cell), Inactivated (Sinopharm) and COVAXIN (Bharat Biotec, India) to enter the mainland; different rules apply for entry to the Azores, where any WHO approved vaccination certificate is recognised, and the Madeira Islands, where certificates of vaccination with SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (Sinopharm), CoronaVac (Sinovac Life, Sciences Co., Ltd.) and Sputnik V (Gamaleya) are accepted.

19. **Spain** still maintains restrictions on entering its territory and requires a vaccination certificate, a negative Covid-19 test or a certificate of recovery but accepts vaccination certificates proving vaccination with any WHO-approved vaccine.

20. **Germany** also imposes entry restrictions on persons coming from "a virus variant area": they must present a proof of vaccination and a negative Covid-19 test. Vaccinations with SARS-CoV-2 Vaccine, Inactivated (Vero Cell) (Sinopharm), CoronaVac (Sinovac Life, Sciences Co., Ltd.) and COVAXIN (Bharat Biotec, India) are accepted.

21. The **Slovak Republic** requires persons entering its territory to present an EU Digital Covid Certificate or "other credible official evidence of vaccination"; third-country nationals should thus present a national certificate proving that they had been vaccinated and fulfilling some strict formal criteria. It is not clear to which vaccines those requirements apply.

22. To enter **Luxembourg**, third-country nationals, who do not hold a residence permit, must meet one of the four conditions specified in law. One of them refers to holding a certificate proving a complete vaccination schedule and "considered equivalent in Luxembourg" (however, this country authorised for marketing only the EMA-conditionally-authorised vaccines).

<sup>&</sup>lt;sup>93</sup> With some exceptions concerning "very high risk" areas, but no country is on such a list for a moment.

<sup>&</sup>lt;sup>94</sup> In the Netherlands, restrictions still apply for some people from countries outside the European Union/Schengen Area.