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Comments of the Commission on a request for information from the European Ombudsman

- Query by the Tuscan regional Ombudsman, ref. Q4/2021/VB

I. BACKGROUND

To allow for a gradual lifting of restrictions to free movement put in place to limit the spread of COVID-19, the European Parliament and the Council adopted, on 14 June 2021, Regulation (EU) 2021/953 on the EU Digital COVID Certificate¹. It consists on a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement.

Regulation (EU) 2021/954² extends the provisions of Regulation (EU) 2021/953 to third-country nationals who do not fall within the scope of that Regulation, but who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with Union law.

Pursuant to Article 5(1) of Regulation (EU) 2021/953, each Member State shall issue an EU Digital COVID Certificate to persons to whom a COVID-19 vaccine has been administered in that Member State.

Article 5(5) of Regulation (EU) 2021/953 provides that, where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, they shall also accept, under the same conditions, vaccination certificates issued by other Member States in accordance with this Regulation for a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004.

II. THE QUERY

The Tuscan regional Ombudsman raises concerns that several members of the Chinese, Russian and Ukrainian communities in Italy were vaccinated in their countries of origin with COVID-19 vaccines that are not authorised by EMA, namely Sinovac and Sputnik. Consequently, they do not have the EU Digital COVID Certificate and have to be tested, at their own costs, to be able to access the workplace.

The Ombudsman enquires whether the Commission is aware of these issues, and has any advice on how this problem could be addressed. The Ombudsman requests an overview of the legal

¹ 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 (available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R0953>)

² Regulation (EU) 2021/954 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) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0954>)

framework and of the possibilities available to the Member States under Regulation (EU) 2021/953 to address these issues.

III. THE COMMISSION'S COMMENTS

The issuance of EU Digital COVID Certificates

Article 5(1) of Regulation (EU) 2021/953 introduces an obligation on Member States to issue an EU Digital COVID Certificate for every COVID-19 vaccine dose administered in that Member State. This is independent whether the vaccine has been authorised at EU or national level. Thus, where a Member State administers a COVID-19 vaccine that has not been approved at EU level, such as Sputnik, it is nevertheless obliged to issue an EU Digital COVID Certificate.

The EU DCC Regulation provides that Member States may also issue vaccination certificates to persons who have been vaccinated in a third country and who provide all necessary information, including reliable proof to that effect. This is of particular importance to allow the persons concerned to make use of an interoperable and accepted vaccination certificate when exercising their right to free movement within the EU. This should apply in particular to EU citizens vaccinated in a third country in respect of which the health system of a Member State allows for the issuance of an EU Digital COVID Certificate and provided that the Member State has been provided with reliable proof of vaccination. A Member State is not required to issue a vaccination certificate where the COVID-19 vaccine concerned is not authorised for use on its territory.

In addition, Article 8(2) of Regulation (EU) 2021/953 provides for the possibility to recognise as equivalent COVID-19 certificates issued by third countries with the same level of trustworthiness and interoperability as those issued by EU Member States in accordance with the Regulation, and this for the purposes of facilitating the holders' right of free movement within the EU. Such unilateral recognition is done through an implementing act of the European Commission ('equivalence decision').

The acceptance of EU Digital COVID Certificates

Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to that Regulation, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, efficacy follow-up and supervision procedures of medicinal products authorised pursuant to that Regulation are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follow shared standards and are done in a consistent way on behalf of all Member States. Participation of Member States in the review and endorsement of the assessment is ensured through various committees and groups. The assessment also benefits from the expertise of the European medicines regulatory network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the data on efficacy and safety and on the consistency of the batches being used for vaccination.

Regulation (EU) 2021/953 therefore provides that, where Member States accept proof of vaccination in order to waive travel restrictions, they are obliged to accept certificates for vaccines that have been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004.

This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, in particular for vaccines that have been granted a marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines the distribution of which has been temporarily authorised pursuant to Article 5(2) of that Directive, and vaccines that have completed the WHO emergency use listing procedure.

The acceptance of “equivalent” certificates of third countries following an Article 8(2) implementing act, is subject to the same rules as the acceptance of EU Digital COVID Certificates: where they are issued following the administration of an EU-approved vaccine, their acceptance by Member States is mandatory.

For vaccines administered by third countries, it is necessary to determine if they correspond to an EU-authorised vaccine. The Commission supported discussions in the Health Security Committee on this issue, and has published an overview of vaccines administered by third countries, for which most EU Member States would waive travel restrictions, and a list of sublicensed vaccines, for which several Member States waive travel restrictions as they consider them as corresponding to the vaccines that had received EU approval³.

Additional comments

It is important to note that, by including vaccination, test and recovery certificates, Regulation (EU) 2021/953 ensures that as many persons as possible are able to obtain an EU Digital COVID Certificate in order to facilitate their right to free movement.

It is also important to underline that Regulation (EU) 2021/953 is based on Article 21(2) of the Treaty on the Functioning of the European Union and aims to facilitate the right to free movement within the EU. The domestic use of COVID-19 certificates for other purposes than facilitating free movement within the EU does not fall within the scope of the Regulation. Member States may indeed use the EU Digital COVID Certificate for domestic purposes, but are required to provide for a legal basis in national law that must comply, among others, with data protection requirements⁴.

It is up to Member States to determine which health protection measures they consider most appropriate regarding access to, for example, the workplace. The conditions of acceptance for domestic purposes – including which types of certificates to accept for such purposes – do not fall within the scope of the EU Digital COVID Certificate Regulation and thus fall within Member States’ competence in the field of public health.

³ <https://reopen.europa.eu/en>

⁴ Recital 48 of Regulation (EU) 2021/953