

## **Report of the European Ombudsman closing a query from the Tuscan regional Ombudsman concerning the issues faced by individuals vaccinated with COVID-19 vaccines that have not received an EU authorisation (Q4/2021/VB)**

Decision

**Case Q4/2021/VB - Opened on 07/12/2021 - Decision on 24/03/2022**

### **The background**

1. National and regional ombudsmen in the European Network of Ombudsmen may ask the European Ombudsman for written answers to queries about EU law and its interpretation, including those which arise in their handling of specific cases.
2. On 2 November 2021, the Tuscan regional ombudsman [1] submitted a query to the European Ombudsman. The query concerns access to the EU Digital COVID Certificate for people vaccinated with COVID-19 vaccines that have not received an EU authorisation.
3. The EU Digital COVID Certificate aims to facilitate free movement and travel within the EU. Many Member States are also using the certificate as a requirement for accessing certain services or venues. The European Parliament and the Council adopted rules [2] setting up the framework for the issuance, verification and acceptance of the EU Digital COVID Certificate.
4. The European Ombudsman wrote to the European Commission on 7 December 2021, and asked it to reply to questions on the issues raised by the Tuscan regional ombudsman. The Commission replied on 26 January 2022. The Office of the Tuscan regional ombudsman subsequently informed the European Ombudsman that the Commission's reply was clear.

### **The questions addressed to the Commission**

5. Based on the query, the Ombudsman asked the Commission the following questions:
  - Is the Commission aware of the issues faced by certain communities in accessing the EU Digital COVID Certificate because of the vaccine they received? Does the Commission have any advice on how these issues could be addressed?



- Could the Commission also provide an overview of the legal framework and of the possibilities available to the Member States under Regulation 2021/953 to address the issues described in this query?

## The Commission's reply

**6.** Regulation 2021/953 on the EU Digital COVID Certificate aims to facilitate the right to free movement within the EU. The use of the EU Digital COVID Certificate for purposes other than facilitating free movement, established at domestic level, does not fall within the scope of the Regulation.

**7.** If Member States decide to use the EU Digital COVID Certificate for domestic purposes, they have to provide for a legal basis in national law. Therefore, the conditions of acceptance for domestic purposes of a certificate fall within Member States' competence.

### The issuance of the EU Digital COVID Certificate

**8.** Member States have an obligation under Regulation 2021/953 to issue an EU Digital COVID Certificate for every COVID-19 vaccine administered in that Member State, regardless of whether the vaccine has been authorised at EU or national level. [3] An EU Digital COVID Certificate has to be issued also when the vaccine administered has not received an EU authorisation.

**9.** Member States may also issue vaccination certificates to persons who have been vaccinated in non-EU countries and who provide all necessary information, including reliable proof to that effect. However, Member States are not required to issue a vaccination certificate where the COVID-19 vaccine concerned is not authorised for use on its territory.

**10.** Furthermore, the Commission can adopt an 'equivalence decision' to recognise, as equivalent, COVID-19 certificates issued by non-EU countries, where it deems those certificates to be reliable and interoperable with the EU Certificate. [4]

### The acceptance of EU Digital COVID Certificates

**11.** The Commission said, that where Member States accept proof of vaccination in order to waive travel restrictions, they have to accept certificates for vaccines that have been granted an EU marketing authorisation [5] . This does not prevent Member States from accepting vaccination certificates issued for other COVID-19 vaccines such as (i) those that have been granted a marketing authorisation by the relevant authority of a Member State, (ii) those whose distribution has been temporarily authorised, and (iii) those that have completed the WHO emergency use listing procedure [6] .

**12.** The acceptance of certificates from non-EU countries following an 'equivalence decision' is mandatory when the certificate is based on a vaccine that has received an EU marketing



authorisation.

## The European Ombudsman's conclusions

**13.** The Ombudsman notes that the Office of the Tuscan regional ombudsman found the Commission's explanation clear.

**14.** In light of this, the Ombudsman considers that the issues raised in the query have been adequately clarified. The Ombudsman therefore closes the query.

**15.** The Tuscan regional ombudsman and the Commission will be informed of this report.

Rosita Hickey Director of Inquiries

Strasbourg, 24/03/2022

[1] Difensore civico della Toscana.

[2] 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  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953> [Link].

[3] Regulation (EU) 2021/953, Article 5(1).

[4] Regulation (EU) 2021/953, Article 8(2).

[5] Under Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0726> [Link].

[6] Regulation (EU) 2021/953, Article 5(5).