Council of the European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 March 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2022) 2050 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 29.3.2022 amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards exempting minors from the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format

Delegations will find attached document C(2022) 2050 final.

Encl.: C(2022) 2050 final

EUROPEAN
COMMISSION

Brussels, 29.3.2022
C(2022) 2050 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.3.2022

amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards exempting minors from the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic.

On 21 December 2021, the Commission adopted Delegated Regulation (EU) 2021/2288 amending Regulation (EU) 2021/953[1], which established, for the purpose of travel, a standard acceptance period of 270 days for vaccination certificates indicating the completion of the primary vaccination series. It provides that Member States should, to ensure a coordinated approach, not accept vaccination certificates indicating the completion of the primary vaccination series if more than 270 days have passed since the administration of the dose indicated therein. At the same time, Member States should, for the purpose of travel, not provide for an acceptance period shorter than 270 days.

The Commission considers that it is necessary to adapt the rules on the acceptance period established by Delegated Regulation (EU) 2021/2288 as far as vaccination certificates held by persons under the age of 18 years are concerned. This follows a re-evaluation of the approach regarding the acceptance period as mentioned in Recital 15 of that Delegated Regulation.

On 24 February 2022, the European Medicines Agency ('EMA') announced that its Committee for Medicinal Products for Human Use had recommended that a booster dose of the COVID-19 vaccine Comirnaty may be given where appropriate to adolescents from 12 years of age[2]. The Committee considered that the available evidence was sufficient to conclude that the immune response to a booster dose in adolescents would be at least equal to that in adults. No new safety concerns were identified from the data available. On 28 February 2022, the Commission adopted an Implementing Decision amending the conditional marketing authorisation granted to Comirnaty accordingly[3].

The opinion from EMA supports the national vaccination campaigns in those Member States that decide on offering booster vaccinations to adolescents. At the same time, as mentioned by EMA, the decision on whether and when to offer boosters in this age group will need to take into account such factors as the spread and likely severity of the disease in younger persons, especially with the Omicron variant, the known risk of side effects, particularly the very rare but serious complication of myocarditis, and the existence of other protective measures and restrictions. It is thus for the experts guiding the vaccination campaign in each Member State to advise on the optimum decision and timing for their country.

In its technical report on COVID-19 vaccine effectiveness in adolescents aged 12–17 years and interim public health considerations for administration of a booster dose of 8 February

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1 Commission Delegated Regulation (EU) 2021/2288 of 21 December 2021 amending the Annex to Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format indicating the completion of the primary vaccination series (OJ L 458, 22.12.2021, p. 459).

2 https://www.ema.europa.eu/en/news/ema-recommends-authorisation-booster-doses-comirnaty-12-years-age

3 Commission Implementing Decision of 28 February 2022 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", a medicinal product for human use (C(2022) 1351 final).

2022[4], the European Centre for Disease Prevention and Control ('ECDC') concluded that available studies looking at COVID-19 vaccine effectiveness of primary vaccination course against infection, symptomatic disease and severe disease due to the Delta variant of concern showed a very high level of protection in adolescents. According to ECDC, there was limited evidence available of waning of immunity following vaccination among adolescents. The available data suggested a waning of vaccine effectiveness against symptomatic infection five to six months following completion of the primary vaccination course, however no evidence of waning immunity against severe disease was available at that point in time. Mathematical modelling by ECDC suggested that providing booster doses to adolescents is unlikely to have a considerable effect on the population-level transmission of SARS-CoV-2.

When consulted by the Commission, a large number of Member States' experts in the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[5] considered that, even if some Member States might decide, based on the different considerations outlined by EMA, to offer booster vaccinations to minors, it is appropriate to exempt minors from the standard acceptance period established by Delegated Regulation (EU) 2021/2288.

In view of the above, the standard acceptance period should be limited to persons aged 18 and above.

Like the standard acceptance period established by Delegated Regulation (EU) 2021/2288, the exemption for persons under the age of 18 should be implemented at the level of verification, including by adapting the mobile applications used to verify EU Digital COVID Certificates. Given that vaccination certificates include the holder's date of birth, the mobile applications used for verification are able to determine whether the standard acceptance period is to be applied or not. In this context, the exemption should apply to persons below the age of 18 on the day a certificate is verified.

The Commission will continue to carefully and closely monitor the standard acceptance period for vaccination certificates to assess whether adaptations or changes might be needed on the basis of newly emerging scientific evidence.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Before adopting this delegated act, the Commission consulted the EU Digital COVID Certificate Expert Group on 10 February 2022 and 22 March 2022.

The European Parliament and the Council were informed of the meetings of the EU Digital COVID Certificate Expert Group where a draft version of this delegated regulation was discussed and both institutions, therefore, received all relevant documents at the same time as Member States' experts in line with the 2016 Interinstitutional Agreement on Better Law Making and the Common understanding on Delegated Acts annexed to it.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 5(2) of Regulation (EU) 2021/953 empowers the Commission to adopt delegated acts to amend point 1 of the Annex to the Regulation by modifying or removing data fields, or by

[4] https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-considerations-for-booster-doses-in-adolescents-Feb%202022.pdf

[5] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

adding data fields falling under the categories of personal data referred to in points (b) and (c) of the first subparagraph of Article 5(2), where such an amendment is necessary to verify and confirm the authenticity, validity and integrity of the vaccination certificate, in the case of scientific progress in containing the COVID-19 pandemic, or to ensure interoperability with international standards.

Pursuant to Article 5(4) of Regulation (EU) 2021/953, where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the urgency procedure provided for in Article 13 of the Regulation is to apply to delegated acts adopted pursuant to Article 5(2) of that Regulation.

In light of newly emerging scientific evidence as to the administration for boosters to adolescents from 12 years of age, taking into account in particular such factors as the spread and likely severity of the disease in younger persons and the known risk of side effects, as well as to the COVID-19 vaccine effectiveness of the primary vaccination course in this age group, imperative grounds of urgency require the use of the procedure provided for in Article 13 of Regulation (EU) 2021/953. Delaying immediate action would also aggravate the risk of vaccination certificates held by minors no longer being accepted despite these developments.

Article 1 provides for a modification of point 1(h) of the Annex to Regulation (EU) 2021/953, which contains the standard 270-day acceptance period of vaccination certificates indicating the completion of the primary series, according to which the certificates of persons under the age of 18 should be exempt from the acceptance period.

Article 2 provides for a transitional period. To allow for sufficient time for the technical implementation of the modification introduced by Article 1, Member States can apply, until 6 April 2022, the standard acceptance period established by Delegated Regulation (EU) 2021/2288 also to certificates held by persons below the age of 18.

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.3.2022

amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards exempting minors from the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[6], and in particular Article 5(2) and (4) thereof,

Whereas:

(1) Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It also contributes to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) On 21 December 2021, the Commission adopted Delegated Regulation (EU) 2021/2288 amending Regulation (EU) 2021/953[7], which establishes, for the purpose of travel, a standard acceptance period of 270 days for vaccination certificates indicating the completion of the primary vaccination series. That Delegated Regulation provides that Member States are, to ensure a coordinated approach, not to accept vaccination certificates indicating the completion of the primary vaccination series if more than 270 days have passed since the administration of the dose indicated therein. At the same time, Member States are, for the purpose of travel, not to provide for an acceptance period shorter than 270 days.

(3) It is necessary to adapt the rules on the standard acceptance period of 270 days established by Delegated Regulation (EU) 2021/2288 as far as vaccination certificates held by persons under the age of 18 years are concerned. This follows a re-evaluation of the approach regarding the acceptance period as mentioned in Recital 15 of that Delegated Regulation.

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6 OJ L 211, 15.6.2021, p. 1.

7 Commission Delegated Regulation (EU) 2021/2288 of 21 December 2021 amending the Annex to Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format indicating the completion of the primary vaccination series (OJ L 458, 22.12.2021, p. 459).

(4) On 24 February 2022, the European Medicines Agency ('EMA') announced that its Committee for Medicinal Products for Human Use had recommended that a booster dose of the COVID-19 vaccine Comirnaty may be given where appropriate to adolescents from 12 years of age[8]. The Committee considered that the available evidence was sufficient to conclude that the immune response to a booster dose in adolescents would be at least equal to that in adults. No new safety concerns were identified from the data available. On 28 February 2022, the Commission adopted an Implementing Decision amending the conditional marketing authorisation granted to Comirnaty accordingly[9].

(5) The opinion from EMA supports the national vaccination campaigns in those Member States that decide to offer booster vaccinations to adolescents. At the same time, as noted by EMA, the decision on whether and when to offer boosters in this age group will need to take into account such factors as the spread and likely severity of the disease in younger persons, especially with the Omicron variant, the known risk of side effects, particularly the very rare but serious complication of myocarditis, and the existence of other protective measures and restrictions. It is thus for the experts guiding the vaccination campaign in each Member State to advise on the optimum decision and timing for their country.

(6) In its technical report on COVID-19 vaccine effectiveness in adolescents aged 12–17 years and interim public health considerations for administration of a booster dose of 8 February 2022[10], the European Centre for Disease Prevention and Control ('ECDC') concluded that available studies looking at COVID-19 vaccine effectiveness of primary vaccination course against infection, symptomatic disease and severe disease due to the Delta variant of concern showed a very high level of protection in adolescents. According to ECDC, there was limited evidence available of waning of immunity following vaccination among adolescents. The available data suggested a waning of vaccine effectiveness against symptomatic infection five to six months following completion of the primary vaccination course, however no evidence of waning immunity against severe disease was available at that point in time. Mathematical modelling by ECDC suggested that providing booster doses to adolescents is unlikely to have a considerable effect on the population-level transmission of SARS-CoV-2.

(7) When consulted by the Commission, a large number of Member States' experts in the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[11] considered that, even if some Member States might decide, based on the different considerations outlined by EMA, to offer booster vaccinations to minors, it is appropriate to exempt minors from the standard acceptance period established by Delegated Regulation (EU) 2021/2288. Not all

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8 https://www.ema.europa.eu/en/news/ema-recommends-authorisation-booster-doses-comirnaty-12-years-age

9 Commission Implementing Decision of 28 February 2022 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)", a medicinal product for human use (C(2022) 1351 final).

10 https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-considerations-for-booster-doses-in-adolescents-Feb%202022.pdf

11 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Member States are currently offering booster vaccinations to persons below the age of 18.

(8) The standard acceptance period should thus be limited to persons aged 18 and above.

(9) Like the standard acceptance period established by Delegated Regulation (EU) 2021/2288, the exemption for persons under the age of 18 should be implemented at the level of verification, including by adapting the mobile applications used to verify EU Digital COVID Certificates. Given that vaccination certificates include the holder's date of birth, the mobile applications used for verification are able to determine whether the standard acceptance period is to be applied or not. In this context, the exemption should apply to persons below the age of 18 on the day a certificate is verified.

(10) The Commission should continue monitoring and regularly re-evaluating the approach regarding the acceptance period to assess whether adaptations might be needed on the basis of newly emerging scientific evidence, including in relation to the acceptance period for certificates indicating the administration of a booster dose.

(11) Regulation (EU) 2021/953 should therefore be amended accordingly.

(12) In light of newly emerging scientific evidence as to the administration for boosters to adolescents from 12 years of age, taking into account in particular such factors as the spread and likely severity of the disease in younger persons and the known risk of side effects, as well as to the COVID-19 vaccine effectiveness of the primary vaccination course in this age group, imperative grounds of urgency require the use of the procedure provided for in Article 13 of Regulation (EU) 2021/953. Delaying immediate action would also aggravate the risk of vaccination certificates held by minors no longer being accepted despite these developments. Therefore, the urgency procedure provided for in Article 13 of Regulation (EU) 2021/953 is to apply.

(13) This Regulation is without prejudice to Member States' decisions as to their national vaccination campaigns.

(14) To allow for sufficient time for the technical implementation of this Regulation, Member States should be allowed to apply, until 6 April 2022, the standard acceptance period established by Delegated Regulation (EU) 2021/2288 also to certificates held by persons below the age of 18.

(15) Given the urgency of the situation related to the COVID-19 pandemic, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

In point 1 of the Annex to Regulation (EU) 2021/953, point (h) is replaced by the following:

"(h) date of vaccination, indicating the date of the latest dose received (certificates held by persons aged 18 and above indicating the completion of the primary vaccination series shall be accepted only if not more than 270 days have passed since the date of the latest dose in that series);".

Article 2

Until 6 April 2022, Member States may apply point 1(h) of the Annex to Regulation (EU) 2021/953 as amended by Delegated Regulation (EU) 2021/2288 also to certificates held by persons below the age of 18.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29.3.2022

For the Commission
The President
Ursula VON DER LEYEN