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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of 11.3.2021

making the exportation of certain products subject to the production of an export authorisation

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports[1], and in particular Article 6 thereof,

Whereas:

(1) On 30 January 2021, the Commission adopted Commission Implementing Regulation (EU) 2021/111[2] making the exportation of COVID-19 vaccines as well as active substances, including master and working cell banks, used to manufacture these vaccines, subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479. Implementing Regulation (EU) 2021/111 applies for a maximum period of six weeks.

(2) The production capacity of COVID-19 vaccines is still in the building-up phase and remains, for certain vaccine manufacturers, below the pledged quantities to be destined for the Union on the basis of Advanced Purchased Agreements (APAs) concluded with the Union.

(3) In light of the critical situation of COVID-19 vaccines in the Union, and in particular the risk that vaccines produced or packaged in the Union are exported, especially to non-vulnerable countries, in potential breach of contractual commitments entered into by the pharmaceutical industries, continued protective measures are warranted to prevent shortages and delayed deliveries of such vaccines. It is therefore in the Union's interest to maintain, for a limited period of time, a mechanism to ensure that exports of COVID-19 vaccines covered by APAs with the Union are subject to a prior authorisation, so that there are adequate supplies in the Union to meet the vital demand, but without impacting on the Union's international commitments in this respect.

(4) Export authorisations should be granted by the Member States where products covered by this Regulation are manufactured to the extent that the exports concerned do not pose a threat to the continuous supply of the vaccines necessary for the execution of the APAs between the Union and vaccine manufacturers in view of their volume or other relevant circumstances. In order to ensure a coordinated approach at Union level, the Member States should seek the opinion of the Commission in advance and decide in accordance with that opinion.

[1] OJ L 83, 27.3.2015, p, 34.

[2] Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation (OJ L 31 I, 30.1.2021, p. 1).

(5) The administrative modalities for the export authorisations should be left to the discretion of the Member States during the period of application of this temporary mechanism.

(6) An export authorisation may cover multiple export consignments of vaccines and samples. In order to facilitate the administration process while ensuring transparency, the authorisation form should be simplified, allowing that one single request and authorisation form cover one shipment with consignments to multiple final recipients within the same destination country but being released by the same customs office of export. For customs control purposes, the customs office of export should be indicated in the authorisation.

(7) To ensure that the situation is assessed at regular intervals, and in order to ensure transparency and consistency, Member States should provide information to the Commission on requested export authorisations, and their decisions in response to such requests. The Commission should make such information publicly available on a regular basis, due account being taken of their confidential nature.

(8) The single market for medicinal products is closely integrated beyond the boundaries of the Union, and so are its supply chains and distribution networks. This is particularly the case with regard to the neighbouring countries and economies, the Member States of the European Free Trade Area and the Western Balkans, which are engaged in the process of integration with the Union. Subjecting exports of COVID-19 vaccines to those countries to an export authorisation requirement would be counterproductive due to their proximity and dependency on Union supplies of vaccines (most of them do not have their own production capacity for the vaccines in question in adequate quantities) and the fact that vaccines are an essential product necessary to prevent the further spreading of the pandemic. It is therefore appropriate to exempt such countries from the scope of application of this Regulation.

(9) It is likewise appropriate to exempt from the export authorisation requirement the overseas countries and territories listed in Annex II to the Treaty, the Faeroe Islands, Andorra, San Marino, and the Vatican City, as well as territories of Member States specifically excluded from the customs territory, namely Büsingen, Helgoland, Livigno, Ceuta and Melilla, since they have a particular dependency on the metropolitan supply chains of the Member States to which they are attached or on the supply chains of neighbouring Member States, respectively. Likewise, exports to the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to United Nations Convention on the Law of the Sea (UNCLOS) should be exempted from the application of this Regulation.

(10) As only exports from the customs territory of the Union are covered, countries that form part of that customs territory need not to be exempted in order to receive unrestricted shipments from within the Union. This is the case notably for the Principality of Monaco[3].

(11) Based on the principle of international solidarity, exports to enable the provisions of supplies in the context of humanitarian emergency response, exports to the COVAX facilities, and in particular to low and middle-lower income countries, given their vulnerability and limited access to vaccines, exports of COVID-19 vaccines purchased or delivered through COVAX, UNICEF and PAHO with destination to any other

[3] See Article 4(2)(a) of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

COVAX participating country and exports of COVID-19 vaccines purchased by Member States under the Union's APAs and resold or donated to a third country should be exempted from the export authorisation requirement.

(12) Prior authorisation requirements are of an exceptional nature, and should be targeted and of a limited duration. Given the continuing constraints on vaccine production and risks of delays in the delivery of COVID-19 vaccines in the Union, as mentioned in recitals (2) and (3), the export authorisation mechanism should continue to apply for a limited time period.

(13) Due to the limited duration of the measures provided for in Implementing Regulation (EU) 2021/111, this Regulation should enter into force as soon as possible.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 3(1) of Regulation (EU) 2015/479,

HAS ADOPTED THIS REGULATION:

Article 1

Export authorisation

1. An export authorisation established in accordance with the form set out in Annex I shall be required for the export of the following goods:

(a) vaccines against SARS-related coronaviruses (SARS-CoV species) currently falling under CN code 3002 20 10, irrespective of their packaging;

(b) active substances, including master and working cell banks used for the manufacture of such vaccines, currently falling under CN codes ex 2933 99 80, ex 2934 99 90, ex 3002 90 90 and ex 3504 00 90.

2. For the purposes of this Regulation, 'export' means:

(a) an export of Union goods under the export procedure within the meaning of Article 269(1) of Regulation (EU) No 952/2013 of the European Parliament and of the Council[4];

(b) a re-export of non-Union goods within the meaning of Article 270(1) of that Regulation after such goods have been subject to manufacturing operations including filling and packaging within the customs territory of the Union.

3. The export authorisation shall be produced when the goods are declared for export and at the latest at the moment of the release of the goods.

4. The export authorisation shall be granted by the competent authorities of the Member State where products covered by this Regulation are manufactured and shall be issued in writing or by electronic means. For the purposes of this Regulation, manufacturing shall include the filling and packaging of vaccines. If the goods covered by this Regulation are manufactured outside the Union, the export authorisation shall be granted by the competent authorities of the Member State where the exporter is established.

5. The export or re-export declaration shall indicate the number of doses (in case of multi-dose containers, the number of doses for adults).

[4] Regulation (EU) No 952-2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

6. Without the production of a valid export authorisation, the exportation of the goods covered by this Regulation shall be prohibited.

7. The competent authority shall grant an export authorisation, unless it poses a threat to the execution of APAs concluded by the Union with vaccine manufacturers, in view of the volume of exports or any other relevant circumstances.

8. An export authorisation may cover one shipment with more than one consignment of goods mentioned in paragraph 1, provided all consignments are destined to the same destination country and released by the same customs office of export.

9. The following exports shall not be subject to the export authorisation provided for in this Article:

(a) exports to Albania, Andorra, Bosnia and Herzegovina, the Faroe Islands, Iceland, Kosovo*, Liechtenstein, Montenegro, Norway, North Macedonia, San Marino, Serbia, Switzerland, Vatican City, the overseas countries and territories listed in Annex II of the Treaty on the Functioning of the European Union, Büsingen, Helgoland, Livigno, Ceuta and Melilla, Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, Palestine*, Syria, Tunisia, and Ukraine;

(b) exports to low and middle income countries in the COVAX AMC list[5];

(c) exports of goods purchased or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country;

(d) exports of goods purchased by Member States under the APAs entered into by the Union and donated or resold to a third country;

(e) exports in the context of a humanitarian emergency response;

(f) exports to facilities located on the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS.

For exports referred to in point (f) of the first subparagraph, the export declaration shall provide the information about the continental shelf or exclusive economic zone of the Member State to which the goods covered by this Regulation are to be brought by using the relevant additional reference code as defined in data element 2/3 in point 2 of Title II of Annex B of Commission Implementing Regulation (EU) 2015/2447[6].

Article 2

Procedure

1. The request for export authorisation shall contain the information set out in Annex I and the applicable TARIC additional codes in Annex II. In addition it shall also contain information on the number of vaccine doses of goods covered by this Regulation distributed in the Union

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* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

* This designation shall not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of the Member States on this issue.

5 https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc

6 Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

since 1 December 2020 broken down by Member State as well as information on the number of vaccine doses of goods covered by this Regulation distributed in Northern Ireland since the entry into force of Commission Implementing Regulation (EU) 2021/111.

2. The competent authorities of the Member States shall process the requests for export authorisations as soon as possible, and shall issue a draft decision no later than two working days from the date on which all required information has been provided to them by the applicant. Under exceptional circumstances and for duly justified reasons, that period may be extended by a further period of two working days.

3. The competent authorities of the Member States shall immediately notify the request and the draft decision to the Commission at the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu.

4. Where the Commission disagrees with the draft decision notified by a Member State, it shall issue an opinion to the competent authority within one working day from receipt of a notification. If the request is incomplete or inaccurate, that time period shall start from the moment when the required information is provided, at the request of Commission, by the competent authority of the notifying Member State. The Commission shall evaluate the impact of exports for which an authorisation is requested on the execution of the relevant APAs with the Union. The Member State shall expeditiously decide on the request for authorisation in accordance with the Commission's opinion.

5. The vaccine manufacturers that have concluded APAs with the Union shall provide the relevant data concerning their exports since 30 October 2020, together with the first request for authorisation under this Regulation or under Implementing Regulation (EU) 2021/111 to the Commission (at the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu) and to the authorities of the competent Member State. That information shall include the volume of exports of COVID-19 vaccines, the final destination and final recipients and a precise description of the products. The absence of such information may lead to refusal of export authorisations.

6. The competent authorities of the Member States may decide to make use of electronic documents for the purpose of processing requests for export authorisations.

7. The competent authorities of the Member States may verify the information submitted pursuant to paragraph 6 on the premises of the applicant, even after the authorisation has been granted.

Article 3

Notifications

1. Member States shall immediately notify the Commission of the export authorisations granted and those refused.

2. These notifications shall contain the following information:

(a) name and contact details of the competent Authority,

(b) identity of the applicant,

(c) destination country,

(d) acceptance or refusal to grant the export authorisation,

(e) commodity code,

(f) quantity expressed in number of vaccine doses,

(g) units and description of the goods,

(h) information on the number of vaccine doses of goods covered by this Regulation distributed in the Union since 1 December 2020 broken down by Member State in which the vaccines were distributed.

The notification shall be submitted to the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu

3. The Commission shall make the information on the export authorisations granted and refused publicly available, due account being taken of the confidentiality of the data submitted.

Article 4

Entry into force and application

This Regulation shall enter into force on 13 March 2021.

It shall apply until 30 June 2021.

Export authorisations issued in accordance with Annex I of Implementing Regulation 2021/111 shall remain valid after the entry into force of this Regulation.

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

Done at Brussels, 11.3.2021

For the Commission
The President
Ursula VON DER LEYEN