II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/111

of 29 January 2021

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

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 5 thereof,

Whereas:

(1) The COVID-19 virus continues to spread rapidly within the Union, with severe consequences in terms of public health – in particular with a dramatic number of fatal outcomes – as well as economic and societal disruption. A permanent solution to this crisis depends on the deployment of an effective and safe vaccine against the virus.

(2) Under its vaccines strategy, the Commission has financed and secured the production of a sufficient quantity of vaccines in the Union and forged agreements with individual vaccine manufacturers on behalf of Union Member States in order to ensure affordable and timely access to COVID-19 vaccines for all Member States and their population, while leading the global solidarity effort. It is essential that these supplies are effectively delivered by the manufacturers, as production of vaccines in the Union takes place only in a limited number of Member States.

(3) Despite the fact that financial support has been given to increase production, certain vaccine manufacturers have already announced that they would not be in a position to supply the quantities of vaccine destined to the Union that they had pledged, in potential breach of their contractual commitments. Furthermore, there is a risk that vaccines produced in the Union are exported from the Union, in particular to non-vulnerable countries. Such a potential breach of contractual commitments made by the pharmaceutical industries, carries the risk of shortages and therefore delays within the Union. Such delays severely disrupt the Union's plan to inoculate its population.

(4) In the current situation that is marked by the fact that the production and delivery of vaccines is still in the building-up phase and the ensuing temporary global shortage, it is important to ensure the necessary level of transparency about the quantities of vaccines covered by this Regulation produced and the quantities delivered in order to further support the orderly implementation of the vaccination campaigns in the Member States but also elsewhere in countries that depend on Union produced COVID-19 vaccines produced in the Union.

(5) In order to remedy a critical situation and to ensure transparency, it is in the Union interest to take immediate action for a limited duration to ensure that exports of COVID-19 vaccine covered by Advanced Purchased Agreements (APA) with the Union are subject to a prior authorisation so that they are adequate supplies in the Union to meet the vital demand, but without impacting on the Union's international commitments in this respect. The Commission is also mindful of APAs contracted by third countries, and will endeavour that the expectations of these countries to obtain their deliveries will be met as much as possible.

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

(6) In order to avoid the risk that measures are circumvented, vaccines should be covered by this regulation irrespective of their packaging and active substances including master and working cell banks used for the manufacture of such vaccines.

(7) Export authorisation should be granted by the Member States where products covered by this regulation are manufactured to the extent that the volume of exports is not such that it poses a threat to the continuous supply of the vaccines necessary for the execution of the APAs between the Union and vaccines manufacturers. In order to ensure an adequate coordinated decision at Union level, the Member States should seek in advance the opinion of the Commission and decide in accordance with that opinion

(8) The administrative modalities for these authorisations should be left to the discretion of the Member States during the time of this temporary system.

(9) It is not the intention of the Union to restrict exports any more than absolutely necessary, and the Union remains fully committed to international solidarity and strongly supports the principle that any measures deemed necessary to prevent or relieve critical shortages are implemented in a manner that is targeted, transparent, proportionate, temporary and consistent with WTO obligations.

(10) 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 and/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country and exports of COVID vaccine purchased by Member States under the Union's APAs and resold or donated to a third country should be excluded from the export authorisation requirement.

(11) The single market for medical products is closely integrated beyond the boundaries of the Union, and so are its production value 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 a process of deep integration with the Union. Subjecting exports of COVID-19 vaccines to these 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 exclude such countries from the scope of application of this Regulation.

(12) It is likewise appropriate to exclude from the export authorisation requirement the overseas countries and territories listed in Annex II to the Treaty, as well as the Faeroe Islands, Andorra, San Marino and the Vatican City 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.

(13) This Regulation should apply to exports of Union goods from the customs territory of the Union. Therefore countries that form part of that customs territory need not be exempted in order to receive unrestricted shipments from within the Union. This is the case notably for the Principality of Monaco [2]. Conversely, territories of Member States specifically excluded from the customs territory of the Union should not fall under the requirement of export authorisation and should therefore be exempted as well. This concerns the territories of Büsingen, Helgoland, Livigno, Ceuta and Melilla. 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. All these territories, likewise, have a particular dependency on the supply chains of the Member States which they are part of or of neighbouring Member States, respectively

[2] 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).

(14) To assess the situation in regular intervals, and in order to ensure transparency and consistency Member States should report their decisions to grant or reject requests for export authorisations to the Commission. The Commission should make such information publicly available on a regular basis, due account being taken of their confidential nature.

(15) In order to ensure an effective monitoring of the situation and to assess whether the objectives of this regulation are met when the export authorisations are requested, the manufactures that have concluded APAs with the Union should provide to the Member States and to the Commission relevant data concerning their exports in the last three months. This information should 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 refusals of export authorisation.

(16) Due to the urgency of the situation, justified by the fast spreading of the COVID-19 pandemic, the measures provided for in this Regulation should be taken in accordance with Article 3(3) of Regulation (EU) 2015/479.

(17) It is considered that measures should remain in force until 31 March 2021, when full production capacity for COVID-19 vaccines in the EU has been installed and the risk of shortages and diversion of supplies will be reduced.

(18) This Regulation should enter into force on the day following that of its publication. Having regard to Article 5(5) of Regulation (EU) 2015/479, the initial measures should have a duration of six weeks. In order to cover the period until 31 March 2021, the Commission intends to propose an extension of these measures pursuant to Article 6 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 Union goods in the meaning of Article 5(23) of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([3]):
vaccines against SARS-related coronaviruses (SARS-CoV species) falling under CN code 3002 20 10, irrespective of their packaging. It will also cover active substances including master and working cell banks used for the manufacture of such vaccines.

It 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.

2. 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.

3. Without the production of a valid export authorisation, the exportation of such goods is prohibited.

4. The competent authority shall deliver an export authorisation only where the volume of exports is not such that it poses a threat to the execution of Union APAs concluded with vaccines manufacturers.

([3]) See for excluded transactions Article 269(2) 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)

5. Based on the principle of solidarity, the following exports shall not be subject to the measures set out in paragraphs 1 and 2:

— exports to Republic of Albania, Andorra, Bosnia and Herzegovina, the Faeroe Islands, the Republic of Iceland, Kosovo ([4]), the Principality of Liechtenstein, Montenegro, the Kingdom of Norway, the Republic of North Macedonia, the Republic of San Marino, Serbia, the Swiss confederation, Vatican City State, the overseas countries, territories listed in Annex II of the Treaty of the Functioning of the European Union, and exports to Büsingen, Helgoland, Livigno, Ceuta and Melilla, Algeria, Egypt, Jordan, Lebanon, Libya, Morocco, Palestine ([5]), Syria, Tunisia, Armenia, Azerbaijan, Belarus, Georgia, Israel, Moldova and Ukraine.

— exports to low and middle income countries in the COVAX AMC list ([6])

— exports of goods purchased and/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country

— exports of goods purchased by EU Member States under the EU APAs and donated or resold to a third country.

— exports in the context of a humanitarian emergency response.

— 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 such exports, the declaration shall provide the information about the continental shelf or exclusive economic zone of the Member State to which the goods under 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 ([7]).

Article 2

Procedure

1. The request for export authorisation shall be made to the competent authorities of the Member States where products covered by this regulation are manufactured and 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 since 1st December 2020 broken down by Member States 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 the Regulation.

2. The competent authorities of Member States shall process the applications 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 the competent authorities. Under exceptional circumstances and for duly justified reasons, that period may be extended by a further period of two working days.

3. Member States shall immediately notify the applications to the Commission at the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu

4. The competent authority shall notify its draft decision to the European Commission to the same email address.

5. In case of disagreement with the draft decision made by a Member State, the Commission shall issue an opinion to the competent authority within one working day from the receipt of the notification of the draft decision of the 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 decide on the request for authorisation in accordance with the Commission's opinion.

([4]) 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.

([5]) 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.

([6]) https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc

([7]) 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).

6. The vaccine manufacturers that have concluded APAs shall provide electronically to the the Commission (at the following address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu) and to the competent Member State's authorities the relevant data concerning their exports in the last three months prior to the entry into force of this Regulation together with the first request for authorisation. This 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.

7. The competent authorities of the Member States may decide to make use of electronic documents for the purpose of processing the applications for export authorisation.

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

Article 3

Notifications

1. Member States shall immediately notify the Commission of 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 exporter,

(c) destination country,

(d) final recipient,

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

(f) commodity code,

(g) quantity expressed in number of vaccine doses,

(h) units and description of the goods,

(i) information on the number of vaccine doses of goods covered by this Regulation distributed in the Union since 1st December 2020 broken down by Member States.

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

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

Article 4

Final provisions

This Regulation shall enter into force on the day 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 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Model for export authorisation forms referred to in Article 1

Member States shall ensure the visibility of the nature of the authorisation on the form issued. The export authorisation shall be valid in all Member States of the European Union until its expiry date.

<table>
<tr><td colspan="2">EUROPEAN UNION</td><td colspan="4">Export of Covid19 vaccines (Regulation (EU) 2021/111)</td></tr>
<tr><td colspan="2">1. Exporter
(EORI number if applicable) and TARIC additional code</td><td colspan="2">2. Authorisation number</td><td colspan="2">3. Expiry date</td></tr>
<tr><td colspan="2">4. Issuing authority</td><td>5. Destination country</td><td colspan="3">6. Final recipient</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td colspan="2" rowspan="2">9. Unit</td><td colspan="2" rowspan="2">10. Description of the goods</td></tr>
<tr><td>11. Location</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td colspan="2" rowspan="2">9. Unit</td><td colspan="2" rowspan="2">10. Description of the goods</td></tr>
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<tr><td>11. Location</td></tr>
<tr><td colspan="6">12. Signature, place and date, stamp</td></tr>
</table>

Explanatory notes to the export authorisation form

The completion of all the boxes is mandatory except when stated otherwise.

Boxes 7 to 11 are repeated 4 times to allow requesting an authorisation for 4 different products.

Box 1	Exporter	Full name and address of the exporter for whom the authorisation is issued + EORI number if applicable. TARIC additional code as defined in Annex II.
Box 2	Authorisation number	The authorisation number is completed by the authority issuing the export authorisation and has the following format: XXyyyy999999, where XX is the 2-letter geonomenclature code ([1])of the issuing Member State, yyyy is the 4-digit year of issuance of the authorisation, 999999 is a 6-digit number unique within XXyyyy and attributed by the issuing authority.
Box 3	Expiry date	The issuing authority can define an expiry date for the authorisation. This expiry date cannot be later than 6 weeks after the entry into force of this regulation. If no expiry date is defined by the issuing authority, the authorisation expires at the latest 6 weeks after the entry into force of this regulation.
Box 4	Issuing authority	Full name and address of the Member State authority that issued the export authorisation.
Box 5	Destination country	2-letter geonomenclature code of the country of destination of the goods for which the authorisation is issued.
Box 6	Final recipient	Full name and address of the final recipient of the goods, if known at the time of issuance + EORI number if applicable. If the final recipient is not known at the time of issuance, the field is left empty.
Box 7	Commodity code	The numerical code from the Harmonised System or the Combined Nomenclature ([2]) under which the goods to export are classified when the authorisation is issued.
Box 8	Quantity	The quantity of goods measured in the unit declared in box 9.
Box 9	Unit	The measurement unit in which the quantity declared in box 8 is expressed. The units to use are number of vaccines doses.
Box 10	Description of the goods	Plain language description precise enough to allow identification the goods.
Box 11	Location	The geonomenclature code of the Member State where the goods are located. If the goods are located in the Member State of the issuing authority, this box must be left empty.
Box 12	Signature, stamp, place and date,	The signature and stamp of the issuing authority. The place and the date of issuance of the authorisation.

([1]) Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

ANNEX II

Taric additional codes

Company	Taric additional code
Astra Zeneca AB	4500
Pfizer / BioNTech	4501
Moderna Switzerland / Moderna Inc	4502
Janssen Pharmaceutica NV	4503
CureVac AG	4504
Sanofi Pasteur / Glaxosmithkline Biologicals S.A	4505
Novavax	4506
Other	4999