EXPORT REQUIREMENTS FOR COVID-19 VACCINES

FREQUENTLY ASKED QUESTIONS

The authorisation requirement for exports of Covid-19 vaccines and active substances including master and working cell banks has been introduced by Commission Implementing Regulation (EU) 2021/111 of 30 January 2021, which entered into force the same day.

The objective is to tackle the current lack of transparency of vaccine exports from the EU and to ensure timely access to COVID-19 vaccines for EU citizens in accordance with contractual agreements. This mechanism aims at preventing exports from companies with whom the EU has concluded Advance Purchased Agreements (APAs), where they threaten the execution of those APAs.

All relevant documents can be consulted under the following links:

Commission Implementing Regulation
List of competent authorities in Member States

The clarifications provided below are not legally binding, they are for informative purposes only and should serve as a guidance for exporters of Covid-19 vaccines and active substances including master and working cell banks (‘the goods’). Member States customs authorities and competent authorities under the Regulation when implementing the Regulation.

1. RELEVANT FACTORS FOR DECIDING TO ACCEPT/REJECT A REQUEST FOR EXPORT AUTHORISATION

a. On what grounds will Member States/the Commission decide to authorise/refuse export authorisation?

Vaccine manufacturers have been requested to provide information on the number of vaccine doses distributed in the Union since 1 December 2020 and data concerning their exports in the last three months prior to the entry into force of the export authorisation scheme. This information, together with other elements as specified elsewhere in this Q & A, will be used in order to assess whether the exports threaten the execution of the APAs. It will also contribute to giving a picture as to how production delays, etc. are shared between the Union and export destinations. The assessment will be made on a case by case basis, taking into account the specificities of each APA in its specific context.
Member States may also decide to reject any request of export authorisation where the necessary information has not been supplied by the exporter. Member States may also verify the information submitted, even after authorising exports.

b. How will the Member States/the Commission ensure that supplies related to APAs concluded by third countries with vaccine suppliers in the EU will not be disturbed?

The Commission is 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. In case of shortages or delays in the production of vaccines, the Commission will endeavour to ensure that exports are authorised in an equitable manner so that APAs contracted by third countries are respected as much as possible. For that purpose, third country authorities are invited to work together with the Commission to ensure that the Commission has the necessary information at its disposal on the APAs they have concluded with vaccine producers, including, in case of requests for export authorisations to vaccine producing countries, to what extent they share their vaccines with third countries and whether or not APAs concluded by these countries domestically and abroad contain clauses that should privilege domestic supply.

2. **PRODUCT SUBJECT TO THE AUTHORISATION SCHEME**

**General remarks**

The Regulation covers 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.

The Regulation therefore concerns exports of either the finished vaccine in its final form or any product essential for its manufacturing.

This includes:

- The active substance (which can include master and working cell banks if relevant)
- The vaccine in a bulk packaging
- The vaccine in its primary and/or secondary packaging

**a. Does the Regulation apply to exports of small quantities?**

The Regulation does not define any *de minimis* thresholds, which would enable exports of small quantities without an export authorisation. Nevertheless, the competent authorities when assessing whether certain exports could threaten the execution of Union Advance Purchase Agreements (APAs) concluded with vaccines manufacturers may take into consideration the fact that the application concerns a limited quantity to be exported.
Similarly, samples labelled for the conduct of clinical trials are typically exported in small quantities and, in these cases, these exports should be swiftly authorised by Member States since they do not threaten the execution of APAs, unless there are indications that such labelling could be used to circumvent the regulation.

3. **Exclusions from the scope of the Regulation**

   a. **Which countries, economies and/or territories are excluded from the scope of the Regulation?**

   The Regulation concerns exports to all non-EU countries with the following exceptions:

   - European Free Trade Association (‘EFTA’) countries: Iceland, Liechtenstein, Norway, Switzerland;
   - Western Balkans: Albania, Bosnia and Herzegovina, Kosovo\(^1\), Montenegro, North Macedonia, Serbia;
   - Overseas countries and territories listed in Annex II of the Treaty on the functioning of the European Union\(^2\) [note that the territories having special relations with the United Kingdom listed in annex II of the TFEU are subject to the export authorisation\(^3\)];
   - Territories of Member States specifically excluded from the customs territory of the Union: Büsingen, Heligoland, Livigno, Ceuta and Melilla;
   - Andorra, the Faroe Islands, Monaco, San Marino and the Vatican City;
   - Partner countries to the European Neighbourhood policy: Algeria, Egypt, Jordan, Lebanon, Libya, Morocco, Palestine\(^4\), Syria, Tunisia, Armenia, Azerbaijan, Belarus, Georgia, Israel, Moldova and Ukraine;

   b. **Which exports are also excluded from scope of the Regulation based on the principle of solidarity?**

   - Exports of goods purchased/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country
   - exports of goods purchased by EU States under the EU APAs donated or resold to third countries

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\(^1\) 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.


\(^3\) Anguilla, Cayman Islands, Falkland Islands, South Georgia and the South Sandwich Islands, Montserrat, Pitcairn, Saint Helena and Dependencies, British Antarctic Territory, British Indian Ocean Territory, Turks and Caicos Islands, British Virgin Islands, Bermuda.

\(^4\) 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.
• exports in the context of a humanitarian emergency response.

c. **What counts as provisions of emergency supplies in the context of humanitarian aid?**

Humanitarian aid shall comprise assistance, relief and protection operations on a non-discriminatory basis to help people in third countries, including delivering or facilitating the delivery of assistance, providing medical supplies and food, the transfer of humanitarian workers and related assistance or evacuations in accordance with the humanitarian principles. It should, in principle, be guided by the 24 Principles and Good Practice of Humanitarian Donorship and fall under the OECD-DAC purpose codes used to report humanitarian aid activities.

In their assessment of the application, Member States competent authorities are encouraged to refer to existing registries and certifications for organisations providing humanitarian aid, such as the list of organisations which are humanitarian partners of the European Commission.

The Member States competent authorities are also encouraged to keep an internal list of such organisations in order to facilitate the process in subsequent requests.

A list of humanitarian aid partners of the Commission established by DG ECHO and can be consulted here: https://ec.europa.eu/echo/sites/echo-site/files/weblistpartners.pdf. The export to any organisation listed there should be automatically considered as an export in the context of a humanitarian emergency response. This list is however not exhaustive and Member States are welcome to consider other organisations under Article 1(5) of the Regulation.

d. **Does the Regulation apply to goods supplied to the continental shelf or exclusive economic zones of the Member States (e.g. to oil rigs)?**

Continental shelf and exclusive economic zones are not part of the customs territory of the Union. Nevertheless, under Article 1(5) of the Regulation, supplies to facilities located in the continental shelf or the exclusive economic zone of a Member State are exempted from the requirement to submit a valid export authorisation when lodging the customs declaration.

4. **Authorisation procedure**

a. **Where do exporters have to make the request for the export authorisation?**

The request for export authorisation shall be made to the competent authorities of the Member States where products subject to the Regulation (working cells, active substances, primary packaging, secondary packaging, finished products) are physically manufactured.

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5. At EU level, the humanitarian principles are enshrined in the European Consensus on Humanitarian Aid: the principles of neutrality, humanity, independence and impartiality.


b. Where is a product considered to be manufactured?

If a vaccine for which authorisation is sought is already filled and finished, the manufacturer is the entity that filled and finished the products. If the authorisation request concerns the vaccines in bulk, the manufacturer is the entity that produced substance in bulk. If the authorisation request concerns an active substance, the manufacturer is the entity that produced the active substance.

c. Where to find the list of competent authorities in each Member State?

The list of competent authorities is published at the following link:

List of competent authorities in Member States

[Link]

d. What information needs to be submitted by the exporter?

Exporters/manufacturers need to submit the following information to the relevant Member States competent authorities:

- The request for export authorisation shall contain the information set out in Annex I and the applicable TARIC additional codes in Annex II of Regulation 2021/111. This information will be necessary for the Member State to issue the export authorisation. The exporter should use the application form issued by the Member State competent authority or, if not available, may use the template attached in Annex I to this FAQs.

- Each request shall also contain information on the number of vaccine doses of goods covered by this Regulation distributed since 1 December 2020 broken down as indicated in Article 2(1) to the Regulation.

- At the latest together with the first request for an export authorisation request, the vaccine manufacturers that have concluded APAs shall provide electronically to the Member State competent authorities and to the Commission [email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu] the relevant data concerning their exports in the last three months prior to the entry into force of this Regulation. 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 under the form of a table containing the number of doses per destination and recipient (row) and exported per week (column) in Excel or Word format that will be made available by the Commission. The absence of such information may lead to refusal of export authorisations.

- In order to ensure that export authorisations are considered on the basis of all relevant data and to allow the Commission to evaluate any potential impact of exports on the relevant Advanced Purchasing Agreements with the Union, exporters are also encouraged to supply Member States and the Commission [email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu] with estimated production forecasts. The applicants are invited to present this information in a table with the number of estimated doses per Member State (row) and the expected week of delivery (column) in excel format.

e. How is the authorisation request processed and how long will the procedure take?

In line with Article 2(2) and (5) of the Regulation, within two working days from the receipt of a duly completed request for an export authorisation, the Member State competent authority
will issue a draft decision. In case of disagreement with the draft decision, the Commission will issue an opinion on the draft decision within one working day.

In exceptional and duly justified cases, the competent authority may extend the time needed for the draft decision by additional two working days.

**f. Who will decide in the end?**

The Member State competent authority will decide about the request for an export authorisation in accordance with the Commission’s opinion. The Commission will however only give an opinion in cases it disagrees with the Member States’ draft decision.

**g. Can an exporter apply for an export authorisation in any Member State?**

No. The application is made to the competent authority in the Member State where the goods were manufactured. If goods to be exported are located in one or more Member States other than the one where the application for export authorisation has been made, that fact is to be indicated in the application. In case of multiple locations, all locations should be indicated.

**h. Member States shall process applications for export authorisations as soon as possible, but 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. How is this deadline of two days calculated?**

The day, on which a complete export authorisation form is submitted to a competent authority, is not considered as falling within the period of the two working days deadline. This means that the deadlines start counting the first working day after the receipt of the authorisation request. [For a form submitted on a Monday, a draft decision should be taken by the end of the Wednesday.]

Within the 2-day deadline, the Member States must notify the Commission (SANTE-PHARMACEUTICALS-B4@ec.europa.eu) of the draft decision. This means that consulting the Commission does not extend the deadline beyond two days for the Member State to prepare its draft decision. The Commission is bound to issue an opinion within one day from the receipt of the notification of the draft decision of the Member State.

**i. When rejecting a request for an export authorisation, should the competent authority issue a formal rejection, which can be appealed by the exporter, or only a simple reply?**

In cases where the competent authority decides to reject an application for an export authorisation, the competent authority should follow the national law and practice concerning the form, in which the rejection will be communicated to the exporter.

**j. Can a competent authority issue an export authorisation for a global quantity (e.g. the applicant submitted an invoice for 10 000 pcs but applied for an export authorisation for 500 000 pcs)?**

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No, issuing an export authorisation for a global quantity would circumvent the objectives of the Regulation as it would fail to remedy the critical situation concerning the supply of Covid-19 vaccines. It is a case-by-case assessment by the requested Member State in the light of the circumstances at the moment the application for export is assessed.

Competent authorities should refrain from issuing a general authorisation for any types of exports. In the case of small quantities, a general authorisation for exports of small quantities could enable circumvention of the measures (big quantities artificially and only on paper split into several shipments) and could potentially lead to unequal treatment of the exporters where Member States would individually determine the definition of a small quantity.

k. Where can the competent authority find the information necessary to check the destinations or purposes covered by Article 1(5) of the Regulation?

It is for the exporter requesting the export authorisation to indicate if any of the relevant exemptions considered under Article 1(5) of the Regulation apply or if the exports are destined to any of the parties listed in that article, and provide the necessary evidence, potentially with some information provided by the final recipient.

The competent authority should conduct any relevant checks in line with their national law and practice.

l. If the competent authority fails to issue a decision about an application for an export authorisation within the statutory deadlines, can it be interpreted as tacit approval of the application?

No, the Regulation does not provide for the option of an export authorisation issued by tacit approval.

5. What should Member States notify to the Commission and when?

Member States should notify the following information at the following email address: SANTE-PHARMACEUTICALS-B4@ec.europa.eu:

a. Any application received, immediately;

b. Draft decision, as soon as possible and within two working days;

c. Granted or rejected export authorisation immediately, and including the reason for rejection.

The Commission shall periodically make the information on the authorisations granted and those refused publicly available, due account being taken of the confidentiality of the data submitted.
In order for the Commission to have the best overview of the situation and to be able to advise the Member States in a most accurate way possible the above information should be submitted in the form of a table, in a spreadsheet, based on templates that the Commission will make available.

6. **RELATION TO MEMBER STATES MEASURES**

   The Implementing Regulation was adopted with the understanding that Member States should avoid any restrictive national actions taken, formally or informally, concerning either exports to third countries or trade between the Member States within the Single Market of the products subject to the Regulation.

7. **DURATION OF THE EXPORT AUTHORISATION SCHEME**

   The current measures were adopted for a duration of six weeks from the day of their entry into force, i.e. until 14 March 2021. Nevertheless, the Commission intends to adopt an extension of the measures until 31 March 2021 pursuant to Article 6 of Regulation (EU) 2015/479.

8. **CUSTOMS PROCEDURES**

   **General remarks**

   The Regulation is integrated in the TARIC with measures 709 (export control). The list of goods is also inserted in the TARIC, as well as the TARIC additional codes identifying the manufacturers and the document type for the export authorisation (code C089).

   **a. Which export transactions are concerned by the Regulation?**

   The Regulation applies when Union goods are exported, i.e. when they undergo export customs procedures, i.e. customs procedures under codes 10/00 and 11/00.

   In this context, the following transactions, i.e. customs procedures under all other codes, are excluded:

   (a) goods placed under the outward processing procedure;
   (b) goods taken out of the customs territory of the Union after having been placed under the end-use procedure;

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9 Since it is an export restriction, the validity start date cannot be retroactive in the TARIC and is therefore two days after the validity start date published in the OJ.

(c) goods delivered, VAT or excise duty exempted, as aircraft or ship supplies, regardless of the destination of the aircraft or ship, for which a proof of such supply is required;
(d) goods placed under the internal transit procedure;
(e) goods moved temporarily out of the customs territory of the Union in accordance with Article 155.

b. Goods in the scope of the Regulation were imported from a third country to the Union but were not intended for the Union market. On the contrary, they were intended for re-export to another third country. Does the Regulation apply to such goods? Is the exporter obliged to apply for an export authorisation?

The Regulation applies to exports of Union goods. It does not apply to re-exports of non-Union goods. According to Article 5(23) of UCC, **Union goods** are:

(a) goods wholly obtained in the customs territory of the Union and not incorporating goods imported from countries or territories outside the customs territory of the Union;
(b) **goods brought into the customs territory of the Union from countries or territories outside that territory and released for free circulation**;
(c) goods obtained or produced in the customs territory of the Union, either solely from goods referred to in point (b) or from goods referred to in points (a) and (b).

Therefore, in the above described situation, it is decisive whether the goods originating in third country were released for free circulation in the customs territory of the Union before being again exported to a third country or not.

If they were released for free circulation, they are considered Union goods and therefore subject to export authorisation. If they were not released for free circulation, they are considered non-Union goods (Article 5(24) of UCC) and their re-export is not subject to export authorisation.

c. Does the Regulation apply to goods in temporary storage?

The situation of goods in temporary storage is similar to the one of goods in a customs warehouse. According to Article 144 of UCC, “non-Union goods shall be in temporary storage from the moment they are presented to customs”. Moreover, according to Article 149 UCC, “non-Union goods in temporary storage shall be placed under a customs procedure or re-exported within 90 days”. However, these goods cannot be placed under the export procedure, as this procedure is only applicable to Union goods.

Thus, an export authorisation for goods placed in a temporary storage is not required.

d. Does the Regulation apply to goods that were declared for export before the Regulation entered into force but are leaving the customs territory of the Union after the entry into force of the Regulation?

No, a valid export authorisation is required when the export declaration is lodged. Therefore, the Regulation does not apply to goods that were declared for exports before the Regulation entered into force.
e. Does the Regulation apply to intracompany sales of goods covered by the Regulation?

If the subsidiary/related company of an exporter is located in one of the countries falling under the geographical scope of the Regulation, such exports require an export authorisation.

f. Can the customs authorities block exports of goods not covered by the Regulation?

Under Article 46(1) of UCC, customs authorities have the right to detain goods to perform controls.

g. Should the exporter for customs purposes (box 2 on the export declaration) correspond to the “exporter” mentioned on the authorisation (box 1 export authorisation form)? Or can the export declaration be lodged by another exporter?

The Regulation leaves to the discretion of the Member States the modalities for administering the export authorisation system, requiring only for customs that the goods are not released for export if there is no export authorisation. Therefore, if the Member States customs authorities put in place systems to verify that the export is covered by an authorisation, there is no need to require the same exporter in the customs declaration and in the authorisation. The system could identify the relevant export declarations through the CN code of the product (specific for vaccines) and/or the additional TARIC code (Box 44), for instance. Please contact the customs authorities of the Member State where the export declaration of the vaccines is to be lodged.

h. Where should the export authorisation be mentioned in the export declaration?

Box 44 (or data element 2/3) allows to state the authorisation number (document type = C089 + authorisation number) and the additional TARIC code for the producer. The declaration must also contain the specific CN code for vaccines.

i. Is the additional TARIC code of Annex II of Regulation 2021/111 a mandatory element for the exporter?

Yes, it is the export declaration must contain the export authorisation number and the additional TARIC code.
# ANNEX I

Template for application of an export authorisation

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<th>Export of Covid19 vaccines (Regulation EU 2021/111)</th>
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<td>1. Exporter</td>
<td>(EORI number if applicable) and TARIC additional code</td>
</tr>
<tr>
<td>2. Destination country</td>
<td>3. Final recipient</td>
</tr>
<tr>
<td>4. Commodity code</td>
<td>5. Quantity</td>
</tr>
<tr>
<td>9. Location</td>
<td></td>
</tr>
<tr>
<td>10. Date of planned exports</td>
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</tr>
<tr>
<td>12. Signature, place and date, stamp</td>
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