**European Union**
**updated 18 May 2021**

1. **Which of the measures outlined in the WCO Resolution on the role of Customs in facilitating the cross-border movement of situationally critical medicines and vaccines has your Customs administration implemented in practice? Please provide details of the implementation.**

The current existing legal frameworks applicable to Customs controls at imports and exports of vaccines:

1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human (including the falsified medicines Directive 2011/62/EU that amends Directive 2001/83/EC) use – consolidated version:
*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L008320190726*

*As provided for in the resolution, the EU has adopted a specific Combined Nomenclature (CN) code to facilitate the custom procedures. The classification Code for the goods concerned is CN code 3002 20 10*

2) Regulation 765/2008 on market surveillance and product compliance (replaced as from July 2021 by Regulation 1020/2019):
As there are no specific requirements regarding the organization of the controls at the borders in the above mentioned pharmaceutical legislation, Regulation 765/2008 applies (NB: Regulation 2008/765 is in application until 15.7.2021 and Regulation 2019/1020 will only enter in application on 16.7.2021).
In accordance with Art. 27 of Regulation no. 765/2008, Customs authorities check whether medicinal products for human use destined for free circulation display characteristics which give cause to believe that they present a serious risk to health, safety, the environment or any other public interest, which means any risk regarding the quality, safety and efficiency of medicinal products. They can also check whether they are accompanied by documentation and/or marking required by EU legislation on human medicinal products.
If the Customs authorities find problems during their controls, Customs authorities in accordance with Article 27 of Regulation no. 765/2008 suspend the release of the goods until the verification of the consignment by the competent market surveillance authority is finalised. Since Regulation no. 765/2008 does not require such authorities to be appointed for medicinal products, these authorities are the competent national authorities in relation to Directive 2001/83/EC.

3) The Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code is the 'chapeau' regulation providing Customs the necessary powers to control:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R095220200101

4) For export procedures, see details in the reply to question 6 below.

5) Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning Customs enforcement of intellectual property rights applies also, but specifically to protect the rights of right holders related to the concerned goods:
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0608

If the vaccines are protected by an intellectual property right included in the scope of the regulation (such as trademark or patent) and if the right holder has lodged an application for action (being it autonomously or after ex officio action by Customs) for the concerned goods with regards to the concerned intellectual property rights, then the Customs authorities are empowered to act (e.g. suspend the release or detain the goods suspected of infringing an intellectual property right), in case the goods are suspected of infringing an intellectual property right. Regulation 608/2013 applies in all Customs situations, including import, export, transit, warehousing, etc. since the scope of the regulation covers all goods under Customs control).

Imports

Relevant legal provisions relating to imports

Article 6.1, Article 40.3, Article 51.1.(b) of Directive 2001/83/EC

Article 27 of Regulation 765/2008

Article 46, 134 and 201 of Regulation 952/2013

Articles 1, 3, 17 and 18 of Regulation 608/2013

Exports

Relevant legal provisions relating to exports

Article 40.1 of Directive 2001/83/EC

Article 46, 267 of Regulation 952/2013

Articles 1, 3, 17 and 18 of Regulation 608/2013

2. **Was any relevant information concerning the Customs clearance of COVID-19 vaccines and the goods and devices used for their shipment and transportation, made publicly available, for example on the Customs administration's web-site? If yes, please provide a URL. If not made publicly available, was relevant information provided to the supply chain stakeholders – manufacturers, exporters, importers, logistics providers, etc.?**

   Information can be found in the European Commission's website: https://ec.europa.eu/taxation_customs/covid-19-taxud-response/guidance-customs-issues-related-covid-19-emergency_en#heading_0

   The vaccines against SARS-related coronaviruses (SARS-CoV species) fall under a specific CN code to easily identify them: CN code 3002 20 10

   Please also refer to the reply to question 6

3. **Was any dedicated guidance made available to the field Customs officers with regard to the Customs clearance of COVID-19 vaccines for export, transit and import, as well as the goods and devices used for the vaccines' shipment and transportation? If yes, please provide details on how the guidance was disseminated.**

   The European Commission distributed a note via the Prohibitions and Restrictions Customs Control Strategy (PARCS) meeting expert group, the Customs expert group controls and risk management and the members of the expert group on IPR. (NB: This note includes some information relating to Customs risk management and is only destined for EU Member States and is not publically available due to its sensitivity).

4. **Has any training been provided to the staff of your Customs administration in anticipation of the COVID-19 vaccines distribution effort, for example training for handling of time- and temperature-sensitive items, training for handling of dangerous goods (e.g. dry ice), training for identifying the COVID-19 vaccines on import or export documentation?**

   See the practices of individual EU Member States.

5. **What mode of transport was used for the exportation/importation of COVID-19 vaccines from/into your country?**

   See the practices of individual EU Member States.

6. **What are the documents required for the exportation of COVID-19 vaccines from your country? (applies to the Members exporting COVID-19 vaccines)**

   On 30 January, the European Union adopted a set of targeted and temporary measures requiring that exports of vaccines outside the EU be subject to an authorisation by Member States until the end of March 2021. The objective is to ensure timely access to COVID-19 vaccines for EU citizens in accordance with contractual agreements and to tackle the current lack of transparency of vaccine exports from the EU. This mechanism only applies to exports from companies with whom the EU has concluded Advance Purchase Agreements (APAs). Companies are required to provide Member States with information relating to their vaccine deliveries [both inside and outside the EU]. This means, in practice, that European-based pharmaceutical companies must seek authorisation before they export COVID-19 vaccines. To be clear: the aim is to get transparency. We intend to keep restrictions of exports to an absolute minimum. So far, at the date of filling this questionnaire (18 February 2021) all the requests for export authorisations have been accepted by Member States.

   The EU remains fully committed to international solidarity and its international obligations. These measures include a wide range of exemptions from prior authorisation to ensure the EU continues to fully honour its humanitarian aid commitments. We will ensure vaccine delivery to our direct neighbourhood, to 92 low and middle-income countries covered by the COVAX facility and export of vaccines purchased and/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country. These obligations are proportionate, strictly targeted to vaccine manufacturers and are applicable until end of March 2021. They are being handled swiftly in order not to slow down the vaccine trade between the EU and third countries.

   Guidance and FAQ on this Regulation can be found at: https://trade.ec.europa.eu/doclib/docs/2021/february/tradoc_159414.pdf

   Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorisation; Official Journal L 104, 25.03.2021
   Application period: until 30.06.2021
   Administration: Competent authorities in EU Member States
   Authorisations are granted to the extent that the volume of exports is such that it does not pose a threat to the execution of Advance Purchase Agreements that the European Union has concluded with vaccine manufacturers. Authorisations are granted where exports do not pose a threat to the security of supply within the European Union. In order to determine whether the condition above is fulfilled, the competent authorities shall assess the following factors:
   1) Does the destination country restrict its own exports of vaccines or their raw materials, either by law or other means? And
   2) Are the conditions prevailing in the destination country better or worse than the EU's, in particular its epidemiological situation, its vaccination rate and its access to vaccines?
   Exemptions include:
   - exports in the context of humanitarian aid; - exports to low and middle income countries in the COVAX Advance Market Commitment (AMC) list

- exports of goods purchased and/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country; - EU overseas countries and territories;

- Andorra, the Faroe Islands, San Marino, Vatican City, Büsingen, Helgoland, Livigno, Ceuta and Melilla.

7. **Which national authorities are responsible for the checking and clearing the COVID-19 vaccines shipments for exportation? How is the cooperation between these authorities arranged? (applies to the Members exporting COVID-19 vaccines)**

   Please see above reply to Question 6. EU Member States will process applications for export authorisations as soon as possible and no later than two working days after receiving all the required information. Such authorisation shall be granted by the competent authorities of the Member State where the vaccines are manufactured and shall be issued in writing or by electronic means. Companies request an export authorisation in the Member State where the vaccine is manufactured. This period may be extended by a further two working days but only under exceptional circumstances and for duly justified reasons.

   In deciding whether to grant an export authorisation under this Regulation, EU Member States, together with the European Commission, shall assess whether the volume of exports is not such that it poses a threat to the execution of the Advance Purchase Agreements the EU has concluded with vaccine manufacturers.

   Upon receiving the request, EU Member States must immediately notify the European Commission of any application and, after analysis, submit their draft decision to the Commission. If the Commission would disagree with this draft decision, it shall issue an opinion within one working day and the Member State shall decide on the request for authorisation in accordance with the European Commission's opinion.

8. **Is there any exchange of information/data between the Customs authorities of the exporting country and the Customs authorities of the importing country? What type of information is exchanged? How is the exchange of information arranged/regulated?**

   See the practices of individual EU Member States.

9. **Was the Customs transit procedure used for the COVID-19 vaccines imported into your country? If yes, why/what was the rationale?**

   See the practices of individual EU Member States.

10. **Does your administration implement risk management techniques related to the cross-border movement of COVID-19 vaccines?**

    The EU has issued guidelines on the treatment of COVID-19 goods setting up the common risk criteria and standards agreed to cover the crisis. An addendum specifically covering vaccines was provided in January 2021 in order to allow for the facilitation of movements of legitimate consignments whilst addressing the risk of unsafe and non-compliant products. Recently a risk information form was prepared in the Customs risk management system setting up new control measures and new risks to be addressed to implement the implementing regulation 2021/111 on export of vaccines. Member States also share risk information on a daily basis in the Customs risk management system to enable a common treatment of risks at any point of the EU border.

**11. What are the documents required for the importation of COVID-19 vaccines in your country?**

The medical, surgical and laboratory equipment are not exempted from the obligation to lodge an entry summary declaration (ENS), even in emergency cases. However, Article 127(7) UCC provides for the possibility to use commercial, port or transport documents for this purpose, under the condition that these other documents contain the necessary particulars of the ENS and are available before a specific time-limit prior to the arrival of the goods in the EU.

COVID-19 related vaccines must be covered by a security and safety declaration – entry summary declaration (ENS) - and declared using a standard Customs declaration.

Customs shall check on a risk analysis basis that consignments of these products presented for import are accompanied by the relevant authorisation/documentations/certificates i.e. a marketing authorisation issued by the EMA for the vaccine and a manufacturing and import authorisation for the site producing the vaccine.

**12. Which national authorities are responsible for the checking and clearing the COVID-19 vaccines shipments for importation? How is the cooperation between these authorities arranged?**

See the practices of individual EU Member States.

**13. If information is available, what was the time required for the release of the COVID-19 vaccines shipments imported into your country?**

See the practices of individual EU Member States.

**14. Has your government considered duty and tax waivers for the importation of COVID-19 vaccines?**

As notified to the WTO and to the WCO, on 3 April 2020, the European Commission adopted Decision (EU) 2020/491 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020. Validity of this temporary measure is currently extended until 31 December 2021.

This decision allows EU Member States to grant a relief from import duties and VAT exemption for COVID-19 related goods, including vaccines, imported in the EU.

The Decision provides a beneficial Customs and fiscal treatment of imported goods for organisations (e.g. hospital, State bodies, charities) for which both import duties and VAT constitute a cost. However, it does not apply, for example, to goods imported to be subsequently sold and neither to goods imported by private companies for their own needs.

The Council Directive (EU) 2020/2020, adopted on 7 December 2020, however allows Member States to apply a reduced VAT rate to the supply of COVID 19 in vitro diagnostic medical devices (and services closely linked thereto) or to grant an exemption with deductibility of VAT paid at the preceding stage (zero rate) in respect of the supply of COVID 19 vaccines and in vitro diagnostic medical devices (and services closely linked thereto). This measure is still very limited in scope of application and also of temporary nature. [Each MS can complement whether they apply reduced or zero rate to the vaccines.]

With the Commission Implementing Regulation (EU) 2020/2159 of 16 December 2020 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, the EU introduced as from

01/01/2021 a specific code for “Vaccines against SARS-related coronaviruses (SARS-CoV species)” in its nomenclature in order to facilitate the movement of such goods.

**15. Please include any other relevant information you wish to share.**

See the practices of individual EU Member States.