Italian Customs, Monopolies and Excises Agency
23 November 2021

1. Does your administration monitor the imports and/or exports of inputs and components used for the manufacturing, distribution and administering of COVID-19 vaccines? If yes, do you capture and disseminate detailed trade data on these products?

The Italian Customs Authority has monitored all exports of vaccines and related products such as ampules and refrigerating containers to identify any possible non-authorized export of COVID-19 vaccines concealed in cases/containers declared as empty.

The exportation and circulation of COVID-19 vaccines are controlled by the Government. Their distribution and administering is closely and steadily surveilled, as the case is for any other pharmaceutical product destined for virus treatment.

The Agency has performed targeted controls since the beginning of the pandemic and it has been monitoring the circulation of the vaccines in close cooperation with other competent authorities such as the Ministry of Health and AIFA (Agenzia Italiana del Farmaco - Italian Medicines Agency, in charge of authorizing the use of medicines on the national territory), as well as with pharmaceutical companies and other public/private entities and law enforcement bodies involved.

2. What measures has your administration implemented to facilitate the export/ import/ transit of inputs and components used for the manufacturing, distribution and administering of COVID-19 vaccines?

Italy imports COVID-19 vaccines from other countries according to the purchase procedures established by the EU Commission. The relevant import and distribution are managed by the Government supported by Customs, the Army and other public entities involved.

3. In the process of designing those measures, have there been consultations/cooperation with the pharmaceutical companies that import or export those inputs and components in your country? Please provide details.

COVID-19 vaccines are managed at central governmental level and the relevant control measures and procedures are strictly established. Cooperation with pharmaceutical companies is clearly key in the management of the safety/security “chain”.

4. Has your Administration used the guidance material provided by the WCO and has it been useful? Please provide details of which guidance documents have been used and found useful, for example the HS classification reference for vaccines and related supplies and equipment, the Joint Indicative List of Critical COVID-19 Vaccine Inputs, the Secretariat Note on the Role of Customs in facilitating and securing the cross-border movement of situationally critical medicines and vaccines, etc.

The Italian Customs authority is involved in the joint Customs operations organized by OLAF and WCO such as operations STOP and STOP II, and all the information provided is analysed

according to national characteristics and then supplied to the operational offices that perform the necessary controls.

Targeted risk profiles are defined for products aimed to counter the dissemination of the pandemic and will remain valid until necessary. The risk profiles included in the Customs operation control system allowed the Customs Authority to identify and seize remarkable quantities of products not complying with the set standards.

5. Please share any details not covered by the questions above, which you consider to be relevant and beneficial to the broad WCO membership and stakeholders.

All cases considered to be relevant for the other WCO Members have been shared on the CENComm platform.

Beside the implementation of EU provisions and in order to monitor and facilitate the maximum spread of the various anti-COVID-19 vaccines approved by the EU, the Italian Customs and Monopolies Agency (ADM) agreed with the other Member States on the Commission's proposal to establish a new CN code specific for the tariff classification of such vaccines. As a result of comprehensive debate, Implementing Regulation EU 2020/2159 of 16 December 2020 was approved, further amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff and introducing the new CN sub-heading 3002 2010 for anti-Sars-Covid vaccines, including specifications on the number of doses.

At national level, Art. 1, par. 453 of the 2021 Budget Law foresees a derogation to number 114) of Table A, part III, attached to Presidential Decree 633/72, stating that sales of "anti-COVID-19 vaccines authorized by the European Commission or by its Member States and the provision of services closely linked to such vaccines" are exempt from VAT from 20 December 2020 to 31 December 2022.

The provisions of said Art. 1, par. 453, are the transposition into national legislation of EU Directive 2020/2020 of the Council of 7 December 2020, that amended Directive 2006/112/EC by introducing temporary measures in relation to value added tax applicable to COVID-19 vaccines and in vitro diagnostic medical devices in response to the COVID-19 pandemic. According to such Directive and up to 31 December 2022, Member States may grant an exemption with deductibility of VAT paid at the preceding stage in respect of the supply of COVID-19 vaccines, COVID-19 in vitro diagnostic medical devices and services closely linked to those vaccines.

ADM also published on its web portal Circular letter no. 9/21 containing clarifications on the scope of the above-mentioned national provisions, as well as a mandatory list of the goods destined to fight the pandemic – including vaccines – and the relevant Tariff classifications.