Questions and Answers: Transparency and authorisation mechanism for exports of COVID-19 vaccines*

Brussels, 29 January 2021

What is the rationale for the measure?

The objective of this measure is to ensure timely access to COVID-19 vaccines for all EU citizens and to tackle the current lack of transparency of vaccine exports outside the EU.

The European Union has supported the rapid development and production of several vaccines against COVID-19 with a total of €2.7 billion and it is important to protect the integrity of this substantial investment from the EU budget.

The Commission is concerned by the lack of transparency around the ways some companies are operating and wants to have complete information in order to ensure they fulfil their contractual commitments.

It is not our intention to restrict exports any more than absolutely necessary, and the Union remains fully committed to international solidarity and its international obligations.

Scope

What is the nature of the measures the Commission has adopted?

To address this very serious and immediate public health issue, the Commission has adopted a temporary export transparency and export authorisation mechanism on the basis of Regulation 2015/479 on common rules for exports.

This is not an export ban. This measure would specifically target exports of COVID-19 vaccines covered by an Advance Purchase Agreement (APA) with the EU. These exports will be subject to an early notification and authorisation before they are effectively shipped outside the EU.

This measure applies from 30 January 2021 and runs until 31 March 2021.

A large number of exports will be exempted from the mechanism.

Does the Commission measure cover trade between the EU Member States?

An export authorisation foreseen in the Regulation is required for exports outside the Union market (whether or not originating in the Union).

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.

Which exports will be exempt?

Exports to Republic of Albania, Andorra, Bosnia and Herzegovina, the Faeroe Islands, the Republic of Iceland, Kosovo, 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, Heligoland, Livigno, Ceuta and Melilla, Algeria, Egypt, Jordan, Lebanon, Libya, Morocco, Palestine, Syria, Tunisia, Armenia, Azerbaijan, Belarus, Georgia, Israel, Moldova and Ukraine.

Exports to any of the 92 low and middle income countries in the COVAX Advance Market Commitment list.

Exports of COVID vaccines purchased and/or delivered through COVAX, UNICEF and PAHO with destination to any other COVAX participating country.

Exports of purchases by EU Member States under the EU Advance Purchase Agreements and redirected to a third country as a donation or resale.

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 the United Nations Convention on the Law of the Sea.

Third countries/Global dimension

What if a third country has an APA with a manufacturer in the EU?

The Commission is mindful of APAs contracted by third countries, and will endeavour to ensure that the expectations of these countries to obtain their deliveries will be met.

We call on companies with APAs to meet their obligations to deliver on their commitments.

Process

What happens now until 31 March 2021. Why is this limited to end of March? Isn't the measure supposed to be valid only for 6 weeks?

Due to the urgency of the situation, justified by the lack of transparency in a time where the production and delivery of vaccines is still in the building-up phase and the ensuing temporary global shortage, the measure was adopted by the Commission using the emergency procedure.

This allows the Commission to act fast before the Member States are formally consulted.

The Regulation applies from 30 January 2021.

In accordance with the Regulation allowing us to adopt such emergency response, the measures cannot exceed six weeks (Article 5(5) of Regulation (EU) 2015/479).

However, the Commission intends to propose an extension of this measure until the end of March. Pursuant to Article 6 of that Regulation measures can be adopted after this period via comitology.

During the initial six-weeks period, the Member States will be consulted on the potential adaptations of the current measure and any potential future steps.

Has the Commission reacted at the request of the Member States. If yes, which ones? Did the Commission act on its own initiative?

Member States are part of the Steering Committee which discusses all decisions in the context of the negotiations with vaccine producers and their follow-up, including the possibility to include a transparency and authorisation mechanism in relation to the exports of vaccines.

Do MS have a discretion under the measure adopted by the Commission? How does the system work?

Member States are required to set up export authorisation regimes.

Companies request an export authorisation in the Member State where the vaccine is manufactured.

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.

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, Member States, together with the 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, Member States immediately seek the agreement of the Commission.

In order to allow the relevant authorities to assess the request for export authorisation, vaccine producers subject to this Regulation are requested to provide relevant data on their exports since 29 October 2020 toghether with their first request for export authorisation.

Even after authorising an export, the competent Member State authorities can verify the information submitted by the exporter.

What if a company refuses to provide the retroactive data?

The absence of such information may lead to export authorisations being refused.

Will there be a publication of the actions? Who will publish these and where?

The Commission will regularly report on the authorisations granted and refused.

What type of proposal is the export authorisation scheme?

It's an implementing act.

WTO

Is the regulation compatible with WTO and G20 commitments?

It is in line with all of the EU's international obligations and commitments.

The EU 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.

The measure is also fully in line with what the EU has proposed in the context of the WTO trade and health initiative as it gives particular consideration to the interest of the least developed and developing countries with scarce manufacturing capacities and which are highly dependent on imports. The scheme also ensures that the operation of the COVAX facility is not impeded.

The EU will ensure transparency about this measure towards its trading partners at the WTO.

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