European Commission

VACCINE EXPORTS

Temporary transparency and authorisation mechanism

MARCH 2021

From 30 January 2021 to 30 June 2021(*), EU-based pharmaceutical companies must seek authorisation before they export COVID-19 vaccines and their active ingredients.

OBJECTIVE OF THE MEASURE

- **Transparency** of vaccine exports from the EU
- **Timely access to COVID-19 vaccines for EU citizens** in line with contractual agreements
- **Limit the impact on trade partners** and most **vulnerable countries**
- Respect of **international obligations** and of commitments

WHAT IS COVERED BY THIS RULE?

- Exports from companies with whom the EU has concluded **Advance Purchase Agreements** (Astra Zeneca AB, Pfizer / BioNTech, Moderna Switzerland / Moderna Inc, Janssen Pharmaceutica NV, CureVac AG, Sanofi Pasteur / Glaxosmithkline Biologicals S.A, Novavax)

DESTINATION COUNTRIES EXCLUDED FROM THIS MECHANISM

- **Low and middle income countries** in the COVAX AMC list and exports to other countries through the **COVAX facility**
- Exports in the context of **humanitarian emergency response**
- **Donations** or resales to third countries when purchased by Member States under contracts by the EU

(*) The mechanism is renewable.

PROCESS FOR EXPORT AUTHORISATION

1 **Vaccine manufacturers introduce export request to competent authorities of the Member State where products are manufactured**

The request includes:
- application form
- company's vaccine exports since 30 October 2020
- number of vaccine doses distributed in the EU since 1st December 2020, estimated production forecast

2 **Member State notifies the Commission**

3 **Within 2 working days(*), Member State issues draft decision**

Every export request is assessed individually.
Overall assessment takes into consideration:
- contracts are respected
- all required information is provided
- security of vaccine supply to the EU is not jeopardised:
  - reciprocity is warranted by destination country if it is also a supplier of vaccines or vaccine materials
  - proportionality of the epidemiological situation and vaccination rate between EU and destination country

4 **Within one working day the Commission assesses the draft decision. If it wants to contradict the draft decision of the Member State, the Commission's opinion needs to be adopted by the College of Commissioners**

5 **Member State adopts the decision to authorise or refuse the export, in accordance with the Commission's opinion**

(*) May be extended by an additional 2 working days in exceptional and duly justified cases.

For more information, see our Frequently Asked Questions