EUROPEAN COMMISSION

INFORMATION NOTE OF COMMISSION SERVICES

Subject: Distribution of vaccines prior to authorisation.

During the COVID-19 pandemic, the **conditional marketing** authorisations (Article 14–a of Regulation 726/2004) are being used to expedite the approval of safe and effective COVID-19 treatments and vaccines in the EU.

This is in line with EU legislation[1]which foresees that conditional marketing authorisations may be used as **the fast-track authorisation** during public health emergencies to speed up approval and save lives. In a public health emergency, it can also be combined with a **rolling review of data** during the development of a promising medicine, to further expedite the evaluation **by the European Medicines Agency (EMA)**.

Any vaccine developer that wishes to put a vaccine on the market in the EU, should first request a marketing authorisation for the vaccine. The request is submitted to the EMA, which assesses the safety, efficacy and quality of the vaccine. If the EMA gives a positive recommendation, the Commission can proceed with the authorisation of the vaccine on the EU market. Following this authorisation, the manufactures can then proceed to the release and distribution of the vaccine after a batch testing and certification by the company's qualified person (QP).

In addition, EU legislation[2] based on Good Manufacturing Practice Guidelines allows the exceptional possibility of a **distribution under quarantine** to a dedicated destination in a Member State**.** This would mean the distribution under quarantine of the not-yet approved vaccine from the company's premises to a storage facility in the Member State concerned prior to all conditions for batch release being fulfilled.

Member States will have to bear the full responsibility and have in place **processes to secure that the shipped doses remain under quarantine** until the marketing authorisation is granted. Thereafter, based on the release and certification process performed by the manufacturer's QP (Article 51 of Directive 2001/83/EC), the quarantine is lifted by the wholesaler (or receiving entity) where the product is stored.

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1 Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council.

2 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 use.

Moreover, for vaccines, the legislation foresees that the official **batch release is performed by an official control laboratory**. This official batch release should be performed to verify whether the batches will be in conformity with the approved specifications, i.e. it can be only completed post-authorisation (Article 114 of Directive 2001/83/EC).

If the batches shipped prior to authorisation are not according to the specifications of the market authorisation they would not be safe to use and compliance with manufacturing protocols could not be certified. This would then mean that Member States would have to **destroy the batches** and ensure their safe disposal.

In order to ensure **transparency and coordination**, Member States should notify to the Steering Board supporting the purchase of COVID-19 vaccines on behalf of EU Member States, their intention to receive batches of the vaccines under quarantine prior to authorisation. They shall also inform the Steering Board of the delivery dates.

Member States shall take subsequently contact with the company directly to agree on the distribution under quarantine. This should not impact the delivery dates for other Member States nor the number of doses foreseen per Member State in the weekly delivery schedule communicated by the company.

The **step-by-step guide for a distribution under quarantine of COVID-19 vaccines** is as follows: [3]

1. Member States should **notify to the steering board** their intention to receive batches of the vaccine under the distribution under quarantine scheme prior to authorisation.
2. Member States shall take subsequently contact with the company directly to agree on the distribution under quarantine. They shall inform the **steering board** of the **delivery dates**. This should not impact the delivery dates for other Member States nor the number of doses foreseen per Member State in the weekly delivery schedule communicated by the company.
3. The **company** needs to agree and confirm the availability of doses prior to the marketing authorisation and **establish a schedule for distribution** to the MS concerned and communicated to the Commission.
4. The **company** needs also to **agree to ship the product** visibly identified as product under quarantine before the marketing authorisation is granted and the certification by a Qualified Person (QP), subject to the more detailed provisions outlined below. It is a legal requirement for every manufacturer of pharmaceutical products to have a Qualified Person, who certifies the release of every batch of each product; the Qualified Person is essential to the safe control of medicines.
5. Member States concerned should keep the **shipment under quarantine to a dedicated destination** in that Member State that holds the necessary authorisations from the relevant competent authority for distribution of medicines.
6. **Companies and MS** will have to ensure that uncertified batches are not transferred to saleable stock. Measures should be put in place and may be physical in nature, e.g. the use of segregation and labelling or electronic in nature, e.g. the use of validated computerised systems. When uncertified batches are moved from one authorised site to another, the safeguards to prevent premature release should remain. The batches of

[3] Based on Directive2001/83/EC and the Good Manufacturing Practice Guidelines.

the vaccines under the early distribution scheme should be taken into account in the allocations as communicated by the Companies to the Commission.

7. The steps necessary to notify Qualified Person certification to the site where the transfer to saleable stock is to take place should be defined within a **technical agreement between the company** and the MS concerned. Such notification by a Qualified Person to the site should be formal and unambiguous and should be subject to the requirements of the principles and guidelines of good manufacturing practices for medicinal products (Article 47 of Directive 2001/83/EC and Chapter 4 of EudraLex, Volume 4, Part I).
8. **MS would lift the quarantine after the marketing authorisation** has been granted and the Qualified Person and the Official Control Authority Batch Release (OCABR) in the Member State confirms the batch conformity with the necessary documents.
9. **MS will have to bear the full responsibility** and have in place processes to secure that the **shipped doses remain under quarantine** until, based on the release and certification process performed by the of the manufacturer, the quarantine is lifted by the Qualified Person of the wholesaler (or receiving entity) where the product is stored.
10. If **batches** shipped under the early distribution scheme are **not in accordance with the specifications** of the Market Authorisation when granted, the **MS would have to destroy the batches** and ensure their safe disposal. This is because the batches would not be safe to use and the Qualified Person would not be able to certify their compliance with manufacturing protocols (Article 51 of Directive 2001/83/EC).