



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation  
**Medicines: policy, authorisation and monitoring**

Brussels  
SANTE.DDG1.B.5/AL/FI mmc(2020)5727730

**Subject: EU Vaccine Strategy - Regulatory flexibility – Labelling and packaging flexibilities**

Dear Members of the Pharmaceutical Committee, Dear Members of HMA, Dear Members of CMDh, Dear Professor Rasi,

With this letter I would like to provide you with a copy of the agreed labelling and packaging flexibilities for COVID 19 vaccines.

In the context of the recently adopted EU Vaccine Strategy, in particular its Regulatory Pillar, the Commission presented a draft memorandum of understanding (MoU) among Member States on labelling and packaging flexibilities for authorised COVID 19 vaccines, in order to facilitate more rapid deployment of these vaccines.

The document was subsequently shared with the Heads of Medicines Agencies for consultation and then endorsed by the EU Executive Steering Group on 26 August 2020. A written consultation followed with the Pharmaceutical Committee ending on 8 September 2020. No specific comments were received and no further concerns were raised in the subsequent meeting of the Pharmaceutical Committee on the 18th of September; therefore the MoU on labelling and packaging flexibilities for COVID 19 vaccines is now endorsed.

A more detailed guidance on the flexibilities for the labelling and packaging requirements for Covid-19 vaccines may be developed by EMA/HMA, as needed.

Yours faithfully,

(e-signed)

Olga SOLOMON  
Head of Unit

Enclosure: Memorandum of Understanding

To: The Pharmaceutical Committee, The Heads of Medicines Agencies,  
The Coordination Group for mutual recognition and decentralised  
procedures, The European Medicines Agency

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111

Sante-Pharmaceuticals-B5@ec.europa.eu

## **Memorandum of Understanding (MoU) with Member States on regulatory flexibility for COVID-19 vaccines**

### **1.1. Objective**

Regulatory flexibility is one of the two pillars of the recently adopted Commission Communication on the EU Strategy for COVID 19 vaccines<sup>1</sup>, which identifies it as an essential tool to accelerate the development, authorisation and availability of vaccines while maintaining the standards for vaccine quality, safety and efficacy.

In the Communication, the Commission committed to work further together with the Member States on labelling and packaging flexibilities, in order to facilitate more rapid deployment of authorised vaccines.

Those objectives are achieved through a MoU that creates a common understanding with Member States on labelling and packaging aspects.

### **1.2. Flexibility in relation to labelling and packaging requirements of centrally authorised vaccines against COVID-19**

The EU regulatory system contains significant agility when it comes to authorisation procedures, which can facilitate access to a needed vaccine. In the current crisis, the Commission has expressed its ambition of delivering a successful COVID-19 vaccine within a timeframe of 12 - 18 months, while acknowledging that once it is available it would need to be produced in millions-possibly billions- of doses to cover global needs, in addition to the production of other vaccines, which should not be compromised.

Flexibility in the labelling and packaging requirements can facilitate the rapid deployment of the vaccine by increasing production capacity, reducing transport costs and storage space, improving the distribution of the doses between Member States and limit possible impact on the production of other routine vaccines.

Under the current legal framework, competent authorities are empowered to provide exemptions from certain labelling and packaging obligations in line with Article 63(3) of Directive 2001/83/EC:

*“The competent authorities may exempt labels and package leaflets for specific medicinal products from the obligation that certain particulars shall appear and that the leaflet must be in the official language or languages of the Member State where the product is placed on the market, when the product is not intended to be delivered to the patient for self-administration.”*

The Commission may use such flexibility, when specifying the conditions for labelling and packaging conditions in the marketing authorisations for centrally authorised vaccines.

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<sup>1</sup> [https://ec.europa.eu/info/files/communication-eu-strategy-covid-19-vaccines\\_en](https://ec.europa.eu/info/files/communication-eu-strategy-covid-19-vaccines_en)

The Commission having considered the above, intends that for the authorisation of Covid-19 vaccines during the pandemic and under accelerated procedures (e.g. conditional marketing authorisations) for a temporary period:

- a) to alleviate some of the language requirements and limit as a result the information on the immediate and outer packaging to one EU official language, preferably English. In addition, and in order to allow the creation of multilingual labels and facilitate availability, the option of labelling simplification via omission of particulars should also be considered. Details are provided in the relevant published guidance: [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/recommendations-implementation-exemptions-labelling-package-leaflet-obligations-centralised\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/recommendations-implementation-exemptions-labelling-package-leaflet-obligations-centralised_en.pdf)
- b) the acceptability of multi-dose presentations for COVID-19 vaccines (e.g 5 or 10-dose vials) and as supported by scientific assessment and careful considerations of labelling needs (e.g handling instructions). In this context, it is also recognised that manufacturers need to consider available pack sizes and sufficient ranges to avoid wastage.
- c) the possibility of separate distribution of a print out of the package leaflets to accommodate for one patient leaflet per dose (also in line with the decision taken for H1N1 vaccines) and for the accelerated availability of the vaccine respectively. In such cases, package leaflets may not be included inside the product cartons, but will have to be provided separately by the MAH, who would be responsible for the distribution of the printed package leaflet locally in the national language(s). The availability of the package leaflet in electronic form in all languages is guaranteed under the centralised procedure, as this information is published by the Commission. Inclusion of a QR code as an additional means of accessing the Package Leaflet in the respective national language(s) is recommended.
- d) the omission of country specific blue box requirements, and use of one Global Trade Identification Number (GTIN) for serialisation, where possible, respectively.
- e) the creation of a dedicated page on EMA website providing detailed information on the different Covid-19 vaccines which can be referred to in the labelling /packaging of the products.

A more detailed guidance on the flexibilities for the labelling and packaging requirements for Covid-19 vaccines will be developed by EMA /HMA, as needed.