



E-leaflet and Vaccines Common EU Packaging

Introduction

Vaccines have proved to be critical for healthcare systems if supplied in an efficient and timely manner. However, the **enormous language diversity of packaging and leaflets** due to country specific packs for the different EU/EEA countries can significantly reduce supply chains' efficiency, and may limit emergency response to vaccines shortages in the event of sudden outbreaks of vaccines-preventable diseases.



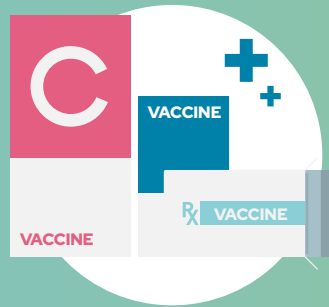
Packaging components

There are 3 distinct elements of vaccine packaging.



The **immediate packaging** is the component in direct contact with the medicinal product (vaccine):

- **Syringes or vials** for most of the vaccines
- **Applicators** for the few vaccines that are administered nasally or orally.



The immediate packaging is placed into the **outer packaging**:

- **Boxes or cartons**

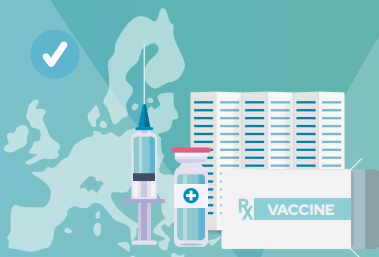


To comply with the EU legislation, the pack also contains a **paper leaflet** which provides information on the vaccine:

- **Patient Information Leaflet (PIL)**

How this works in the European Union

According to EU legislation, information has to appear:



On all 3 packaging components



In the official national language(s) of the country of distribution

There are in total **24 official languages** in the EU/EEA, and some countries have up to **3 official languages**. In addition, Member States may require country-specific information to appear on the outer packaging.

Implications

1 Small volumes of vaccines

The diversity of packaging and leaflets requirements between Member States coupled with the fact that most EU countries are small markets* means that vaccines may have to be delivered in small volumes (sometimes a few thousand doses) under country-specific packs.

This creates a huge complexity that reduces the efficiency of an already complex by nature supply chain.

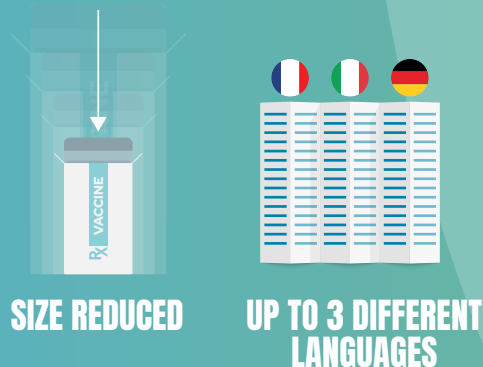
*18 EEA countries have less than 10 million inhabitants



2 Logistical constraints

The use of multilingual packs/package leaflets for vaccines is limited by logistical constraints. The vast majority of vaccines have to be stored in refrigerated conditions (2°C to 8°C) which have a limited amount of space. This means:

- The size of the packs has to be reduced as much as possible to facilitate storage.
- The content of the pack needs to be minimised, so multilingual packs for vaccines are limited to a maximum of three different languages, **creating further complexities.**

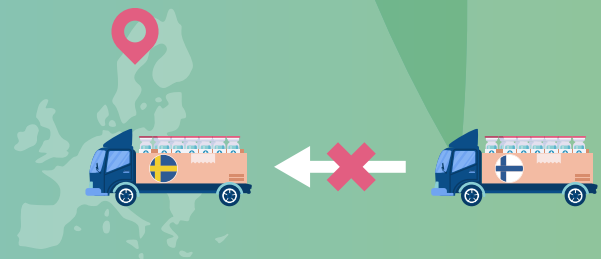


3 Shortages

The requirement for vaccine packs and paper leaflets to be packaged according to the requirements of the country of destination may prevent that a shortage situation in one country can be immediately solved by temporarily using supply produced for another country. Although in the case of a shortage or in emergency situations, some countries accept the transfer of doses in a foreign pack, this is not a general rule*.

This adds to the inefficiencies of the supply chain and is one of the root causes of vaccine shortages in Europe.

*This option must be discussed on a case-by-case basis with the National Competent Authority of the concerned Member State.



Recommendation

To simplify the production process of vaccines in Europe, reduce the time to access for the population and facilitate the transfer of vaccines throughout the EU where they are needed, Vaccines Europe recommends:

- Adopting a single common EU packaging accepted by all EU countries
- Replacing the paper leaflet with an electronic leaflet that can be easily updated and is available immediately in all EU languages.

