

POSITION PAPER

Potential labelling/packaging improvements to facilitate vaccine supply

Europe is a long-standing leader in vaccines. Maintaining this position and ensuring vaccine availability in times of increased demand and supply constraints can only be achieved by a committed industry, operating in a stable environment, able to produce vaccines of the highest quality and to innovate to meet future vaccine needs.

Shortages of medicines, including vaccines, are of increasing concern in the EU and globally. The causes are multiple. Finding solutions requires a concerted effort by all key stakeholders. Vaccines Europe is contributing to finding such solutions.

Vaccines Europe fully supports the need to provide comprehensive, accurate and up-to-date information on vaccines to health care professionals, patients and distribution chain actors. Such information must be easily accessible and with the required level of detail for the most effective and safe use of products.

Why labelling/packaging has a direct impact on vaccines supply capacity?

The diversity and complexity of labelling and packaging requirements, globally and across EU/EEA Members States, is one of the factors that impact vaccine supply, reduce supply flexibility and ultimately lead to an increased risk of shortage.

Due to a combination of factors such as the size of the market, limited shelf life or conditions imposed by tenders, vaccines may have to be delivered in small volumes (sometimes a few thousand doses) of country-specific packs. For that, packaging lines have to be stopped to allow the changes of label, leaflet and carton, and quality controls have to be performed. Frequent changes significantly reduce the capacity of packaging lines.

As soon as vaccine syringes or vials are labelled or packed in a country-specific format they can no longer be transferred to another country without agreement from authorities of the new destination country or without repackaging, which is associated with a risk of error and cold chain disruption, and should be avoided from a good manufacturing practice perspective.

Possibilities exist to reduce the number of specific national labelling and packaging requirements without any impact on the product information quality. Use of such possibilities would streamline vaccine manufacturing, optimize existing capacity and increase availability.

In that respect, vaccines have some specifics which should be taken into account, such as the requirement for administration by health care professionals, presentation in syringes or vials, strict cold chain conditions and, in general, small pack sizes to facilitate cold chain distribution and storage.

Even if some countries show flexibility (usually for small annual volumes) by accepting the use of English only on packaging materials, most of the EU/EEA Member States insist on local national languages on all packaging material (i.e. on the label, carton and leaflet). Latin characters are used in most countries but there are some exceptions (Cyprus, Greece and

Bulgaria). The use of multilingual packaging material is normally allowed provided that the text is identical between the different countries.

In case of shortages with potential impact on public health, the possibility to use vaccines initially packed for another EU/EEA Member State has to be discussed on a case-by-case basis with the national competent authorities (NCAs). The management of pack transfers between Member States is complex, depending on the situation and the country; the acceptance of a foreign language by NCAs may be limited to some packaging components (e.g. for immediate pack, the syringe or vial label) and/or to specific distribution channels (e.g. distribution to hospitals only).

What practical solution could be implemented to facilitate the supply?

Vaccines Europe proposes the following improvements:

- The use of the same abbreviations and language on the immediate pack across all EU/EEA Member States

The EU Directives 2001/83 on the Community code relating to medicinal products for human use 2C, appendix IV EMA/211583/20 14 rev.10# and the Tables of non-standard abbreviations EMA/27236/2003 rev. 13# describe the content of the information to be mentioned and the standard abbreviations to be used, although allowing country specificities (e.g.: I.M., i.m., im for intramuscular injection). Allowing the use of the same abbreviations and a single language in the different EU/EEA countries would provide significant flexibility in terms of supply. For vaccines, with long production lead times due in large part to the quality control performed by manufacturers and Official Control Authority Batch Release (OCABR), having a unique label for primary container may allow (depending on the packaging process of the company) to allocate the doses to a specific country during the secondary packaging rather than at the stage of the primary packaging. This would provide significant flexibility to better adapt the production depending on the country needs.

In specific circumstances such as shortages the use of a unique label would facilitate the reconditioning of the primary container in another secondary pack when required by NCAs.

- The use of multilingual secondary packaging and leaflets in all EU/EEA Member States

The use of multilingual packs and the harmonization of product information (PI) content/requirements between Member States for nationally authorised products should be a common objective between industry and regulators.

Having EU guidance on packaging exemptions in case of shortage with potential impact on public health could facilitate dialogue between manufacturers and NCAs and reduce the need for repackaging. A proactive approach with more systematic use of English on multilingual packs could facilitate the transfer of vaccine doses between Member States.

The introduction of the packaging safety features linked to the Falsified Medicines Directive (Directive 2011/62/EU) and the 2016 delegated act on safety features (Commission Delegated Regulation (EU) 2016/161 of medicinal products for human use) should not restrict the use of multilingual packaging and should not block the transfer of vaccine doses from one Member State to another one as needed. Therefore, harmonization of the unique identifier (UI) and 2D barcode with widespread use of GTIN (Global Trade Identification Number) code in EU/EEA Member States should be promoted. This also requires that those countries requiring the inclusion of the national

reimbursement number (NHRN) in the 2D data matrix barcode abandon such a requirement. Indeed the current global data standards specifications do not allow the combined use of national/national healthcare reimbursement numbers to be encoded in the 2D data matrix barcode.

- The replacement of the paper leaflet by an e-leaflet

Vaccines Europe would like to propose new ways for providing product information and replacing the patient information leaflet in the carton by taking advantage of the current alternative mechanisms for information dissemination such as the Internet, mobile devices or direct print-outs at the dispensing level. In addition to facilitating supply, this would enable much faster updates of the information with improved readability to patients in all EU languages. Another advantage would be that recalls and destruction of vaccines due to errors on package leaflet would be avoided. Some countries outside EU/EEA have already implemented the use of e-leaflet for pharmaceutical products (e.g. In Australia, paper leaflet has been removed from the pack and replaced by e-leaflet for self administered products).

In EU/EEA, a recent assessment report from the European Commission to the European Parliament (Brussels, 22.3.2017 COM(2017) 135 final) already recommends to explore the use of electronic media to provide the information included in the Summary of Product Characteristics and Package Leaflet in the future. The report mentions that e-leaflet formats should be complementary to paper PLs that are required by the legislation and should not replace them at this stage in order to ensure availability of the information for all patients.

Local initiatives have been launched to demonstrate what are the benefits of e-leaflet for patients (project coordinated by VFA, the German association of research-based pharmaceutical companies) and to demonstrate that e-leaflet is equivalent to paper leaflet for patients in the hospital setting (project proposed by pharma.be, the Belgian association of research-based pharmaceutical companies). Vaccines Europe welcomes these initiatives and encourages the reflection on the possibility of replacing the package leaflet by an e-leaflet for vaccines in the future, particularly given that vaccines are always administered by Health Care Professionals whatever the channel of distribution. As all hospitals and pharmacies will be connected to the system of national repositories being set in the context of the implementation of the Falsified Medicines Directive (Directive 2011/62/EU) and its Delegated Regulation on safety features (EU 2016/161), it would be worth exploring if this system could also be used to access the package leaflet that would be uploaded in dedicated repositories.

Proper consideration of all of the above proposals would improve sustainability and flexibility of vaccine supply while still providing the relevant comprehensive, accurate and up-to-date information on medicinal products to health care professionals, patients and those in the distribution chain for the ultimate benefit of public health.