Vaccines Europe reflection on the Falsified Medicine Directive (FMD) implementation

Background information:
The Falsified Medicines Directive (2011/62/EU) and complementing Delegated Regulation (Commission Delegated Regulation (EU) 2016/161) introduce harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled[1]. These measures, which should be implemented by 9 February 2019, include:

- obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines,
- a common, EU-wide logo to identify legal online pharmacies,
- tougher rules on import of active pharmaceutical ingredients,
- strengthened record-keeping requirements for wholesale distributors.

Vaccines Europe fully supports the initiatives to protect European pharmaceutical supply chain from the entry of falsified medicines and its members are preparing to be ready by the 9th of February 2019, however some difficulties and risks have been noticed regarding the decommissioning of vaccines:

- Article 23 specifies the provision to accommodate specific characteristics of Members States' supply chains and request a wholesaler (or industry when it is acting as distributor) to verify the safety feature and to decommission the product in some particular cases. Due to lack of clarity on the use of Art.23 in the different European countries, industry cannot be ready for decommissioning of large volumes of vaccines by the date of FMD implementation. This situation may have an impact on the patients' access and public health;

- The inter-market packs exchanges are largely used to address vaccine shortages. After FMD implementation, repackaging will be more complex and time consuming (adding decommissioning, repackaging, reserialization and recommissioning steps). In addition there may be situations of potential transfer of non-serialised vaccines packs (e.g.: from Italy) to Member States requiring serialization.

Vaccines Europe requests that all EU/EEA Member States:
- restrict the use of Art. 23 to very specific cases in view of not losing the spirit of the FMD to ensure decommissioning is close to the end–user;
- inform as quickly as possible all stakeholders involved in the distribution or administration of vaccines (such as GPs) that they should be prepared for decommissioning;
- accept vaccine packs from other EU/EEA Member States without imposing repackaging to address emergency situations.

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[1] Q&A - Questions and Answers document (version 10, July 2018)