European Commission's Public consultation "In preparation of a legal proposal to combat counterfeit medicines for human use"

OUR KEY POINTS

- Sanofi-aventis supports the Commission's step
- Legislation should guarantee original packs integrity all a long the supply chain. This supposes the implementation of **tamper evidence** on the secondary packs of all pharmaceutical products as well as a **ban on repackaging** at European level
- Sanofi-aventis supports the **concept of mass serialization** of all the medicines associated with a systematic control of packs at the dispensing point as described in the EFPIA project for coding and identification of pharmaceutical products in Europe
- This includes a harmonization of pharmaceutical products codification throughout Europe via the implementation of a serialized **datamatrix** on secondary packaging of all products sold in Europe
- Nevertheless, due to the technical complexity and costly implementation sanofi-aventis does not support the implementation of a full track & trace concept, and favour a mandatory check at the dispensing point
- Sanofi-aventis would recommend to implement the above measures (tamper evidence, authentication features, the serialization,…) with a phased schedule, country by country using a risk based a pproach
- **Internet** is a growing threat for the security of the supply chain of medicines and the safety of patients. We would recommend **communication to patients to increase awareness** of the risk and, measures to secure the trade of medicines on internet

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From a global point of view, sanofi aventis supports the commission's step and strengthened measures toward a better s ecurity of supply chain and protection of patients' health.

We would like to comment some points that we consider as to be of practical interest to set up these measures:

Section 4.1.3. Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk -based approach, supported by a ban on repackaging.

Sanofi aventis supports the following principles:

1- Legislation should guarantee original packs integrity all along the supply chain, i.e. it should be forbidden to anyone in the distribution chain to open original manufacturers' packs. The right to opening packs has to be restricted to the original full marketing authorisation holder and the end user (hospital, health care professional or patient). No oth er parties in the distribution chain (such as wholesalers, brokers, traders, agents, business to business platforms) should be allowed to open the packs, unless they have obtained a specific authorisation from the original marketing authorisation holder.
This supposes the implementation of tamper evidence on the secondary packs of all pharmaceutical products as well as a ban on repackaging at European level, as proposed by the European Commission. As already done by some manufacturers, authentication security features can also be added on the secondary packs of medicines on a risk based approach.

2- Each pharmaceutical company should have the choice of the technology to be used to implement pack tamper evidence as well as authentication features in order to take into account the technical specificities of its packaging lines as well as its own manufacturing and distribution organisation.

3- Considering the important technical and economical impact of these anti - counterfeiting measures, tamper evidence and authentication features implementation should be done according to a phased schedule, considering a risk based approach.

Section 4.1.4. Centrally accessible record to facilitate traceability of batches throughout the distribution chain
Section 4.1.5. Mass serialisation for packaging and authenticity checks on a case by case basis

4- Sanofi Aventis supports the concept of mass serialization of all the medicines associated with a systematic control of packs at the dispensing point (Pharmacies or hospital), as described in the EFPIA project for coding and identification of pharmaceutical products in Europe (see appendix 1 enclosed for complete description) :

- Harmonization of pharmaceutical products codification throughout Europe via the implementation of a serialized datamatrix (ECC 200) on secondary packaging of all products sold in Europe. The product information contained in the datamatrix would include the product code, the batch number, the expiry date and a randomized serial number (according to GS1 international open standards).

- Verification of the pharmaceutical products at their dispensing point in order to check that the serial number exist in the manufacturers database and that it has not been already sold in another pharmacy. This systematic control would allow to break the business model of the counterfeiters.

As pack serialisation efficiency to fight counterfeit is fully dependant on the capability to control of these serial numbers, it is fully essential that a systematic control of the serialized products (product code, batch number, expiry date and serial number) is done at the point of dispense of the medicines (i.e. in pharmacies and hospitals where the safety risk is maximum for the patient). It is therefore essential to guarantee that the original code of the manufacturer printed on the packs will not be modified during the distribution process, which supposes a ban on repackaging associated with the implementation of tamper evidence on all the packs.

5- Sanofi aventis does not support the implementation of a full track & trace concept based on the control of the serial numbers at all the stages of the distribution chain (i.e. wholesalers, …) because controlling each pack at all the supply chain levels is technically extremely complex and costly and would not bring any additional patient safety benefit compared to the systematic control at the dispensing point. It would in addition present an important number of issues for the manufacturers :

- Increased costs and technical/feasibility issues for implementing filiations/inference between unit of sales and cases (using Datamatrix) or for deploying double technologies (Datamatrix and RFID)

- Additional complexity and extended timelines for developing interoperable communication network between all the actors of the supply chain

6- Considering that pack serialisation is a complex and costly operation for the manufacturers, Sanofi Aventis would recommend to implement the serialization (EFPIA) concept with a phased schedule, country by country using a risk based approach.

7- As additional comments, we would like to draw the attention of the European Commission on the fact that internet is a growing threat for the security of the supply chain of medicines and the safety of patients . This problem should be rapidly dealt with an international approach. We would recommend communication to patients to increase awareness of the risk and, measures to secure the trade of medicines on internet.