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Comments on Consultation Sanco.ddg1.d.3(2011)1342823

This response has been established by the European Union of The Social Pharmacies (EUSP) (www.eurosocialpharma.org). EUSP was established in September 1960 and covers currently 6 European Member States (BE, FR, IT, NL, UK) and 1 EEA State (CH). EUSP includes more than 6000 pharmacists, 3000 pharmacies and 30 Wholesaler under the co-operative or associative legal form.
The (EUSP) welcomes the opportunity to respond to this public consultation and would like to highlight particularly worrying elements of the concept paper.

General comments

Regularly takes place exchange of information under the form of authentic copies of authorizations issued to the operators by the competent authorities, between legal pharmaceutical companies and legal stakeholders in the distribution (wholesaler Dispatcher), delivery (pharmacy). This information on the authorizations should be made public and easily searchable, as introduced by directive 62/2011.
This procedure of mutual recognition between operators is essential to the security and integrity of the "supply chain". Pharmaceutical companies communicate on this occasion the list of medicinal products for which they hold a marketing authorization and the exclusive distribution.
The principles and guidelines of good distribution practices provide that no operator can sell to - or acquire from – an unauthorized operator. In addition, any authorized operator must document at any time the origin and destination of medicinal products held, purchased, or sold.

These principles provide a likely seal of the distribution/delivery chain. The pharmacy being subjected to the same procedure, there is a low probability to find a non-compliant medicinal product in a “normal” European pharmacy.
If an operator returns a medicinal product to the sender, this operator is considered as a provider and this operator assumes all the rights and duties of documentation and information to the recipient. This compliance is also of application for recall and quarantine.
It is understood that the persons to which the QP delegates the operational part of its responsibilities are required to observe the procedures GMP/GDP. If such is not the case, it is a serious professional offense.

For example, any discrepancy between what, on the one hand, was commissioned and confirmed in the forms and deadlines by the supplier to the recipient and, on the other hand, what is provided to the recipient, results in the immediate quarantine of the whole delivery and, if necessary, a simple return to the sender. A non-ordered delivery also undergoes the application of this same procedure. It is nothing more, or less, than the simple application of the Community code on medicinal products.
Reminder: this vision and these obligations were not lifted by directive 62/2011.

As there is no available evidence quantifying and qualifying the extent of falsified medicinal products in the EU, the EUSP warrants caution and encourages the EU Commission to **carefully consider the benefits and risks of such a delegated act,** before implementing the safety measures as proposed. Such investment could impact medicines’ costs and reduce the sustainability of wholesalers and community pharmacies **without any benefit for public health.**
The only related data available at EU level concerns counterfeit medicinal products; as reported by the EU’s authorities, medicinal products represent 2.29% of all counterfeits seized at EU borders (equivalent to 3.1% in volume).
From these, the large majority (more than 60%) are postal deliveries from online pharmacies located outside the EU, which remain outside the scope of the Falsified Medicinal products Directive.

A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer

2. Policy option n°1/2: Harmonisation through regulation
Consultation item n°1: Comment on points 1 and 2 (policy options n°1/1 and n°1/2). Benefits and disadvantages of each policy option: See below.
2.1. Regulation of the composition of the serialisation number
2.1.1. Manufacturer product code and pack number
Consultation item n°2: Advantages and disadvantages of the approach set out in Manufacturer product code and pack number
2.1.2. Additional product information
Consultation item n°3: Advantages and disadvantages of the approach set out in Additional product information
Option 1: The national reimbursement number is replaced by the abovementioned serialisation number: Best Choice.
Option 2: The abovementioned serialisation number includes the national reimbursement number.
Consultation item n°4: Advantages and disadvantages of the two options set out under point 2.1.2.

2.2. Regulation of the technical characteristics of the carrier
2.2.1. Linear barcode: **obsolete solution**
2.2.2. 2D-Barcode: **Best Choice**
2.2.3. Radio-frequency identification (RFID): **Un-payable costs, technical sensitivity, privacy questions.**
Consultation item n°5: Benefits and disadvantages of each of the three concepts. Costs for each concept:
- Costs for reading devices for the different carriers;
- Costs for adapting packaging lines of medicines packaged for the EU market.

It will be important for the delegated act to set a meaningful framework at EU level and Member States level.
The choices should be harmonised through the EU to avoid asymmetry across companies and a diversity of norms.
In order to ease product recall, management, storage and verification of expiry dates at various points in the chain, EUSP welcomes the adoption of a 2D barcode containing:

- manufacturer product code;
- expiry date;
- **storage temperature range**;
- batch number.

Separately produced and applied: the unique identifier (UID) of the pack.

B. CONSULTATION TOPIC N° 2 -MODALITIES FOR VERIFYING THE SAFETY FEATURES

The implementation of random verifications proposed in the concept paper must be understood with the **systematic process described in our general comments**. A permanent randomised verification by wholesalers and pharmacists during storage (thus before shipping to retailers or delivery to patients) should be advisable.

Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point
Consultation item n°6: Other points of dispensation to be considered: Hospitals, Internet parcel services
Policy option n°2/2: Additional random verifications
Policy option n°2/3: Additional systematic verifications
Consultation item n°7: Benefits and disadvantages, costs of each of these policy options.

C. CONSULTATION TOPIC N°3 -PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

EUSP ask for a clear definition of the notion of "repository" (Storehouse?)
The costs of repository systems, if this means the safety features, are included in the price of the medicinal product.
EUSP would recommend national governance. Stakeholders can and should be associated but the oversight of any co-regulation should be under the responsibility of the national competent authorities.
Such information is vital to uphold public health and increase patient safety and should be therefore the responsibility of the national competent authorities.

1. Policy option n°3/1 – 'stakeholder governance'

2. Policy option n°3/2 – EU governance

3. Policy option n°3/3 – national governance

Consultation item n°8: Benefits and disadvantages. Costs of each of these policy options: estimated one-off costs and running costs for a repositories system. Information on past experiences with a repositories system at individual company level and at national level.

4. Other issues related to the repositories system

4.1. Information of a commercially sensitive nature

Some of such data that are deemed to be of public interest and should always be made accessible to national competent authorities at all times.
This would include, among others:

- number of packs manufactured : can be of great value to forecast consumption rates, prevent stock-outs and help procurement procedures;
- Information about the point of dispensation of a pack: the sales at a particular retailer can be tracked.

Consultation item n°9: Other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act.

4.2. Protection of personal data

The repositories should not include any collection of private patient information, particularly in the case of heavily monitored PoM.

4.3. Re-packaging of medicinal products

To be considered as a production and manufacturing activity (GMP).

Consultation item n°10: Aspects to be taken into consideration in the delegated act.

D. CONSULTATION TOPIC N°4 - LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

1. Identification criteria

EUSP would encourage identification through the use of a combination of the International Non-proprietary Name (INN) and the Anatomical Therapeutic Chemical (ATC) classification.

Consultation item n°11: Most plausible approach. Other arguments and identification criteria to be considered.

2. Classification criteria

Consultation item n°12: Comment on the quantified approach.

- Price of medicinal products is the major driving factor for falsification and fraud;
- The sales volume of a medicinal product, just entered the market, might be low. Yet its uptake might be reasonably fast. By only taking into account the its initial sales volume, there is a high risk of underestimation of the likelihood of falsification;
- Product characteristics – It would be important to distinguish between the characteristics of the active ingredient and those of the dosage form. An active ingredient might have a therapeutic effect at low dose and therefore present a higher risk of harm for a patient if falsified. A given dosage form might be easier to falsify than others. The example given in the concept paper focuses on the distribution pathway rather than on the characteristics of the product.
- Pharmaceutical companies deliver also medicinal products directly to retailers;
- Other potential risks to public health - We would warrant caution in inserting such a vague statement. Clarification is needed.