

Fighting against “counterfeit medicines” should not be used as a pretext to track data on medicines’ sales

• *Medicines in Europe Forum’s Response to the Concept Paper on the Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its verification.*

The Medicines in Europe Forum (MIEF) welcomes the opportunity to respond to the public consultation on the Concept Paper on the Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use¹ and would like to highlight particularly worrying elements of the concept paper.

General comments

First, the MIEF wishes to remind that **there is no evidence quantifying and qualifying the extent of falsified medicines in the European Union**². The only related data available at EU level concerns counterfeit medicines; as reported by the European Union’s authorities counterfeit medicines represent only 2.29% of all counterfeits seized at EU borders (equivalent to 3.1% in volume)³. From these, the large majority (more than 60%) are postal deliveries from online pharmacies located outside the EU, which remain outside the remit of the Falsified Medicines Directive.

The MIEF also wants to emphasise that **modest prices for medicines would significantly decrease the profitability of defrauding**. Reforming of the current system where unjustified exorbitant prices are granted would reduce incentives to produce counterfeit medicines⁴.

MIEF therefore requests caution: **is the palliative solution of costly investments aimed at ensuring extensive traceability all along the logistics channel a proportionate answer to fight with efficiency against counterfeits medicines? MIEF encourages the EU Commission to carefully consider the benefits and risks of such a delegated act, before implementing sophisticated and costly safety measures**. Such investment could affect medicines’ price and the sustainability of wholesalers and community pharmacies without any benefit for public health. Moreover, **the data gathered** (i.e. information on the number and types of medicines delivered by a particular community pharmacy)

¹- European Commission Health and Consumers Directorate-general “Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its verification” Concept paper submitted for public consultation. Brussels, 18/11/2011 (Sanco.ddg1.d.3(2011)1342823). Available at:

http://ec.europa.eu/health/files/counterf_par_trade/safety_2011-11.pdf : 19 pages.

²- Prescrire Editorial Staff "Counterfeit drugs: recognising the real issues" *Prescrire Int* 2009; 18 (101): 135-1 - 135-5.

³- European Commission. Report on EU customs enforcement of intellectual property rights. Results at the EU Border 2010. Taxation and Customs Union. Available at:

http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/statistics_2010.pdf. Accessed on 18 April 2012.

⁴- Velásquez G “Rethinking The R&D Model for Pharmaceutical Products: A Binding Global Convention, Policy Brief 8,

April 2012” www.southcentre.org/index.php?option=com_content&view=article&id=1704%3Arethinking-the-rad-model-for-pharmaceutical-products-a-binding-global-convention&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en

could be used by pharmaceutical companies for commercial purposes (i.e. to monitor their promotional strategies, the effectiveness of their sales representatives, etc.) (read below).

Topic 1: Characteristics and technical specifications of the unique identifier

It makes sense to harmonise the choice of the unique identifier (as well as its characteristics and technical specifications) through EU legislation.

In order to ease product recall for pharmacovigilance reasons or in case of doubts that a product might have been counterfeit, a serialisation number containing a manufacturer product code, a unique identification number of the pack and eventually a batch number would suffice. From a public health point of view, no distinction should be made into prescription or over-the-counter medicines. Regarding National reimbursement numbers, it should not be replaced by the serialisation number because it could affect parallel imports.

Any identification system to ensure the trade of safe and quality medicines should not hinder access to medicines. Adopting methods such as radiofrequency identification (RFID) in the chain of supply can inadvertently increase medicines prices, reducing access to medicines and slowing down generic competition. Moreover, RFID may interfere with the quality of certain medicines. Therefore, the MiEF would encourage the adoption of 2D barcode (for instance, the Datamatrix used in France).

Topic 2: Modalities for verifying the safety features

As to the different modalities to verify safety features along the supply chain, the MiEF would be in favour of a verification of the serialisation number at the dispensing point (retailer or pharmacy), by scanning the serialisation number (policy option n°2/1). Such a check out should be done when retailers or pharmacies receive the products rather than at the moment when they dispense them to the patients to avoid delay in dispensation and dispensation errors if the pharmacist has to concentrate on such administrative practices. The ultimate goal of any attempt to decrease medicines falsification should in fact be that of reducing drug-induced harm to medicines users.

The verification of the serialisation number at the dispensing point would represent a final hurdle to eventual falsified medicines, thus contributing to patients' confidence in the pharmaceutical quality of the medicines they receive. In addition, the implementation of additional random verifications at the level of the wholesale distributors before shipping to retailers as proposed in the concept paper (option n°2/1) would be advisable.

Topic 3: Provisions on the establishment, management and accessibility of the repositories system

The information contained in repositories system is sensitive. Pharmaceutical companies pay a huge price to specialised companies to get such information in order to analyse the sales of their competitors and to assess their market share^{5,6}.

MiEF recommends:

- that a national governance oversees the infrastructure of the repositories system (option policy n°3/3), since the information contained in the system is, according to this concept paper, relevant for pharmacovigilance and pharmacoepidemiology purposes. Stakeholders can and should be consulted, but the oversight should be the responsibility of the nationally designated body (an independent and state-governed institution);
- that data enabling the medicinal product to be traced to the final dispensing point are not made available to the manufacturer in order to protect retailers' and pharmacies' data on their sales, prescribers' freedom of prescription and consumers' privacy;

⁵- Prescrire Rédaction "IMS Health : une entreprise qui vous veut du bien" *Rev Prescrire* 2010 ; **30** (316) : 154-155.

⁶- Prescrire Rédaction "Les firmes observent prescriptions et ventes pour affiner leur promotion" *Rev Prescrire* 2010 ; **30** (315) : 66-67.

- that alert announcements and product recalls are made publicly available without delay on the competent authorities websites.

Commercially sensitive information

The number of packs manufactured should be made publicly available and not fall into the scope of “commercial confidentiality data” since it represents scientific data needed to estimate consumption rates and assess the level of exposure of the population in the case of a pharmacovigilance issue.

Data that are deemed to be of public interest should be made accessible to national competent authorities at all times. For example, information that would allow the number of packs manufactured to be established can be of great value to prevent stock-outs and help procurement procedures.

Protection of personal data

It is imperative that the repositories not include any collection of private patient information (i.e. patient contact details, their age, type of condition, duration medical history, etc.).

Particularly in the case of heavily monitored prescription-only medicines, there is a potential for a breach of patient privacy.

Topic 4: Lists containing the medicinal products or product categories which shall/shall not bear the safety features

On the classification criteria, MiEF would like to highlight the following aspects:

- **High price is the major driving factor for falsification** and should weight more than the other criteria in the decision process to include or not a medicinal product in the lists;
- **Brand popularity** is also an important driving factor for falsification and should be taken into account (i.e. medicines that are widely promoted, with promotional costs representing more than 10% of the revenue a medicine brings);
- The sales volume of a medicine that has just entered the market might be low, yet its uptake might be reasonably fast. By only taking into account its initial sales volume, you might be underestimating the likelihood of falsification;
- Accounting for the number and frequency of incidents of falsified medicines in a third country might not be at all relevant for the European Union, since the focus of falsification might vary greatly with the geographic distribution; i.e. anti-malarials are more likely to be falsified in Africa than in Europe;
- The characteristics of the product: It would be important to distinguish between the characteristics of the active substance and the characteristics of the dosage form. An active substance might have a big therapeutic effect at low dose and therefore have a higher potential to harm a consumer when it is falsified. A given dosage form might be easier to falsify than others. Such aspects must also be taken into account. The example given in the concept paper focuses on the distribution pathway rather than on the characteristics of the product. Most notably, several pharmaceutical companies (originator and generics) deliver products directly to retailers;
- Other potential risks to public health - We require caution in inserting such a vague statement. Clarification is needed.

Identification criteria

In order to avoid confusion among different products and pharmaceutical forms, MiEF encourages identification using medicines labeling provisions as provided in Title V of Council Directive 2001/83/EC [as amended]: following the brand name of the medicine, reference to all common name(s) of the active substances in the formulation and dosage.

The Medicines in Europe Forum

MiEF. The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and

consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the European Union and is testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.