EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 737

PHARMACEUTICAL COMMITTEE
27 October 2017

Subject: **Falsified Medicines Directive – Update on the implementation of the safety features (medicine traceability)**

Agenda item 2i

This document intends to share with the Pharmaceutical Committee the state of play of the implementation of the safety features and the new medicine verification system which will become applicable as of February 2019.

Updates

Progress setting up the repositories system:

Stakeholders (acting through non-profit European or National Medicine Verification Organisations) are setting up the national/supranational databases where the unique identifiers (and related data) are stored, as well as a European hub acting as an information and data router. The timely setup of the repositories system is essential to be able to verify the authenticity of medicines as of February 2019.

Concerning progress, the overall setting up of the repositories system is currently behind schedule and there are still some issues with stakeholder integrations, although the situation in certain Member States is better than others:

- While 25 NMVOs have been established (out of 31 EU + EEA Member States; >75%), only 14 IT contracts for the setting up of national repositories have been signed to date (< 50%).
- The participation of stakeholders in a number of NMVOs is still incomplete, as wholesalers, pharmacies or hospitals are not integrated in the NMVO setup in certain Member States.

In addition, HOPE, the European association representing hospitals, informed the Commission of a worrying lack of hospital budget plans covering the necessary resources for the implementation of the new rules. Specific budget needs to be allocated for equipment, such as scanners, IT equipment as well as dedicated personnel. The situation is of particular concern for hospitals/health centres which are publicly owned.

Member States help is needed to ensure a timely implementation of the new rules. In particular, Member States are encouraged to continue working with national stakeholders and push for the finalisation of the remaining 17 IT contracts as a matter of priority. Member States should also encourage the inclusion in the NMVO of all stakeholders concerned by the verification operations, in particular pharmacies and hospitals.

Finally, Member States should ensure the presence of appropriate budget plans covering the necessary equipment and personnel costs for the implementation of the new rules in public hospitals.

NCA Access to data contained in the repositories system

Directive 2011/62/EU and Delegated Regulation (EU) 2016/161 allow Member States to use the information contained in the repositories system for the purposes of investigation incidents of falsification, reimbursement, pharmacovigilance or pharmacoepidemiology.

In order to ensure that the repositories are built with the necessary capabilities, the Expert Group on the safety features has prepared four documents detailing the Member States' needs in terms of data access in the following areas:

- Investigation of potential incidents of falsification;
- Reimbursement;
- Pharmacovigilance & Pharmacoepidemiology;
- Supervision of stakeholders.

These 4 documents are being discussed with stakeholders, in particular the EMVO (European Medicine Verification Organisation). In spite of a difficult beginning (stakeholders were very reluctant to grant access to commercially sensitive data), the dialogue has recently made very good progress and finalised documents are expected by the end of the year.

Regulatory implementation of the safety features:

EFPIA and Medicines for Europe complain that the CMDh implementation plan for the introduction of the safety features on the packaging of nationally authorised medicinal products for human use is subject to divergent interpretation by NCAs in different MS – causing issues for MAHs when introducing necessary regulatory changes to product information.

Member States are invited to harmonise their approach and apply the plan they had agreed at CMDh level.

Application of the Delegated Regulation by BE, IT and EL:

BE notified the Commission that it will not apply the extra 6 years. The Commission will publish a Notice in the Official Journal to ensure that the BE decision is made public.

Background

Directive 2011/62/EU introduced obligatory ‘safety features' - a unique identifier and an anti-tampering device - on the outer packaging of prescription medicinal products and

mandated[1] the Commission to detail their technical specifications and verification modalities via delegated acts.

On 9th February 2016, the Commission published Delegated Regulation (EU) 2016/161 detailing the characteristics and technical specifications of the unique identifier and setting up a new verification and traceability system for prescription medicines:

1. The unique identifier is to be placed in a **2D barcode** (Data Matrix) and contain the product code, a randomised serial number, a national reimbursement number (if requested by Member States), the batch number and the expiry date.

2. The authenticity of prescription medicines is guaranteed by an **end-to-end verification** system where the unique identifier applied by manufacturers is systematically verified at pharmacy/hospital level before the medicinal product is dispensed to patients. This simple action will ensure the medicines being dispensed are not falsified, do not come from a stolen lot, or have not been recalled/withdrawn due to quality defects. Medicines at higher risk of falsification (returns or medicines not being distributed directly by manufacturers or marketing authorisation holders or wholesalers distributing on their behalf) are additionally checked at wholesaler level, thereby facilitating the early detection of falsified medicines which may have entered the supply chain.

3. The unique identifiers are stored in a **repositories system** which is **set up and managed by stakeholders** (stakeholder's model). The structure of the repositories system is distributed: National/supranational databases (National Medicine Verification Systems) serve the territory of one or more Member States and, where needed, exchange information and data through a central, European "hub" (European Medicine Verification System). National competent authorities are able to access and supervise the repositories.

Delegated Regulation (EU) 2016/161 will apply as of 9 February 2019 in all Member States. BE, EL and IT have the possibility of deferring the application of part of the Regulation for up to 6 years.

To facilitate the implementation of the delegated Regulation and the new rules on medicine verification, the Commission has published a "Questions and Answers" document on its public health website: http://ec.europa.eu/health/files/falsified_medicines/qa_safetyfeature.pdf.

In addition, the regulatory requirements to be followed to notify the EMA of the placing of the unique identifier and/or the anti-tampering device on centrally authorised products are detailed in an implementation plan, developed by the EMA and the European Commission and published in the "product information templates" section of the EMA website:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/02/WC500201413.pdf

The regulatory requirements for nationally authorised products have been made available by the CMDh on its website:

[1] Art. 54a(2) of Directive 2001/83/EC.

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Falsified_Medicines/CMDh_345_2016_Rev00_02_2016_1.pdf

At the end of 2011, the Commission created a Member State Expert Group on the Safety Features with a view to drafting the Delegated Regulation. After the publication of the Delegated Regulation, the Commission continues to host and coordinate the work of this Group to ensure a smooth and harmonised implementation of the new rules.

Action to be taken:
For information