EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 744

PHARMACEUTICAL COMMITTEE
8 March 2018

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

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 for medicine verification:

Stakeholders (acting through non-profit European or National Medicine Verification Organisations) are setting up the national/supranational databases where the medicine serialisation data (unique identifiers and master data) are stored, as well as a European hub acting as an information and data router.

Setting up the repositories system is a multi-step process: (1) Establish a National Medicines Verification Organisation (NMVO) in each Member State; (2) identifying and signing an IT contract with the IT provider which will set up the database infrastructure; (3) setting up the database itself and pilot-testing its functioning; (4) onboarding and training of users;

The timely setup and testing 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, with approximately half the repositories which are late:

1. *Establishing a National Medicines Verification Organisation (NMVO).* 27 NMVOs have been established (out of 31 EU + EEA Member States; >85%). The 4 missing NMVO include those in IT and EL which have up to 6 additional years to implement this legislation.

2. *Identifying an IT provider and signing the contract*. 21 IT contracts have been signed to date (approx. 67%): AT, BE, BG, CZ, DE, DK, EE, ES, IE, FI, FR, HR, LT, LU, NL, PL, SE, SI, SK, IS and NO.
3. *Setting up the database and pilot-testing its functioning*. The technical implementation of national repositories has started in 19 Member States; 10 of those repositories are expected to go live and start the pilot-testing phase around April 2018. Additional 6 repositories are expected to follow by summer 2018.

In addition to the setting up of the repositories, there are still some issues with stakeholder integrations, although the situation in certain Member States is better than others. Wholesalers, pharmacies or hospitals are not integrated in a number of NMVOs. In addition, preparedness of hospitals is still a concern.

The Commission has sent letters to both European stakeholder associations and Member States encouraging a stepping up of efforts to ensure a timely implementation of the safety features. Stakeholders have been invited to renew efforts and encourage their members to (1) progress more rapidly in setting up and on-boarding the European/national databases and (2) budget for and acquire the necessary equipment, software and personnel to perform the verification/decommissioning tasks as of February 2019. In parallel, Member States have been reminded of their responsibilities for implementation and enforcement at national level, in particular ensuring that the necessary infrastructure is in place and hospitals have sufficient assistance and resources to perform their tasks as of February 2019.

All Member States need to work closely with their national hospitals to help them implement the new rules. Member States should also maintain a continued dialogue with stakeholders to monitor their progress and push them forward, where needed.

In parallel, the Commission is working with the Expert Group on safety features to identify solutions to simplify decommissioning by hospitals.

NCA Access to data contained in the repositories system

After 18 months of discussions, an agreement was finally found on access of National Competent Authorities to data in the repositories system. At its last board meeting, the EMVO endorsed the 4 position papers prepared by the Member State Expert Group on the safety features detailing the Member States' needs in terms of data access in the areas of (1) Investigation of potential incidents of falsification; (2) Reimbursement; (3) Pharmacovigilance & Pharmacoepidemiology; (4) Supervision of stakeholders.

Commission Report on penalties.

On 26 January 2018, the Commission published a report on the penalties EU countries apply to those involved in the production and circulation of falsified medicines: https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/com2018_49_final_en.pdf

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 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. BE has informed the Commission that it will apply the delegated Regulation as of 9 February 2019.

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: https://ec.europa.eu/health/human-use/falsified_medicines_en, section on "safety features".

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

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

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