The Malta Medicines Authority and Industry Stakeholders to host workshops relating to the EU Falsified Medicines Directive

Event Date: 23rd August 2017

The EU Falsified Medicines Directive (FMD) 2011/62/EU introduces the requirement for manufacturers / Marketing Authorisation Holders (MAHs) – including parallel distributors - to add safety features (anti-tampering device and an unique identifier) to the outer packaging of specified medicines for human use and to fund an Europe-wide verification system which will enable the authentication of medicines before the unique identifier is decommissioned and the pack is dispensed to a patient.

The Commission Delegated Regulation (EU) 2016/161 sets out the details of how the Directive is to be implemented and clarifies the obligations on other stakeholders in the pharmaceutical supply chain, such as wholesalers, distributors and pharmacists, including the obligation to check the safety features and in some circumstances to decommission the unique identifier.

http://ec.europa.eu/health/files/eudralex/vol-/reg_2016_161/reg_2016_161_en.pdf

The mandatory implementation of the regulation must be completed no later than 3 years from its publication, i.e. by the 9th February 2019.

Aims of the workshops

The Malta Medicines Authority, the European Medicines Verification Organisation (EMVO) representing all major impacted supply chain stakeholders, and the leading industry organisations in Malta (PRIMA, Chamber of Pharmacists, Chamber of Commerce and GRTU), who are charged with implementing the systems and processes required to achieve compliance with the Falsified Medicines Directive, would like to provide the industry and healthcare sectors with specific opportunities to engage with us in relation to the implementation of these systems.

This will include two workshop sessions as detailed below:

The first will be held in the morning and will be for all Marketing Authorisation Holders (MAHs) and their representatives, manufacturers, importers and all local distributors having a wholesale dealers licence.

The second meeting will be held in the afternoon for all other stakeholders, to address the obligations, technical and organisational aspects of interest to them.

Who Should Attend

Morning workshop: Stakeholders such as MAHs, manufacturers, repackagers or parallel distributors

Afternoon workshop: All stakeholders, including the above, pharmacist, wholesalers and distributors

Fee & Venue Details

These workshops are free of charge.

Date: 23rd August 2017

10:00-12:00 Meeting with MAH representatives, manufacturers, wholesale dealers and importers at Central Auditorium, Mater Dei hospital

13:30-15:30 Meeting with pharmacists and other stakeholders at Central Auditorium, Mater Dei Hospital

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