AWTORITÀ DWAR IL-MEDIĊINI

Circular number: MA15/12

8th November 2012

Addressed to all:

Qualified Persons, Responsible Persons and Managing Pharmacists;

Licence Holders of Manufacturing and Importation Authorisations, Wholesale Dealers and Pharmacies.

RE: Public Consultations on Implementing or Delegated Acts issued under Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

The Medicines Authority wishes to draw once more your attention to the ongoing EU Commission Public Consultation documents on various implementing or delegated acts to be issued under Directive 2011/62/EU, also known as the Falsified Medicines Directive (FMD), mentioned in the above caption.

Currently on the EU Commission website, health section (link:http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm) or specifically under the section of the FMD (link: http://ec.europa.eu/health/human-use/falsified_medicines/developments/index_en.htm), there are the following public consultations, amongst others, which are still open for pubic comments:

- Public consultation on the delegated act on the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced in the Union but not intended to be placed on the market. Closing date for public consultation: 10th December 2012

- Public consultation on the implementing act on a common logo for legally-operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public. Closing date for public consultation: 17th January 2013

Any comments to these EU Commission Public Consultations should be sent directly to the EU Commission (copied only to the Medicines Authority if you wish so on, info@medicinesauthority@gov.mt).

Though the Medicines Authority periodically issues such circulars as this one drawing your attention to some particular public consultations on Community legislation which may be of relevance to your line of work, I wish hereby to gently remind you that however you have also a professional obligation to keep yourselves updated and to track any communication and public consultation issued by the Commission through periodical review of the Commission's website.

Regards,

Mark Cilia
Director IED

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