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04/09/2015

INFORMATION ON THE DELEGATED ACT ON SAFETY FEATURES FOR MEDICINAL PRODUCTS FOR HUMAN USE

On 8 June 2011, the European Parliament and the Council adopted Directive 2011/62/EU (the Directive), amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, which strengthens public health protection by providing measures to fight the falsification of medicines even where there is no infringement of intellectual property rights.

Directive 2011/62/EU introduces obligatory 'safety features' (a unique identifier and an anti-tampering device) as part of the outer packaging of prescription medicinal products, although certain derogations apply. It places the Commission under an obligation to adopt delegated acts setting out the details relating to the unique identifier and anti-tampering device. It is envisaged that the Delegated Act pursuant to Directive 2011/62/EU will be published by the EU end September 2015, and that it has to be implemented within three years. Further information on the final draft of the delegated act can be found on the following link:
http://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&num=306&Country_ID=EU&dspLang=EN&BASDATEDEB=&basdatedeb=&basdatefin=&baspays=EU&basnotifnum=306&basnotifnum2=306&bastypepays=EU&baskeywords

The repositories system where the information on the safety features shall be contained, should be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features. The purpose of this communication is to put in motion the process to set up this non-profit legal entity. Following meetings with stakeholders, it was agreed that an invitation for participation in this non-profit legal entity will be sent to all stakeholders. This non-profit legal entity will represent stakeholders in implementing and maintaining the repositories system in compliance with the Falsified Medicines Directive and Delegated Act.

It is important that all stakeholders understand their obligations as required by the EU Falsified Directive 2011/62/EU. One must also note it is in the interest of all stakeholders to be represented in this non-profit legal entity. If any entity is not represented in this non-profit legal entity, one must understand that they are still required to implement the safety features requirements, either on their own, in which case they will bear all involved costs for their systems, or if opting to join the non-profit legal entity at a later stage, they would automatically then be accepting to abide by all the decisions made by the non-profit legal entity for the implementation and maintenance of the safety features.

In view of the above, it is imperative that your organisation or your stakeholder representative (example Chamber of Commerce/GRTU) nominates a representative to form part of this non-profit legal entity by completing the attached form. It is important that you indicate any restrictions your organisation or company may have, as declared in the companies' memorandum of articles, or in any other company policy. This information will be reviewed and a decision as to which kind of organisation will be set up will be taken (example Foundation, Company, NGO etc.).

Kindly forward the **scanned signed copy of the attached form to the following email address miau.medicinesauthority@gov.mt by not later than 18th September 2015.**

The **nominated representatives** are invited to attend a meeting at the **Medicines Authority on Wednesday 30th September 2015 at noon** to discuss the way forward following the feedback received.

Should any further information be required kindly contact the Medicines Authority by email on miau.medicinesauthority@gov.mt.