ICEMVO LYFJAAUÐKENNI

Lyfjastofnun
Icelandic Medicines Agency

Reykjavik, 20. November 2017

Communication to all Marketing Authorisations Holders in Iceland.

Dear Sir, Dear Madam,

The Falsified Medicines Directive

This communication is regarding amendment of the Directive 2001/83/EC and a new regulation that determines additional rules for the directive´s provisions on safety features on the packaging of medicinal products (Commission Delegated Regulation (EU) 2016/161); henceforth called the Falsified Medicines Directive (FMD).

The measures taken in the FMD is to secure the pharmaceutical supply chain in Europe from falsified medicines and it requires prescription medicines and certain non-prescription medicines to be labelled with a unique identifier and an anti-tampering device – the so-called safety features. It furthermore requires the establishment of a European Database and a National Repository System – also called a verification system for prescription medicines and selected non-prescription medicines.

The work to build the system has already started and all systems must be functional from the 9th Feb 2019, which is the legally binding date for implementation in Europe.

The Icelandic market

In line with the EU Falsified Medicines Directive, companies representing the market authorisation holders ("MAH's") active in Iceland created the Icelandic Medicine Verification Organisation (ICEMVO) Lyfjaauðkenni, a non-profit organisation.

ICEMVO's primary non-profit purpose is – on behalf of the MAH who place medicines on the Icelandic market – to act as National Medicines Verification Organisation in Iceland, to establish and manage the National Repository System in the same country, as well as to establish and manage the link with the European database.

The FMD stipulates that manufacturers and parallel importers pay the expenses in connection with establishment, implementation and maintenance of the verification system, and therefore your company shall enter into a contract with ICEMVO, just as the company shall upload the required information to the European database. Further information, including the conditions for how you upload data to the European database are available on https://emvo-medicines.eu/.

A contract with ICEMVO and uploading of data is a prerequisite if your company still would like to place the medicinal products in question on the Icelandic market after February 8th, 2019.

The Icelandic Medicines Agency finds, like ICEMVO, that for the sake of the security of supply, it is extremely important that companies providing medicinal products to the Icelandic market are aware of the new rules and as soon as possible contact ICEMVO and prepare the necessary changes to the packaging material of medicines that shall contain safety features as of February 9th 2019.

With a view to the future collaboration between ICEMVO and your company, we kindly ask you to contact ICEMVO before November 30th in order to inform us who we can contact for the purpose of having a dialogue on contract information. Please confirm contact information (name, title, e-mail address and telephone number) to be forwarded to info@lyfjaaudkenni.is, or through the *Contact Us* option available at www.lyfjaaudkenni.is.

For further information and questions, please do not hesitate to contact ICEMVO at telephone number + 354 660 3707 or e-mail: info@lyfjaaudkenni.is.

Yours sincerely,

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