DMVO Dansk Medicin Verifikation Organisation

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Copenhagen, June 9, 2017

Dear manufacturer / parallel importer

On February 9, 2019 we will have new rules of medicinal products for human use.

It is regarding amendment of the directive 2001/83/EU and a new regulation that determines additional rules for the directive's provisions on safety features on the packaging of medicinal products (regulation (EU) 2016/161). The purpose of the rules is to prevent falsified medicines entering the legal supply chain.

It appears from the rules, among other things, that the prescription medicines and certain non-prescription medicines as of February 9, 2019 shall be labelled with a unique identifier and an anti-tampering device – the so-called safety features.

Furthermore, a data storage system - also called a verification system must be established. The system shall include prescription medicines and selected non-prescription medicines.

In order for Denmark to meet the EU directive, the IT construction and implementation of this new verification system have started.

In accordance with the requirements of the EU legislation, The Danish Medicines Verification Organisation (DMVO) has the responsibility for establishment, administration and running of the verification system.

The directive prescribes 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 a contract with DMVO, just as the company shall upload the required information to a European database. Further information, including the conditions for how you upload data to the European database are available on: https://www.emvo-medicines.eu.

Contract formation and uploading of data is a prerequisite if your company still would like to offer the medicinal products in question on the Danish market after February 8, 2019.

The Danish Medicines Agency finds like DMVO that for the sake of the security of supply it is extremely important that companies providing medicinal products to the Danish market are aware

of the new rules and as soon as possible contact DMVO and prepare the production that the packaging of the medicines shall contain safety features as of February 9, 2019.

With a view to the future collaboration between DMVO and your company, we shall kindly ask you to contact DMVO no later than June 26, 2017 in order to inform us who we can contact for the purpose of having a dialogue on contract formation.

As soon as we have received your contact information, we will contact the person in question, and further information will be forwarded.

We would like contact information (name, title, e-mail address and telephone number) to be forwarded to info@dmvo.dk.

Furthermore, we refer to the Danish Medicines Agency's web site http://laegemiddelstyrelsen.dk and DMVO's web site http://www.dmvo.dk for further information.

Should this letter give rise to further questions, please do not hesitate to contact DMVO at telephone number: 3915 0951 or e-mail: info@dmvo.dk.

Yours sincerely

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