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Koopia: Clinigen Regulatory Affairs <regulatory@clinigengroup.com>
Teema: Medicinal Products Act / Import authorisation query (unlicensed medicines)

Tähelepanu! Tegemist on väljastpoolt asutust saabunud kirjaga. Tundmatu saatja korral palume linke ja faile mitte avada.
Dear State Agency of Medicine,
I am contacting you as a Senior Regulatory Affairs Associate at Clinigen with an enquiry in relation to the import of medicinal products in to Estonia according to the Medicinal Products Act.

We understand that in order to import an unlicensed drug in to Estonia:
* An import permit is required where the product does not have a marketing authorisation in any of the EEA member states
* An import permit is not required where the product has a marketing authorisation in an EEA member state (instead the medicines agency should be notified no later than 5 working days after the import)

Please can you kindly clarify if an import permit is required when importing an unlicensed drug into Estonia, where the product is authorised in the UK (and supplied in UK commercial packaging):
1. In the case that there is a marketing authorisation for the same active substance/pharmaceutical form in an EEA member state
2. If there is not a marketing authorisation for the same active substance/pharmaceutical form in an EEA member state
The UK are no longer part of the EEA however our understanding is that wholesalers in Estonia may refer to EMAs Article 57 database () to determine if an import permit is required, and this database still includes products with a marketing authorisation in the UK.

Thank you in advance.Kind regards,Jenna

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The information you need, directly to you: