

Saatja: Jenna Bruce <jenna.bruce@clinigengroup.com>
Saadetud: 24.01.2024 16:18
Adressaat: Ravimiamet <info@ravimiamet.ee>; Eriluba
<eriluba@ravimiamet.ee>
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

Jenna Bruce Regulatory Affairs Associate

t: +358 1932 824000

m: +358 7880 201227

e: jenna.bruce@clinigengroup.com

The information you need, directly to you:

This email (and any attachments) is intended solely for the addressee. It is confidential and may be subject to copyright. It may contain legally privileged or proprietary information. If you are not the intended addressee, immediately notify the sender, permanently delete it and do not read, use, copy, store, disclose or rely on the information contained in this email (or any attachment). Emails sent to and from Clinigen Limited and/or its subsidiaries (Clinigen) may be monitored and read for legitimate business purposes, including compliance with the law and our regulatory obligations. Emails and their attachments cannot be guaranteed to be secure or error-free: you should protect your systems. Clinigen cannot accept responsibility for any loss or damage sustained as a result of computer viruses and the recipient must ensure that the email (and attachments) are virus free. Clinigen does not accept any liability arising from delay, interception, corruption, loss or destruction of this email (including any attachment), or received incomplete or with viruses. Your privacy is important to us. Please see our [privacy policy](#) for further details. Clinigen Limited is a private limited company (registered in England and Wales with registered number 06771928) whose registered office is at Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW. Clinigen Limited's subsidiary trading companies registered in England and Wales can be found [here](#).