

Dear Sir or Madam,

Your organisation has been identified as a Marketing Authorisation or Parallel Import Licence Holder with authority to market a medicine and make it available to patients and healthcare professionals in the UK. The Falsified Medicines Directive (2011/62/EU) and associated Delegated Regulation ([EU 2016/161](#)) has applied in the UK since 09 February 2019.

SecurMed UK is the non-profit legal entity established in the UK to set up and manage the UK repository system as required by the Falsified Medicines Directive and Delegated Regulation in line with the European Medicines Verification Organisation Blueprint Model and under the supervision of the UK National Competent Authority.

Entities that market medicines in the UK with at least one valid and active Marketing Authorisation or Parallel Import Licence to which the Delegated Regulation applies (collectively termed MAHs) are required under the Regulation to bear the costs of establishing and managing the UK repository system.

In order to satisfy the obligations of the Delegated Regulation as set out above, MAHs are required to register with SecurMed UK and to pay the applicable fees. Without timely payment of fees, your medicines will not be able to be verified, or authenticated at the time of supply to patients in the UK and you may therefore be in breach of your legal obligations, including under the Delegated Regulation.

You should now:

- Download the [Registration Form](#) from the SecurMed UK website (www.securmed.org.uk).
- Complete a separate Form for each MAH active in the UK after 09 February 2019 and provide contact details of an authorised signatory .
- Send the completed Registration Form(s) by email to mah@securmed.org.uk
- Sign the [MAH-Agreement](#)

The MAH will then receive an invoice from SecurMed to pay within 30 days. There is a Micro Fee Waiver scheme available for companies that can prove to SecurMed that they match the criteria. For more information: www.securmed.org.uk/wp-content/uploads/2018/12/Micro-MAH-Fee-Waiver-explanation-v3.pdf PLEASE NOTE: fees are required to be paid by each MAH, so a company with multiple MAHs valid for the UK will be required to pay a Set-Up Fee and any other applicable fees for each MAH.

This letter relates only to payment obligations of MAHs to the UK repository system and is independent from any other obligations you may have under or related to the Falsified Medicines Directive and the Delegated Regulation.

For any enquiries, please contact mah@securmed.org.uk

Yours faithfully,



Jerome Bertin
General Manager
SecurMed UK