

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](#)) shall apply in the UK on, and after, 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. This will initially be by way of payment of a Set-Up Fee per MAH as detailed in Table 1. There is also an annual fee to be paid by 09 February 2019.

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. It is therefore crucially important that you take prompt action in response to this letter.

Table 1 – SecurMed UK MAH Set-Up Fee model

Date of Receipt of MAH Setup Fee by SecurMed (dates inclusive)	Percentage (%) Discount on MAH Setup Fee	Set-Up Fee Payable	Discount on Annual MAH Operational Fees
01-Apr-2018 to 31-May-2018	52%	GBP £17,000	20% for first 2 years
01-Jun-2018 to 30-Sep-2018	38%	GBP £22,000	10% for first 2 years
01-Oct-2018 to 30-Nov-2018	23%	GBP £27,000	N/A
01-Dec-2018 to 31-Dec-2018	15%	GBP £30,000	N/A
01-Jan-2019 to 08-Feb-2019	6%	GBP £33,000	N/A
09-Feb-2019 or thereafter	N/A	GBP £35,000	N/A

You should now:

- Download the [Registration Form](#) from the SecurMed UK website (www.securmed.org.uk).
- Complete a separate Form for each MAH which will be active in the UK on 09 February 2019 and indicate your preferred payment schedule for each, and provide contact details of an authorised signatory .
- Send the completed Registration Form(s) by email to mah@securmed.org.uk

Following receipt of your Registration Form(s), SecurMed UK will require the MAH to:

Sign an Agreement and return the signed Agreement by email as soon as possible.

The MAH will then receive an invoice from SecurMed to pay by your preferred payment deadline.

To avoid MAH(s) paying increased fees do not miss the deadline corresponding to your preferred payment schedule. All MAHs that miss their payment deadline will automatically be transferred to the following payment deadline. A supplementary invoice will be issued for the increase in fee resulting from any delayed payments.

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.

The Delegated Regulation will apply from 09 February 2019 and as detailed in the [attached letter] the UK Government has confirmed its intention to implement EU obligations including laws made to implement the Falsified Medicines Directive and has confirmed that the duties under the Delegated Regulation will continue to apply in the UK unless specifically revoked.

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

Yours faithfully,

Jerome Bertin
General Manager

SecurMed UK