SecurMed
The UK Medicines Verification Organisation

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. Early and prompt payment will reduce the Set-Up Fee by up to 52%, and also attract additional discount from future Annual Operational Fees for the first 2 years from 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 by no later than 30 April 2018.

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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, and no later than 18 May 2018, if maximum discount is to be achieved.

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

Department of Health

From the Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health (Lords)

Department of Health
39 Victoria Street
London
SW1H 0EU

Tel: 020 7210 4850

Warwick Smith
Chair, SecurMed UK

09 APR 2018

Email: Warwick.Smith@instinctif.com

Dear Warwick,

It was very helpful to meet before Easter and to hear first-hand the challenges faced by SecurMed and its Directors in building the UK's system to deliver the Falsified Medicines Directive (FMD). I wanted to thank you again for your ongoing commitment to finding a solution and take this opportunity to provide you with some further reassurance about the Government's ambition to continue to collaborate with the EU in this area in the interest of public health and safety following our exit from the EU.

Our position on medicines regulation remains clear - we want to retain a close working partnership with the EU to ensure patients continue to have timely access to safe medicines and medical innovations.

The Prime Minister reiterated in her Mansion House speech on 2 March that the UK wants the broadest and deepest possible future partnership with the EU – covering more sectors and co-operating more fully than any Free Trade Agreement anywhere in the world today. In particular, the Prime Minister was also clear that this involves us wanting to make sure our regulators continue to work together; as they do with regulators internationally, highlighting that this would be essential in continuing to get new drugs to patients quickly. On goods, including medicines, a fundamental principle is that the UK-EU border is as frictionless as possible and products would only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including

the European Medicines Agency and the wider EU medicines regulatory framework. Whatever the outcome of those negotiations, our overall aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines, and be assured that their safety is protected through ongoing cooperation and the strongest regulatory framework.

We have also sought to agree a time-limited implementation period that gives further certainty to people and businesses. As I know you are aware, the UK and EU negotiating teams reached an agreement on the terms of the implementation period that will start on 30 March and lasts until 31 December 2020. The agreement that has been reached on the implementation period, endorsed by the March European Council, provides a clear political statement of intent from both sides. The implementation period will protect economic and regulatory cooperation, ensuring there is no sudden change as the UK builds our future partnership with the EU.

It is in everyone's interests to secure a good deal for both sides and we believe that this is the most likely outcome. We are increasingly confident that we will secure a deal with the EU and that the prospect of leaving negotiations with 'no deal' has reduced significantly. However, even if we do not achieve our desired future relationship with the EU, the European Union (Withdrawal) Bill will ensure that, as far as possible, the same rules and laws will apply in the UK after exit as the day before. The Bill will convert existing direct EU law, such as EU regulations, into UK law as it applies in the UK at the date of exit. It will also preserve the laws we have made in the UK to implement our EU obligations, such as laws made to implement the FMD. This means that the duties of the regulations under the FMD would continue to apply, unless specifically revoked.

We remain committed to continuing to work closely with SecurMed and I hope that this provides you with the necessary clarity to continue your preparations to implement the FMD in full from February 2019.

Thank you for all your work on this.

JAMES O'SHAUGHNESSY