



**(1) SECURMED UK**

**(2)**

**MAH AGREEMENT**

SecurMed UK Confidential

THIS AGREEMENT DATED

BETWEEN

(1) **SECURMED UK**, the United Kingdom Medicines Verification Organisation, a non-profit company, with its business address at PO Box 528, Twickenham, TW1 9PT, United Kingdom, and registered in the United Kingdom, registered number **10276927**, ("**SecurMed UK**"); and

(2)

whose registered office is at

(the "Company").

Both SecurMed UK and the Company are hereinafter also individually referred to as a "Party" and collectively as the "Parties".

WHEREAS

- (A) SecurMed UK is the non-profit organisation set-up by stakeholders in the medicines supply chain in the United Kingdom pursuant to Article 31 of the Delegated Regulation (terms as defined below), to establish and manage the National Medicines Verification System in the United Kingdom.
- (B) The UK Medicines Verification System (UK MVS) is to form part of the European Medicines Verification System (EMVS) and must be implemented in accordance with the Directive and the Delegated Regulation.
- (C) Pursuant to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the UK MVS shall be borne by MAHs.
- (D) This Agreement sets out the terms and conditions on which the Fees shall be paid by the Company to SecurMed UK and the Parties' related obligations.

IT IS AGREED AS FOLLOWS

## 1 DEFINITIONS AND INTERPRETATION

1.1 In this Agreement unless expressly stated to the contrary, the following expressions shall have the following meanings:

**Affiliate** means, in relation to a party, any group undertaking (as defined in section 1161 of the Companies Act 2006) of that party, in each case from time to time;

**Agreement** means this agreement and its appendix;

**Annual Operational Fee** means the annual fee payable by the Company to SecurMed UK, further details of which are set out at 2.4.1;

**Data** means information uploaded, processed, transferred, generated or stored in the EMVS or the UK MVS as set out in the Directive and the Delegated Regulation (in particular its Article 33(2));

**Delegated Regulation** means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council which lays down detailed rules for the safety features appearing on the packaging of medicinal products for human use;

**Directive** means the Directive on Falsified Medicines 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, as well as, the relevant implementing laws of England and Wales, as applicable;

**EMA** means the European Medicines Agency, a decentralized agency of the European Union (EU), with responsibility for scientific evaluation, supervision, and safety monitoring of medicines in the European Union;

**EMVO** means the European Medicines Verification Organisation, which is the non-profit legal entity established to set up and manage the European Hub in accordance with the Directive and Delegated Regulation;

**EMVS** means the European Medicines Verification System, which is set up and managed in accordance with Chapter VII of the Delegated Regulation. The EMVS consists of the European Hub and the National Systems and allows wholesalers and persons authorised or entitled to supply Medicinal Products to the public to verify the authenticity of Medicinal Products in accordance with the provisions of the Directive and the Delegated Regulation;

**European Hub** means the component of the EMVS that serves as a central information and data router for the transmission of Data to and from and between the National Systems;

**Fees** means the Set-Up Fee, the Annual Operational Fee and any other fees which SecurMed UK may charge the Company from time to time;

**Funding Obligation** means the obligation under the Delegated Regulation on the MAHs to bear the costs of the UK MVS;

**Insolvency Event** means any corporate action, application, order, proceeding or appointment or other step taken or made by or in respect of SecurMed UK for any composition or arrangement with creditors generally, winding-up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, or if SecurMed UK is unable to pay its debts as they fall due, or if a distress, execution or other legal process is levied against any of its assets;

**IT Service Provider** means the provider(s) of IT services SecurMed UK engages in relation to the development, implementation and operation of the UK MVS;

**MAH** means an entity holding one or more authorisations to market a Medicinal Product with effect in the territory of the United Kingdom on or after 9 February 2019. Authorisations include the following categories:

- A marketing authorisation issued under the EMA Centralised Procedure giving the MAH the authorisation to market a medicinal product in all EU member states with no

additional local marketing authorisation being required from the national competent authority.

- A marketing authorisation issued by the MHRA under the EMA De-Centralised Procedure or EMA Mutual Recognition Procedure.
- A marketing authorisation specific to the UK issued by MHRA.
- A Parallel Importation License specific to the UK issued by MHRA.
- A Parallel Importation Notification Letter issued by EMA;

**Medicinal Products** means those medicinal products which are required by the Delegated Regulation to bear safety features on their packaging;

**MHRA** means the Medicinal Healthcare products Regulatory Agency which regulates medicines, medical devices and blood components for transfusion in the UK;

**National Medicines Verification System** or **National System** means a national medicines verification system that is connected to the European Hub and allows wholesalers and persons authorised or entitled to supply Medicinal Products to the public to verify the authenticity of Medicinal Products in accordance with the provisions of the Directive and the Delegated Regulation;

**Set-Up Fee** means the fee set in accordance with clause 2.3 and the Appendix; and

**UK MVS** means the UK National Medicines Verification System implemented by SecurMed UK.

- 1.2 References to statutes or statutory provisions shall be construed to include references to those statutes or statutory provisions as amended or re-enacted from time to time and shall include any orders, regulations, instruments or other subordinate legislation under them.
- 1.3 The headings in this Agreement are for ease of reference only and shall not in any way affect its construction or interpretation.
- 1.4 Reference to a party to this Agreement shall include its personal representatives, successors in title and permitted assigns.
- 1.5 The terms of this Agreement shall apply to the exclusion of any terms and conditions of the Company.
- 1.6 Unless expressly stated to the contrary in this Agreement:
  - 1.6.1 words denoting the singular include the plural and vice versa, words denoting any one gender include all genders and vice versa, and references to persons include individuals, partnerships, bodies corporate and unincorporated associations;
  - 1.6.2 the words and phrases “other”, “including” and “in particular” shall not limit the generality of any preceding words or be construed as being limited to the same class as the preceding words where a wider construction is possible.
  - 1.6.3 Any capitalised terms not defined in this Agreement are given the meaning allocated to them in the Directive and/or the Delegated Regulation.

## 2 PAYMENT OF FEES

- 2.1 The Company shall pay to SecurMed UK:
  - 2.1.1 the Set-Up Fee;
  - 2.1.2 the Annual Operational Fee; and

- 2.1.3 such other fees as SecurMed UK may require from time to time.
- 2.2 The Company acknowledges the benefit to it that may be derived from the development, implementation, operation or maintenance of the UK MVS.

### 2.3 **The Set-Up Fee**

2.3.1 When registering with SecurMed UK as a MAH, the Company can select a date by which to pay the Set-Up Fee (the Relevant Date). The Company will receive from SecurMed UK an invoice with the Relevant Date upon it. SecurMed UK must receive the relevant Set-Up Fee in cleared funds from the Company by the Relevant Date. If the Set-Up Fee has been invoiced but is not received by SecurMed UK by the Relevant Date, then without prejudice to any other rights and remedies, SecurMed UK will issue an additional invoice for, and the Company shall pay, the difference between the amount originally invoiced and the Set-Up Fee that would be payable in the next period listed in the Appendix (and SecurMed UK may continue issuing additional invoices in this way until payment is received).

### 2.4 **Additional Fees**

2.4.1 The Annual Operational Fee is yet to be determined but:

- (a) is expected to be in the region of GBP £20-25,000 in 2019; and
- (b) is expected to be invoiced in January each year for payment by 9 February of the relevant year.

The Company acknowledges that this sum and payment schedule is an estimate and may change once the budget for 2019 and the number of MAHs to be invoiced in 2019 are confirmed.

2.4.2 As set out in the Table in the Appendix, the Company will benefit from a percentage discount from the Annual Operational Fee where it pays the Set-Up Fee prior to 30 September 2018.

2.4.3 SecurMed UK has the right to vary the amount of, or charge additional, Fees where required in order to satisfy the Funding Obligation, including instances where SecurMed UK's IT Service Provider or EMVO increases its fees or charges to SecurMed UK or if the costs or anticipated costs related to the development, testing, implementation, operation, maintenance or update of the UK MVS increase for any other reason consistent with its status as a non-profit company.

2.4.4 SecurMed UK shall notify the Company in writing of any variation to, or additional, Fees at least thirty (30) days in advance of charging such varied or additional Fees.

## 3 **PAYMENT TERMS**

3.1 Unless otherwise specified pursuant to this Agreement (for example in relation to the Set-Up Fee or any dates for payment of the Annual Operational Fee) the Company shall pay to SecurMed UK the Fees within thirty (30) days from the date of the invoice.

3.2 All payments under or in connection to this Agreement will be made in Sterling and all Fees expressed herein are exclusive of Value Added Tax (VAT). The Company shall be responsible for the payment of any withholding taxes, similar taxes, duties levies and such payments relating to the Fees payable under this Agreement.

3.3 For the avoidance of doubt, Fees paid to SecurMed UK are non-refundable. To the extent that any amounts received by SecurMed UK exceed the current requirements of the UK MVS, they

will be put towards future costs of the UK MVS and in this way may reduce future Fees payable by the Company.

- 3.4 The Company may request in writing that an Affiliate is invoiced and pays the Fees on the Company's behalf. SecurMed may at its discretion agree to this (particularly in circumstances where an Affiliate owns or controls or carries out payment functions on behalf of the Company). In such circumstances the Company will remain liable under this Agreement for the payment (or non-payment) of such Fees.

#### **4 CONSEQUENCES OF NON-PAYMENT**

- 4.1 Any sums payable by the Company hereunder which remain outstanding after the date for payment shall carry interest which shall accrue in accordance with Late Payment of Commercial Debts (Interest) Act 1998.
- 4.2 In addition to any other rights and remedies available to SecurMed UK, if the Company fails to pay an invoice in accordance with this Agreement, SecurMed UK reserves the right to:
- 4.2.1 notify the MHRA of the Company's breach of the Funding Obligation;
  - 4.2.2 prevent or suspend the upload of the Company's Data to the UK MVS; and/or
  - 4.2.3 request EMVO to prevent or suspend the upload of the Company's Data to the European Hub.

#### **5 ADDITIONAL OBLIGATIONS NOT COVERED BY THIS AGREEMENT**

- 5.1 The Parties acknowledge and agree that this Agreement relates only to the Funding Obligation and is independent from any other obligations under or related to the Directive and the Delegated Regulation.
- 5.2 The Company acknowledges that there will be additional agreements that the Company may be required to sign up to in order to use the UK MVS or EMVS, such as a relevant end user agreement covering detailed terms of access.

#### **6 CONFIDENTIALITY**

- 6.1 Neither party shall without the prior written consent of the other party (during and after termination of this Agreement) use (other than in the performance of the Agreement) or disclose to any other person any confidential information of the other party, save that this shall not prevent any disclosure of confidential information which is required by law, court order or any legal or regulatory authority or disclosures to a party's professional advisors.
- 6.2 Upon termination of this Agreement, the receiving Party shall return to the disclosing Party the confidential information received from it or, upon the disclosing Party's request, certify destruction of the same. The receiving Party shall, however, be entitled to retain such material as is required by applicable law.

#### **7 LIMITATION OF LIABILITY**

- 7.1 Notwithstanding any other provision of this Agreement, but subject to clause 7.4 the total liability of SecurMed UK arising out of or in connection with this Agreement, and/or the UK

MVS in aggregate in respect of all claims, however arising, shall in no circumstances exceed a sum equal to the Fees paid by the Company.

- 7.2 Notwithstanding any other provision of this Agreement, but subject to clause 7.4 SecurMed UK shall have no liability however arising out of or in connection with this Agreement and/or the UK MVS for any direct or indirect loss of or damage to profit, revenue, business or goodwill.
- 7.3 The term “however arising” when used or referred to in this clause 7 covers all causes and actions giving rise to the liability of SecurMed UK arising out of or in connection with this Agreement and/or the UK MVS Services whether arising by reason of any misrepresentation (whether made prior to and/or in the Agreement) negligence, breach of statutory duty, other tort, repudiation, renunciation or other breach of contract, restitution or otherwise.
- 7.4 The limitation of liability will not apply to the extent prohibited or limited by law and in particular nothing in this Agreement shall affect liability:
- 7.4.1 for death or personal injury caused by negligence to the extent prohibited by law; or
- 7.4.2 for fraudulent misrepresentation or other fraud.

## **8 TERM AND TERMINATION**

- 8.1 This Agreement shall be binding from the date set out above and shall continue unless terminated in accordance with its terms.
- 8.2 SecurMed UK shall be entitled to terminate this Agreement by notice in writing at any time without any liability to the Company:
- 8.2.1 by giving at least sixty (60) days’ notice to the Company;
- 8.2.2 if the agreement between EMVO and SecurMed UK for the use of the European Hub is terminated for any reason; or
- 8.2.3 upon occurrence of an Insolvency Event.
- 8.3 This Agreement may only be terminated by the Company when the Company no longer acts as a MAH.
- 8.4 Notwithstanding the termination of the Agreement, the Company shall remain liable for any Fees that are due to SecurMed UK and unpaid at the date of termination of the Agreement, or as otherwise required to discharge the Funding Obligation relating to a period when the Company was a MAH.
- 8.5 Clauses 3, 4, 5, 6, 7, 8 and 9 will survive the termination of this Agreement.

## **9 GENERAL**

- 9.1 Other than in relation to the amount of the Fees as set out in clause 2, amendments and modifications to this Agreement are valid only if they are made in writing and signed by the duly authorised representatives of both Parties.
- 9.2 The Company may not assign or novate this Agreement, in whole or in part, without SecurMed UK’s prior written consent. SecurMed UK may assign or novate this Agreement to a successor organisation, in whole or in part, without the Company’s consent at any time upon notice to the Company.
- 9.3 Any failure to exercise or delay by a party in exercising a right or remedy arising in connection herewith or by law shall not constitute a waiver of such right or remedy or of any other rights or remedies.
- 9.4 Save as expressly provided herein, the rights and remedies provided by these terms are cumulative and (subject as otherwise provided in these terms) are not exclusive of any right

or remedy provided by law. No exercise by a party of any one right or remedy shall (save unless expressly provided otherwise) operate so as to hinder or prevent the exercise by it of any other right or remedy.

- 9.5 This Agreement constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes and replaces any prior proposals, negotiations, agreements and other written or oral communications between the Parties relating to the subject matter of this Agreement.
- 9.6 This Agreement may be executed in any number of counterparts, each of which when executed by one or more of the parties hereto shall constitute an original but all of which, when dated with the same date, shall constitute one and the same agreement.
- 9.7 Any notice to be given shall be in writing (but excluding fax transmission) and may be served by leaving it at, or by sending it by pre-paid first class post, electronic mail or recorded delivery to, the intended recipient's address. The address of a party for service of notices is the address set out in this Agreement or such other address as a party may designate by notice given in accordance with this clause. A notice is deemed to be received when left at the recipient's address or, if sent by pre-paid first class post or recorded delivery, 48 hours from the date of posting, or if sent by electronic mail at the time of sending. If such deemed receipt is not within business hours (being between 9.00 am and 5.00 pm Monday to Friday on a day that is not a public holiday in the place of receipt), the notice is deemed to be received when business hours next commence.
- 9.8 The construction, validity and performance of this Agreement and all non-contractual obligations arising from or connected with this Agreement shall be governed by, and construed in accordance with, the Laws of England and Wales and, subject to the remainder of this clause, any dispute arising out of this Agreement shall be subject to the exclusive jurisdiction of the courts of England to which both Parties hereby agree to submit for these purposes

## Signatures

**For SecurMed UK:**

*Signature:*

\_\_\_\_\_

*Name:*

**Jerome Bertin**

*Title:*

**General Manager**

*Date:*

\_\_\_\_\_

**For the Company:**

*Signature:*

\_\_\_\_\_

*Name:*

*Title:*

*Date:*

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## APPENDIX

### TABLE OF SET-UP FEES

Date of receipt of Set-Up Fee by SecurMed UK (dates inclusive)	Percentage (%) Discount on Set-Up Fee	Set-Up Fee payable MAH	Discount on Annual Operational Fees
1 <sup>st</sup> Apr 2018 to 31 <sup>st</sup> May 2018	52%	GBP £17,000	20% for first 2 years
1 <sup>st</sup> Jun 2018 to 30 <sup>th</sup> Sep 2018	38%	GBP £22,000	10% for first 2 years
1 <sup>st</sup> Oct 2018 to 30 <sup>th</sup> Nov 2018	23%	GBP £27,000	N/A
1 <sup>st</sup> Dec 2018 to 31 <sup>st</sup> Dec 2018	15%	GBP £30,000	N/A
1 <sup>st</sup> Jan 2019 to 8 <sup>th</sup> Feb 2019	6%	GBP £33,000	N/A
9 <sup>th</sup> Feb 2019 and later	N/A	GBP £35,000	N/A