END USER LICENCE AGREEMENT

FOR THE USE OF THE UKNI MEDICINES VERIFICATION SYSTEM

1. APPLICATION OF END USER LICENCE AGREEMENT

1.1. This End User Licence Agreement (**EULA**) applies to the connection, access to and use (**Use** (and **Using** shall be construed accordingly)) of the Medicines Verification System of the United Kingdom or part of it, including the United Kingdom in respect of Northern Ireland ("UK MVS"). (**UKMVS**), which is operated by SecurMed UK (company number 10276927), a company limited by guarantee, whose registered address is at Milton Park Innovation Centre, 99 Park Drive, Milton Park, Abingdon, Oxfordshire OX14 4RY (**SecurMed UK**) and established in Northern Ireland at Arthur House, Arthur Street, Belfast, BT1 4GB.

1.2. This EULA applies to any Undertaking, other type of legal entity or sole trader wishing to Use the UK MVS (**End User**) and any Authorised Representative (where applicable).

1.3. References to a 'party' means a reference to either of SecurMed UK or the End User (as the context requires) and references to the 'parties' shall be construed accordingly.

1.4. In accepting this EULA, the End User acknowledges:

1.4.1. SecurMed UK licenses use of the UKMVS and other components of the EMVS to the End User on the terms and subject to the conditions of this EULA; and

1.4.2. SecurMed UK does not sell the UK MVS nor any component of the EMVS to the End User and SecurMed UK or its licensors remain the owners of the UKMVS and any component of the EMVS at all times.

1.5. The End User is invited to print a copy of this EULA for future reference.

2. ACCEPTANCE OF THIS EULA

2.1. Please read this EULA carefully before accessing or using the UK MVS in any manner. By Using the UK MVS, clicking 'I Accept' or by continuing to Use the UK MVS, the End User hereby confirms that this EULA constitutes a legally binding agreement between the End User and SecurMed UK that governs the End User's Use of the UK MVS.

2.2. If the End User operates through one (or more) Undertaking, each such Undertaking must separately agree to this EULA and in doing so shall separately be bound to the terms of the EULA.

2.3. It you, as an Authorised Representative, are accepting this EULA on behalf of any End User that is an Undertaking, any other type of legal entity or sole trader, you hereby warrant, represent and undertake that you are entitled to bind such End User. SecurMed UK reserves the right to require you or the End User to provide evidence of such authorisation from time to time.

2.4. If the End User does not accept or agree to be bound by this EULA, or has not authorised an Authorised Representative to accept this EULA on its behalf, the End User is not authorised to Use the UK MVS.

3. PURPOSE OF THIS EULA

3.1. The purpose of this EULA is to define the rights of SecurMed UK and the rights and obligations of the End User with respect to the Use of the UK MVS by the End User in order to verify the authenticity of, and to decommission, the unique identifier of medicinal products

in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation (**Purpose**).

4. GRANT OF RIGHTS TO THE END USER

4.1. Subject to the End User's agreement to and continued compliance with this EULA, SecurMed UK grants to the End User a limited, revocable, non-exclusive, non-transferable, personal license right to Use the UK MVS, solely for the Purpose.

4.2. The rights granted to the End User pursuant to this EULA are limited to those expressly granted herein. SecurMed UK (and its respective licensors) reserves all other rights.

5. LICENCE RESTRICTIONS

5.1. Except as expressly provided in this EULA or as necessary for the Purpose, the End User may not and warrants, represents and undertakes that it shall not:

5.1.1. use, copy, maintain, distribute, sell, publish, display, sublicense, rent, make corrections to, or modify the UK MVS nor any component thereof;

5.1.2. modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer, or otherwise translate the UK MVS or any component thereof, unless to the extent the foregoing restrictions are expressly prohibited by applicable law;

5.1.3. use or sublicense use of the UK MVS or any component thereof:

5.1.3.1. to or for the benefit of a third party; and/or

5.1.3.2. for any purpose other than the Purpose; or

5.1.4. store, access or transmit information or data on the UK MVS or any other component of the EMVS that:

5.1.4.1. is inaccurate;

5.1.4.2. has not been legally obtained;

5.1.4.3. is in violation of or which could give rise to claims in respect of any other applicable Intellectual Property Right; or

5.1.4.4. is in violation of the EU Falsified Medicines Directive or Delegated Regulation.

5.2. Without prejudice to any other right that SecurMed UK may have, if at any time SecurMed UK considers (acting reasonably) that the Use of the UK MVS by the End User:

5.2.1. endangers or potentially could endanger the security or functioning of the UK MVS or the EMVS (in whole or in part), SecurMed UK is entitled immediately and without prior notice to disconnect the End User from the UK MVS. SecurMed UK shall notify the End User about such measure and the reasons thereof as soon as reasonably practicable following any such disconnection. Any reconnection of the End User to the UKNI MVS shall be at SecurMed UK's discretion and only once SecurMed UK is satisfied that there is no longer any danger to the security or functioning of the UK MVS or part of the EMVS; and

5.2.2. is in breach of this EULA, SecurMed UK is entitled immediately to disconnect the End User from (or restrict the End User's access to) the UK MVS (and may then exercise its further rights in accordance with this EULA), provided that, if such breach is capable of cure, the End User fails to cure the breach within thirty (30) calendar days (or such shorter period as may be notified by SecurMed UK, acting reasonably) following the notification of the breach to the End User by SecurMed UK.

5.3. If, at any time, the End User has reasonable and objective grounds to consider that the (further) connection, access to or use of the UK MVS immediately and substantially endangers the security of the End User, the End User may disconnect from the UK MVS, it being agreed that the End User shall inform SecurMed UK about such measure and the reasons thereof at the End User's earliest convenience, and that the connection of the End User shall be re-established as soon as there is no longer any immediate and substantial danger to the security of the End User. This is without prejudice to the End User's unilateral decision to disconnect from the UK MVS at any time (this without prejudice to the End User's obligations under the EU Directive on Falsified Medicines and Delegated Regulation).

6. OBLIGATIONS OF THE END USER

6.1. The End User undertakes to Use the UK MVS solely for the Purpose and in accordance with this EULA and the EU Falsified Medicines Directive and the Delegated Regulation.

6.2. The End User represents, warrants and undertakes that:

6.2.1. the End User is responsible for and shall maintain the security of its system(s) and the confidentiality of its credentials and passwords to connect to the UK MVS, and is solely responsible for any activities carried out through its account within the UK MVS and on its system(s), including for the correctness and accuracy of any information or Data uploaded or generated by the End User on the UK MVS;

6.2.2. the End User's own system(s) and any connection or access by the End User to the UK MVS shall be protected by appropriate security measures, as necessary to protect against unauthorised access, interception, disruption or other Security Breach, including the security measures as notified by SecurMed UK to the End User from time to time; and

6.2.3. the End User shall notify SecurMed UK of any Security Breach as soon as it becomes aware of such Security Breach and shall take all necessary measures to mitigate such Security Breach, in so far as this is possible, and comply with any of SecurMed UK's reasonable requirements in connection with the same.

6.3. Notwithstanding any other provision of this EULA, the End User represents, warrants and undertakes that it shall not:

6.3.1. Use the UK MVS in any unlawful manner, for any unlawful purpose, or in any manner inconsistent with this EULA or the EU Falsified Directive Medicines and Delegated Regulation or act fraudulently or maliciously (for example (without limit), by hacking into or inserting malicious code, including viruses, or inaccurate, false or harmful data into the UKMVS);

6.3.2. infringe any Intellectual Property Rights in or relating to the UKMVS, or those of SecurMed UK or any third party in relation to the use of the UKMVS; or

6.3.3. Use the UK MVS in a way that could, or is reasonably likely to, damage, disable, overburden, impair or compromise the UK MVS or interfere with other Users.

6.4. (Bulk) verifications can only be performed by End Users in respect of products under their physical control. Decommissioning of unique identifiers by End Users can only be performed by or after verifying and scanning individual packs under their physical control and in hand.

6.5. The End User may authorise its End User Representatives to Use the UK MVS on behalf of the End User as necessary for the Purpose, subject to the following conditions:

6.5.1. The End User procures that End User Representative is informed of and is bound by and is required to observe and does comply with the terms of this EULA;

6.5.2. the End User remains fully responsible and liable for any act or omission of its End User Representative(s); and

6.5.3. without prejudice to other remedies, in the event that the End User Representative breaches the terms of this EULA (or causes the End User to be in breach of the terms of this EULA), SecurMed UK reserves the right to require (without any liability for SecurMed UK) the End User to suspend or withdraw the authorisation granted by the End User to the relevant End User Representative in accordance with this Section 6.4, and the End User shall comply with any such request.

7. OBLIGATIONS OF SECURMED UK

7.1. SecurMed UK shall take appropriate measures to ensure that the UK MVS shall be developed, implemented, tested and operated for the whole period of time set forth in Section 13 of this EULA in accordance with: (i) the EU Directive on Falsified Medicines and Delegated Regulation; and (ii) this EULA.

7.2. Without prejudice to the generality of the above, SecurMed UK undertakes in accordance with Article 36(1)(g) of the Delegated Regulation and without prejudice to Article 35(1)(h) thereof and Section 7.3.1 below, that it shall allow access by the verified Wholesalers to the list of Wholesalers referred to in Article 33(2)(h) of the Delegated Regulation for the purpose of determining whether they have to verify the unique identifier of a given medicinal product in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

7.3. Without prejudice to the generality of the above, SecurMed UK shall:

7.3.1. use all reasonable efforts to set up the UK MVS in a diligent manner and shall take appropriate measures so that the UK MVS and Data on the UK MVS are protected by appropriate security measures, including against unauthorised access, interception or disruption;

7.3.2. appoint a key contact point for the performance of this EULA; and

7.3.3. provide reasonable support to the End User and provide it with access to all relevant material and documentation in order to allow the End User to connect to the UK MVS for the Purpose.

8. INTERNAL AUDIT BY SECURMED UK

SecurMed UK shall carry out regular audits, by appropriate means, of its own compliance with its own requirements under the Delegated Regulation (in particular all technical and organisational security aspects relating to the set-up and the operation of the UK MVS), as required under the Falsified Medicines Directive, Delegated Regulation and this EULA.

9. INTELLECTUAL PROPERTY RIGHTS

The End User acknowledges and agrees that all rights, title and interest in and to, and all underlying Intellectual Property Rights in the UK MVS, including (without limit) any application programming interfaces and graphical user interfaces or any other component of the EMVS anywhere in the world, belong to SecurMed UK and EMVO respectively (or their licensors), and are licensed (not sold) to the End User. The End User has no rights in, or to, any component of the UKMVS or any component of the EMVS, other than the right to use them for the Purpose in accordance with this EULA.

10. DATA PROTECTION AND OWNERSHIP

10.1. In accordance with Article 35(1)(h) of the Delegated Regulation, the structure of the UK MVS shall be such as to guarantee the protection of Personal Data and information of a commercially confidential nature and the ownership and confidentiality of the data generated when the End User interacts with it, in accordance with Article 38 of the Delegated Regulation, as described below.

10.2. As a principle, the Data contained in the EMVS belongs to the User who generates the relevant Data when interacting with the EMVS ('whoever creates the Data, owns the Data'). The EMVS repositories system shall hold the following data components:

10.2.1. static data (i.e. the information listed under Article 33(2) of the Delegated Regulation); and

10.2.2. dynamic data, being:

10.2.2.1. the status of the unique identifier, i.e. 'active' or 'de-commissioned'. In case of 'de-commissioned' unique identifier, dynamic data also includes the detail, e.g. dispensed, recalled, stolen, etc; and

10.2.2.2. changes to the complete record (**Audit Trail**) as referred to in Article 35(1)(g) of the Delegated Regulation, which contains a record of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations.

10.3. As per the principle outlined above, dynamic data and static data contained in the EMVS belong to the operator who generates the Data when interacting with the system. This information must not be accessible for any other party, with exception of the static data and the information on the status of a unique identifier for the sole purpose of verification (Article 38(1) of the Delegated Regulation) and without prejudice to the right of access by national competent authorities as provided for under Article 39 of the Delegated Regulation.

10.4. Data generated by an End User's own IT system (e.g. sales or transactional data, stock movements, pricing information, etc.) by electronic or manual means, or captured with the same, is exclusively owned and may be freely used without any restriction whatsoever by the End User. For the avoidance of doubt, this means that Pharmacists own the data generated by their own IT system, that Wholesalers own the data generated by their own IT system, and that manufacturers and/or marketing authorisation holders own the data generated by their own IT system.

10.5. Without any restriction whatsoever to the use of the data generated by an End User's own IT system as mentioned above, access to and/or use of any Data (static or dynamic) extracted from, copied from or downloaded from the EMVS for purposes outside of the scope of the Falsified Medicines Directive and Delegated Regulation needs to be agreed by all the stakeholders owning that Data on a case-by-case basis in compliance with relevant legislation.

10.6. In accordance with Article 35(1)(g) of the Delegated Regulation, the UKNI MVS shall maintain an Audit Trail of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations. SecurMed UK shall not access the Audit Trail stored on the UKNI MVS and the Data contained therein without the written agreement of the legitimate data owners (determined in accordance with Sections 10.1 to 10.5 above), except for the purpose of:

10.6.1. investigating potential incidents of falsification flagged in the EMVS in accordance with Article 36(b), Article 37(d) and Article 38(2) of the Delegated Regulation;

10.6.2. discharging the obligations imposed on SecurMed UK by Articles 37(c) – (e) of the Delegated Regulation;

10.6.3. granting access to the national competent authorities in accordance with Article 39 of the Delegated Regulation; or

10.6.4. for the purpose of maintenance, repair, work or other alterations to the UKNI MVS as evidentially and essentially necessary for its operation.

The access to and use of the data contained in the Audit Trail shall be strictly limited to these purposes it being noted that the SecurMed UK representative that will conduct the operation of accessing the Audit Trail will be restricted on a need-to-know basis as necessary for the above purposes and that SecurMed UK shall ensure that the SecurMed UK representative is made aware of and agrees in writing to be bound by substantially equivalent limitations and obligations as imposed on SecurMed UK under this EULA to the fullest extent permitted by applicable law.

10.7. SecurMed UK shall only grant access to the UKNI MVS and the Data contained therein to competent authorities for its territory for the purposes set forth under Article 39 of the Delegated Regulation and in so far as they concern SecurMed UK's own territory (which may cover multiple countries in the case of a supranational repository), unless otherwise required under the EU Directive on Falsified Medicines and Delegated Regulation, or under relevant legislation applicable to SecurMed UK.

10.8. In the instances of competent authority access referred to under Section 10.7, except where Data are accessed for purposes of supervision and investigation (Article 39 of the Delegated Regulation) or would otherwise compromise the supervision of the repositories system as required by Article 44 of the Delegated Regulation, or where explicitly prohibited by law or not foreseen under applicable legislation, the owner of the Data contained in the UK MVS may request to be informed about access to its Data by competent authorities. SecurMed UK should confirm with the competent authorities that such information may be provided. The modalities for the provision of this information – including the delay for the provision of the information - are to be defined by SecurMed UK at its discretion in line with any guidance provided by the competent authorities, i.e. the respective reporting capabilities, their development, use and the associated cost allocations are to be decided at national level.

11. CONFIDENTIALITY

11.1. SecurMed UK and the End User, each with respect to Confidential Information received from the other party, undertakes to:

11.1.1. take all necessary precautions to prevent the other party's Confidential Information in its possession, custody or control from being copied, stolen or otherwise misappropriated;

11.1.2. keep the other party's Confidential Information secret and confidential, and without limiting the foregoing, not disclose such Confidential Information to any person, except as expressly otherwise permitted by this EULA or the Falsified Medicines Directive and Delegated Regulation;

11.1.3. exercise the same degree of care and protection with respect to the other party's Confidential Information that it exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with best care;

11.1.4. only use the other party's Confidential Information for the Purpose or as otherwise provided under the Falsified Medicines Directive and Delegated Regulation, at the exclusion of any other purpose; and

11.1.5. take all necessary precautions in order to prevent any unauthorised misuse, disclosure, theft or other loss of the Confidential Information, and to notify immediately the other party upon becoming aware of the same and take all necessary measures

in order to reduce the effects of such unauthorised misuse, disclosure, theft or other loss.

11.2. The restrictions on use or disclosure of Confidential Information as defined above do not extend to information which:

11.2.1. is or comes into the public domain through no breach of this EULA;

11.2.2. will be lawfully received by the other party on a non-confidential basis after the Effective Date or has been lawfully received by SecurMed UK or the End User on a non-confidential basis prior to the Effective Date from a third party;

11.2.3. is independently developed by SecurMed UK or the End User;

11.2.4. is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, SecurMed UK or the End User, if permitted, gives the other party immediate notice thereof, and give the other party reasonable time under the specific circumstances, so that it may seek a protective order or other appropriate relief, or waive compliance with the non-disclosure provisions of this EULA. In such case, SecurMed UK or the End User shall cooperate with the other party, by all legal means, in order to limit the effects of the disclosure and to prevent the disclosure of any other Confidential Information; and

11.2.5. is to be disclosed as necessary for the Purpose.

11.3. SecurMed UK shall take appropriate measures in relation to the protection of the identity of the End Users, without prejudice to SecurMed UK's obligation to take appropriate measures to ensure that the UK MVS shall be used and operated for the duration that this EULA is in force for the Purpose, in accordance with: (i) the EU Directive on Falsified Medicines and the Delegated Regulation; and (ii) this EULA.

12. LIMITATION OF WARRANTY AND LIABILITY

12.1. **Disclaimer of warranty.** Except as expressly provided in this EULA, the UK MVS is provided "as is", and all warranties, conditions, terms and liabilities express or implied, statutory or otherwise, on the part of SecurMed UK, including (without limit) in respect of compliance with descriptions, quality or fitness for purpose are excluded except to the extent such exclusion is prohibited or limited by law. Specifically, without prejudice to SecurMed UK's obligations under the EU Falsified Medicines Directive and Delegated Regulation, SecurMed UK does not warrant that the UK MVS will be error and defect free (whether apparent or hidden/latent) or will perform in an uninterrupted manner.

12.1. **Exclusion of Indirect Damages.** Without prejudice to Section 12.1 above, neither party shall be liable for any claims, demands, costs, expenses, losses, liabilities and damages, howsoever arising or caused, that are indirect or consequential, including any loss of profits, loss of benefit, loss of turnover, loss of income, loss of savings, loss of contract, loss of use, loss of business or business interruption, loss of opportunity, loss of goodwill, loss of data, loss of clientele, third party's claim, or any other indirect, special, incidental or consequential damages of any kind (**Indirect Damages**) whether arising out of or in connection with a contractual breach, tort (including negligence and gross negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable, in connection with or arising out of Use of the UK MVS.

12.2. In addition, without prejudice to SecurMed UK's obligations under the EU Falsified Medicines Directive and Delegated Regulation, SecurMed UK shall not be liable to the End User for any damage or prejudice caused by third parties accessing, uploading or downloading Data in, to or from the European Hub (e.g. manufacturers or parallel distributors or other NMVOs and their End Users), including any direct or indirect consequences of inaccurate, incomplete

or corrupted data, or any malicious software, malware or other code transferred, uploaded or downloaded through the UK MVS by such third parties.

12.3. **Liability Cap.** Subject to Sections 12.4 and 12.5, SecurMed UK's maximum aggregate liability to the End User arising out of, or in connection with this EULA, for claims, demands, costs (including legal costs on a full indemnity basis) expenses, losses, liabilities and damages, howsoever arising or caused, whether arising out of or in connection with a contractual breach, tort (including negligence and gross negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable, shall in no event exceed £5,000. The End User's maximum aggregate liability arising out of, or in connection with this EULA, for damages, howsoever arising or caused, whether arising out of or in connection with a contractual breach, tort (including negligence and gross negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable, shall in no event exceed £5,000.

12.4. **Cumulative Liability Cap.** Subject to Section 12.5, SecurMed UK's maximum cumulative aggregate liability to all End Users, on a collective basis, arising out of or in connection with the UK MVS for claims, demands, costs (including legal costs on a full indemnity basis) expenses, losses, liabilities and damages, howsoever arising or caused, whether arising out of or in connection with a contractual breach, tort (including negligence and gross negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable shall in no event exceed £2,000,000 in aggregate for all claims.

12.5. **Exclusion.** Nothing in this EULA will exclude or limit the parties' liability:

12.5.1. for fraud or wilful misconduct;

12.5.2. for death or personal injury arising from the party's negligence or, in the case of the End User, that of the End User Representatives; and

12.5.3. any other liability which cannot be limited or excluded under applicable law.

12.6. **Losses suffered by other Users of the UK MVS.** The parties acknowledge and agree that any losses suffered by any other Users of the UK MVS in connection with this EULA arising in connection with any act or omission of the End User will be deemed to be actual losses suffered by SecurMed UK under this EULA, and SecurMed UK will be entitled to recover such losses directly against the End User in accordance with this Section 12.

13. TERM AND TERMINATION

13.1. This EULA shall come into force on the Effective Date and shall continue, unless earlier terminated in accordance with the terms of this EULA, for a period of 12 months (**Initial Term**). After the Initial Term, this EULA will continue unless and until terminated by either party: (i) giving the other at least ninety (90) days' notice in writing, such notice to expire no earlier than the end of the Initial Term; or (ii) in accordance with the other terms of this EULA. Notwithstanding this, this EULA shall automatically expire at the end of the EMVS Operational Phase.

13.2. Without prejudice to other remedies under applicable law, either party may terminate this EULA at any time on giving written notice to the other party if the other party:

13.2.1. commits an irremediable material breach of this EULA;

13.2.2. commits a material breach of this EULA which is capable of being remedied but has failed to remedy such breach within 30 days after having received written notice from the terminating party requiring the same; or

13.2.3. has any corporate action, application, order, proceeding or appointment or other step taken or made by or in respect of it for any composition or arrangement with creditors generally, winding-up other than for the purpose of a bona fide scheme of solvent reconstruction or amalgamation, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, or if it is unable to pay its debts as they fall due, or if it ceases to trade or if a distress, execution or other legal process is levied against any of its assets which is not discharged or paid out in full within three business days or if any event analogous to any of the foregoing shall occur in any jurisdiction in which the other party is incorporated, resident or carries on business.

13.3. Without prejudice to the above, SecurMed UK is entitled to terminate this EULA immediately without liability to the End User:

13.3.1. if the contract between EMVO and SecurMed UK for the use of the European Hub by SecurMed UK is terminated or expires for whatever reason;

13.3.2. if:

;

13.3.2.1. the relevant legislation ceases to apply in the United Kingdom (or any part thereof);

13.3.2.2. a regulatory body, EMVO or the European Commission (or any other analogous competent body) requires SecurMed UK to disconnect from the EMVS; or

13.3.2.3. SecurMed UK considers that it ceases to be possible to contract with the End User on the basis of the terms of this EULA as a result of any event analogous or similar to those set out in Sections 0 to 13.3.2.2;

13.3.3. if SecurMed UK suffers any of the events in Section 13.2.3 (or anything analogous to the same);

13.3.4. if the End User is no longer authorised or entitled to distribute medicinal products or supply medicinal products to the public ; and

13.3.5. pursuant to Section 15.2.

13.4. Upon termination or expiry of this EULA, each party shall return to the other party any Confidential Information of the other party in its possession, or at the other party's request shall destroy any such Confidential Information. A receiving party shall, however, be entitled to retain such Confidential Information as may be required by applicable law.

14. CHANGES AND UPDATES TO THE UK MVS

14.1. SecurMed UK may update, change and/or modify the UK MVS at any time.

14.2. For the EMVS Operational Phase, the SDK/API and the updates or amendments to the SDK/API shall be provided from time to time by SecurMed UK to the End User. The SDK/API will be communicated by means of email to the contact point named by the End User, with copy to the email address notified by the End User to SecurMed UK, and copy to SecurMed UK helpdesk for record.

14.3. Release Management

Any updates and changes to the SDK/API referred to in Section 14.2 follow a specific release management process similar to ITIL V3 or newer. The release management distinguishes between Emergency Fix, Minor Release and Major Release, as follows:

(i) Emergency Fix

An Emergency Fix is used to correct urgent errors in the UK MVS or the interfaces. Threats to data security, data integrity or system security are explicitly considered as urgent errors. Emergency Fixes typically include hot fixes and/or bug fixes. Due to the nature of the threats that should be fended off, time is a crucial factor. Therefore Emergency Fixes can be applied prior to distributing the SDK/API. Nevertheless the relevant connected parties should be informed as soon as possible about the Emergency Fix. Given the nature of the system described, backward compatibility is an essential aspect of any change including emergency changes.

(ii) Minor Release

A Minor Release is used to bundle a set of smaller improvements, corrections and/or known bugs. Typically a Minor Release does not include changes of interfaces. If such changes are included, they are backward compatible. Minor Releases will be distributed at least 30 calendar days prior to becoming effective.

(iii) Major Release

A Major Release is used to roll out new functionality and/or processes. Backward compatibility is not necessary. After a transitional period a Major Release completely replaces the former Major Release. Major Releases will be distributed at least 60 calendar days prior to becoming effective.

14.4. If the deployment or installation of such updates, changes and/or modifications to the UKMVS imply a (temporary) restriction or interruption of the End User's access to parts or all of the UK MVS, SecurMed UK shall endeavour to provide the End User with reasonable prior notice that allows to mitigate the impact and shall endeavour to take all diligent efforts to minimise any restriction or interruption.

14.5. All updates, changes or modifications to the UKMVS or any of its components shall be the sole property of SecurMed UK.

14.6. All maintenance, repair work, alterations, updates, changes and modifications of any nature whatsoever to the UK MVS shall be carried out at SecurMed UK's discretion.

15. GENERAL PROVISIONS

15.1. The End User may not assign this EULA, in whole or in part, without SecurMed UK's prior written consent and any attempted assignment in violation of this provision shall be null and void. SecurMed UK may assign its rights under this EULA without the End User's consent at any time, it being agreed that SecurMed UK shall inform the End User about such assignment and the reasons thereof at SecurMed UK's earliest convenience.

15.2. SecurMed UK shall not be liable under this EULA to the extent such liability results from circumstances beyond its reasonable control, including but not limited to strikes, lockouts or other industrial action, acts of God, war, riot, civil commotion, acts of terrorism, theft, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, failure or breakdown of plant, machinery, systems or vehicles, fire, flood, extreme weather conditions, power failure, failure of telecommunications networks or default of suppliers or sub-contractors (**Force Majeure Event**). If a Force Majeure Event continues for a period of 30 days or more, SecurMed UK shall be entitled to terminate this EULA on giving written notice to the End User.

15.3. The End User is responsible for all facilities, utilities and equipment necessary to use and access the UK MVS or any other component of the EMVS, including appropriate computer equipment and internet connections, in each case at the End User's sole risk and expense.

15.4. The End User must report any Security Breaches or any other alerts or incidents of which they, their End User Representatives or their IT Service Provider have become aware in relation to the use of and access to the UK MVS (or any other component of the EMVS) to SecurMed UK and respond to any request for information from SecurMed UK in a timely manner.

15.5. Termination or expiry of this EULA shall not affect the continuance in force of any provision hereof which expressly or by implication is intended to come into or continue in force after termination or expiry, including Sections 5, 9, 10, 11, 12, 15 and 16.

15.6. Upon termination or expiry of this EULA, the End User shall destroy all copies of the UK MVS, any other component of the EMVS and related documentation, in each case which are in his/her possession, (if any), except where the retention of such copies is necessary for the End User to comply with its obligations under the EU Directive on Falsified Medicines and Delegated Regulation or under applicable law, in which case the End User shall inform SecurMed UK of such legal obligation and the basis thereof and shall keep all these copies securely.

15.7. Notices

15.7.1. Any notice given under this EULA shall be in writing (but excluding fax transmission and electronic mail) and may be served by leaving it at, or by sending it by pre-paid first class post or recorded delivery to, the intended recipient's address. The address of a party for service of notices is, in the case of SecurMed, the address set out in this EULA and in the case of the End User, the address provided during the on-boarding process, or in each case 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, forty-eight hours from the date of posting. 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.

15.7.2. Each party agrees that without preventing any other mode of service permitted by any rule of court, any document in any proceedings (including but not limited to any claim form or other originating process) may be served on any party by being delivered to or left for that party at its postal address for service of notices under Section 15.7.1 and each party undertakes to maintain such an address at all times in the United Kingdom and to notify the other party in advance of any change from time to time of the details of such address in accordance with the manner prescribed for service of notices under Section 15.7.1.

15.8. Choice of law and jurisdiction

15.8.1. This EULA and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

15.8.2. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

16. DEFINITIONS

As used in these provisions, the following capitalised terms shall have the meanings set forth

below:

16.1. **Authorised Representative** shall mean any person nominated by the End-User during the SecurMed UK on-boarding process, authorised legally to bind the End User and accept the terms of the EULA on the End User's behalf;

16.2. **Confidential Information** shall mean

(i) all information of any nature whatsoever (including, but not limited to, all data, trade secrets, know-how, business information, plans, reports, analyses, studies, drawings, designs, models, concepts, ideas, discoveries, techniques, sketches, tools, computer programs, flow charts, processes, timetables, specifications and technical and quality standards (such as draft and signed contracts, business and/or financial records, samples, correspondence, presentations)),

on whatever support and in whatever form, format, or medium (including, but not limited to, written, oral, graphic, electronic, html pages, pictures, audio, video),

that a disclosing party discloses to the receiving party, or to which the receiving party obtains access, and that relates to the EMVS, its development, implementation, testing or operation, including but not limited to respective information of EMVO members, SecurMed UK members, third parties involved in the development, implementation, testing or operation of the UK MVS and of End Users;

(ii) all Data;

(iii) all information and software for or related to the UK MVS (including the UK MVS interface); and

(iv) any information which, if not otherwise described above, is designated by the disclosing party as confidential or is of such a nature that a reasonable person would believe it to be confidential.

16.3. **Data** shall mean any information uploaded, processed, transferred, generated or stored on or through the EMVS as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation (in particular its Article 33, para. 2), irrespective of whether such Data are stored in the European Hub or a National System and whether or not these include Personal Data.

16.4. **Delegated Regulation** shall mean the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

16.5. **Effective Date** shall mean the date on which the End User accepts this EULA in accordance with Section 2 above.

16.6. **EMVS Implementation Phase** shall mean the ramp-up period for the limited scale and preliminary operational mode of part of the EMVS that shall automatically terminate on the 8th February 2019, at 23:59:59 CET.

16.7. **EMVS Operational Phase** shall mean the full scale (day-to-day) operational mode of the EMVS, which starts on the 9th February 2019, at 00:00 CET.

16.8. **End User Representative** shall mean any of the End User's directors, officers, employees, contractors, agents or similar from time to time (and which may include the Authorised Representative).

16.9. **EU Directive on Falsified Medicines** shall mean Directive 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, where appropriate, the relevant implementing national laws in the relevant EEA Member States.

16.10. **European Hub** designate the component of the EMVS under the responsibility of EMVO that serves as a central information and data router according to Article 32, para. 1, a) of the Delegated Regulation for the transmission of Data to and from the National Systems; it is set up and managed by EMVO.

16.11. **European Medicines Verification Organisation or "EMVO"** shall mean the non-profit legal entity established to set up and manage the European Hub in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

16.12. **European Medicines Verification System or "EMVS"** shall mean the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems, and allows the End Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

16.13. **Intellectual Property Rights** shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, trademarks, service marks, author rights, copyrights, neighbouring rights and related rights, database rights, trade and business names, domain names, know-how, rights in computer software, proprietary marketing materials, trade secrets, and any and all other intellectual or industrial property rights in all their patrimonial and moral aspects, as well as any application therefore, anywhere in the world (whether registered or not).

16.14. **National Medicines Verification Organisation(s)** or "**NMVO(s)**" mean the non-profit legal entity (entities) established in the Union that is(are) responsible to set up and manage a national and/or supranational repository(ies) in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation (and of which SecurMed UK is one).

16.15. **Personal Data** shall mean any and all information relating to an identified or identifiable individual as defined under the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 and national laws implementing the Data Protection Directive as applicable , including (without limit) the Data Protection Act 2018.

16.16. **Pharmacists** shall mean persons authorised or entitled to supply medicines to the public.

16.17. **Security Breach** shall mean any event that endangers the security or the functioning of the EMVS, including but not limited to any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or unauthorized access to Data or (other) Confidential Information, as well as the unauthorized upload of data or the upload of illegitimate data on the EMVS.

16.18. **Undertaking** shall have the meaning given to it in s.1161 Companies Act 2006.

16.19. **Wholesaler** shall mean persons authorised to supply and distribute medicines who hold an MHRA Wholesaler Dealer License (WDA(H)).

16.20. **User(s)** shall mean any authorised user, including the End User, of the EMVS or National System as referred to under the EU Directive on Falsified Medicines and the Delegated Regulation.