TERMS AND CONDITIONS

FOR THE USE OF IRISH MEDICINES VERIFICATION SYSTEM BY END-USERS

Last update: 24th January 2019

Print version available at: https://www.imvo.ie/stakeholders1/register-imvo

IMPORTANT NOTICE

These general terms and conditions (the "**End-User Licence Agreement**") apply to the connection, access to and use of the Irish Medicines Verification System (**"IMVS"**), which is operated by Irish Medicines Verification Organisation ("**IMVO**"), a company limited by guarantee, with its registered office at IPHA offices, Wilton Park House, Wilton Place, Dublin 2, Ireland, and registered in Ireland, registered number 602266.

Please read this End-User Licence Agreement carefully before accessing or using the IMVS in any manner. By accepting this End-User Licence Agreement, the End-User confirms that it constitutes a legally binding agreement between the End-User and IMVO that governs the connection, access to and use of the IMVS.

IMVO licenses use of the IMVS and other components of the European Medicines Verification System (**"EMVS"**) to the End-User subject to this End-User Licence Agreement. IMVO does not sell the IMVS nor any component of the EMVS to the End-User and IMVO (or its licensors) remains the owner of the IMVS and any component of the EMVS at all times.

IMVO will process the End-User's Personal Data in accordance with the IMVO Data Privacy Policy which can be found at https://www.imvo.ie/about/data-privacy-policy.

The End-User is invited to print a copy of this End-User Licence Agreement for future reference.

Now it is hereby agreed in consideration of the sum of €1.00 (the receipt of which is hereby acknowledged by the End-User) as follows:

1. ACCEPTANCE OF THIS END-USER LICENCE AGREEMENT

By clicking 'Accept' during IMVO's registration process for End-Users who wish to connect to, access and use the IMVS, the End-User acknowledges that it has read, understood and consents to be bound by this End-User Licence Agreement and that its electronic acceptance of this End-User Licence Agreement will be recognised as equivalent, for all legal purposes, to a signed version of this End-User Licence Agreement. If it is not possible for technical reasons to accept these terms by clicking 'Accept' as described above, the End-User may confirm its acceptance by email to IMVO and, in doing so, any such email acceptance once received by IMVO will be recognised as equivalent, for all legal purposes, to a signed version of this End-User Licence Agreement.

When entering into this End-User Licence Agreement on behalf of a company, organisation, or other legal entity, you (as an individual) hereby agree – and declare and represent – that you are the Authorised Representative of the End-User, that you are entitled to and (have the legal capacity to) represent and bind such company,

organisation, or other legal entity, and that such company, organisation or other legal entity that you represent consents to be bound by this End-User Licence Agreement.

If you are not the Authorised Representative, or the End-User does not accept this End-User Licence Agreement, the End-User is not authorised to connect to or use the IMVS.

2. PURPOSE OF THIS END-USER LICENCE AGREEMENT

2.1. The purpose of this End-User Licence Agreement is to define the respective rights and obligations of IMVO and the End-User with respect to the connection, access to and use of the IMVS by the End-User in order to verify the authenticity of, and decommission, the unique identifier of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation (the "**Purpose**").

2.2. Both IMVO and the End-User are hereinafter also individually referred to as a "Party" and collectively as the "Parties".

3. GRANT OF RIGHTS TO THE END-USER

3.1. Subject to the End-User's agreement to and continued compliance with this End-User Licence Agreement, IMVO hereby grants to the End-User a limited, revocable, non-exclusive, non-transferable, personal licence right to connect, to access to and to use the IMVS, solely for the Purpose.

3.2. Licence rights granted to the End-User are limited to those expressly granted herein. IMVO (and its respective licensors) reserves all other rights.

4. LICENCE RESTRICTIONS

4.1. Except as expressly agreed in writing herein or as provided in this End-User Licence Agreement or as necessary for the Purpose, the End-User may not (i) use, copy, maintain, distribute, sell, publish, display, sublicense, rent, make corrections to, or modify the IMVS nor any component thereof; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer, or otherwise translate the IMVS or any component thereof, save where the foregoing restrictions are expressly prohibited by applicable law; (iii) use or sublicense use of the IMVS or any component thereof for the benefit of a third party, and more generally, for any purpose other than the Purpose, (iv) store, access or transmit information or data on the IMVS or any other component of the EMVS that is inaccurate or that has not been legally obtained or that is in violation of any other applicable Intellectual Property Right, or that is in violation of the EU Falsified Medicines Directive or Delegated Regulation.

4.2. If, at any time, IMVO has reasonable and objective grounds to believe that the (further) connection, access to or use of the IMVS by the End-User:

4.2.1. immediately and substantially endangers the security or functioning of the EMVS (in whole or in part, including the IMVS), IMVO is entitled immediately and without prior notice to disconnect the End-User from the IMVS or, it being agreed that IMVO shall inform the End-User about such measure and the

reasons thereof as soon as possible, and that the connection of the End-User to the IMVS shall be re-established as soon as possible when there is no longer any immediate and substantial danger to the security or functioning of the IMVS or any other component of the EMVS; and

4.2.2. is in breach of this End-User Licence Agreement but does not immediately and substantially endanger the security or functioning of the IMVS or the EMVS (in whole or in part), IMVO is entitled to disconnect the End-User from (or restrict the End-User's access to) the IMVS (and may then exercise its further rights in accordance with this End-User Licence Agreement), provided that, if such breach is capable of remedy, the End-User has failed to remedy the breach within thirty (30) calendar days (or such period as agreed by IMVO) after such remediable breach is notified to the End-User by IMVO.

4.3. If, at any time, the End-User has reasonable and objective grounds to believe that the (further) connection, access to or use of the IMVS immediately and substantially endangers the security of the End-User, the End-User may disconnect from the IMVS, it being agreed that the End-User shall inform IMVO 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 IMVS at any time (this without prejudice to the End-User's obligations under the EU Directive on Falsified Medicines and Delegated Regulation).

4.4. The Parties shall fully cooperate so that any disconnection as foreseen under Sections 4.2 and 4.3 is only used as a last resort.

5. OBLIGATIONS OF THE END-USER

5.1. The End-User undertakes to connect to, access and use the IMVS to verify the authenticity of the unique identifier of medicinal products and decommission the unique identifier in accordance with this End-User Licence Agreement and all its obligations under the EU Directive on Falsified Medicines and the Delegated Regulation.

5.2. The End-User warrants that:

5.2.1. the End-User is responsible for maintaining the security of its system(s) connected to the IMVS and the confidentiality of its credentials and passwords used to connect to the IMVS (which shall include the appointment of a suitably qualified Super User), and is solely responsible, subject to Section 14.6 of this End-User Licence Agreement, for any activities carried out through its account /connection 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 IMVS;

5.2.2. the End-User's own system(s) and any connection or access by the End-User to the IMVS 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 IMVO to the End-User

from time to time; and

5.2.3. the End-User shall notify IMVO 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

5.2.4. where the End-User utilises a system provided by the End-User IT Software Provider to access the IMVS and the End-User IT Software Provider is an external provider, that:

5.2.4.1. the End-User has a contract with the End-User IT Software Provider; and

5.2.4.2. that contract has provisions that require reasonable technical measures to be in place to protect against unauthorised access, interception, disruption to the IMVS or other Security Breach via the End-User system; and

5.2.5. the End-User that is a Healthcare Institution shall not cause IMVO to breach the terms of the Co-Operation Agreement or the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation by its use of Data Files to decommission unique identifiers.

5.3. In any case, the End-User shall not (i) use the IMVS in any unlawful manner, for any unlawful purpose, or in any manner inconsistent with this End-User Licence Agreement or the EU Directive on Falsified Medicines and the Delegated Regulation, or act fraudulently or maliciously, for example, by hacking into or inserting malicious code, including viruses, or inaccurate, false or harmful data into the IMVS (or any other component of the EMVS); (ii) infringe any Intellectual Property Rights relating to the IMVS, or those of any third party in relation to the use of the IMVS, or (iii) use the IMVS in a way that could damage, disable, overburden, impair or compromise the IMVS (or any other component of the EMVS) or interfere with other Users.

5.4. Save as set out in the remainder of this Section 5.4, (bulk) verifications may only be performed by End-Users in respect of products under their physical control.

Nothing in this section 5.4 shall preclude an End-User that is a Healthcare Institution from decommissioning unique identifiers by way of Data Files supplied by the wholesaler or manufacturer from whom they have obtained the relevant packs, in accordance with any Relevant Guidance.

Where the End-User uses or provides Data Files for decommissioning purposes, it shall ensure that the process is no less secure than the security provided by the EMVS and shall have in place appropriate auditing procedures to verify the appropriateness of its security arrangements.

The End-User shall indemnify IMVO for any and all losses, damages and third party claims suffered by IMVO due to the End-User's use of Data Files to decommission unique identifiers, including any Security Breach that occurs as a result of the End-User's use of Data Files.

5.5. The End-User may authorise directors, officers, employees, agents or operating units (with no distinct legal personality from the End-User) to benefit from its rights under this End-User Licence Agreement and to connect to, access and use the IMVS on behalf of the End-User as necessary for the Purpose, subject to the following conditions:

5.5.1. said representatives are informed of and are bound by and required to observe all terms, limitations and conditions applying to the End-User as set forth in this End-User Licence Agreement;

5.5.2. the End-User remains fully responsible and liable for any act or omission of said representatives;

5.5.3. without prejudice to other remedies, in case of material breach of this End-User Licence Agreement by a representative of the End-User, IMVO reserves the right to require the End-User to suspend or withdraw the authorisation granted to the said representative in accordance with this Section 5.5, without any indemnity being due to the End-User; and

5.5.4. it is expressly agreed that, as far as the End-User's employees are concerned, the provisions under this Section 5.5 shall be sufficiently met provided that such employees are duly informed about this End-User Licence Agreement and have a duty to comply with it as per their contract of employment with the End-User, and the End-User remains fully responsible and liable for its employees, their actions and any inappropriate use of the EMVS (including the IMVS).

6. OBLIGATIONS OF IMVO

6.1. IMVO shall take appropriate measures to ensure that the IMVS shall be developed, implemented, tested and operated for the whole period of time set forth in Section 12.1 of this End-User Licence Agreement in accordance with (i) the EU Falsified Medicines Directive and the Delegated Regulation, and (ii) this End-User Licence Agreement.

6.2. The IMVS shall satisfy all conditions as set forth under Article 35, para. 1 of the Delegated Regulation, including without limitation:

6.2.1. it shall allow the reliable electronic identification and authentication of individual packs of medicinal products by the End-User, in accordance with the requirements of the Delegated Regulation;

6.2.2. it shall have application programming interfaces able to transfer and exchange data with the software used by the End-User and, where applicable, national competent authorities;

6.2.3. when the End-User queries the IMVS for the purposes of verification of authenticity and decommissioning of a unique identifier, the response time of the IMVS, not considering the speed of the Internet connection, shall be lower than 300 milliseconds in at least 95% of queries; the IMVS performance shall allow the End-User to operate without significant delay; and

6.2.4. in the exceptional case of a failure of the End-User's own software, the IMVS shall include graphical user interfaces providing direct access to the IMVS by the End-User verified in accordance with Section 6.3.3 below, for the purposes of verifying the authenticity of the unique identifier and decommissioning it.

6.3. Without prejudice to the generality of the above, IMVO undertakes:

6.3.1. to use its best efforts to set up the IMVS in a diligent manner and shall take appropriate measures so that the IMVS and Data on the IMVS be protected by appropriate security measures, including against unauthorised access, interception or disruption;

6.3.2. to use its best efforts so that no malicious software, malware or other code is introduced into the EMVS, or any component thereof, through the IMVS;

6.3.3. in accordance with Article 37, para. 1, b) of the Delegated Regulation, to put in place security procedures ensuring that only End-Users whose identity, role and legitimacy has been verified may access the IMVS or upload Data to the IMVS;

6.3.4. in accordance with Article 36, para. 1, b) of the Delegated Regulation, that the IMVS shall provide for the triggering of an alert in the IMVS and in the terminal where the verification of the authenticity of a unique identifier is taking place when such verification fails to confirm that the unique identifier is authentic and shall continuously monitor the IMVS for events alerting to potential incidents of falsification and provide for immediate investigation of all potential incidents of falsification flagged in the IMVS as required under the Delegated Regulation;

6.3.5. in accordance with Article 36, para. 1, g) of the Delegated Regulation and without prejudice to Article 35, para. 1, h) thereof and Section 6.3.1 above, the IMVS shall allow access by verified wholesalers to the list of wholesalers referred to in Article 33 para. 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;

6.3.6. to appoint a key contact point for the performance of this End-User Licence Agreement; and

6.3.7. to support the End-User and provide access to all relevant material and documentation and framework for training, in order to allow the End-User to connect to the IMVS for the Purpose.

7. INTERNAL AUDIT BY IMVO

7.1. **Internal audit by IMVO.** IMVO shall carry out regular audits, by appropriate means, of its own compliance with the requirements under the Delegated Regulation (in particular all technical and organisational security aspects relating to the set-up and the operation of the IMVS), as required under the Falsified Medicines Directive, Delegated Regulation and this End-User Licence Agreement.

8. INTELLECTUAL PROPERTY RIGHTS

8.1. The End-User acknowledges and agrees that all rights, titles and interests to, and all underlying Intellectual Property Rights in the IMVS, including any application programming interfaces and graphical user interfaces or any other component of the EMVS anywhere in the world, belong to IMVO and EMVO respectively (or their IT service providers), and are licensed (not sold) to the End-User. The End-User has no rights in, or to, the IMVS, including any application programming interfaces and graphical user interfaces or any component of the EMVS, other than the right to use them for the Purpose in accordance with this End-User Licence Agreement and the Falsified Medicines Directive and the Delegated Regulation.

8.2. IMVO represents that it holds sufficient right, title and interest in and to the IMVS to grant the licence herein under this End-User Licence Agreement.

9. DATA PROTECTION AND OWNERSHIP

9.1. In accordance with Article 35, para. 1, h) of the Delegated Regulation, the structure of the IMVS 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.

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

9.2.1. Static data (i.e., the information listed under Article 33, para. 2 of the Delegated Regulation); and

9.2.2. Dynamic data i.e.:

9.2.2.1. 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/supplied, recalled, stolen, etc.; and

9.2.2.2. changes to the complete record ("**Audit Trail**") as referred to in Article 35, para. 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.

9.3. 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, para. 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.

9.4. 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 concerned 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 manufacturing and/or marketing authorisation holders own the data generated by their own IT system.

9.5. 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.

9.6. In accordance with Article 35, para. 1, g) of the Delegated Regulation, the IMVS shall maintain an Audit Trail of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations. IMVO shall not access the Audit Trail stored on its IMVS and the Data contained therein without the written agreement of the legitimate data owners (determined in accordance with Sections 9.1 to 9.5 above), except for the purpose of 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 or for the purpose of granting access to the national competent authorities in accordance with Article 39 of the Delegated Regulation or for the purpose of maintenance, repair work or other alterations to the IMVS as evidentially and essentially necessary for its operation.

9.6.1. The access to and the use of the data contained in the Audit Trail shall be strictly limited to these purposes it being noted that the IMVO 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 provided that IMVO informs the IMVO Representative of the restrictions as to the access and use of the data contained in the Audit Trail and ensures that its IMVO Representative is bound by a confidentiality undertaking or obligations of confidence which protect the data contained in the Audit Trail to at least the extent that it is protected under these End-User Licence Agreement.

9.7. IMVO shall only grant access to its IMVS and the Data contained therein to competent authorities for Ireland for the purposes set forth under Article 39 of the Delegated Regulation and in so far as they concern IMVO'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 IMVO.

9.8. In the instances of competent authority access referred to under Section 9.7, except where data are accessed for the purpose of investigation (Article 39 of the Delegated Regulation) or where explicitly prohibited by law or not foreseen under applicable legislation, the owner of the Data contained in the IMVS may request to be informed about access to its data by national competent authorities. IMVO should confirm with the national 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 IMVO at its discretion in line with any guidance provided by the national competent authorities, i.e. the respective reporting capabilities, their development, use and the associated cost allocations are to be decided at national level.

10. CONFIDENTIALITY

10.1. IMVO and the End-User, each with respect to Confidential Information received from the other Party, undertakes to:

10.1.1. 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;

10.1.2. 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 End-User Licence Agreement or the Falsified Medicines Directive and Delegated Regulation;

10.1.3. 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;

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

10.1.5. 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.

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

10.2.1. is or comes into the public domain through no breach of this End-User Licence Agreement;

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

10.2.3. is independently developed by IMVO or the End-User;

10.2.4. is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, IMVO 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 End-User Licence Agreement. In such case, IMVO 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

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

10.3. IMVO shall take appropriate measures in relation to the protection of the identity of the End-Users, without prejudice to IMVO's obligation to take appropriate measures to ensure that its IMVS shall be used and operated for the whole Term of this End-User Licence Agreement for the Purposes, in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation and (ii) this End-User Licence Agreement.

11. LIMITATION OF WARRANTY AND LIABILITY

11.1. **Disclaimer of warranty.** Except as otherwise provided in this End-User Licence Agreement, the IMVS is provided "as is", and, IMVO makes no warranties, whether express or implied, or statutory regarding or relating thereto. Specifically, without prejudice to IMVO's obligations under the EU Falsified Medicines Directive and the Delegated Regulation, IMVO does not warrant that the IMVS will be error and defect free (whether apparent or hidden/latent) or will perform in an uninterrupted manner.

11.2. To the maximum extent allowed by law, IMVO specifically disclaims all implied guarantees and warranties, including any warranty of condition, quality, performance, satisfactory quality, merchantability or fitness for a particular purpose (even if IMVO had been informed of such purpose), including for latent or hidden defects, with respect to any part of the IMVS.

11.3. **Exclusion of Indirect Damages.** Without prejudice to Sections 11.1 and 11.2 above, neither Party shall be liable for any claims, proceedings, damages, expenses, costs and losses 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 goodwill, loss of data, loss of clientele, third party claim, or any other indirect, special, incidental or consequential damages of any kind ("**Indirect Damages**") whether based on 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 access to or use of the IMVS.

11.4. In addition, without prejudice to IMVO's obligations under the EU Falsified Medicines Directive and the Delegated Regulation, IMVO shall not be held responsible or 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 IMVS by such third parties.

11.5. **Liability Cap.** IMVO's maximum aggregate liability vis-à-vis the End-User arising out of, or in connection with this End-User Licence Agreement, for damages, howsoever arising or caused, whether or not arising from breach of contract or tortious conduct, negligence, hidden/latent defects, shall in no event exceed €10,000 (ten thousand Euro). The End-User's maximum aggregate liability arising out of, or in connection with this End-User Licence Agreement, for damages, howsoever arising or caused, whether or not arising from the End-User's breach of contract or tortious conduct, negligence, hidden/latent defects shall in no event exceed €10,000 (ten thousand Euro).

11.6. **Exclusion.** Nothing in this End-User Licence Agreement will exclude or limit the Parties' liability:

11.6.1. for fraud or wilful misconduct;

11.6.2. for death or personal injury arising from the Party's negligence or that of its representatives;

11.6.3. for breach of anti-bribery legislation;

11.6.4. for breach of the indemnity provided in Section 5.4; and

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

11.7. **Losses suffered by other Users of the IMVS**. The Parties acknowledge and agree that any losses suffered by any other Users of the IMVS in connection with this End-User Licence Agreement will be deemed to be actual losses suffered by IMVO under this End-User Licence Agreement, and IMVO will be entitled to recover such losses directly against the End-User in accordance with this Section 11.

12. TERM AND TERMINATION

12.1. The initial period of time of this End-User Licence Agreement is 12 months as of the Effective Date. After the initial period of time, this End-User Licence Agreement will continue to apply, unless:

12.1.1. either Party decides to terminate this End-User Licence Agreement for convenience by sending a notice in writing to the other with ninety (90) days' notice; or

12.1.2. the End-User refuses to agree a revised End-User Licence Agreement in accordance with Section 13.8 and serves a notice on IMVO (and this End-User Licence Agreement shall therefore terminate immediately).

12.2. Without prejudice to other remedies under applicable law, either Party is entitled to dissolve this End-User Licence Agreement forthwith, in its own right and without prior intervention of any court or arbitral body, without indemnity, by mere notification to the other Party, if (i) the latter is in breach of any material obligation under this End-User Licence Agreement and, (ii) the defaulting Party fails to remedy such breach within ninety (90) calendar days after such remedy has been requested in writing if such breach is capable of being remedied.

12.3. Without prejudice to the above, IMVO is entitled to terminate this End-User Licence Agreement immediately, without indemnity, (i) if the contract between EMVO and IMVO for the use of the European Hub by IMVO is terminated or expires for whatever reason, or (ii) if the End-User is no longer authorised or entitled to sell medicinal products by wholesale or to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and Delegated Regulation.

12.4. The expiration or termination of this End-User Licence Agreement shall not affect provisions thereof that by their terms and meaning are of a continuing nature, in accordance with Section 14.4 below.

13. CHANGES AND UPDATES TO THE IMVS AND THE END-USER LICENCE AGREEMENT

13.1. IMVO may apply updates, changes and/or modifications to the IMVS at any time in accordance with the following during the EMVS Operational Phase.

13.2. Relevant Artifacts

During the EMVS Operational Phase, IMVO shall provide a copy of the SDK/API in electronic form and updates or amendments to the SDK/API from time to time to the End-User IT Software Provider.

13.3. Communication of the SDK/API

The SDK/API will be communicated by means of email or secure online link (Confluence) to the End-User IT Software Provider and a copy to IMVO for its own record.

13.4. Release Management

Any updates and changes to the Relevant Artifacts follow a specific release management process similar to ITIL V3 or newer. Release management distinguishes between Emergency Fix, Minor Release and Major Release.

(i) Emergency Fix

An emergency fix is used to correct urgent errors in the IMVS or the interfaces ("**Emergency Fix**"). 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 need to be addressed, time is a crucial factor. Therefore, Emergency Fixes may 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 ("**Minor Release**"). Typically, a Minor Release does not include changes of interfaces. If such changes are included, they are

backward compatible. After a Minor Release becomes effective, the older version of the SDK/API will be maintained and supported for at least 60 days.

(iii) Major Release

A major release is used to roll out new functionality and/or processes ("**Major Release**"). Backward compatibility is not necessary. After a transition period, a Major Release completely replaces the former Major Release. For changes that affect the End-User system API, IMVO (or its IT service provider) will release multiple versioned APIs side-by-side in the IMVS production environment and will then manage the retirement of older versions of the API. The End-User IT Software Provider will be provided with advance notice of the change by IMVO (and/or by its IT service provider) and given a realistic period of time to introduce the necessary changes to their software, including testing in the IMVS IQE. IMVO (or its IT service provider) will provide timely and repeated notification to the End-User IT Software Provider, of the date of retirement of an API version.

13.5. If the deployment or installation of such updates, changes and/or modifications to the IMVS imply a temporary restriction on or interruption of the End-User's access to parts or all of the IMVS, IMVO shall provide the End-User with reasonable prior notice that allows the End-User to mitigate the impact and shall take all diligent efforts to minimise any restriction or interruption.

13.6. All updates, changes or modifications shall be the sole property of IMVO.

13.7. All maintenance, repair work, alterations, updates, changes and modifications of any nature whatsoever to the IMVS shall be done at IMVO's discretion, subject to Section 13.1 above.

13.8. IMVO may, from time to time, update this End-User Licence Agreement to reflect changes to the service. If IMVO amends the terms of this End-User Licence Agreement, it will provide thirty (30) days' notice of any change. The End-User will be deemed to have accepted the change to the End-User Licence Agreement unless it serves a notice under Section 12.1.2.

14. GENERAL PROVISIONS

14.1. The End-User may not assign or novate this End-User Licence Agreement, in whole or in part, without IMVO's prior written consent and any attempted assignment or novation in breach of this provision shall be null and void. IMVO may assign or novate any this End-User Licence Agreement without the End-User's consent at any time, it being agreed that IMVO shall inform the End-User about such assignment (or novation) and the reasons thereof at IMVO's earliest convenience.

14.2. The End-User must supply all necessary facilities, utilities and equipment necessary to use and access the IMVS or any other component of the EMVS, including appropriate computer equipment and Internet connections, at the End-User's sole risk and expense.

14.3. The End-User must report any alerts or incidents they or their representatives (as

per Section 5.5) or the End User IT Software Provider have witnessed in relation to the use of and access to the IMVS (or any other component of the EMVS) to IMVO and respond to any request for information from IMVO in a timely manner.

14.4. The provisions of this End-User Licence Agreement which by their nature should survive termination (including without limitation Sections 4, 8, 9, 10, 11, 12, 14 and 15) shall remain in force for a term of 5 years as from the date of termination or expiry of this End-User Licence Agreement, unless otherwise agreed between the Parties.

14.5. Upon termination of this End-User Licence Agreement, the End-User must destroy all copies of the IMVS, any other component of the EMVS and related documentation 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 IMVO of such legal obligation and the basis thereof and shall keep all these copies securely.

14.6. Neither Party shall be in breach of this agreement nor liable for delay in performing, or failure to perform, any of its obligations under this agreement if such delay or failure result from events, circumstances or causes beyond its reasonable control. In such circumstances the affected Party shall be entitled to a reasonable extension of the time for performing such obligations.

14.7. The affected Party shall notify the other Party in writing of the event, circumstances or causes as soon as reasonably practicable after the start of said event and the effect of the event on its ability to perform any of its obligations under this End-User Licence Agreement, and shall use all reasonable endeavours to mitigate the effect of the event on the performance of its obligations.

14.8. If the period of delay or non-performance continues for fourteen (14) days, the Party not affected may terminate this agreement by giving thirty (30) days' written notice to the affected Party.

14.9. Choice of law and jurisdiction

This End-User Licence Agreement and any contractual or non-contractual (including pre-contractual) matters in connection with its conclusion, validity, interpretation, enforcement, performance and termination shall be governed by and construed in accordance with the laws of Ireland and, subject to the remainder of this sub-section, any dispute arising out of this End-User Licence Agreement shall be subject to the exclusive jurisdiction of the courts of Ireland to which both Parties hereby agree to submit irrevocably for these purposes.

In the event of any dispute arising out of or relating to this Agreement ("**the Dispute**"), the Parties shall first seek settlement of the Dispute as set out below:

The Dispute shall be referred as soon as practicable to the Authorised Representative (or such person as notified in advance by the End-User to IMVO) and to IMVO's General Manager respectively.

(i) If the Dispute has not been resolved within fifteen (15) business days (or such longer period as may be agreed in writing by the Parties) of being referred to the nominated representative, then either Party may refer the Dispute to an independent mediator, the identity of whom shall be agreed in advance by the Parties. If the Parties are unable to agree on a mediator or if the mediator agreed upon is unable/unwilling to act, either Party may within twenty-one (21) days from the date of the proposal to appoint a mediator or within twenty-one (21) days of notice to either Party that the mediator is unable to act, apply to the Centre for Effective Dispute Resolution (CEDR Ireland) to appoint a mediator.

(ii) Any submissions made to and discussions involving the mediator, of whatever nature, shall be treated in strict confidence and without prejudice to the rights and/or liabilities of the Parties in any legal proceedings and, for the avoidance of doubt, are agreed to be without prejudice and legally privileged. The Parties shall make written submissions to the mediator within ten (10) business days of his/her appointment.

(iii) The Parties shall share equally the cost of the mediator. The costs of all experts and any other third parties who, at the request of any Party, shall have been instructed in the mediation, shall be for the sole account of and shall be discharged by that Party.

For the avoidance of doubt, the obligations of the Parties under this End-User Licence Agreement shall not cease, or be suspended or delayed, by the reference of a Dispute to mediation. The End-User shall comply fully with the requirements of the Agreement at all times.

15. DEFINITIONS

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

Authorised Representative shall mean the person nominated by the End-User during the IMVO registration process, authorised to legally bind the End-User and accept the terms of the End-User Licence Agreement.

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 (including the IMVS), its development, implementation, testing or

operation, including but not limited to respective information of EMVO members, IMVO members, third parties involved in the development, implementation, testing or operation of the EMVS (including the IMVS) and of End-Users;

(ii) all Data;

(iii) all information and software for or related to the IMVS (including the IMVS 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.

Co-operation Agreement shall mean the agreement between the IMVO and EMVO granting IMVO access to the European Hub.

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.

Data File shall mean a standardised file containing a list of unique identifiers as well as other potentially relevant data (handling instructions etc.) that is provided to a Healthcare Institution to facilitate decommissioning of medicinal product packs without having to scan each pack individually. The Data File is generated by a wholesaler or manufacturer by scanning the barcode on all packs in a consignment or shipment intended for delivery to the Healthcare Institution. The Data File is made available to the Healthcare Institution by secure means, for example, via a server controlled by the Healthcare Institution or Health Service Executive. For the avoidance of doubt, any such server is not part of the IMVS.

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.

Effective Date shall mean the date on which the End-User accepts this End-User Licence Agreement in accordance with Section 1 above.

End-User shall mean a wholesaler or a person authorised or entitled to supply medicines to the public that accepts the End-User Licence Agreement in order to establish connections to the IMVS from software system(s) on specific terminals in specific location(s) in their organisation. All references to End-User in this End-User Licence Agreement shall refer to the End-User and End-User Affiliate.

EMVS Operational Phase means the full scale (day-to-day) operational mode of the EMVS, which starts on the 9th February 2019, at 00:00 CET and which is governed by this Agreement.

End-User Affiliate shall mean any person that:

(i) directly or indirectly controls the End-User;

(ii) is controlled by the End-User; or

(iii) is under common control with another person and the End-User.

End-User Licence Agreement shall mean the End-User Licence Agreement entered into between IMVO and the End-User relating to the use of and access by the End-User to the IMVS for the purpose of verifying the authenticity of medicinal products bearing the unique identifier in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

End-User IT Software Provider(s) shall mean either:

(i) the End User's internal IT department; or

(ii) an externally contracted IT software provider

that:

(i) has completed the obligatory IMVO onboarding process for IT software providers; and

(ii) has been nominated by the End-User to facilitate its connection with the IMVS.

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.

European Hub shall mean 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.

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.

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. For the avoidance of doubt, the IMVS is a National System within the EMVS.

Healthcare Institution means a hospital, in- or outpatient clinic or health centre as defined in the Delegated Regulation and related national legislation in Ireland.

IMVO shall mean the Irish Medicines Verification Organisation, an NMVO for the territory

of Ireland, which is a Party to this End-User Licence Agreement.

IMVO Representative shall mean an authorised director, office, employee, agent or IMVO's IT service provider.

IMVS Portal shall mean the graphical user interface provided by the IMVO's IT service provider for access by the End-User.

Intellectual Property Right(s) shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, trade marks, service marks, author rights, copyrights, neighbouring rights and related rights, database rights[1], 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).

IQE means integrated quality environment of the IMVS, a validated test environment that matches the IMVS production environment in all aspects other than data content. The IQE enables the End-User IT Software Provider to perform full functional and non-functional system testing. Data in this environment will respond and react to End User IT Software Provider transactions in exactly the way as data in the live production environment.

Irish Medicines Verification System or **"IMVS"** shall mean the National System for Ireland that is under the responsibility of IMVO.

ITIL V3 shall mean the third version of the Information Technology Infrastructure Library, a globally recognised collection of best practices for managing information technology.

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.

National (Medicines Verification) System or "**NMVS**" shall mean a national or supranational repository of the EMVS according to Article 32, para. 1, b) of the Delegated Regulation under the responsibility of one NMVO; it is connected to the European Hub 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.

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 General Data Protection Regulation (EU) 2016/679as applicable.

Relevant Guidance shall mean any guidance issued by the European Commission, the Member State expert group on safety features or any other expert group established by the Commission and/or by a competent authority in respect of the EMVS, IMVS, EU

[1] including sui generis database rights resulting from Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.

Directive on Falsified Medicines and Delegated Regulation.

Relevant Artifacts shall mean the SDK/API.

SDK/API shall mean the technical documentation to establish the connection and the interactions between the End-User and the IMVS available for the End-User (or a third party as indicated by it) on the development portal provided by IMVO.

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, unauthorised disclosure of, or unauthorised access to Data or (other) Confidential Information, as well as the unauthorised upload of data or the upload of illegitimate data on the EMVS.

Super User shall mean the person within the End-User organisation appointed by the Authorised Representative to manage user roles and client credentials for the End-User within the IMVS Portal. For the avoidance of doubt, the Authorised Representative may have this role.

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.