AGREEMENT FOR THE USE OF THE FINNISH MEDICINES VERIFICATION SYSTEM BY END USERS

# Parties

1. Suomen Lääkevarmennus Oy (Business ID/Company Number: 2801478-9), whose registered office is at Porkkalankatu 1, 00180 Helsinki, Finland (the Finnish Medicines Verification Organisation, “**FiMVO**”); and
2. […](Business ID/Company Number: [..]), whose registered office is at [..] (the “**End User**”)

Both FiMVO and the End User are hereinafter also individually referred to as a “Party” and collectively as the “Parties”.

# Purpose of This Agreement

* + 1. This agreement applies to the connection, access to and use of the Finnish Medicines Verification System (the “**System**”), which is operated by FiMVO.
    2. The purpose of this Agreement is to set the respective rights and obligations of FiMVO and the End User with respect to the connection, access to and use of the System by the End User in order to verify the authenticity of, and to decommission, the unique identifiers of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation (the “**Purpose**”).
    3. FiMVO licenses use of the System and other components of the EMVS to the End User subject to this Agreement. FiMVO does not sell the System nor any component of the EMVS to the End User and FiMVO (or its licensors) remain the owners of the System and any component of the EMVS at all times.
    4. It is expressly agreed that EMVO and the NMVOs develop and operate the EMVS, including the European Hub and the National Systems, in view of the verification of the authenticity and the decommissioning of the unique identifiers of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation. The EMVS, including the European Hub and National Systems, is therefore still being designed, developed and tested and could therefore be substantially amended, without any indemnity being due to the End User.

# Grant of Rights to the End User

* + 1. Subject to the End User’s agreement to and continued compliance with this Agreement, FiMVO hereby grants to the End User a limited, revocable, non-exclusive, non-transferable, personal license right to connect, to access to and to use the System, solely for the Purpose, in accordance with the EU Directive on Falsified Medicines and the Delegated Regulation.
    2. License rights granted to the End User are limited to those expressly granted herein. FiMVO (and its respective licensors) reserves all other rights.

# License Restrictions

* + 1. Except as expressly agreed in writing herein or as provided in this 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 System nor any component thereof; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer, or otherwise translate the System or any component thereof, unless to the extent the foregoing restrictions are expressly prohibited by applicable law; (iii) use or sublicense use of the System 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 System 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 Directive on Falsified Medicines or the Delegated Regulation.
    2. If, at any time, FiMVO has reasonable and objective grounds to believe that the (further) connection, access to or use of the System by the End User:

### immediately and substantially endangers the security or functioning of the System or the EMVS (in whole or in part), FiMVO is entitled to immediately and without prior notice disconnect the End User from the System, it being agreed that FiMVO 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 System shall be re-established as soon as possible when no immediate and substantial danger to the security or functioning of the System or part of the EMVS remain; and

### is in breach of this Agreement but does not immediately and substantially endanger the security or functioning of the System or the EMVS (in whole or in part), FiMVO is entitled to disconnect the End User from the System (and may then exercise its further rights in accordance with this Agreement), provided that, if such breach is capable of being cured, the End User failed to cure the breach within ninety (90) calendar days (or such shorter period where justified) after such cure has been demanded in writing by FiMVO.

* + 1. If, at any time, the End User has reasonable and objective grounds to believe that the (further) connection, access to or use of the System immediately and substantially endangers the security of the End User, the End User may disconnect from the System, it being agreed that the End User shall inform FiMVO 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 no immediate and substantial danger to the security of the End User remain. This is without prejudice to the End User's unilateral decision to disconnect from the System at any time (this without prejudice to the End User's obligations under the EU Directive on Falsified Medicines and the Delegated Regulation).

# Obligations of the End User

* + 1. The End User undertakes to connect, to access to and to use the System to verify the authenticity of the unique identifiers of medicinal products and decommission the unique identifiers in accordance with this Agreement and all its obligations under the EU Directive on Falsified Medicines and the Delegated Regulation. The End User also undertakes to provide FiMVO with technical and organisational information reasonably requested by FiMVO from time to time to facilitate FiMVO’s fulfilment of its obligations under this Agreement.
    2. In order to be authorised to connect, to access or to use the System, the End User is obligated to ensure, at all times, that is has engaged in a valid and binding agreement with FMVO. If the End User does not accept this Agreement and conclude a valid agreement with FiMVO, the End User is not authorised to connect, to access nor to use the System.
    3. The End User warrants that:

### the End User is responsible for maintaining the security of its system and the confidentiality of its credentials and passwords to connect to the System, and is solely responsible for any activities carried out through its connection and on its system, including for the correctness and accuracy of any information or Data uploaded or generated by the End User on the System and any activities carried out by End User’s IT service providers;

### the End User’s own system and any connection or access by the End User to the System 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 FiMVO to the End User from time to time; and

### the End User shall notify FiMVO 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.

* + 1. In any case, the End User must not (i) use the System in any unlawful manner, for any unlawful purpose, or in any manner inconsistent with this 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 System; (ii) infringe any Intellectual Property Rights relating to the System, or those of any third party in relation to the use of the System, or (iii) use the System in a way that could damage, disable, overburden, impair or compromise the System or interfere with other Users.
    2. The End User may authorise its End User Representatives to benefit from its rights under this Agreement and to connect, to access to and to use the System on behalf of the End User as necessary for the Purpose, subject to the following conditions:

### the End User Representative is informed of and is bound by and required to observe all terms, limitations and conditions applying to the End User as set forth in this Agreement;

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

### without prejudice to other remedies, in case of material breach of this Agreement by the End User Representative, FiMVO 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

### 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 Agreement and have a duty to observe them as per their employment agreement 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.

# Obligations of FiMVO

* + 1. FiMVO shall take appropriate measures to ensure that the System shall be developed, implemented, tested and operated for the whole period of time set forth in Section 12.1 of this Agreement in accordance with (i) the EU Directive on Falsified Medicines and the Delegated Regulation, and (ii) this Agreement.
    2. The System shall satisfy all conditions as set forth under Article 35, para. 1 of the Delegated Regulation, including without limitation:

### 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;

### 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;

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

### in the exceptional case of a failure of the End User’s own software, the System shall include graphical user interfaces providing direct access to it to 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.

* + 1. Without prejudice to the generality of the above, FiMVO undertakes:

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

### to use its diligent efforts so that no malicious software, malware or other code is introduced into the EMVS, or any component thereof, through its System;

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

### in accordance with Article 36, para. 1, b) of the Delegated Regulation, the System shall provide for the triggering of an alert in the system 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, shall continuously monitor the System for events alerting to potential incidents of falsification and provide for immediate investigation of all potential incidents of falsification flagged in the system as required under the Delegated Regulation;

### 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 System shall allow the access by verified wholesalers to the list of wholesalers referred to in Article 33 para. 2, h) of the Delegated Regulation (i.e. wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf), 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 the Delegated Regulation;

### to appoint a key contact point for the performance of this Agreement; and

### to support the End User and provide it with access to all relevant material and documentation and framework for training, in order to allow the End User to connect to the System for the Purpose.

# Internal Audit by FiMVO

* + 1. FiMVO 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 System), as required under the EU Directive on Falsified Medicines and the Delegated Regulation.

# Intellectual Property Rights

* + 1. The End User acknowledges and agrees that all rights, titles and interests to, and all underlying Intellectual Property Rights in the System, including any application programming interfaces and graphical user interfaces or any other component of the EMVS anywhere in the world, belong to FiMVO, respectively EMVO, and are licensed (not sold) to the End User. The End User has no rights in, or to, the System, 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 Agreement and the EU Directive on Falsified Medicines and the Delegated Regulation.
    2. FiMVO represents that it holds sufficient right, title and interest in and to the System to grant the license herein under this Agreement s.

# Data Protection and Ownership

* + 1. In accordance with Article 35, para. 1, h) of the Delegated Regulation, the structure of the System 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.
    2. As a principle, the Data contained in the EMVS belongs to the User generating this Data when interacting with the EMVS (‘whoever creates the Data, owns the Data’). The EMVS repositories system shall hold the following data components:

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

### Dynamic data i.e.:

#### 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

#### changes to the complete record (the "**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.

* + 1. 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.
    2. 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.
    3. 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, copied or downloaded from the EMVS for purposes outside the scope of the EU Directive on Falsified Medicines and the Delegated Regulation needs to be agreed by all the stakeholders owning that Data on a case-by-case basis in compliance with relevant legislation.
    4. In accordance with Article 35, para. 1, g) of the Delegated Regulation, the System shall maintain an Audit Trail of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations. Unless otherwise required to comply with any request by competent authorities, FiMVO shall not access the Audit Trail stored on its System and the Data contained therein without a 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, para. 1, b) of the Delegated Regulation.
    5. End User grants FiMVO a non-exclusive license to use End User’s Data solely for the Purpose.
    6. Unless otherwise required to comply with any request by competent authorities, FiMVO shall grant access to its System 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 FiMVO's own territory, unless otherwise required under the EU Directive on Falsified Medicines and the Delegated Regulation, or under relevant legislation applicable to FiMVO.
    7. In these instances, as referred to under Section 9.8 above, the owner of such Data has to be informed, as the case may arise, through their national organisations or representative associations (unless such information would be prohibited by law).

# Confidentiality

* + 1. FiMVO and the End User, each with respect to Confidential Information received from the other Party, undertake to:

### 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;

### 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 Agreement or the EU Directive on Falsified Medicines and the Delegated Regulation;

### 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 the best care;

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

### 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.

* + 1. The restrictions on use or disclosure of Confidential Information as defined above do not extend to information which:

### is or comes into the public domain through no breach of this Agreement;

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

### is independently developed by FiMVO or the End User;

### is required to be disclosed by law or by court or governmental order, provided that before making such disclosure, FiMVO or the End User, if permitted, gives the other Party immediate notice thereof, and gives 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 Agreement. In such case, FiMVO 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

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

# Limitation of Warranty and Liability

* + 1. Disclaimer of warranty. Except as otherwise provided in this Agreement, the System is provided “as is”, and FiMVO makes no warranties, whether express or implied, or statutory regarding or relating thereto. Specifically, without prejudice to FiMVO’s obligations under the EU Directive on Falsified Medicines and the Delegated Regulation, FiMVO does not warrant that the System will be free of errors and defects (whether apparent or hidden/latent) or will perform in an uninterrupted manner.
    2. To the maximum extent allowed by law, FiMVO 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 FiMVO had been informed of such purpose), including for latent or hidden defects, with respect to any part of the System.
    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’s claim, or any other indirect, special, incidental or consequential damages of any kind (the "**Indirect Damages**") whether based on a contractual breach, tort (including 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 System.
    4. In addition, without prejudice to FiMVO’s obligations under the EU Directive on Falsified Medicines and the Delegated Regulation, FiMVO shall not be held responsible or liable towards 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 System by such third parties.
    5. Liability Cap. FiMVO’s maximum aggregate liability towards the End User arising out of, or in connection with this 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 €20 000. The End User’s maximum aggregate liability arising out of, or in connection with this 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 €20 000.
    6. Exclusion. Nothing in this Agreement will exclude or limit the Parties’ liability:

### for fraud or wilful misconduct or gross negligence;

### for death or personal injury arising from the Party's negligence or that of its Representatives;

### breach of the anti-bribery legislation; and

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

* + 1. Losses suffered by other Users of the System. The Parties acknowledge and agree that any losses suffered by any other Users of the System in connection with this Agreement will be deemed to be actual losses suffered by FiMVO under this Agreement, and FiMVO will be entitled to recover such losses directly against the End User in accordance with this Section 11.

# Term and Termination

* + 1. The initial period of time of this Agreement being in force is 16 months as of the Effective Date but not exceeding the EMVS Implementation Phase. After the initial period of time, this Agreement will be tacitly renewed for additional periods of time of 12 months each, unless either party objects to such renewal by sending a notice in writing to the other at least ninety (90) days prior to the renewal date.
    2. Without prejudice to other remedies under applicable law, either Party is entitled to terminate this Agreement for cause, 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 Agreement and, (ii) the defaulting Party fails to cure such breach within ninety (90) calendar days after such cure has been demanded in writing if such breach is capable of being cured.
    3. Without prejudice to the above, FiMVO is entitled to terminate this Agreement immediately, without indemnity, (i) if the contract between EMVO and FiMVO for the use of the European Hub by FiMVO is terminated or expires for whatever reason, or (ii) if the End User is no longer authorised or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation.
    4. The expiration or termination of this Agreement shall not affect provisions thereof that by their terms and meaning are of a continuing nature, in accordance with Section 14.4 below.

# Changes and Updates to the System

* + 1. FiMVO may apply updates, changes and/or modifications to the System at any time in accordance with the following.
    2. Relevant Artifacts

For the EMVS, the Software Development Kit (the “**SDK**”) and the updates or amendments to the SDK shall be provided from time to time by FiMVO to the End User in accordance with the following:

### copy of the SDK documentation – (to be found at www.sws-nmvs.eu] in electronic form.

* + 1. Communication of the SDK

The SDK 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 FiMVO and copy to the FiMVO Helpdesk for record.

* + 1. Release Management

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

1. Emergency Fix

An Emergency Fix is used to correct urgent errors in the NMVS 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. 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.

1. 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.

1. 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 sixty (60) calendar days prior to becoming effectiveIf the deployment or installation of such updates, changes and/or modifications to the System imply a (temporary) restriction or interruption of the End User’s access to parts or all of the System, FiMVO shall provide the End User with reasonable prior notice that allows to mitigate the impact and shall take all diligent efforts to minimize any restriction or interruption.

## All updates, changes or modifications shall be the sole property of FiMVO.

## All maintenance, repair work, alterations, updates, changes and modifications of any nature whatsoever to the System shall be done at FiMVO’s discretion, subject to Section 13.1 above.

# General Provisions

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

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

## The End User must report the incidents he/she witnessed in relation with the use of and access to the System or any other component of the EMVS to FiMVO and respond to any request for information from FiMVO in a timely manner.

## The provisions of this Agreement which by their nature should survive termination, including without limitation Sections 10, 11, 14.5 and 15 shall remain in force for a term of five (5) years as from the Effective Date of this Agreement, unless extensions or stipulations are agreed between FiMVO and the End User and/or arising from the future contractual relations and unless earlier terminated.

## Upon termination of this Agreement, the End User must destroy all copies of the System, 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 the Delegated Regulation or under applicable law, in which case the End User shall inform FiMVO of such legal obligation and the basis thereof and shall keep all these copies securely.

# Governing law and dispute resolution

This Agreement and any contractual or non-contractual (including pre-contractual) matters in connection with their conclusion, validity, interpretation, enforcement, performance and termination shall be governed by and construed in accordance with the laws of Finland.

Any dispute between the parties arising out of or in connection with this Agreement and/or their conclusion, validity, interpretation, enforcement, performance and termination shall be submitted to and finally decided by arbitration in accordance with the Arbitration Rules of the Finland Chamber of Commerce. The number of arbitrators will be one, and the seat of arbitration will be Helsinki, Finland. The language of the arbitration will be Finnish.

# Definitions

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

* + 1. “**Confidential Information**” means

1. 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, FiMVO shareholders, third parties involved in the development, implementation, testing or operation of the System and of End Users;

1. all Data;
2. all information and software for or related to the System (including the System interface); and
3. 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 consider it to be confidential.
   * 1. “**Data**” means 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.
     2. “**Delegated Regulation**” means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
     3. “**Effective Date**” means the date on which this Agreement is signed.
     4. “**EMVS Implementation Phase**” means 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.
     5. “**End User Representative**” means any End User's authorised director, officer, employee or agent.
     6. “**EU Directive on Falsified Medicines**” means 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.
     7. “**European Hub**” means 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.
     8. “**European Medicines Verification Organisation**” or “**EMVO**” means the non-profit legal entity established to set up and manage the European Hub in accordance with the EU Directive on Falsified Medicines and the Delegated Regulation.
     9. “**European Medicines Verification System**” or “**EMVS**” means 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.
     10. “**Intellectual Property Rights**” means 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[[1]](#footnote-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).
     11. “**National Medicines Verification Organisation(s)**” or “**NMVO(s)**” means 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.
     12. “**National (Medicines Verification) System**” or “**NMVS**” means 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.
     13. “**Finnish Medicines Verification Organisation**” or “**FiMVO**” means the Finnish National Medicines Verification Organisation, which is a Party to this Agreement.
     14. “[National Contact Point, NCP] **National (Medicines Verification) System**” means the National Medicines Verification System that is under the responsibility of FiMVO.
     15. “**FiMVO Representative**” means a director, officer, employee or agent authorised by FiMVO, or FiMVO IT company.
     16. “**Personal Data**” means any and all information relating to an identified or identifiable individual as defined under the Data Protection Directive 95/46/EC of 24 October 1995, as will be repealed by the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 once it comes into effect on 25 May 2018, and national laws implementing the Data Protection Directive and the General Data Protection Regulation as applicable.
     17. “**Security Breach**” means 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.
     18. “**Terms**” means the terms set out in this Agreement entered into between FiMVO and the End User relating to the use and access by the End User to the System 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.
     19. “**Territory**” means the European Economic Area and Switzerland.
     20. “**User(s)**” means 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.

# Signatures

As an End User, or as a competent representative of the End User, the undersigned hereby confirms to have read and understood this Agreement and consents to and/or confirms that the End User consents to be bound by them. Where entering into this Agreement on behalf of a company, organisation, association or other legal entity, the undersigned hereby agrees – and declares and represents – that the undersigned is entitled and has the legal capacity to represent and bind such company, organisation, association or other legal entity, and that such company, organisation, association the undersigned represents consents to be bound by this Agreement. If the End User is operating under one (or more) legal entity(ies), (each) such legal entity must agree and be bound by this Agreement.

This Agreement has been drawn up and executed in two (2) identical copies (which may also be electronic), of which each Party has received one (1) copy.

|  |  |  |
| --- | --- | --- |
| Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |
| [**End User**] |  | **Suomen Lääkevarmennus Oy** |
|  |  |  |
| Name:  Title:  [**End User**] |  | Nina Ekholm-Wenberg  Chairman of the Board  **Suomen Lääkevarmennus Oy** |
| Name: Title: |  | Maija Gohlke-Kokkonen  General Manager |

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. [↑](#footnote-ref-1)