COOPERATION AGREEMENT

1. Parties

(i) 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

(ii) Company name:

Business ID/Company Number:

VAT Number:

Company Address :

(the "**Company**").

The Company is the representative of the marketing authorization holders listed in Appendix 2 in Finland.

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

2. Definitions

"Agreement" means this Cooperation Agreement and its appendices;

"Confidential Information" means any and all technical and/or commercial information and other material of a Party relating to, without limitations, its business, business plans, financial details, customers, partners, intellectual property, facilities, products, techniques and/or processes whether in oral, written or electronic form, that is specifically marked or otherwise communicated as being confidential at the time of disclosure or reasonably should be understood as being confidential. FiMVO's Confidential Information includes EMVO's documents and other confidential information;

"Data" means information uploaded, processed, transferred, generated or stored in the EMVS or the FiMVS as set out in the Directive and the Delegated Regulation (in particular its Article 33, paragraph 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;

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

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

"EMVS" means the European Medicines Verification System, which is set up and managed in accordance with Chapter VII of the Delegated Regulation. The EMVS consists of the European Hub and the National Systems and allows the wholesalers and retailers to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

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

"**FiMVO**" means the Finnish Medicines Verification Organisation, which is responsible for the implementation of the National System in accordance with the Directive and the Delegated Regulation;

"**FiMVS**" means the Finnish National Medicines Verification System implemented by FiMVO;

"**Intellectual Property Rights**" means patents of any type, design rights, utility models or other similar invention rights, copyrights, trade secrets, trademarks, trade names and service marks and any other intangible property rights, including applications and registrations for any of the foregoing, in any country, arising under statutory law or by contract and whether or not perfected, now existing or hereafter filed, issued, or acquired;

"**MAH**" means the Company as well as other holders of marketing authorization for a medicinal product with effect on the territory of Finland, during the term of this Agreement. MAH also includes parallel importers of medicinal products in Finland;

"**National (Medicines Verification) System**" means a national medicines verification system that is connected to the European Hub and allows the wholesalers and retailers to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

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

Any other capitalized terms not defined in this Agreement are given the meaning allocated to them in the Directive and/or the Delegated Regulation.

3. Background and purpose of the Agreement

In the application of the Directive and the Delegated Regulation, a National Medicines Verification System will be set up in Finland. The Finnish Medicines Verification System, FiMVS, will be part of the European Medicines Verification System and will be implemented by FiMVO by the end of 2018. FiMVS will be operational by February 2019 in accordance with the Directive and the Delegated Regulation.

According to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the National Medicines Verification System shall be borne by MAHs for medicinal products in the relevant market. Therefore, the Company, together with other MAHs, is responsible for the aforesaid costs of the FiMVS in the form of paying the fees in accordance with this Agreement. The Company and other MAHs shall each be severally liable for the amount of fees allocated to them.

The purpose of this Agreement is to agree on the implementation and maintenance of the FiMVS by FiMVO, the financing of the FiMVS, the invoicing of the Company by FiMVO and the Parties' related obligations.

The Parties agree that amendments to EU legislation regarding the Directive and the Delegated Regulation may lead to extra responsibilities on the Parties, in which case the Parties may need to update or amend this Agreement accordingly. Furthermore, the Parties agree to update or amend this Agreement, if necessary based on the agreement between FiMVO and EMVO or FiMVO and its IT service provider.

4. Obligations of FiMVO

FiMVO undertakes to:

(i) develop, implement and maintain the FiMVS in compliance with the Directive, Delegated Regulation and this Agreement;

(ii) take appropriate security measures to protect the integrity and safety of the FiMVS as well as the confidentiality of the Data in the FiMVS against e.g. Security Breaches or other similar risks;
(iii) cooperate in good faith with the Company and other MAHs in the development, testing, implementation, operation and maintenance of the FiMVS;
(iv) give access to the FiMVS, as set out in this Agreement, only to persons designated by the Finnish Medicines Agency ("**Fimea**") as licensed wholesalers and retailers of medicinal products and their authorised representatives so as to allow them and their necessary IT service providers access to the system when necessary; and
(v) process in the FiMVS the Data of MAHs that have signed an agreement with FiMVO and that have connected and entered into the European Hub either directly or via the connection of an affiliated company, unless otherwise required by Fimea.

FiMVO shall publish on its official website, or some other manner deemed appropriate by FiMVO, information about changes in the circumstances of its legal status (e.g., registered address and address of management, representative etc.) and on the process of the development and implementation of the FiMVS.

Upon due and lawful request in compliance with applicable law, FiMVO may provide the competent national authorities with access to the Company's Data available in the FiMVS within the scope specified in Article 39 of the Delegated Regulation, in which case FiMVO will inform the Company thereof without undue delay.

5. Obligations of the Company

The Company undertakes to:

(i) perform its obligations set out in the Directive, Delegated Regulation and this Agreement duly and in a timely manner;
(ii) timely pay the respective amounts according to Section 6 of this Agreement;
(iii) inform FiMVO in writing of any change in the circumstances of its legal status (e.g., registered address and address of management, representative etc.), and of any change in the status of the MAH's;
(iv) designate a contact person for the purposes of this Agreement and communicate it to FiMVO;
(v) Upon FiMVO's reasonable and detailed request, report to FiMVO on the performance of its obligations under this Agreement, the Directive and the Delegated Regulation
(vi) directly or indirectly connect and enter the Data to the European Hub (if applicable);
(vii) cooperate in good faith with FiMVO in the development, testing, implementation, operation and maintenance of the FiMVS; and
(viii) provide FiMVO with reasonably available information on all its subsidiaries and affiliates acting in the Finnish market directly or indirectly, including the name of the contact persons, details of its legal status: registered address, registration number and/or national identification code, tax number and other data as applicable for its identification.

The Company warrants that the Data relating to the medicinal products for which it is the MAH of, or the representative of the MAH, have been entered in the European Hub correctly, fully, accurately and not misleadingly, and that such Data will meet the requirements of the proper functioning of the FiMVS and EMVS in compliance with the Directive and the Delegated Regulation when used by other MAHs, wholesalers and retailers.

6. Financing of the FiMVS

6.1 Fees

The Company, together with other MAHs, shall pay to FiMVO an annual flat fee per each represented MAH for the development, testing, implementation, operation, maintenance and update of the FiMVS. The annual fee will cover the yearly costs of operation and further development of the FiMVS, Finland's share of the costs of the European Hub and all necessary and legally compulsory activities of FiMVO in relation to FiMVS.

If the Company represents more than one MAH, the aforesaid fees will be charged according to the number of MAHs represented.

The estimated costs of the annual fees, the set-up fees, and the detailed payment schedule are set out in Appendix 1 to this Agreement. The Company acknowledges that the fees set out in Appendix 1 are estimates and may change once the budget and amount of MAHs are confirmed. In such case, the fees in Appendix 1 will be updated accordingly as notified by FiMVO to the Company in writing.

FiMVO has the right to, at any time during the term of this Agreement, amend the fees, if FiMVO's service provider or EMVO changes its fees or charges additional fees to FiMVO or if the fees related to the development, testing, implementation, operation, maintenance, or update of the FiMVS increase due to any other reasons. FiMVO shall notify the Company of such amendment in fees without undue delay in advance and describe the reasoning behind the amendment.

6.2 Payment terms

All payments will be made in euro. The fees do not include any value added tax (VAT). The Company shall be responsible for the payment of any withholding taxes, similar taxes, duties levies and such payments relating to the fees payable under this Agreement.

Payment term is thirty (30) days net from the date of the invoice. Interest for delayed payments will accrue in accordance with the Finnish Interest Act. In addition to any other rights and remedies available to FiMVO, if the Company is in delay of its payment obligation by more than thirty (30) days from the written payment reminder provided by FiMVO to the Company, FiMVO shall i) notify Fimea of the non-fulfilment of the Company's obligation under Article 31 paragraph 5 of the Delegated Regulation and ii) reserve the right to suspend the access to the FiMVS until the due fulfilment of the payment obligations.

The Company's invoicing address or electronic invoicing details are set out in Appendix 1. The Company shall inform FiMVO immediately in case of any changes in its invoicing address by filling in and submitting a form available on FiMVO's website as set out in Appendix 1.

If the fees are paid by a third party on behalf of the Company, the Company shall in any case remain solely responsible and liable for the compliance with this Agreement, including the Directive and the Delegated Regulation.

7. Intellectual Property Rights

Subject to Section 8 (Ownership and right of Data), the Intellectual Property Rights to the FiMVS and the EMVS will be held by FiMVO, EMVO and/or their subcontractors and/or service providers. The Company and the users of the FiMVS and the EMVS will not obtain any Intellectual Property Rights to the FiMVS or EMVS.

8. Ownership and right of Data

Any Company entity that lawfully generates Data in the FiMVS or EMVS will be the owner of and responsible for such Data in accordance with Article 38 of the Delegated Regulation. Except for the Data listed under Article 33 paragraph 2 of the Delegated Regulation and the information on the status of a unique identifier for the sole purpose of verification (Article 38, paragraph 1 of the Delegated Regulation), the Data will not be accessible for any other party. However, as set out in Article 4(3) above, FiMVO may allow access to all Data in the FiMVS to national competent authorities as provided for under Article 39 of the Delegated Regulation.

The Company has the right of access only to the Data for medicinal products for which it is the MAH or is duly authorized for this purpose as the representative of the MAH. The Company bears full responsibility for its actions when accessing the Data.

FiMVO will only grant access to the FiMVS and the Data contained therein to competent authorities for its territory for the purposes set out in Article 39 of the Delegated Regulation and in so far as they concern FiMVO's own territory, unless otherwise required under the Directive, Delegated Regulation, or under relevant legislation applicable to FiMVO. In the aforesaid case, FiMVO will inform the Company without undue delay of granting access to the Company's Data (unless such information would be prohibited by law).

9. Processing of personal data

If either Party processes the other Party's Personal Data, the Parties shall conclude a separate data processing agreement before beginning the processing activities. The data processing agreement will include terms and conditions in accordance with applicable data protection laws, including the EU General Data Protection Regulation.

10. Security breaches

FiMVO shall be responsible for taking appropriate security measures to protect the confidentiality of the Data in the FiMVS, including against unauthorized access, interception or disruption, and to use appropriate efforts to ensure that no malicious software, malware or other code is introduced into the EMVS, or any component thereof, by FiMVO or any other third party under FiMVO's control.

If either Party becomes aware of a Security Breach that might have effects on the other Party, it shall notify the other Party without undue delay thereof. The notification shall contain: (i) the nature of the Security Breach, including the categories and number of persons affected, and the categories and number of relevant Data records; (ii) the consequences of the Security Breach; (iii) in case a Security Breach is caused by a fault or failure of a Party, such Party shall notify the other Party of the measures undertaken by the Party concerned to repair the Security Breach and limit its consequences; and (iv) the measures that are or will be undertaken by the Party concerned to prevent such Security Breach in the future.

In the event of a Security Breach, the Company shall upon FiMVO's request: (i) cooperate with FiMVO in investigating the Security Breach; (ii) take all reasonable steps to repair the Security Breach and limit its consequences; (iii) take all reasonable steps to prevent the recurrence of such Security Breaches in the future; and (iv) assist FiMVO in measures required by applicable law.

11. Confidentiality

For the purposes of this Agreement, the Parties may provide Confidential Information to each other. Each Party receiving Confidential Information from the other Party shall:

(i) use the other Party's Confidential Information only for the purposes of this Agreement or as otherwise provided under the Directive or the Delegated Regulation;
(ii) keep the other Party's Confidential Information secret and confidential and not disclose it to any third party, expect as expressly permitted under this Agreement or the Directive or the Delegated Regulation;
(iii) exercise the same degree of care and protection with respect to the other Party's Confidential Information as it exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with reasonable care; and
(iv) take necessary precautions to prevent unauthorised use or disclosure of the other Party's Confidential Information, and to notify immediately the other Party upon becoming aware of the same and take necessary measures in order to reduce the effects of such unauthorized misuse or disclosure.

Each Party may disclose the other Party's Confidential Information to its affiliates or subcontractors on a need to know basis for the purpose of this Agreement and under at least as stringent confidentiality obligations as set out in this Section 11. Notwithstanding this Section, either Party shall be allowed to disclose information to the extent required by a lawful request made or decision taken by a competent authority or court of law.

The confidentiality obligations set out in this Section 11 do not apply to material and information that:

(i) is generally available or otherwise public without the receiving Party being in breach of this Agreement; or
(ii) the receiving Party has received from a third party without breach of confidentiality; or
(iii) was in the possession of the receiving Party without confidentiality obligation prior to receiving the information from disclosing Party; or
(iv) the receiving Party has independently developed without using the information or material received from the disclosing Party.

Upon termination of this Agreement, the receiving Party shall return to the disclosing Party the Confidential Information received from it or, upon the disclosing Party's request, certify destruction of the same. The receiving Party shall, however, be entitled to retain such material as is required by applicable law.

The obligations under this Section 11 will remain in force after termination of this Agreement.

12. Force Majeure

Neither Party shall be liable for delay or damage caused by an impediment beyond the Party's control and which the Party could not have reasonably taken into account at the time of conclusion of this Agreement and the consequences of which the Party could not reasonably have avoided or overcome. A strike, lockout, boycott and other similar industrial action shall also be considered a force majeure event even when the Party concerned is the target or a party to such an action.

A force majeure event suffered by a subcontractor of a Party shall also be considered a force majeure event in relation to that Party if the work to be performed under subcontracting cannot be done or acquired from another source without incurring unreasonable costs or significant loss of time.

Each Party shall without delay inform the other Party in writing of a force majeure event and the termination of the force majeure event.

13. Limitation of liability

FiMVO does not warrant that the FiMVS will not contain any errors or defects (whether visible, hidden or likely to occur in the future). FiMVO does not warrant that the FiMVS will function without faults. FiMVO shall, however, use all reasonable efforts to ensure the proper functioning of the FiMVS.

FiMVO shall not be liable for the actions of EMVO or any other third party outside FiMVO's control. FiMVO shall not be liable for the content, integrity, or completeness of the Data in the FiMVS or the EMVS and for such Data being up to date.

Neither Party will be liable towards the other Party for any indirect or consequential damages. The total aggregate annual liability of a Party towards the other Party under this Agreement will be limited to the amount of fees paid or payable to FiMVO by the Company annually under this Agreement. The limitation of liability will not apply, if the damage has been caused by (i) wilful misconduct or gross negligence; (ii) breach of confidentiality and/or non-use obligations; or (iii) breach of Intellectual Property Rights.

14. Term and termination

This Agreement enters into force when it has been signed by the duly authorized representatives of both Parties.

Since this Agreement covers the execution of compulsory legal provisions as set out in the Directive, the Delegated Regulation, and possible other applicable legislation, both Parties acknowledge and agree that this Agreement may only be terminated when the Company no longer acts as a MAH or as a representative of any MAHs or when the applicable legislation ceases to apply to either the Company or FiMVO.

Furthermore, FiMVO shall have the right to terminate this Agreement without any liability to the Company, if the agreement between EMVO and FiMVO for the use of the European Hub is terminated for any reason.

Subject to the aforementioned, this Agreement shall remain in force for consecutive calendar years unless terminated in writing by either Party for convenience ninety (90) days prior to the end of the then current calendar year. This Agreement may also be terminated with immediate effect by written notice by the non-defaulting Party in the event that the other Party commits a material breach of this Agreement and fails to remedy such breach within thirty (30) days after having been given written notice in respect thereof.

In case this Agreement is terminated by either Party, the Company will have no rights whatsoever to be refunded of the already paid fees (neither as a whole nor pro rata).

Sections 7, 8, 11, 13 and 18 will survive the termination of this Agreement.

15. Amendment and assignment

Amendments and modifications to this Agreement are valid only if they are made in writing and signed by the duly authorized representatives of both Parties.

The Company may not assign this Agreement, in whole or in part, without FiMVO's prior written consent, which shall not be unreasonably withheld. Any attempted assignment in violation of this provision shall be invalid. FiMVO may assign this Agreement, in whole or in part to its successor, without the Company's consent at any time, it being agreed that FiMVO shall inform the Company about such assignment and the reasons thereof FiMVO's earliest convenience.

16. Anti-bribery and anti-corruption

Each Party agrees that it shall comply, at all times, with all applicable anti-corruption laws and regulations.

Either Party shall be entitled to terminate this Agreement immediately on written notice to the other Party, if the other Party is in breach of its obligations set out in this Section 16.

17. Entire Agreement

This Agreement constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes and replaces any prior proposals, negotiations, agreements and other written or oral communications between the Parties relating to the subject matter of this Agreement.

18. Governing law and dispute resolution

This Agreement is governed and construed under the laws of Finland, excluding its choice of law rules.

All disputes, controversies or claims relating to or arising out of this Agreement will first and foremost be settled in negotiations between the Parties. In the event that the negotiations do not lead to a solution, such dispute, controversy or claim will be finally settled 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 English, unless the Parties separately agree in writing that the language will be Finnish.

19. Appendices

Appendix 1 Fees and invoicing
Appendix 2 List of marketing authorization holders represented by the Company

If there is any discrepancy between the main body of this Agreement and the appendix, the main body of this Agreement prevails.

20. Signatures

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

Suomen Lääkevarmennus Oy

_____

Name: Maija Gohlke
Title: General Manager

Company Name:

_____

Name:
Title:

_____

Name:
Title:

Appendix 1 Estimated fees and invoicing plan

The estimated annual fees and the payment schedule are set out below. The fees are estimates and may change as the annual budgets of FiMVO and amount of MAHs are confirmed. Confirmed annual fees are announced on the FiMVO website and in writing to MAHs.

Annual fee, range estimation *5 000 – 10 000 euro/MAH*

New MAHs will be charged from the registration quarter onwards.

Time of registration	Fee
January - March	Full annual fee
April - June	3/4 of annual fee
July - September	2/4 of annual fee
October - December	1/4 of annual fee

The Company's invoicing address or electronic invoicing details are set out below. The Company shall inform FiMVO immediately in case of any changes in its invoicing address:

Company name:

Business ID:

VAT number:

Invoicing address:

Invoicing email address:

PO number: Valid until:

Appendix 2

List of MAHs represented by the Company:

Note! All MAHs must be listed, even when the signatory company and MAH are the same.

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