SERVICE AGREEMENT

This Service Agreement is made on [ ] 2018 by and between:

(i) **Nacionalinė vaistų verifikacijos organizacija** (*National Medicines Verification Organisation*), a public non-profit organization incorporated and existing under the laws of Lithuania, registered office at Lvovo str. 25, Vilnius, Republic of Lithuania, and registered in the Register of Legal Persons under No. 304548374 (the "**NVVO**"); and

(ii) **[ ]**, a marketing authorization holder incorporated and existing under the laws of [ ], company registration number [ ], whose registered office is at [ ] (the "**Company**").

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

1. Definitions

"**Agreement**" means this Service 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. NVVO'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 NMVS 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 Lithuanian laws, as applicable;

"**EMVO**" means the European Medicines Verification Organization, 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 medicines verification 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 medicines verification systems; it is set up and managed by EMVO;

"Intellectual Property Rights" 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 (including sui generis database rights resulting from Directive 96/9/EC of 11 March 1996), 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);

"**NVVO**" means the National Medicines Verification Organization, which is responsible for the implementation of the National System in Lithuania in accordance with the Directive and the Delegated Regulation;

"**NMVS**" means the Lithuanian national medicines verification system (repository) implemented by NVVO according to Article 32, paragraph 1 (b) of the Delegated Regulation 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;

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

"**Security Breach**" means event that endangers the security or the functioning of the EMVS or the NMVS, 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 NMVS.

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

2. Background and purpose of the Agreement

2.1. In the application of the Directive and the Delegated Regulation, the NMVS will be set up in Lithuania. The Lithuanian Medicines Verification System, NMVS, will be part of the European Medicines Verification System and will be implemented by NVVO by the end of 2018. NMVS will be operational by February 2019 in accordance with the Directive and the Delegated Regulation.

2.2. According to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the NMVS shall be borne by marketing authorization holders for medicinal products in the relevant market. Therefore, the Company, together with other MAHs, is responsible for the aforesaid costs of the NMVS.

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

2.4. 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 NVVO and EMVO or NVVO and its IT service provider.

3. Obligations of NVVO

3.1. NVVO undertakes to:

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

(ii) take appropriate security measures to protect the confidentiality of the Data in the NMVS;

(iii) cooperate in good faith with the Company and other MAHs in the development, testing, implementation, operation and maintenance of the NMVS;

(iv) give access to the NMVS only to persons designated by the State Medicines Control Agency ("**SMCA**") as licensed wholesalers and retailers of medicinal products and their authorised representatives so as to allow the necessary IT service providers to access the system when necessary; and

(v) process in the NMVS the Data of MAHs that have signed an agreement with NVVO and that have connected and entered into the European Hub, unless otherwise required by SMCA.

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

3.3. Upon due request in compliance with applicable law, NVVO may provide the competent national authorities with access to the Company's Data available in the NMVS within the scope specified in Article 39 of the Delegated Regulation, in which case NVVO will inform the Company within a reasonable time.

4. Obligations of the Company

4.1. The Company undertakes to:

(i) perform its obligations set out in the Directive, Delegated Regulation and this Agreement duly and in a timely manner and report to NVVO on the performance of such obligations as reasonably requested by NVVO;

(ii) timely pay the respective amounts according to Section 5 of this Agreement;

(iii) inform NVVO 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 marketing authorizations for medicinal products for which it is the holder;

(iv) designate a contact person for the purposes of this Agreement and communicate it to NVVO;

(v) report to NVVO on the performance of its obligations under this Agreement, the Directive and the Delegated Regulation;

(vi) directly connect and enter the Data to the European Hub;

(vii) cooperate in good faith with NVVO in the development, testing, implementation, operation and maintenance of the NMVS; and

(viii) provide NVVO with exhaustive and up-to-date information on all its subsidiaries and affiliates, including the name of the 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.

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

5. Financing of the NMVS

5.1 Fees

5.1.1. The Company, together with other MAHs, shall pay to NVVO an annual flat fee for the development, testing, implementation, operation, maintenance and update of the NMVS. The annual fee will cover the yearly costs of operation and further development of the NMVS, Lithuania's share of the costs of the European Hub and all necessary and legally compulsory activities of NVVO in relation to NMVS. The invoicing of the annual fees will begin from 2nd of January 2019 onwards.

5.1.2. In addition to the annual fees, the Company, together with other MAHs for medicinal products placed on the Lithuanian market, must pay a one-off entry fee determined by NMVO. This fee is payable within 30 (thirty) calendar days following the signing date of this Agreement. If the Company directly or indirectly (i.e. through a relevant industry association) participates in the financing of ramp-up costs (by

means of loans, service pre-payment or other agreed arrangements), NVVO reserves the right not to charge or to discount the one-off entry fee to the Company.

5.1.3. The estimated costs of the annual fees, one-off entry fee, 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 NVVO to the Company in writing.

5.1.4. NVVO has the right to, at any time during the term of this Agreement, increase the annual fees if NVVO's service provider or EMVO increases its fees or charges additional fees from NVVO or if the fees related to the development, testing, implementation, operation, maintenance or update of the NMVS increase due to any other reasons. NVVO shall notify the Company of such increases in fees in advance.

5.2 Payment terms

5.2.1. All payments will be made in euro, VAT to be added if required under the law. 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.

5.2.2. Payment term is thirty (30) days net from the date of the invoice. Interest for delayed payments will accrue in accordance with the Lithuanian Civil Code. In addition to any other rights and remedies available to NVVO, if the Company is in delay of its substantial payment obligation, NVVO shall i) notify SMCA 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 NMVS until the due fulfilment of the payment obligations.

5.2.3. The Company's invoicing address or electronic invoicing details are set out in Appendix 1. The Company shall immediately inform NVVO in writing (or by e-mail) in case of any changes in its invoicing address.

5.2.4. 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.

6. Intellectual Property Rights

The Intellectual Property Rights to the NMVS and the EMVS will be held by NVVO, EMVO and/or their subcontractors and/or service providers. The Company and the users of the NMVS and the EMVS will not obtain any Intellectual Property Rights to the NMVS or EMVS.

7. Ownership and right of Data

7.1. Any person that lawfully generates Data in the NMVS 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, NVVO may allow access to all Data in the NMVS to national competent authorities as provided for under Article 39 of the Delegated Regulation.

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

7.3. NVVO will only grant access to the NMVS 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 NVVO's own territory, unless otherwise required under the Directive, Delegated Regulation, or under relevant legislation applicable to NVVO. In the aforesaid case, NVVO will inform the Company of granting access to the Company's Data (unless such information would be prohibited by law).

8. 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.

9. Security breaches

9.1. If the Company becomes aware of a Security Breach, it shall notify NVVO immediately. 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) measures that are or will be undertaken by the Company to repair the Security Breach and limit its consequences; and (iv) the measures that are or will be undertaken by the Company to prevent such Security Breach in the future.

9.2. In the event of a Security Breach, the Company shall upon NVVO's request: (i) cooperate with NVVO 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 NVVO in measures required by applicable law.

10. Confidentiality

10.1. 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.

10.2. 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.

10.3. 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.

10.4. 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.

10.5. The obligations under this Section 10 will remain in force after termination of this Agreement.

11. Force Majeure

11.1. 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.

11.2. 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.

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

12. Limitation of liability

12.1. NMVS is provided "as is" and NVVO makes no warranties, whether express or implied, or statutory regarding or relating thereto. Specifically, without prejudice to the NVVO's obligations under the Directive and Delegated Regulation, NVVO does not warrant that the NMVS will be error and defect free (whether apparent or hidden/latent) or will perform in an uninterrupted manner.

12.2. To the maximum extent allowed by law, the NVVO 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 the NVVO had been informed of such purpose), including for latent or hidden defects, with respect to any part of the NMVS.

12.3. NVVO shall not be liable for the actions of EMVO and of the persons to whom access to the NMVS and the EMVS has been provided. NVVO shall not be liable for the content, integrity, or completeness of the Data in the NMVS or the EMVS and for such Data being up to date.

12.4. Neither Party will be liable towards the other Party for any indirect or consequential damages. The total aggregate liability of a Party towards the other Party under this Agreement will be limited to the amount of payments received by NVVO from the Company 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 obligations; or (iii) breach of Intellectual Property Rights.

13. Term and termination

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

13.2. 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 when the applicable legislation ceases to apply to either the Company or NVVO. Furthermore, NVVO shall have the right to terminate this Agreement without any liability to the Company, if the agreement between EMVO and NVVO for the use of the European Hub is terminated for any reason.

13.3. 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.

13.4. 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.

13.5. 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 6, 7, 10, 12 and 16 will survive the termination of this Agreement.

14. Amendment and assignment

14.1. 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.

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

15. 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.

16. Governing law and dispute resolution

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

16.2. 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 an amicable solution, such dispute, controversy or claim will be finally settled by Lithuanian courts.

17. Appendices

Appendix 1 Fees and invoicing

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

18. Signatures

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: _____
VšĮ "Nacionalinė vaistų verifikacijos organizacija"	[**Company**]
_____	_____
Name:	Name:
Title:	Title:

APPENDIX 1
FEE SCHEDULE

1. One-off entry fee

1.1. To cover the implementation costs of NMVS during the period from 2017 to 8th February 2019, a one-off entry fee must be paid by all the Companies who have a market authorization in Lithuania on 9th February 2019 and thereafter.

1.2. If the Company directly or indirectly (i.e. through a relevant industry association) participates in the financing of ramp-up costs (by means of loans, service pre-payment or other agreed arrangements), NVVO has the right not to charge or to discount the one-off entry fee to the Company.

1.3. The one-off entry fee is payable within 30 (thirty) calendar days following the signing date of the Agreement:

Payment deadline (dates inclusive)	**Fee (VAT excl.)**	**Discount**	**Amount to pay (VAT excl.)**
1 July 2018	€ 2000	50%	€ 1000
31 December 2018	€ 2000	25%	€ 1500
After 31 December 2018	€ 2000	No discount	€ 2000

1.4. NMVO must receive the entry fee from the Company by the relevant date in above Table for the Company to receive a discount. If the fee has been invoiced but not received by NMVO by the relevant cut-off date, an additional invoice for the difference between the amount invoiced for and the fee that would be payable in the next period will be issued by NMVO

1.5. The companies joining the NMVS after 9th February 2019 will also be required to pay a one-off entry fee of EUR 3000 to NMVO, in addition to the annual fee specified in paragraph 2 of this Appendix 1.

2. Annual flat fee

2.1. In line with EMVO recommendation, NMVO has decided for an annual flat fee contribution to be paid by the Company from February 2019.

2.2. The payment deadline for the annual flat fee is 9th February 2019 and thereafter by 2nd of March each year.

2.3. The annual flat fee is expected to be in the region of EUR 5200 - 7000 in 2019. The Company acknowledges that this sum is an estimate and may change once the budget for 2019 and the number of MAHs to be invoiced in 2019 are confirmed. In such case, the fee will be updated accordingly as notified by NMVO to the Company in writing.

2.4. The level of the annual flat fee will be based on actual cost of running the NMVS and NMVO short and long term. The Company acknowledges that the amount of the annual flat fee may fluctuate from time to time. The amount of the annual flat fee for any given year will be notified by NMVO to the Company in writing no later than by 31st of December during the previous calendar year.

Place and date: _____

VšĮ “Nacionalinė vaistų verifikacijos organizacija”

_____
Name:
Title:

Place and date: _____

[**Company**]

_____
Name:
Title: