

COOPERATION CONTRACT NO [REDACTED]

Association “Latvijas Zāļu verifikācijas organizācija”, registration No. 40008259320, legal address: Krišjana Barona street 15-50, Riga, LV-1011, Latvia (hereinafter referred to as “the LZVO”), represented by Inese Erdmane, acting on basis of articles of organisation,

AND

[Name of the company], registration No. [registration number], legal address: [legal address], [which is the authorised representative of the marketing authorisation holders listed in Appendix 1 of the Contract] (all collectively and individually hereinafter referred to as the “Company”), represented by [title1],[name]; [title2],[name]; [title3],[name]; [title4],[name], acting on basis of [legal basis], each hereinafter referred to as a “Party”, and together as the “Parties”,

WHEREAS:

- A) The LZVO is a non-profit organisation set-up by stakeholders in the medicines supply chain in Latvia pursuant to Article 31 of the Delegated Regulation, to establish and manage the LZVS in Latvia;
- B) The LZVO must conclude the Contract with the Company on a non-exclusive basis to co-finance costs of the LZVS and all other expenses to maintain and operate the LZVS;
- C) The LZVS is part of the EMVS and is implemented by the LZVO by the end of 2018. The LZVS is operational by February 2019 in accordance with the Directive and the Delegated Regulation;
- D) Pursuant to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the LZVS and all related activities must be borne by MAHs for Medicinal Products in the relevant market. The Company, together with other MAHs, is responsible for the abovementioned costs of the LZVS in the form of paying the fees pursuant to the Contract;
- E) The Company is the authorised representative of the MAHs listed in **Appendix 1** and concludes the Contract also on their behalf. The Company and the MAHs listed in Appendix 1 all are Parties to the Contract. The Company and each of the MAHs listed in Appendix 1 to the Contract are individually responsible for their fulfilment of the contractual obligations under the Contract. However, unless explicitly agreed otherwise, in respect of the MAHs listed in Appendix 1 only the Company is contractually liable for payment of the fees under the Contract;
- F) The purpose of the Contract is to agree on the implementation and maintenance of the LZVS by the LZVO, the financing of the LZVS, the invoicing of the Company by the LZVO and the Parties’ related obligations;
- G) The Parties agree that amendments to EU legislation relating to falsified medicines, including the Directive and the Delegated Regulation, may lead to extra responsibilities on the Parties, in which case the Parties may need to amend the Contract accordingly. Furthermore, the Parties agree to amend the Contract, if necessary, based on changes to the Contract between the LZVO and EMVO, or the LZVO and the IT service provider (with whom the LZVO has signed an agreement regarding implementation and operation of the LZVS);

NOW, therefore, the Parties conclude this Cooperation Contract (“Contract”) as follows:

1. DEFINITIONS

“Company” is the legal entity indicated on the front page of the Contract. The Company is also each and all of the entities listed in Appendix 1 of the Contract represented on basis of a power of attorney by the legal entity indicated on the front page of the Contract. Unless explicitly stated otherwise, references to the Company mean also references to the MAHs listed in Appendix 1 of the Contract;

“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, whether or not it is specifically marked or otherwise communicated as being confidential at the time of disclosure. The LZVO’s Confidential Information includes information provided by the EMVO under a non-disclosure Contract with the LZVO and other confidential information;

“Data” means information uploaded, processed, transferred, generated or stored in the EMVS or in the LZVS as set out in the Directive and the Delegated Regulation (in particular its Article 33(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 Latvian 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 medicines verification systems and allows wholesalers and persons authorised or entitled to supply medicinal products to the public 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;

“Intellectual Property Rights” means all patents and patent rights, trademarks and trademark rights, trade names and trade name rights, service marks and service mark rights, service names and service name rights, brand names, copyrights and copyright rights, trade dress, business and product names, logos, slogans, trade secrets, industrial models, utility models, design models, designs, rights in confidential information, software, know-how, rights in the nature of unfair competition rights and rights to sue for passing off, and all pending applications for and registration of patents, trademarks, service marks and copyrights together with all connected and similar or analogous rights in any country or jurisdiction for the full term thereof;

“LZVO” means the Latvian Medicines Verification Organisation, which is responsible for the implementation of the LZVS in accordance with the Directive and the Delegated Regulation;

“LZVS” means the Latvian National Medicines Verification System implemented by the LZVO;

“MAH” means the Company as well as other marketing authorisation holders, including parallel importers and parallel distributors, for a Medicinal Product with effect on the territory of Latvia;

“Medicinal Products” for the purposes of the Contract means medicinal products which are required by the Delegated Regulation to bear safety features on their packaging;

“Security Breach” means an event that endangers the security or the functioning of the EMVS (including, where applicable, the LZVS), including but not limited to any security breach 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 to the EMVS, including, where applicable, the LZVS.

2. SUBJECT OF THE CONTRACT

The LZVO is responsible for the development, implementation, operation and maintenance of the LZVS. The Company bears its part of the costs for the foregoing and the financing of the LZVO pursuant to provisions of the Contract.

3. RIGHTS AND OBLIGATIONS OF THE PARTIES

3.1. The LZVO undertakes to:

- 3.1.1. develop, implement, operate and maintain the LZVS in compliance with the Directive, Delegated Regulation and the Contract. The LZVO may also substantially amend, suspend or even terminate the LZVS without any indemnity being due to the Company;
- 3.1.2. take appropriate security measures to protect the integrity and safety of the LZVS, as well as confidentiality and safety of the Data in the LZVS;
- 3.1.3. cooperate in good faith with the Company in the development, testing, implementation, operation and maintenance of the LZVS;
- 3.1.4. give access to the LZVS only to wholesalers and persons authorised or entitled to supply the Medicinal Products whose identity, role and legitimacy has been verified by the LZVO as required by Article 37(b) of the Delegated Regulation, as well as to give access to their IT software provider(s) when necessary;
- 3.1.5. process in the LZVS the Data of the Companies that have signed a Contract with the LZVO and that have connected and entered into the European Hub, unless otherwise required by the State Agency of Medicines of Latvia (“ZVA”); and
- 3.1.6. upon due request in compliance with applicable law, provide Latvia’s national competent authorities with access to the Company’s Data available in the LZVS within the scope specified in Article 39 of the Delegated Regulation, in which case the LZVO informs the Company thereof without undue delay, unless doing so is prohibited by law.

3.2. The Company undertakes to:

- 3.2.1. perform its obligations set out in the Directive, Delegated Regulation and the Contract duly and in a timely manner;
- 3.2.2. timely pay fees to the LZVO in accordance with Section 4 of the Contract;
- 3.2.3. inform the LZVO in writing of any relevant change in its legal status, invoicing or contact details, or the marketing authorisation(s) for Medicinal Product(s) of which the Company is the holder, where the result of such change would be that the Company’s Data is no longer held in the LZVS;
- 3.2.4. upon the LZVO’s reasonable request, report to the LZVO on the performance of the Company’s obligations under the Contract, the Directive and the Delegated Regulation;
- 3.2.5. designate a contact person for the purposes of the Contract and communicate it to the LZVO;
- 3.2.6. directly or indirectly connect and enter the Data to the European Hub (if applicable);

- 3.2.7. cooperate in good faith with the LZVO in the development, testing, implementation, operation and maintenance of the LZVS; and
- 3.2.8. provide the LZVO with the information necessary for execution of the Contract, and the payment of fees, including, without limitation, details of its legal status: registered address, registration number, tax number and other data as applicable for the identification of the Company and any third person nominated by the Company to pay on its behalf fees due to the LZVO. The Company immediately notifies the LZVO of any changes in the information that has been supplied to the LZVO.
- 3.3. The Company warrants that the Data relating to the Medicinal Products for which it is the MAH, are entered in the European Hub correctly, fully, accurately and not misleadingly, and that such Data ensures the proper functioning of the LZVS and the EMVS in compliance with the Directive and the Delegated Regulation.

4. FINANCING OF THE LZVS

- 4.1. The Company pays the following fees to the LZVO in the amounts and by the dates as reasonably set by the LZVO in its decisions adopted pursuant to its articles of association:
 - 4.1.1. a one-off registration fee – for covering the implementation costs of the LZVO until 9 February 2019, and especially but not limited to the investment in and setup of the IT system to run the LZVS; and
 - 4.1.2. an annual flat fluctuating fee – for covering, *inter alia*, the annual costs of the operation and further development of the LZVS, costs inherited from the EMVO and all necessary and legally compulsory activities of the LZVO.
- 4.2. If the Company represents MAHs for the Medical Products within the Latvian territory, the applicable fees are charged from the Company according to the number of MAHs as set in Appendix 1 to the Contract. The number of MAHs in the Appendix 1 to the Contract may be reduced no later than by 31 October each year.
- 4.3. The LZVO has the right to, at any time during the term of the Contract, amend the fees as unilaterally set by the LZVO in its decisions with a prior written notice in any event including (but not limited to) instances where the LZVO's service provider or the EMVO changes its fees or charges additional fees to the LZVO, or if the fees related to the development, testing, implementation, operation, maintenance or update of the LZVS increase or decrease for any other reasons.
- 4.4. All payments are made in Euro and are exclusive of value added tax (VAT). The Company is responsible for the payment of any withholding taxes, similar taxes, duties levies and such payments relating to the fees payable under the Contract.
- 4.5. Payment term is 30 (thirty) days from the date of the invoice. The invoice from the LZVO is not raised against a purchase order number from the Company.
- 4.6. The invoice is considered to be paid when the money is received in the LZVO bank account in full amount. The contractual penalty for late payments is 8.5% per annum. Payment of the contractual penalty does not release the Company from the obligation to compensate losses.
- 4.7. If the fees are paid by a third person on behalf of the Company, it in any case remains solely liable for fulfilment of its obligations under the Contract, the Directive and the Delegated Regulation.

5. ACCESS TO THE LZVS

- 5.1. As of 9 February 2019, a valid Contract, no undue payments, including the contractual penalties, are cumulative requirements for accessing the Company's Data on the LZVS.
- 5.2. In addition to any other rights and remedies available to the LZVO, if the Company fails to pay an invoice within 14 (fourteen) days of the invoice due date, the LZVO may:
 - 5.2.1. notify the ZVA of the non-fulfilment of the Company's obligation under Article 31(5) of the Delegated Regulation; and
 - 5.2.2. suspend access to the LZVS in respect of the Company's Data until all overdue invoices are settled.
- 5.3. Termination of the Contract by either of the Parties or a failure to settle the invoice for more than 14 (fourteen) days is subject to immediate suspension of access to the Company's Data on the LZVS by the LZVO. No separate warning is sent regarding the suspension.
- 5.4. The LZVO resuspends the access to the Company's Data on the LZVS within 5 (five) working days from the moment the obstacles for suspension of the access are eliminated.

6. INTELLECTUAL PROPERTY RIGHTS

The Intellectual Property Rights to the LZVS are held by the LZVO (and/or its subcontractors) and to the EMVS – by the EMVO (and/or its subcontractors). For the avoidance of doubt, the Company and the users of the LZVS and the EMVS do not obtain any Intellectual Property Rights to the LZVS or the EMVS.

7. OWNERSHIP AND ACCESS TO DATA

- 7.1. The ownership of (and access to) the Data is determined in accordance with Articles 38 and 39 of the Delegated Regulation. Any person that lawfully generates Data in the LZVS is the owner of the said Data.
- 7.2. The LZVO only grants access to the LZVS and the Data contained therein to Latvia's national competent authorities for the purposes outlined in Article 39 of the Delegated Regulation unless it is otherwise required to do so under the Directive, Delegated Regulation or other applicable legislation.

8. SECURITY BREACHES

- 8.1. The LZVO is responsible for taking appropriate security measures to protect the confidentiality of the Data in the LZVS, including against unauthorised access, interception, intervention or disruption.
- 8.2. If either Party becomes aware of a Security Breach that might affect the other Party or the Data, it notifies the other Party immediately, indicating:
 - 8.2.1. the nature of the Security Breach, including the categories and number of persons affected, and the categories and number of relevant Data records;
 - 8.2.2. the consequences of the Security Breach;
 - 8.2.3. measures that are or is undertaken by the Company or the LZVO as the case may be to repair the Security Breach and limit its consequences; and
 - 8.2.4. the measures that are undertaken by the Company or the LZVO as the case may be to prevent such Security Breach in the future.

- 8.3. In the event of a Security Breach, the Party who has made a notification to the other Party under this Section 8, upon request of the other Party:
 - 8.3.1. cooperates with the other Party in investigating the Security Breach;
 - 8.3.2. takes all reasonable steps to repair the Security Breach and limit its consequences;
 - 8.3.3. takes all reasonable steps to prevent the recurrence of such Security Breaches in the future; and
 - 8.3.4. assists the other Party in measures required by the law.

9. CONFIDENTIALITY

- 9.1. For purposes of the Contract, the Parties may provide Confidential Information to each other. Each Party receiving Confidential Information from the other Party:
 - 9.1.1. uses the other Party's Confidential Information only for the purposes of the Contract or as otherwise provided under the Directive or the Delegated Regulation;
 - 9.1.2. keeps the other Party's Confidential Information secret and confidential and does not disclose it to any third person, except as expressly permitted under the Contract or the Directive or the Delegated Regulation; and
 - 9.1.3. takes necessary precautions to prevent unauthorised use or disclosure of the other Party's Confidential Information and notifies immediately the other Party upon becoming aware of the same and takes necessary measures in order to reduce the effects of such unauthorised misuse or disclosure.
- 9.2. 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 the Contract and under at least as stringent confidentiality obligations as set out in this Section 9.
- 9.3. The confidentiality obligations set out in this Section 9 do not apply to material and information that:
 - 9.3.1. is generally available or otherwise public without the receiving Party being in breach of the Contract; or
 - 9.3.2. the receiving Party has received from a third person without breach of confidentiality; or
 - 9.3.3. was in the possession of the receiving Party without any confidentiality obligation prior to receiving the information from disclosing Party; or
 - 9.3.4. the receiving Party has independently developed without using the information or material received from the disclosing Party.
- 9.4. Upon termination of the Contract, the receiving Party returns to the disclosing Party the Confidential Information received from it or, upon the disclosing Party's request, certifies destruction of the same. The receiving Party, however, is entitled to retain such material as is required by the law.

10. FORCE MAJEURE

- 10.1. Neither Party is 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 the Contract and the consequences of which the Party could not reasonably have avoided or overcome. A strike, lockout, boycott and other similar industrial action is also considered a force majeure event even when the Party concerned is the target or a party to such an action.

- 10.2. A force majeure event suffered by a subcontractor of a Party is also considered a force majeure event in relation to that Party if the work to be performed by a subcontractor cannot be done or acquired from another source without incurring unreasonable costs or significant loss of time.
- 10.3. Each Party without delay informs the other Party in writing of a force majeure event and the termination of the force majeure event.

11. LIMITATION OF LIABILITY

- 11.1. The LZVO does not warrant that the LZVS does not contain any errors or defects (whether visible, hidden or likely to occur in the future). The LZVO does not warrant that the LZVS functions without faults.
- 11.2. The LZVO is not liable for the actions of the EMVO and of the persons to whom access to the EMVS and, where applicable, the LZVS, has been provided. The LZVO is not liable for the content, integrity, or completeness of the Data in the LZVS or the EMVS and for such Data being up to date.
- 11.3. The LZVO is not liable towards the Company for any special, indirect, incidental, punitive or consequential damages, loss of goodwill or reputation, whether arising out of the Contract, tort, or otherwise. The total aggregate annual liability of the LZVO towards the Company and all of the MAHs listed in Appendix 1 is limited to the amount of payments received under the Contract by the LZVO from the Company in that year when the dispute arose.

12. TERM AND TERMINATION

- 12.1. The Contract enters into force when it has been mutually signed by the Parties and is concluded for an undefined period.
- 12.2. Since the Contract covers the execution of compulsory legal provisions as set out in the Directive and the Delegated Regulation, the Parties acknowledge and agree that the Contract may only be terminated by either Party when the Company no longer acts as a MAH in Latvia or when the applicable legislation ceases to apply to either the Company or the LZVO. Furthermore, the LZVO has the right to terminate the Contract without any liability to the Company, if the Contract between the EMVO and the LZVO for the use of the European Hub is terminated for any reason.
- 12.3. Notwithstanding Clause 12.2, the Contract remains in force unless terminated in writing by either Party with a 90 (ninety) day prior written notice to the other Party.
- 12.4. The Contract may also be terminated with immediate effect by a written notice by the non-defaulting Party in the event that:
- 12.4.1. the other Party breaches Section 9 obligations under the Contract;
 - 12.4.2. the other Party breaches other obligations under the Contract that is so substantial that it defeats the purpose of the Parties in concluding the Contract (as described in the Recitals) or makes performance of the Contract entirely or partially impossible and gives the non-breaching Party the right to terminate the Contract and take legal action for losses, after giving the breaching Party 30 (thirty) days to remedy the non-performance; or
 - 12.4.3. the other Party's legal protection proceedings, out-of-court legal protection proceedings, or insolvency proceedings have been initiated, or a decision has been adopted to stop its operations.

- 12.5. In case of termination of the Contract by either Party the Company has no rights whatsoever to a refund of fees already paid to the LZVO (neither as a whole nor *pro rata*). For the avoidance of doubt, the Company remains liable for any fees that are due to the LZVO and unpaid at the date of termination of the Contract.
- 12.6. Sections 7, 9, 10, 11, 12, and Clauses 13.4 and 13.5 survive termination of the Contract.

13. OTHER PROVISIONS

- 13.1. Amendments to the Contract are valid only if they are made in writing and signed by the duly authorised representatives of the Parties.
- 13.2. A Party cannot assign or otherwise transfer any of their rights or obligations under the Contract without the other Party's prior written consent, which may not be unreasonably withheld. Notwithstanding the above, the LZVO may assign or otherwise transfer any of its rights or obligations under the Contract. The LZVO informs the Company of such assignment or transfer at the LZVO's earliest convenience.
- 13.3. The Contract constitutes the entire agreement between the Parties with respect to the subject matter of the Contract and supersedes and replaces any prior proposals, negotiations, Contracts and other written or oral communications between the Parties relating to the subject matter of the Contract.
- 13.4. The construction, validity and performance of the Contract and all non-contractual obligations arising from or connected with the Contract is governed by, and construed in accordance with, the laws of the Republic of Latvia.
- 13.5. Any dispute, controversy or claim arising out of or relating to the Contract, or its breach, termination or invalidity, must be settled in the Latvian Chamber of Commerce and Industry Court of Arbitration (*in Latvian: Latvijas Tirdzniecības un rūpniecības kameras Šķīrējtiesa*) in Riga in accordance with the UNCITRAL Arbitration Rules. The language of the arbitration is English. For monetary disputes in the value not exceeding EUR 50,000 (fifty thousand euro) the number of arbitrators is one, but for monetary disputes exceeding EUR 50,000 (fifty thousand euro) or for other kind of disputes the number of arbitrators is three.
- 13.6. Any notices, correspondence, documents and other communication in relation to the Contract must be prepared in English, in writing and sent to the addresses of the Parties indicated in Appendix 1 of the Contract. The documents are regarded as duly delivered to the other Party if sent by registered mail, delivered in person against signature, or by e-mail.
- 13.7. The Contract has been drawn up and executed in 2 (two) identical copies (which may also be electronic) of which each Party receives 1 (one) copy.

For the LZVO:

For the Company:

Inese Erdmane

[●]

Date: [●]

Date: [●]

APPENDIX 1

Contact and invoicing details of the Parties

The LZVO:	
Name	Latvijas Zāļu verifikācijas organizācija
Registration No.	40008259320
VAT Registration No.	LV40008259320
Address	Krišjāņa Barona street 15-50, Riga, LV-1011, Latvia
Contact person	Inese Erdmane
Contact person title	Chairwoman of the Board
E-mail address	inese.erdmane@lzvo.lv
Phone No.	+371 29485950

The Company must ensure that the invoicing address and other contact information specified below is correct and up to date during the term of the Contract. The Company must fill in the below form for itself and one form for each of the MAHs which the Company represents for purposes of the Contract. Should the address, other contact information or number of the MAHs change, it is the responsibility of the Company to inform the LZVO immediately by sending an updated Appendix 1. If the data in the tables are not updated, the Company bears all related costs (regarding re-issuance of the invoices etc.).

The Company:	
Name	
Registration No.	
Legal Address	
Postal Address	
Contact person #1 name	
Contact person title	
E-mail address	
Phone No.	
Contact person #2 name	
Contact person title	
E-mail address	
Phone No.	

Invoicing details for the Company and the MAHs (if any):		
Name of legal entity to be invoiced:		
Registration No.		
Invoice address: (if different to the Company address):		
Contact person for invoices:	Name:	
	E-mail:	
	Phone no.:	
VAT number of legal entity to be invoiced:		
Bank name, BIC/SWIFT code:		
IBAN number:		
Bank account number, sort code:		
Other bank information:		
Purchase order (PO) number required?	Yes / No	If YES, please send PO number by e-mail info@lzvo.lv
Any other special invoicing instructions?	Yes / No	If YES, please provide precise details:

List of MAHs represented by the Company in Latvia

The Company represents the following MAH No. 1:	
Name	
Address	
Alert contact person	
Alert e-mail address	
Alert contact person phone number	

The Company represents the following MAH No. 2:	
Name	
Address	
Alert contact person	
Alert e-mail address	
Alert contact person phone number	

The Company represents the following MAH No. 3:	
Name	
Address	
Alert contact person	
Alert e-mail address	
Alert contact person phone number	