

# COOPERATION AGREEMENT

## 1. Parties

(i) SMVS Schweizerische Gesellschaft für die Verifizierung von Arzneimitteln GmbH, whose registered office is at Baarerstrasse 2, 6300 Zug (hereinafter referred to as “**SMVS**”)

and

(ii) [...] (VAT number/commercial register number: [...]), whose registered office is at [...] (hereinafter referred to as the “**Company**”)

Both SMVS and the Company are hereinafter referred to individually as a “Party” and collectively as the “Parties”.

## 2. Definitions

“**Agreement**” means this Cooperation Agreement and its appendices;

“**Delegated Regulation**” means the Commission Delegated 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, as amended from time to time;

“**Directive**” means the Directive 2011/62/EU of the European Parliament and of the Council 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 (Falsified Medicines Directive) and the relevant implementing laws, insofar as applicable;

“**TPA**” means the Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act – *Bundesgesetz vom 15. Dezember 2000 über Arzneimittel und Medizinprodukte, Heilmittelgesetz, HMG, SR 812.21*);

“**Law**” means collectively the provisions of the TPA and its ordinances enacted pursuant thereto, the Delegated Regulation and the Directive;

“**Confidential Information**” means any and all technical and/or commercial information and other material of a Party relating to, without limitation, 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. Confidential Information of SMVS includes documents and other confidential information of EMVO;

“**Data**” means information uploaded or transferred to, processed, generated or stored in the EMVS or the NVMS-System in accordance with Article 17a of the TPA and the future ordinance enacted pursuant thereto, the Directive and the Delegated Regulation (in particular Article 33(2) thereof);

**“Security Breach”** means an event that endangers the security or the functioning of the EMVS or the NVMS-System, 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, and the unauthorised upload of Data or the upload of unlawful Data to the EMVS or the NVMS-System;

**“Company”** is a pharmaceutical entity, which is registered in a Swiss or Liechtenstein commercial register as an active entity. The Company has one or more Swissmedic authorisations;

**“Marketing Authorisation Holders” (“MAHs”)** are the Company and all other holders of marketing authorisations for medicinal products, which are valid in the territories of Switzerland and Liechtenstein during the term of this Agreement;

**“EMVO”** is the European Medicines Verification Organisation, which is the non-profit legal entity established to set up and manage the European Hub in conformity with the Delegated Regulation;

**“EMVS” (“EMVS System”)** is the European Medicines Verification System, which is set up and managed in accordance with Chapter VII of the Delegated Regulation. The EMVS persons entitled to supply medicinal products to verify the authenticity of medicinal products in accordance with the Law;

**“European Hub”** or **“EU 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;

**“National System” (“NMVS”, “NMVS-System”, National Medicines Verification System)** is the national medicines verification system for Switzerland and Liechtenstein connected to the European Hub that allows the wholesalers and persons authorised and entitled to supply medicinal products in Switzerland and Liechtenstein to verify the authenticity of medicinal products and decommission the unique identifier in conformity with the Law;

“**LIMVO**” (LiMVO Stiftung für die Verifizierung von Arzneimitteln in Liechtenstein) is the Liechtenstein Medicines Verification Organisation and the organisation responsible for implementing, in cooperation with SMVS, the NMVS-System in conformity with the Law;

“**SMVO**” (SMVO Schweizerischer Verband für die Verifizierung von Arzneimitteln) is the Swiss Medicines Verification Organisation, a non-profit association of stakeholders that is the sole shareholder of SMVS. It is the organisation responsible for ensuring that SMVS implements the NMVS-System in conformity with the Law;

“**NMVO**”, National Medicines Verification Organisation comprises the SMVO and the LiMVO, the two organisations responsible for implementing the NMVS-System in Switzerland respectively in Liechtenstein in accordance with the law in cooperation with the SMVS.

“**SMVS**” (SMVS Schweizerische Gesellschaft für die Verifizierung von Arzneimitteln GmbH) works on behalf of the LiMVO and the SMVO and is responsible for the implementation of the NMVS-System in conformity with the Law;

“**National Competent Authorities**” (“**NCAs**”) are the national authorities concerned, i.e. the Swiss Federal Office of Public Health, Swissmedic and the Liechtenstein Health Department.

### **3. Background and purpose of the Agreement**

An NMVS System will be established in execution of the Law. The NMVS-System is a component of the EMVS System.

The Law obliges the MAHs of medicinal products in the respective market to bear the costs for the management, development, implementation, operation and maintenance of the NMVS System. As a result, the Company will be responsible for the above-mentioned costs of NMVO and SMVS and will pay fees to SMVS in accordance with this Agreement. The Company will be severally liable for the fees that it is required to pay.

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

The Parties note that amendments to the Law may lead to changes in the Parties' obligations so that they may need to update or amend this Agreement accordingly. Furthermore, the Parties agree to update or amend this Agreement, if necessary, on the basis of the agreement between LiMVO and EMVO or between NMVO and its IT service provider.

#### **4. Obligations of SMVS**

SMVS undertakes to

(i) develop, test, implement, operate, update and maintain the NMVS-System in accordance with the Law and this Agreement;

(ii) take appropriate security measures to protect the integrity and safety of the NMVS-System and the confidentiality of the Data in the NMVS-System against, for example, Security Breaches or other similar risks and to comply with the applicable legislation;

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

(iv) give access to the NVMS-System described in this Agreement only to authorised wholesalers and persons entitled to supply medicinal products so as to allow them and their IT service providers access to the NVMS-System when necessary;

(v) process in the NVMS-System the Data of MAHs that have signed an agreement with SMVS and that have connected with the European Hub either directly or via an affiliated company;  
and

(vi) if there is an NMVS-System alarm due to suspected falsification, work together with the Company and the NCAs to completely uncover the truth about the case and to provide the necessary information.

SMVS shall publish, on its official website or in some other manner deemed appropriate by SMVS, information about changes in its legal status (e.g. registered office, address of the management, representatives) and on the status of the development and implementation of the NMVS-System.

Upon receipt of a justified request pursuant to the relevant statutory provisions, SMVS may provide the NCAs with access to the Company's Data which are available in the NMVS-System.

## **5. Obligations of the Company**

The Company undertakes to

- (i) perform its obligations in accordance with the Law and this Agreement properly and in a timely manner;
- (ii) pay the respective amounts pursuant to clause 6 of this Agreement in a timely manner;
- (iii) inform SMVS in writing of any change in its legal status (e.g. registered office, address of the management, representatives) and of any change in the status of the MAHs;
- (iv) designate a contact person – single point of contact (SPOC) – for the purposes of this Agreement and communicate this to SMVS (Appendix 2);
- (v) upon receipt of a justified and detailed request from SMVS, report to SMVS on the performance of its obligations under this Agreement and the Law;
- (vi) directly or indirectly connect with the European Hub and enter the Data there (if applicable);

(vii) if there is an NMVS-System alarm due to suspected falsification, work together with SMVS and the NCAs to completely uncover the truth about the case and to provide the necessary information;

(viii) cooperate in good faith with SMVS in the development, testing, implementation, operation and maintenance of the NMVS-System;

(ix) provide SMVS with the information that is reasonably available on all its subsidiaries and affiliated companies acting directly or indirectly in the Swiss and Liechtenstein markets, which according to the definition of “Company” are not subject to this Agreement, including the names and details of contact persons and the legal status of the subsidiaries and affiliated companies, for example, their registered office, Swiss Business Identification Number (UID), GS1 Global Location Number (GLN) and other data used for identification (Appendix 3); and

(x) upon request from SMVS, have its SPOC submit annually a self-declaration via the self-declaration online portal, listing the medicinal product packs sold in the territory concerned and the relevant ex factory turnover.

The Company warrants that the Data of the medicinal products for which it is the MAH or the MAH’s representative have been entered in the European Hub correctly, fully, accurately and unambiguously, and that such Data will meet the requirements of the proper functioning of the NMVS-System and the EMVS in compliance with the Law when used by other MAHs, wholesalers and persons entitled to supply medicinal products.

## **6. Financing of SMVS and the NMVS-System**

### **6.1 Fees**

The Company shall pay SMVS an annual fee for the management services of NMVO and SMVS and for the development, testing, implementation, operation, maintenance and updating of the NMVS-System. The annual fee will cover the yearly costs of operating, maintaining and updating the NMVS-System, Switzerland’s and Liechtenstein’s share of the costs of EMVO and all necessary and mandatory statutory activities of NMVO and SMVS in relation to the NMVS-System.

The invoicing of the annual fees as set forth in detail in Appendix 1 will begin with the official launch date of the NMVS-System, but not before 9 February 2019.

In addition to the annual fees, the Company will be required to pay a one-time membership fee for the costs of establishing the NMVS-System. SMVS will, starting from August 2018, charge a one-time fee for these costs.

The amount of the annual fees, the one-time membership fee and the detailed payment schedule are set out in Appendix 1 to this Agreement.

SMVO has the right to adjust the annual fees for the following year.

## **6.2 Payment terms**

All payments will be made in Swiss francs. All fees are exclusive of value added tax (VAT).

Payment is net thirty (30) days from the invoice date. SMVS i) may notify the NCA of the Company's failure to fulfil its obligations under Article 17a of the TPA and ii) reserves the right to suspend access to the NVMS-System until the Company has fulfilled its payment obligations.

The Company's invoicing address and/or electronic invoicing details are set out in Appendix 1. The Company shall inform SMVS of any changes in its invoicing address without delay.

## **7. Ownership of and rights to Data**

Any company that lawfully generates Data in the NMVS-System or the EMVS will be the owner of and responsible for the correctness of such Data unless Article 17a of the TPA or the future concretizing ordinance enacted pursuant thereto or Article 38 of the Delegated Regulation provides otherwise. Except for the Data listed in Article 33(2) of the Delegated Regulation and the information on the status of a unique identifier for the sole purpose of verification (Article 38(1) of the Delegated Regulation), the Data will not be accessible to any other party. However, as set out in the last paragraph of clause 4, SMVS may, in accordance with Article 39 of the Delegated Regulation and the relevant provisions of the future ordinance on Art. 17a TPA, allow the NCAs access to all of the Data in the NMVS-System.



The SMVS grants the NCAs access to the NMVS system and the data contained therein within the framework of existing legal bases for their respective territories and for the purposes specified in Article 39 of the delegated regulation and in the relevant provisions of the future ordinance for Art. 17a TPA. In the case referred to above, SMVS shall immediately inform the Company of the access granted to the Company's data (unless the disclosure of this information is prohibited by law).

## **8. Security Breaches**

NMVO will take appropriate security measures to protect the confidentiality of the Data in the NMVS-System, including providing protection against unauthorised access, interception or disruption. It undertakes to take all necessary security measures to ensure that no malicious software, malware or other code is introduced into the EMVS, or any component thereof, by SMVS or any other third party under the control of SMVS.

If either Party becomes aware of a Security Breach that might affect the other Party, it shall notify the other Party without delay. The notification must contain information on

(i) the nature of the Security Breach, including the categories and number of persons affected and the categories and number of relevant Data entries;

(ii) the consequences of the Security Breach;

If a Security Breach is caused by the fault or failure of a Party, the breaching Party must notify the other Party of

(i) the measures undertaken by the breaching Party to remedy the Security Breach and limit its consequences; and

(ii) the measures that are or will be undertaken by the breaching Party to prevent such Security Breaches in the future.

In the event of a Security Breach, the Company shall, upon request from SMVS,

- (i) cooperate with SMVS in investigating the Security Breach;
- (ii) take all reasonable steps to remedy 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 SMVS in measures required by applicable laws.

## **9. Confidentiality**

For the purposes of this Agreement, the Parties may provide each other with Confidential Information. Where one Party (the “Receiving Party”) receives Confidential Information from the other Party (the “Disclosing Party”), it must

- (i) use the Disclosing Party’s Confidential Information only for the purposes of this Agreement or as otherwise provided under the Directive, the Delegated Regulation or in Art. 17a TPA and its future concrete regulation;
- (ii) keep the Disclosing Party’s Confidential Information secret and confidential and not disclose it to any third party unless expressly permitted to do so under this Agreement, the Directive, the Delegated Regulation or in accordance with the relevant provisions of the TPA and its ordinances;
- (iii) exercise the same degree of care and provide the same degree of protection in respect of the Disclosing Party’s Confidential Information as it would do in respect of similar proprietary and confidential information of its own, but in no event exercise or provide less than reasonable care; and
- (iv) take the necessary precautions to prevent unauthorised access to or unauthorised disclosure of the Disclosing Party’s Confidential Information and, upon becoming aware of such an event, immediately notify the Disclosing Party and take the necessary measures to reduce the effects of such unauthorised use or disclosure.

Each Party may disclose to its affiliated companies or subcontractors the other Party's Confidential Information on a need-to-know basis for the purpose of this Agreement and under at least as stringent confidentiality obligations as set out in clause 9. Notwithstanding this section, either Party may disclose information to the extent necessary to comply with a lawful request or decision by a competent authority or a competent court.

The confidentiality obligations set out in clause 9 do not apply to material and information which

(i) are generally available or otherwise public without a breach of this Agreement by the Receiving Party; or

(ii) the Receiving Party has received from a third party without a breach of the Receiving Party's confidentiality obligations; or

(iii) were, without a breach of the Receiving Party's confidentiality obligations, in the possession of the Receiving Party prior to its receiving the information from the Disclosing Party; or

(iv) the Receiving Party has itself developed without using the information or material received from the Disclosing Party.

Following the 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, shall certify that the Confidential Information has been destroyed. The Receiving Party will, however, be entitled to retain materials received insofar as it is required to do so by applicable laws.

The obligations in clause 9 will remain in force following the termination of this Agreement.

## **10. Force majeure**

Neither Party will be liable for delay or damage caused by an impediment beyond that Party's control and which the Party could not have reasonably taken into account at the time of concluding 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 will also be considered an event of force majeure even if the Party affected is the target of or a party to such an action.

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

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

#### **11. Warranty/limitation of liability**

SMVS does not warrant that the NVMS-System will be free from faults or defects. SMVS must make every reasonable effort to ensure that the NVMS-System functions properly.

The liability of SMVS will only be unlimited if it is guilty of

- (i) wilful misconduct; or
- (ii) gross negligence.

Under no circumstances will either Party be liable for lost profits.

SMVS will be liable for the acts and omissions of its employees.

SMVS will not be liable for the acts of EMVO or other third parties that are beyond the control of SMVS. SMVS is not liable for the content, integrity or completeness of the Data contained in the NVMS-System or in the EMVS or for such Data being up to date.

#### **12. Term and termination**

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

This Agreement is concluded for a minimum term of five years and will be extended thereafter automatically for five additional years at a time unless it is terminated by one of the Parties giving 12 months' written notice to the end of any year. The foregoing is without prejudice to the right to terminate the Agreement for good cause.

Good cause exists in particular where

- (i) the Company no longer acts as a MAH or as a representative of any MAHs;
- (ii) the applicable legal provisions cease to apply to either the Company or SMVS;
- (iii) the Agreement between EMVO and LiMVO is terminated for any reason;
- (iv) the other Party breaches its obligations under this Agreement.

If this Agreement is terminated by either Party, the Company will not be entitled to a refund of fees already paid (either in their entirety or on a pro rata basis).

Clauses 7, 9, 11 and 16 of this Agreement will remain in effect following the termination of this Agreement.

### **13. Amendment and assignment**

Amendments and additions to this Agreement are valid only if they are made in writing and signed by the duly authorised representatives of the respective Parties. The Company may not assign this Agreement, either in whole or in part, without the prior written consent of SMVS, which must not be unreasonably withheld. Any attempted assignment in violation of this provision will be invalid. SMVS may, at any time, assign this Agreement to its successor without obtaining the Company's consent; it is agreed that SMVS will inform the Company about such assignment and the reasons for it as soon as possible.

#### **14. Provisions to combat active and passive bribery**

The Parties acknowledge that they must, at all times, comply with all applicable laws and regulations to combat active and passive bribery.

Either Party will be entitled to terminate this Agreement in writing with immediate effect if the other Party is in breach of its obligations in clause 14.

#### **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 drafts, 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**

This Agreement is governed by and construed in accordance with Swiss law. The Parties consent to the jurisdiction of the courts at the place where SMVS has its registered office.

Prior to taking any legal action, the Parties will endeavour to mutually resolve any disputes or differences of opinion of any kind whatsoever by concluding a settlement agreement.

#### **17. Appendices**

Appendix 1 Fees and invoicing

Appendix 2 List of the Marketing Authorisation Holders represented by the Company

Appendix 3 Contact details of the Company's Single Point of Contact (SPOC)

In the case of any conflicts between the body of the Agreement and the appendices, the provisions contained in the body of the Agreement will prevail.

**18. Signatures**

This Agreement has been executed in two (2) counterparts (which can also be provided in electronic form). Each Party will receive one (1) counterpart.

Place, date

Place, date

\_\_\_\_\_  
SMVS GmbH, family name, given name

\_\_\_\_\_  
Company, family name, given name

\_\_\_\_\_  
SMVS GmbH, family name, given name

\_\_\_\_\_  
Company, family name, given name

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Appendix 1:

**1. One-time membership fee**

Ex factory turnover for prescription drugs in CHF million	Application by 30.08.2018	Application by 31.12.2018	Application by 01.01.2019
0 to 30,000,000	5,000	7,500	10,000
30,000,001 to 200,000,000	10,000	15,000	20,000
200,000,001 and over	20,000	25,000	30,000

**2. Annual recurring fees**

Fees for using the system will be charged, for the first time, as from 9 February 2019, at the earliest, and will be based on sales data from 2018.

Basic fixed fee: CHF 1,500.00			
Sales-based component		Volume-based component	
Ex factory turnover for prescription drugs in CHF thousand	Annual fee in CHF	Prescription packs sold	CHF per pack
0–100,000	0.00	0 to 50,000	0.009
100,001–3,000,000	2,000.00	50,001 to 1,000,000	0.007
3,000,001–10,000,000	5,000.00	1,000,001 to 2,000,000	0.005
10,000,001–30,000,000	15,000.00	2,000,001 and over	0.003
30,000,001–50,000,000	20,000.00		
50,000,001–70,000,000	25,000.00		
70,000,001–100,000,000	30,000.00		
100,000,001–150,000,000	40,000.00		
150,000,001–200,000,000	50,000.00		
200,000,001–300,000,000	60,000.00		
300,000,001 and over	70,000.00		

The recurring fee for using the NMVS-System is made up of the following components:

- **Basic fixed fee**  
The basic fixed fee is the same for all companies.
- **Sales-based scale of fees**  
The sales-based component is calculated based on the turnover generated in the respective previous year through ex factory sales of prescription drugs to persons entitled to supply medicinal products in Switzerland and Liechtenstein (self-declaration).
- **Volume-based scale of fees**  
The volume-based component is calculated based on the prescription drugs sold to persons entitled to supply medicinal products in Switzerland and Liechtenstein (self-declaration) in the respective previous year. The amount is progressively reduced. For example, the price per pack for the first 50,000 packs is CHF 0.009 per pack and for the next 950,000 packs CHF 0.007 per pack, etc.



Appendix 2

**Contact details of the Company's Single Point of Contact (SPOC)**

Form of address: \_\_\_\_\_  
Title: \_\_\_\_\_  
Given name: \_\_\_\_\_  
Family name: \_\_\_\_\_  
Position: \_\_\_\_\_  
  
Phone: \_\_\_\_\_  
E-mail: \_\_\_\_\_

non-binding translation

Appendix 3

**List of the Marketing Authorisation Holders represented by the Company**

(if necessary, make additional copies of this sheet of paper)

Entity: \_\_\_\_\_

UID: \_\_\_\_\_

GLN: \_\_\_\_\_

Street: \_\_\_\_\_

Additional address information: \_\_\_\_\_

Postcode/town or city: \_\_\_\_\_

**Represented by**

Form of address: \_\_\_\_\_

Title: \_\_\_\_\_

Given name: \_\_\_\_\_

Family name: \_\_\_\_\_

Position: \_\_\_\_\_

Phone: \_\_\_\_\_

E-mail: \_\_\_\_\_

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