Belgian Medicines Verification Organisation vzw
Regus kantoren - Luxemburgstraat 20
9140 TEMSE - België

**MARKETING AUTHORISATION HOLDER AGREEMENT FOR THE OPERATIONAL PHASE**

Between:

**Belgian Medicines Verification Organisation vzw**, with its registered address at Luxemburgstraat 20, 9140 TEMSE, Belgium, registered with the Belgian Crosspoint Bank for Enterprises under the number 0675.740.701 (hereafter "**BeMVO**");

And: (company)**,**

with its registered address at

registered with the official companies' register of (country),

under the number (registration number),

with SPOR OMS Registration number (hereafter the **"Company")**

Both hereafter referred to as a "Party", and together as the "Parties".

Whereas:

(i) In line with the EU Falsified Medicines Directive 2011/62/EU ("FMD") and the EU Delegated Regulation 2016/161 the „Delegated Regulation"), the constituencies (as defined in the statutes of BeMVO) representing the marketing authorisation holders ("MAHs") active in Belgium created BeMVO, a non-for profit organisation.

(ii) The Company is a Marketing Authorisation Holder (MAH) as defined in this Agreement.

(iii) BeMVO's primary non-profit purpose is to act as National Medicines Verification Organisation in Belgium, to establish and manage the National Repository System ("BeMVS"), as well as to establish and manage the link with the European Hub in compliance with the European Medicines Verification System ("EMVS") and all Blueprint requirements.

(iv) The BeMVS is part of the EMVS. The BeMVS will be operational by 9 February 2019 in accordance with the Directive and the Delegated Regulation.

(v) As the Delegated Regulation stipulates, the cost for the purposes described above and all related activities to fulfil these purposes must be borne by the MAHs.

(vi) In view of this, BeMVO must conclude a cooperation agreement with the MAHs defining the scope of the services to be rendered by BeMVO to the MAHs and the costs for such services.

(vii) In line with the blueprint approach, BeMVO has opted for a yearly flat fee contribution to be paid by the MAHs as from 2019.

The purpose of this Agreement is to agree on the management and maintenance of the BeMVS by BeMVO, the invoicing of the Company by BeMVO and the Parties' related obligations.

The Parties therefore agree as follows:

**1. Definitions**

"**Agreement**" means this cooperation agreement and its appendices;

"**BeMVO**" means the Belgian Medicines Verification Organisation that is a Party to this Agreement, which is responsible for the implementation and the management of the National Medicines Verification System for Belgium and Luxembourg in accordance with the Directive and the Delegated Regulation;

"**BeMVS**" means the Belgian National Medicines Verification System, as implemented and managed by BeMVO; The BeMVS is a supra-national system that will provide the functionalities as stipulated in the Directed Regulation for End Users in Belgium and in Luxembourg;

"**Confidential Information**" means all commercial and/or technical information and other material of a Party relating to, *inter alia*, its business, financial details, customers, partners, intellectual property, facilities, products, techniques or processes, whether in writing, oral, or in electronic form, that is marked or communicated as being confidential at the time of disclosure or reasonably should be understood as being confidential;

"**Data**" means any information relating to individual medicinal products that are uploaded, processed, transferred, generated, enhanced or stored on or through the EMVS or the BeMVS as foreseen under the Directive and the Delegated Regulation (in particular its Article 33, para. 2);

"**Data Protection Legislation**" means the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 ("GDPR") and any applicable national legislation on privacy and/or data protection in Belgium and/or Luxembourg;

"**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;

"**Directive**" or "**Falsified Medicines Directive"** or "**FMD**" 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;

**"End User"** means any wholesaler, pharmacy or other person authorized or entitled to supply Medicinal Products to the public as foreseen under the Directive and the Delegated Regulation or as otherwise foreseen under applicable law.

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

"**EMVS**" or "**European Medicines Verification System**" means the European system for medicines verification, set up and managed in accordance with Chapter VII of the Delegated Regulation; EMVS consists of the European Hub and the National Systems, and allows End Users to verify the authenticity of Medicinal Products in accordance with the Directive and the Delegated Regulation;

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

"**Intellectual Property Rights**" means any and 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, trade and business names, domain names, know-how, rights in computer software, proprietary marketing materials, trade secrets, rights in good will or to sue for passing off, rights in trade dress or get-up, topography rights, rights in confidential information (including know-how, proprietary marketing materials and trade secrets), to the extent applicable, 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);

"**MAH(s)**" or "**Marketing Authorisation Holder(s)**" means any holders of a marketing authorisation for a Medicinal Product with effect on the territory of Belgium and/or Luxembourg, as defined in the Directive and the Delegated Regulation. MAH(s) also includes parallel importers of Medicinal Products in these countries;

"**Medicinal Products**" means medicinal products that are required by the Delegated Regulation or the Directive, including any extension by the national authorities based on article 2 (c) of the Delegated Regulation, to bear safety features on their packaging;

"**National Medicines Verification System**" or "**National System**" or "**NMVS**" means a national or supranational medicines verification system that is connected to the European

Hub and allows End Users to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

"**Personal Data**" means personal data as defined under the applicable Data Protection Legislation;

"**Security Breach**" means an event that endangers the security or the functioning of the EMVS (including, where applicable, the BeMVS), 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 BeMVS;

"**SPOR OMS**" means Organisation Management Services for SPOR data, a programme of the European Medicines Agency for the centralised management of master data in pharmaceutical regulatory processes in four domains (substance, product, organisation, and referential data), as further explained on the website of the European Medicines Agency (https://spor.ema.europa.eu/sporwi/)

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

## 2. Obligations of BeMVO

BeMVO undertakes to:

(i) develop, implement, manage and maintain the BeMVS in compliance with the Directive, the Delegated Regulation and this Agreement;
(ii) take appropriate security measures to protect the integrity and safety of the BeMVS and of the Data in the BeMVS;
(iii) cooperate in good faith with the MAHs and the End Users in the development, testing, implementation, operation and maintenance of the BeMVS;
(iv) give access to the BeMVS only to End Users authorised or entitled to supply medicinal products whose identity, role and legitimacy has been verified by BeMVO as required by the Delegated Regulation; and
(v) process in the BeMVS the Data of MAHs that have signed a cooperation agreement with BeMVO and that have connected with the European Hub.

## 3. Obligations of the Company

The Company undertakes to:

(i) perform its obligations as set out in the Directive, the Delegated Regulation and this Agreement, duly and in a timely manner;
(ii) pay the fees to BeMVO in accordance with this Agreement;

(iii) inform BeMVO in writing of any relevant change (this includes changes to the information mentioned in Annex 2) in the status of the marketing authorisation(s) for Medicinal Product(s) of which the Company is the holder;

(iv) designate all relevant contact persons (as mentioned in Annex 2) for the purposes of this Agreement and communicate them to BeMVO;

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

(vi) cooperate in good faith with BeMVO in the development, testing, implementation, operation and maintenance of the BeMVS; and

(vii) provide BeMVO with all up-to-date information requested for the execution of this Agreement, including for the payment of fees.

The Company warrants that

i. the Data relating to the Medicinal Products for which it is a MAH, will be entered in the European Hub correctly, fully, and accurately, in compliance with the Directive and the Delegated Regulation and in compliance with the data load specifications provided by BeMVO and EMVO;

ii. the Data for all serialized packs that have been brought on the market in Belgium before 9P$^{th}$P February 2019 will be entered in the European Hub no later than 8P$^{th}$P February 2019;

iii. the Data for serialized packs that are brought on the market in Belgium as from 9P$^{th}$P February 2019 will be entered in the European Hub before the packs are released to the market;

iv. For as long as required by NCA, the relation between the MAH's product code (GTIN) and the Belgian National Code (CNK) will be communicated before the data of these Medicinal Products are entered in the European Hub.

**4. Financing of BeMVS - fees**

(i) The Company agrees to pay the fees as set out in Annex 1 of this Agreement. These fees will be charged to cover, inter alia, the yearly costs of the operation and further development of the BeMVS and the BeMVO IT System, costs inherited from the EMVO and all necessary and legally compulsory activities of BeMVO

(ii) All payments will be made in Euro. All fees expressed in Annex 1 are exclusive of 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.

(iii) Payment term is thirty (30) days from the date of the invoice. Interest for delayed payments will accrue in accordance with the European Communities (Late Payment in Commercial Transactions) Regulations 2012.

(iv) In addition to any other rights and remedies available to BeMVO, if the Company fails to pay an invoice within sixty (60) days of the invoice due date, BeMVO reserves the right to: (a) notify the competent authorities of the non-fulfilment of the Company's obligation

under Article 31(5) of the Delegated Regulation, and (b) suspend access to the BeMVS in respect of the Company's Data until all overdue invoices are correctly paid.

(v) In case a fee mentioned in Annex 1 is paid by a third party, acting in name and/or on behalf of the Company, the Company will always remain solely responsible and liable for compliance with this Agreement (including payment obligations), and with the Directive and the Delegated Regulation.

(vi) The Company must ensure that the invoicing address and other contact information specified in the Company Identification form in annex 2 is correct and up to date. Should the address or other contact information change, it is the responsibility of the Company to inform the BeMVO immediately.

(vii) In case a third party supplier qualification process is in place at the Company, BeMVO will provide the necessary information allowing for such qualification prior to payment of invoices.

(viii) BeMVO commits itself to properly manage the development of the BeMVS and the IT System, its operations and its activities. An essential focus of BeMVO will be to minimise its costs where possible, while always ensuring full compliance with the applicable laws and regulations.

(ix) The level of the yearly fee contribution will be agreed upon by voting at the General Assembly of BeMVO upon proposal of its Board of Directors. Both Parties agree that the amount of the yearly fee (IT-cost and operational cost of BeMVO divided by number of MAHs) may fluctuate from time to time.

(x) BeMVO has the right to, at any time during the term of this Agreement, amend the fees, if BeMVO's service provider or EMVO changes its fees or charges additional fees to BeMVO or if the fees related to the development, testing, implementation, operation, maintenance, or update of the BeMVS increase or decrease. BeMVO shall notify the Company in writing of such amendment in fees at least 90 days in advance, and describe the reasoning behind such amendment.

(xi) The Parties agree that when European legislation regarding Falsified Medicines and guidelines lead to extra responsibilities, an **addendum or annex** to this Agreement will need to be entered into, that will outline in more detail the rights and obligations of both Parties with regard to the subject matter of this Agreement. Such addendum will not jeopardize the rights of BeMVO with regard to the stipulations on fee payment as mentioned in this Agreement.

(xii) All amounts paid by the MAH are definitely acquired by BeMVO and are non-reimbursable. Each Party guarantees that all Confidential Information received from the other Party before, during and after the conclusion of the Agreement shall remain confidential.

## 5. Limitation of liability

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

BeMVO shall not be liable for the actions of EMVO, of the persons to whom access to the EMVS and the BeMVS has been provided, or of other parties outside BeMVO's control. BeMVO shall not be liable for the content, integrity, or completeness of the Data in the BeMVS or the EMVS and for such Data being up to date.

BeMVO shall not be liable for any impact resulting from the bad quality of Data or incomplete Data loaded by the Company or a third party. The Company will be solely responsible to load its Data in a correct and complete way in the BeMVS. The Company shall hold BeMVO harmless from any claims resulting from the loading of incorrect, incomplete or bad-quality Data by the Company.

Neither Party shall be liable towards the other Party or any third party under or in connection with this Agreement or its termination, in contract, pre-contract, tort or otherwise, for (i) any economic loss (including loss of revenues, profits, contracts, business or anticipated savings); (ii) any loss of goodwill or reputation; (iii) any damage direct or indirect to the Company, IT, or communications infrastructure; or (iv) physical injuries. These losses include any direct, indirect, special, incidental, statutory, punitive or consequential losses or damages as well as any losses or damages caused by interruption of operations.

Without prejudice of the foregoing, the total aggregate annual liability of a Party towards the other Party under this Agreement will in any case be limited to the amount of fees paid or payable to BeMVO by the Company annually under this Agreement. This limitation of liability will not apply, if the damage has been caused by (i) wilful misconduct or gross negligence or (ii) breach of confidentiality (in which case the total liability of BeMVO towards all MAHs together will be limited to 250.000 euros in aggregate).

## 6. Ownership of Data and access to Data

Ownership of (and access to) the Data shall be determined in accordance with Articles 38 and 39 of the Delegated Regulation.

BeMVO will only grant access to the BeMVS and the Data contained therein to Belgium's national competent authorities for the purposes outlined in Article 39 of the Delegated Regulation, unless BeMVO is otherwise required to do so under the Directive, the Delegated Regulation or other applicable legislation.

## 7. Intellectual Property Rights

The Intellectual Property Rights to the BeMVS will be held by BeMVO (and/or its subcontractors and/or IT Service Provider).

The Intellectual Property Rights to the European Hub will be held by EMVO (and/or its subcontractors and/or IT service provider).

## 8. Processing of Personal Data

BeMVO shall in respect of any Personal Data received from the Company:

(i) process such Personal Data only to the extent necessary to perform this Agreement, and only subject to the instructions and authorisation of the Company;

(ii) adopt and maintain appropriate security measures for processing Personal Data in order to protect such data against unauthorised or accidental access, loss, alteration, disclosure or destruction, and against all other unlawful forms of processing of such data;

(iii) take all reasonable steps to ensure that its officers, employees and agents are aware of any comply with this clause;

(iv) promptly comply with requests from the Company requiring BeMVO to amend, transfer or delete such Personal Data;

(v) provide full co-operation and assistance to the Company if it receives a complaint, correspondence, notice or request from a data subject under applicable Data Protection Legislation, e.g. to obtain access to Personal Data; and

(vi) shall not process or otherwise transfer any Personal Data outside of the European Economic Area without the Company's prior written consent.

## 9. Security Breaches

If a Party becomes aware of a Security Breach that might affect the other Party, it shall notify the other Party immediately. The notification shall contain:

- the nature of the Security Breach, including the categories and number of persons affected, and the categories and number of relevant Data records;
- the consequences of the Security Breach;

- the measures that are or will be undertaken to repair the Security Breach and limit its consequences; and
- the measures that are or will be undertaken to prevent such Security Breach in the future.

In the event of a Security Breach, the Party who made a notification to the other Party under this clause shall, upon request of the other Party:

- cooperate with the other Party to investigate the Security Breach;
- take all reasonable steps to repair the Security Breach, to limit its consequences, and to prevent the recurrence of such Security Breach in the future; and
- assist the other Party in measures required by applicable law.

**10. Anti-bribery and anti-corruption**

Each Party confirms and warrants that it shall at all time comply with all applicable anti-bribery and anti-corruption legislation, as relevant for this Agreement.

Each Party shall have the right to terminate this Agreement immediately upon written notice to the other Party, in case the other Party is in breach of its obligations under this section.

**11. Confidentiality**

Each Party receiving Confidential Information from the other Party shall:

- 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;
- keep the other Party's Confidential Information confidential and not disclose it to any third party, except as expressly permitted under this Agreement or the Directive or the Delegated Regulation;
- 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 confidential information, but in no case less than with reasonable care; and
- take all necessary precautions to prevent unauthorised use or disclosure of the other Party's Confidential Information, and notify immediately the other Party upon becoming aware of the same and take necessary measures in order to reduce the effects of such unauthorised 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 Agreement.

The confidentiality obligations set out in this article do not apply to information that:

- is generally available or otherwise public without the receiving Party being in breach of this Agreement; or
- the receiving Party has received from a third party without breach of confidentiality; or
- was in the possession of the receiving Party without any confidentiality obligation prior to receiving the information from disclosing Party; or
- 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 all Confidential Information received from it or, upon the disclosing Party's request, certify destruction of it. The receiving Party shall, however, be entitled to retain such material as is required by applicable law.

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

## 12. Force Majeure

No Party shall be liable for a delay or damage or failure to perform its obligations hereunder if this results from a cause or circumstance beyond the Party's reasonable control, including without limitation earthquake, labour disputes, shortages of supplies, actions of governmental entities, riots, war, fire, flood, storm, revolution, acts of terrorism, civil commotion strike, lockout, boycott and other similar industrial 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. If an event of force majeure occurs, the date(s) for performance of the obligation affected shall be postponed for as long as is necessary by the event of force majeure, provided that if any event of force majeure continues for a period of or exceeding three (3) months, each Party shall have the right to terminate this Agreement forthwith by written notice to the other Parties.

## 13. Termination

Since this Agreement covers the execution of compulsory legal provisions (mentioned in the Directive, the Delegated Regulation, and other legislation), both Parties understand and agree that this Agreement may be terminated when the Company no longer has activities as a MAH in Belgium or when the applicable legislation ceases to apply to either the Company or BeMVO.

Also, BeMVO shall have the right to terminate this Agreement without any liability to the Company, if the agreement between EMVO and BeMVO for the use of the European Hub is terminated for any reason whatsoever. In the event of termination, the Company will have no rights whatsoever to be refunded for fees already paid (neither as a whole nor pro rata).

This Agreement shall remain in force unless terminated in writing by either Party on at least ninety (90) calendar days' prior written notice to the other Party.

This Agreement may 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) calendar days after having been given written notice.

In the event that this Agreement is terminated by either Party, the Company will have no rights to a refund of fees already paid to BeMVO (neither as a whole nor pro rata).

**14. Miscellaneous**

a. In the event that the roll- out of the BeMVS or the EMVS as a whole or the development of the IT-System more specifically would be postponed, all development activities and ramp-up activities may need to be suspended.
b. 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.
c. This Agreement shall be governed by the laws of Belgium. Jurisdiction shall lie exclusively in the competent courts of Brussels. Prior to initiating any legal action arising under or relating to this Agreement, a Party shall provide the other Party written notice of a dispute and the Parties shall actively and in good faith negotiate with a view to speedy resolution of such dispute within thirty (30) business days of the receipt of such notice.
d. The Company may not assign this Agreement, in whole or in part, without BeMVO's prior written consent, which shall not be unreasonably withheld; however, the Company may assign its rights and obligations under this Agreement to an affiliate company or in connection with the sale of all or substantially all of its assets or the merger, acquisition or other consolidation of the Company with or into another party and BeMVO's consent shall not be required hereunder in connection therewith. BeMVO may assign this Agreement to a successor organization, in whole or in part, without the Company's consent at any time upon notice to the Company.
e. Amendments and modifications to this Agreement are valid only if they are made in writing and signed by the duly authorised representatives of both Parties.

Made and entered into in on ,in

two original counterparts, each Party agrees to having received one original counterpart.

**BeMVO**

Name: Ann Adriaensen
Function: Chairman of BeMVO
Date: 02/01/2024
Signature:

[**NAME OF COMPANY**]

Name:
Function:
Date:
Signature:

Name:
Function:
Date:
Signature:

## Annex 1: FEES

This annex (hereafter "Annex 1") is an annex to the Cooperation Agreement between BeMVO and the Company (as defined hereunder).

1. Registration Fee

The one-time registration fee is due by any MAH who has products, in scope for FMD in Belgium, on the market.

The one-time registration fee is set to € 10.000.

2. Annual Fee

The Company will pay an annual MAH user fee to BeMVO as from 2019. An invoice will be issued to the Company each year in January and will be due for payment within 30 (thirty) days.

The amount of the annual fee will be notified by BeMVO to the Company in writing no later than November of the previous calendar year.

The annual fee under the Cooperation Agreement for 2024 is € 6.000 (excl. VAT) for each MAH.

Companies with a lower turnover for the Medicinal Products in scope for Belgium can apply for a reduced annual fee. The reduced annual fee can be approved by BeMVO under following conditions:

- The MAH must take the initiative and request to be eligible for a reduced annual flat fee
- The reference year is Y-2 (ex. 2022 for the 2024 flat fee)
- The MAH must bring sufficient proof of the lower turnover for the products in scope. Such proof can consist of the following elements (not exhaustive list): official financial accounts, reports from a company auditor, external market measurement data, … The documentation needs in each case to include the list of Medicinal Products that have been considered in this regard.
- BeMVO can request at any moment additional information.

BeMVO reserves the right to reject the request at its own discretion, independent of the elements and information that has been provided by the MAH.

The current defined thresholds for a reduced flat fee and the estimated annual amounts are as follows:

| **Current defined category** | **Annual Flat Fee** |
|---|---|
| MAH Turnover < €1.000.000 | € 3 750 (without VAT) |
| MAH Turnover < €100.000 | € 1 500 (without VAT) |

BeMVO has the right to define new turnover categories for a reduced flat fee each year.