**PARTICIPATION AGREEMENT**

This Participation Agreement (“Agreement”) by and between Lyfjaauðkenni ehf, Icelandic Medicines Verification Organisation (“ICEMVO”), a corporation organized under the laws of Iceland having a place of business at Kringlan 7, 103 Reykjavik, Iceland and registered with the Icelandic Business Authority under ID-no. 510717-0820, and INSERT NAME, (“Company”) a INSERT COUNTRY corporation having a principal place of business at INSERT ADDRESS and registered under company registration number INSERT NUMBER, and INSERT NAME, (“National Representative”) having a principal place of business at INSERT ADDRESS and registered under company registration number INSERT NUMBER, is entered into as of the date last written below (“the Effective Date”). All hereafter referred to as a “Party”, and together as the “Parties”.

A. WHEREAS, the ICEMVO is established to set up and manage the Icelandic Medicines Verification System or ICEMVS in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

B. WHEREAS, the ICEMVO concluded an agreement (the National Blueprint Agreement) with the National System IT Company in order to implement, develop, test and operate the ICEMVS and its interfaces with other systems.

C. WHEREAS, the costs of the development, implementation, operation and the maintenance of the ICEMVS and all related activities shall be born, by Marketing Authorization Holders (MAHs) for medicinal products in the relevant market.

D. WHEREAS, the ICEMVO must conclude an Agreement with Company on a non-exclusive basis to co-finance the set-up costs of the ICEMVS and all other expenses to maintain and operate the ICEMVS.

E. WHEREAS, it is a pre-condition for entering into this Agreement that there has been signed an additional Agreement with EMVO regarding the upload of product data into the European Hub.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties agree as follows:

1.0 Definitions

1.1 Definitions. In this Agreement, the Definitions are set out in Exhibit A (“Definitions”), unless the context otherwise requires.

2.0 Scope. Pursuant to the Falsified Medicines Directive and the Commission Delegated Regulation (EU) 2016/161, the costs of the development, implementation, operation and maintenance of national medicines verification systems (ICEMVS) are to be borne by marketing authorisation holders (MAHs) for in-scope medicinal products in the relevant markets. In the Icelandic market, this mandatory function will be carried out by the Icelandic Medicines Verification Organisation (ICEMVO/Lyfjaaudkenni ehf).

2.1 Financing the ICEMVS. This Agreement sets forth the terms and conditions for payment of the applicable fees that Company has to pay to co-finance the ICEMVS.

3.0 Fee Schedule, Payment and Registration Form.

3.1 Fee Schedule. Fees shall be those specified in ICEMVO’s then-current fee schedule in Exhibit B. All stated prices are exclusive of any taxes, fees and duties or other amounts, however designated, and including without limitation value added and withholding taxes which are levied or based upon such charges, or upon this Agreement. Company shall pay any taxes related to products or services purchased or licensed pursuant to this Agreement, or Company shall present an exemption certificate acceptable to the taxing authorities. Applicable taxes shall be billed as a separate item on the invoice, to the extent practical. ICEMVO may change fees annually by issuance of a revised fee schedule in Exhibit B or other announcement of a change in fee. Subject to and expressly conditioned upon compliance with the terms and conditions of this Agreement the EU Directive on Falsified Medicines and the Delegated Regulation, including the obligation for Company to pay the applicable fees set forth in the Fee Schedule in Exhibit B, ICEMVO grants Company a non-exclusive, non-transferable, non-sublicensable, personal license to make use of the ICEMVS to process Data. The ICEMVO has set up the ICEMVS and will subsequently maintain and operate the ICEMVS based on such fees. If the Company represents Affiliates and/or Marketing Authorization Holders/ MAHs for medical products within the Icelandic territory, the applicable fees will be charged according to the number of MAHs. Under no circumstances will anything in this Agreement be construed as granting, by implication, estoppel or otherwise, a license to any system technology or proprietary right belonging to the other party other than as expressly set forth under this Agreement.

3.2 Payment. The payment term shall be net thirty (30) days from the date of invoice. All payments shall be made in Icelandic Krona (ISK)\* or equivalent in Euro (€). Any sum not paid by Company or National Representative, when due, shall bear interest until paid at a rate of 1.5% per month (18% per annum) or the maximum rate permitted by law, whichever is less. If at any time, Company is delinquent in the payment of any invoice, or is otherwise in breach of this Agreement, ICEMVO shall i) notify the Icelandic Medicines Agency 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 access to the ICEMVS until the due fulfilment of the payment obligation. All fees are exclusive of any taxes, fees and duties or other amounts, however designated, and including without limitation value added and withholding taxes which are levied or based upon such charges, or upon this Agreement. Any taxes related to this Agreement shall be paid by Company unless Company can present an exemption certificate acceptable to the taxing authorities. Applicable taxes shall be billed as a separate item on the invoice, to the extent possible. If fees are paid by a third party on behalf of Company, the Company shall in any case remain solely responsible and liable for the compliance with the Agreement, including the EU Directive on Falsified Medicines and Delegated Regulation.

\* ISK exchange rate information can be found on the website of The Central Bank of Iceland: <https://www.cb.is/statistics/official-exchange-rate/>.

3.3 Registration Form. The Company must ensure that the invoicing address and other contact information specified in the registration form in Exhibit C is correct and up to date. Should the address, other contact information or number of Affiliates and MAHs change, it is the responsibility of the Company to inform the ICEMVO in writing by immediately sending a new updated and signed Exhibit C and Exhibit D.

3.4 All Fees are non-reimbursable. Except as otherwise decided by the ICEMVO board all amounts paid by the Company are definitely acquired by the ICEMVO and are non-reimbursable.

3.5 Each Party shall bear its own costs. Each party shall bear its own costs for the entering into and performance of its rights and obligations under this Agreement.

4.0 Costs, Loans & Other Activities.

4.1 Affiliates of Company and MAH(s) whom Company represents and Icelandic Representative. Company shall pay the applicable fee as set forth in the fee schedule mentioned in Exhibit B to ICEMVO under this Agreement. Company hereby guarantees the performance by such Affiliates and MAH(s) of the financial and other contractual obligations set forth in this Agreement and represents and warrants that it is empowered to enter into this Agreement on behalf of such Affiliates, and MAH(s) and to bind (and does so bind) such Affiliates and MAH(s) to the terms and conditions of this Agreement. Company may require certain of the listed Affiliates and MAH(s) to execute an agreement with ICEMVO such that the legal relationship shall be between ICEMVO and Company’s Affiliate and/or MAH(s). The appointed National Representative, on behalf of Company, shall receive invoices from ICEMVO, and handle payments of these invoices on behalf of Company and cross-charge Company for ICEMVO invoiced fees. Any breach by Company or by an Affiliate or by MAH(s) of this Agreement, shall entitle ICEMVO to terminate this Agreement with Company, Affiliate or MAH(s) pursuant to Section 8. The limits of liability set forth in this Agreement shall be deemed an aggregate limit of liability, not per Affiliate or MAH, regardless of whether an Affiliate or MAH has executed a separate Agreement with ICEMVO.

4.2 Payment of Outstanding Costs. In the event that the implementation of the EU Directive on Falsified Medicines as a whole or the development of the ICEMVS more specifically would be postponed, all development activities and ramp-up activities may need to be amended, suspended or even terminated. The Parties understand that, in such case, the incurred costs and accepted but still outstanding invoices addressed to ICEMVO need to be paid. The potential costs and/or penalties to be paid to the National System IT Company will be provisioned as well as the cost for the salaries and lay-off costs of the personnel, freelancers and/or third-party consultants on the payroll of the ICEMVO or any outstanding loans. Both Parties understand and agree that such additional costs may result in additional invoices by ICEMVO to Company.

5.0 Indemnification

5.1 The ICEMVS may be substantially amended, suspended or even terminated by the ICEMVO without any indemnity being due to Company, Affiliate(s) or MAH(s).

6.0 Limited Warranty and Limitation of Liability.

6.1 ICEMVO does not warrant that the ICEMVS will be error-free or will operate without interruption. Company’s exclusive remedy for breach of this section 6.1 shall be to notify ICEMVO of the problem, in which event ICEMVO shall use reasonable efforts to correct such problem or provide a work-around.

6.2 ICEMVO will proactively monitor EMVO guidance and policies in order to secure compliance with necessary requirements. ICEMVO shall not be liable for actions of EMVO and of the persons to whom access to the ICEMVS and the EMVS has been provided. ICEMVO shall not be liable for the content, integrity, or completeness of the Data in the ICEMVS or the EMVS and for such Data being up to date.

6.3 The aggregate total liability of ICEMVO and its suppliers under or in connection with this Agreement or otherwise, whether in contract, tort or otherwise, shall be limited to money paid to ICEMVO under this Agreement in the twelve (12) month period prior to the event or circumstances giving rise to the liability.

7.0 Consequential Damages Waiver.

7.1 Except for statutory limitations, in no event shall ICEMVO or its suppliers be liable for any special, incidental or consequential damages, or lost revenue or profits, or lost or damaged Data, or any indirect damages, whether arising in contract, tort (including negligence), or otherwise.

8.0 Term and Termination.

8.1 Since this Agreement covers the execution of compulsory legal provisions (mentioned in the EU Directive on Falsified Medicines, Delegated Regulation and possible other legislation) this Agreement shall be effective upon the Effective Date and shall remain in force unless otherwise terminated as provided herein.

8.2 This Agreement may be terminated immediately by either party through written notice to the other Party if the Company no longer acts as MAH in the Icelandic market. In such case, the Company will have no rights whatsoever to be refunded of the already paid fees (neither in whole nor pro rata).

8.3 This Agreement may be terminated if the applicable legislation ceases to apply to the undersigned Company or the ICEMVO. Safe for Section 4.2, the board of directors of ICEMVO has the sole and exclusive right to decide on whether to refund any remaining funds, and to decide on the modalities of a potential refund (including timing and proportion). Such potential refund will be paid on a pro rata basis of all amounts paid by the Company and other eligible parties that are still active in Iceland at the time of the decision by the ICEMVO board.

8.4 ICEMVO will have the right to terminate the Agreement without any liability to Company, if the agreement between EMVO and ICEMVO, for the use of the European Hub is terminated for any reason.

8.5 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) days after having been given written notice in respect thereof.

8.6 The rights and obligations of the parties contained in Sections 5, 6, 7, 8, 9 and 10 will survive any expiration or termination of this Agreement.

9.0 Confidential Information.

9.1 Each Party guarantees that all information of a confidential nature received from the other Party or their advisors before, during and after the conclusion of the Agreement shall remain confidential.

9.2 The obligations of confidentiality set forth herein shall not apply to information which (a) has entered the public domain except where such entry is the result of Company’s, Affiliate’s, National Representative’s or MAH(s) breach of this Agreement; (b) prior to disclosure hereunder was already rightfully in Company’s possession; or (c) subsequent to disclosure hereunder is obtained by Company, Affiliate, National Representative’s or MAH on a non-confidential basis from a third party who has the right to disclose such information to Company, Affiliate, National Representative’s or MAH. Neither party shall disclose, advertise, or publish the terms and conditions of this Agreement without the prior written consent of the other party. Any press release or publication regarding this Agreement is subject to prior review and written approval of the parties.

10.0 General Terms and Conditions.

10.1 Assignment. Neither party may assign this Agreement or any interest or rights granted hereunder to any third party without the prior written consent of the other party. A change of control or reorganization of either party pursuant to a merger, sale of assets or stock will be deemed to be an assignment under this Agreement. This Agreement will terminate immediately upon occurrence of any prohibited assignment.

10.2 Relationship of Parties. The parties are independent contractors under this Agreement and no other relationship is intended, including a Membership, franchise, joint venture, agency, employer/employee, fiduciary or other special relationship. Neither party will act in a manner which expresses or implies a relationship other than that of independent contractor. Neither party has the right or authority to, and will not, assume or create any obligation of any nature whatsoever on behalf of the other party or bind the other party in any respect whatsoever.

10.3 Notices. Any notice required or permitted to be given by either party under this Agreement will be in writing and will be delivered to the persons identified, and at the addresses specified, in the Notice section of Exhibit D attached hereto.

10.4 Governing Law. This Agreement and any action related thereto will be governed, controlled, interpreted and defined by and under the Laws of Iceland and any dispute shall be subject to the exclusive jurisdiction of the Icelandic courts, without regard to the conflicts of laws provisions thereof, provided that either party shall at all times have the right to commence proceedings in any other court of its choice of appropriate jurisdiction to obtain injunctive relief for protection of intellectual property proprietary rights or Data.

10.5 No Waiver. Failure by either party to enforce any provision of this Agreement will not be deemed a waiver of future enforcement of that or any other provision. Any waiver, amendment or other modification of any provision of this Agreement will be effective only if in writing and signed by the parties.

10.6 Entire Agreement. This Agreement, including all exhibits which are incorporated herein by reference, constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes and replaces all prior and contemporaneous understandings or agreements, written or oral, regarding such subject matter. No modification or attempted modification of this Agreement will be effective unless agreed to in writing by both ICEMVO, Company and National representative. Parties agree that when European legislation regarding by example the EU Directive on Falsified Medicines and guidelines lead to extra responsibilities, an addendum to this Agreement will need to be entered into which will outline in more detail all rights and obligations of both Parties with regard to the subject matter of this Agreement. Such addendum will not jeopardize the rights of the ICEMVO with regard to the stipulations on the flat fee payment as mentioned in the fee schedule in Exhibit B. Furthermore, the parties agree to update or amend this Agreement, if necessary due to revised agreements between EMVO and ICEMVO or ICEMVO and National IT Service Provider.

10.7 Exhibits. If there is a discrepancy between the main body of this Agreement and the Exhibits, the main body of this Agreement prevails.

10.8 Signatures. This Agreement has been drawn up and executed in three (3) identical copies of which each Party has received one (1) copy.

|  |  |
| --- | --- |
| Lyfjaauðkenni ehf, Icelandic Medicines Verification Organisation (“ICEMVO”) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (“Company”) |
| By: | By: |
| Name: Hjörleifur Thorarinsson | Name: |
| Title: Executive Director | Title: |
| Date: | Date: |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (“National Representative”) |
|  | By: |
|  | Name: |
|  | Title: |
|  | Date: |
|  |  |

**DEFINITIONS EXHIBIT A**

1. **Definitions**

As used in this Agreement, the following capitalized terms shall have the meanings set forth below:

1.1. **Affiliate** are the entities owned by Company and listed on Exhibit C to this Agreement of which at least 50.1% of the voting power is owned by Company, but only for so long ownership remains at 50.1% or above.

1.2. **Agreement** shall mean this Agreement for the financing of the Icelandic Medicines Verification System, and any and all Exhibits attached thereto, as well as any other document expressly incorporated into this Agreement. A mere reference to another document shall not constitute an explicit incorporation.

**1.3 Company** is the legal entity listed on the front page of this Agreement. Company can have multiple MAHs affiliated to it for which they pay the applicable fee(s) (please see definition of Affiliates above). In addition, Company can represent Marketing Authorization Holders (MAH) on behalf of which it will pay the applicable fees. In the latter case, ICEMVO may at its option request either: i) a co-signed Agreement between MAH, Company and ICEMVO such that the legal relationship shall be between ICEMVO, Company and MAH; and/or ii) proof of Company being authorized to represent MAH in the form of Proxy or an attorney in fact.

1.4. **National Representative** is a legal entity operating by appointment by Company to represent Company on Icelandic territory.

1.5. **Icelandic (Medicines Verification) System or ICEMVS** or **National (Medicines Verification) System or NMVS** shall mean a national or supranational repository of the EMVS under the responsibility of one national medicines verification organisation; it is connected to the European Hub and allows authorized users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

1.6. **Data** shall mean information uploaded, processed, transferred, generated or stored in the EMVS or the ICEMVS as set out in the EU Directive on Falsified Medicines and the Delegated regulation (in particular its Article 33, paragraph 2).

1.7. **Delegated Regulation** shall mean 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 as amended from time to time.

1.8. **ICEMVO** shall mean Icelandic Medicine Verification Organisation, Lyfjaauðkenni ehf.

1.9. **ICEMVS** shall have the meaning set forth in 1.5 above.

1.10. **Effective Date** shall mean the date on which this Agreement has been signed by all Parties, as indicated by the last signature date mentioned in the signature block at the end of the Agreement.

1.11. **EMVO** shall mean the European Medicines Verification Organisation

1.12. **EU Directive on Falsified Medicines** shall mean Directive 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 amended from time to time.

1.13. **European Hub** designates the component of the EMVS under the responsibility of the EMVO that serves as a central information and data router for the transmission of data to or from the National Systems; it is set up and managed by the EMVO.

1.14. **European Medicines Verification System or EMVS** shall mean the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems and allows authorized users to verify the authenticity of medicinal products.

1.15 **MAH(s)** shall mean the Marketing Authorization Holder(s) that operate and place prescriptive medicines on the market for sale in Iceland. Each MAH markets at least one product within the Icelandic territory.

1.16. **National System IT Company** shall mean the IT company that is developing and operating the ICEMVS on behalf of the ICEMVO subject the separate agreement.

**FEE SCHEDULE EXHIBIT B**

|  |
| --- |
| *Company will fill in and sign this Agreement with a view to pay the fees mentioned in this Exhibit B.*  *The ICEMVO has the right to, at any time during the term of this Agreement, increase the fees, if the National System IT Company or EMVO increases its fees or charges additional fees from ICEMVO or if the fees relate to the development, testing, implementation, operation, maintenance or update of the ICEMVO increases due to any other reason. Likewise, Company acknowledges that the fees set out in Exhibit B are estimates and may change once the budget and number of participating Companies with market authorizations in Iceland are confirmed. ICEMVO may in accordance with Section 3.1 change fees annually by issuance of a revised fee schedule in Exhibit B or other announcement of a change in fee. The Fee (excluding all taxes/VAT, if applicable) to be paid by the Company per MAH under this Agreement shall be calculated and invoiced by ICEMVO directly to Company or the Icelandic Representative of Company in accordance with Point A and B below:*  *For a MAH to be invoiced for participation in the Icelandic medicine verification system (ICEMVS), it needs to have recorded in-market sales in Iceland or have intentions to market pharmaceutical products in Iceland. Sales information is obtained from The Icelandic Drug Market data (IDM) that is based on Price to Pharmacy list price.* |
| **Annual flat fee contribution** |
| *As from February 2019, an annual flat fee contribution will be payable by Company, its Affiliates and Representatives to the ICEMVO. The annual flat fee will be charged per market authorization holder to cover, inter alia, the annual costs of the operation and further development of the ICEMVS, costs inherited from the European Medicines Verification Organization and all necessary and legally compulsory activities of the ICEMVO. The level of the annual flat fee contribution will be based on actual cost of running the ICEMVO short and long term. Both Parties agree that the amount of the yearly flat fee (IT-cost and operational cost of ICEMVO divided by number of MAH’s) may fluctuate from time to time.*  ***ICEMVO 2022 Annual fee as decided by ICEMVO Board of Directors:***   * *For MAH with 2021 IDM sales turnover above EUR 80,000: EUR 3,969.-.* * *For MAH with 2021 IDM sales turnover below EUR 80,000: EUR 1,215.-.* * *For MAH with 2021 IDM sales turnover below EUR 16,000: EUR 365.-.* |

**REGISTRATION AND INVOICING INFORMATION EXHIBIT C**

|  |  |
| --- | --- |
| *Company must ensure that the invoicing address and other contact information specified in the below registration form is correct and up to date during the term of the contract. Company shall fill in one of the below forms for Company and one form for each of the MAHs that Company pays for in the Icelandic market.*  *Should the address, other contact information or number of MAHs change, it is the responsibility of Company to inform the ICEMVO immediately by sending a new updated and signed Exhibit C and Exhibit D to the ICEMVO. If the data in the below tables are incorrect or not updated then all costs related to the re-issuance of invoices will be borne by Company.*  *The Company may nominate a National Representative for invoicing purposes.*  *Please complete all sections of form, marking ‘not applicable’ or N/A’ where appropriate.*  **INVOICING DETAILS FOR COMPANY** | |
| **Registration for Company** | |
| **Name of Company** |  |
| **Address** |  |
| **Company Registration No.** |  |
| **VAT number to use on invoice - (only if no national representative is appointed)** |  |
| **Purchase order (PO) number required? YES/NO** | If YES, please send PO number by email info@lyfjaaudkenni.is |
| **Contact details:** | *Email:* |
|  | *Phone no.:* |
| **Registration and Invoicing Information for National Representative** | |
| **Name of Company** |  |
| **Address** |  |
| **Company Registration No.** |  |
| **VAT number to use on invoice** |  |
| **Any other special invoicing instructions?** *(e.g. fees for different MAHs to be included on one invoice)* | If YES, please provide precise details: |
| **Contact details:** | *Email:* |
|  | *Phone no.:* |
| **DETAILS OF MAH 1** | |
| **Name of MAH :** *(full legal name)* |  |
| **Address** |  |
| **Company Registration No.** |  |
| **DETAILS OF MAH 2\*** | |
| **Name of MAH :** *(full legal name)* |  |
| **Address** |  |
| **Company Registration No.** |  |

**\*Please add rows as needed for additional MAH registration**

**Checklist:**

1. Have you completed all parts of this form?
2. If a PO number is required, have you provided one?
3. If applicable, have you included information about an Icelandic representative?

**Please return the completed form as soon as possible to** [info@lyfjaaudkenni.is](mailto:info@lyfjaaudkenni.is)**.**

**If required, invoices may be issued before the MAH Agreement is signed.**

**Any queries about the form or the MAH registration process in general should also be sent to** [info@lyfjaaudkenni.is](mailto:info@lyfjaaudkenni.is)**.**

**CONTACT INFORMATION FOR NOTICES AND ALERTS EXHIBIT D**

**NOTICE CONTACT:**

|  |  |
| --- | --- |
| **ICEMVO / Lyfjaauðkenni ehf** | **Company** |
| Hjörleifur Thorarinsson |  |
| Executive Director |  |
| Kringlan 7, IS 103 Reykjavik, Iceland |  |
| Phone: + 354 660 3707 | Phone |
|  |  |
| e-mail: info@lyfjaaudkenni.is | e-mail |

**QUERIES RELATING TO ALERTS / SPOC: :**

|  |  |
| --- | --- |
| **ICEMVO / Lyfjaauðkenni ehf** | **Company** |
| alerts@lyfjaaudkenni.is |  |