

**NON-DISCLOSURE AGREEMENT FOR PARTICIPATION IN ON-BOARDING  
PROJECT OF THE EUROPEAN MEDICINES VERIFICATION SYSTEM**

**This Agreement is made and entered into between:**

**EUROPEAN MEDICINES VERIFICATION ORGANIZATION**, a non-profit association with registered office at 1040 Brussels (Belgium), Rue de la Loi 28, VAT BE 0638.801.022 RPM Brussels,

represented by Andreas Walter, EMVO General Manager,

Hereinafter referred to "**EMVO**";

**and**

[**FILL IN COMPANY NAME AND LEGAL FORM**\_\_\_\_\_],

having its registered office at  
[place\_\_\_\_\_]  
\_\_\_\_\_],

\_\_\_\_\_],

Legal Entities' Registry or equivalent number [number\_\_\_\_\_],

represented herein by [name\_\_\_\_\_], [function\_\_\_\_\_],

hereinafter referred to as the "**On-boarding Partner**" or "**OBP**";

EMVO and the OBP being hereinafter referred to individually as a "Party" and collectively as the "Parties".

**Preamble**

**WHEREAS**, EMVO is the non-profit legal entity established to set up and manage the European Hub in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

**WHEREAS**, EMVO and key stakeholders in the supply chain of medicinal products in Europe are collaborating to develop the European Medicines

Verification System (EMVS) in accordance with the EU Directive on Falsified Medicines and its Delegated Regulation.

**WHEREAS**, EMVO intends to set the EMVS into preliminary operational mode on a limited scale as part of the On-boarding Project.

**WHEREAS**, in order to allow the OBP to assess and resolve on its participation to the On-boarding Project, EMVO will provide EMVO Confidential Information to the OBP subject to the terms of this Agreement.

**Now, therefore, the Parties have agreed as follows:**

## **1. Definitions**

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

- 1.1. **Affiliate** shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).
- 1.2. **Agreement** shall mean this non-disclosure agreement.
- 1.3. **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.
- 1.4. **Effective Date** means the date on which this Agreement is signed by the OBP, as indicated in the signature block of the OBP at the end of the Agreement.
- 1.5. **EMVO Confidential Information** shall mean any information (whether in oral, written or electronic form) belonging or relating to EMVO, its business affairs or activities which is not in the public domain and which:  
(i) EMVO has marked as confidential or proprietary, (ii) EMVO, orally or in writing, has advised the OBP is of a confidential nature, (iii) due to its character or nature, a reasonable person in a similar position to the OBP of such information in the frame of or for the purpose of (assessing) participation to the On-boarding Project, and under similar circumstances,

would treat as confidential, or (iv) consists of any and all information relating to the On-boarding Project and the European Medicines Verification System and its development, implementation, testing, use and operation, including the European Hub, the interfaces to the manufacturers'/parallel distributors' systems and to the National Systems, as well as the Software Development Kit and the EMVO Gateway, as well as any underlying software and EMVO Documentation provided by EMVO to the OBP in the frame of or for the purpose of (assessing) participation to the On-boarding Project.

- 1.6. **EMVO Documentation** shall mean any and all specifications, manuscripts, user guides, explanatory material and operating manuals, reports and other written documents and/or machine-readable text and files, whether in electronic form or hard copy, as EMVO may in its discretion provide to the OBP from time to time, for or in connection with the development, implementation, testing, use or operation of the EMVS or a component thereof, as updated by EMVO from time to time.
- 1.7. **EMVO Gateway** shall mean the solution provided by EMVO that will allow the OBP to upload OBP Data to the European Hub and to perform a set of transactions, e.g., to verify a pack or to obtain a report, during the On-boarding Project.
- 1.8. **EMVO Software** shall mean any and all computer software program(s) to be provided by EMVO, or on behalf of EMVO, to the OBP in object code form in any form or media, in the frame of or in connection with this Agreement, and all Updates to such program, as well as the relevant sections of the EMVO Documentation.
- 1.9. **EU Directive on Falsified Medicines** means 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.
- 1.10. **European Hub** designates the component of the EMVS under the responsibility of EMVO that serves as a central information and data router for the transmission of OBP Data to or from the National Systems; it is set up and managed by EMVO.
- 1.11. **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.

- 1.12. **Intellectual Property Rights** shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, trade marks, service marks, author rights, copyrights, neighbouring rights and related rights, database rights, trade and business names, domain names, know-how, trade secrets, confidential information, patterns, drawings, rights in computer software, proprietary marketing materials, and any and all other intellectual or industrial property rights in all their patrimonial and moral aspects, as well as any application therefor, anywhere in the world (whether registrable, patentable or not).
- 1.13. **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.
- 1.14. **OBP Data** shall mean any information to be uploaded by the OBP to the European Hub via the OBP Interface or via the EMVO Gateway for transfer to National Systems, as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation (in particular its Article 33, para. 2), irrespective of whether or not these include Personal Data.
- 1.15. **OBP Interface** shall mean the solution (either through a system-to-system direct connection or through a gateway provided by an OBP Connection Provider) to be developed, implemented, tested, used and/or operated by the OBP, at OBP discretion, in accordance with the Software Development Kit, as may be amended from time to time by EMVO, that will allow connecting the OBP System to the European Hub to upload OBP Data to the European Hub and to perform a set of transactions.
- 1.16. **OBP System** shall mean the system that is owned by the OBP and holds the OBP Data for transmission to National Systems through the European Hub.
- 1.17. **On-boarding Project** means the limited scale preliminary operational mode of part of the European Medicines Verification System under which the OBP shall be entitled to (i) use the EMVO Gateway and/or (ii) develop,

implement, test, use and/or operate an OBP Interface to the European Hub in accordance with the Software Development Kit provided by EMVO, for the transfer of OBP Data to National Systems through the European Hub.

- 1.18. **Personal Data** shall mean any and all information relating to an identified or identifiable individual (or to a legal entity if protected as personal data under applicable data protection law).
- 1.19. **Purposes** shall mean the purpose of allowing the OBP to assess and resolve on its participation to the On-boarding Project (subject to the entering into of an agreement with EMVO for the participation in the On-boarding Project of the EMVS).
- 1.20. **Software Development Kit ("SDK")** shall mean all EMVO Software, specifications and EMVO Documentation provided by EMVO to the OBP in any form or media, for the development, implementation, testing, use and operation of the OBP Interface and/or the EMVO Gateway in connection with the European Hub, as may be amended by EMVO from time to time.

## **2. Non-Disclosure of EMVO Confidential Information**

- 2.1. Pursuant to this Agreement, EMVO intends to maintain the confidential nature of EMVO Confidential Information which has already been – or is due to be – disclosed to the OBP. For the avoidance of doubt, the OBP hereby expressly agrees that the obligations of confidentiality contained in this Agreement shall apply and have full force and effect in respect of any and all EMVO Confidential Information disclosed to the OBP both before and after the Effective Date of this Agreement.
- 2.2. In consideration of EMVO agreeing to disclose EMVO Confidential Information to the OBP, the OBP undertakes to:
- keep EMVO Confidential Information secret and confidential, and without limiting the foregoing, not disclose EMVO Confidential Information to any person, other than to its Affiliates and Representatives in accordance with Article 4, except with the specific prior written consent of EMVO, or as expressly otherwise permitted by the terms of this Agreement;
  - only use EMVO Confidential Information for the Purposes contemplated under this Agreement, at the exclusion of any other purpose;

- exercise the same degree of care and protection with respect to EMVO Confidential Information that the OBP exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with best care; and
  - take all necessary precautions in order to prevent any unauthorised misuse, disclosure, theft or other loss of EMVO Confidential Information, and to notify immediately EMVO upon becoming aware of the same and take all necessary measures in order to reduce the effects of such unauthorised misuse, disclosure, theft or other loss.
- 2.3. The OBP shall be liable, and shall indemnify and hold harmless EMVO, for any damages, loss, or costs, expenses or liability arising out of or resulting from the breach by the OBP (or of its Affiliates or Representatives referred to in Article 4) of the terms of this Agreement, as well as for any loss, theft or other unauthorized use or disclosure of EMVO Confidential Information caused by the OBP or its Affiliates' or Representatives' fault or negligence.
- 2.4. The OBP agrees that if any of the provisions of this Agreement are not performed in accordance with their respective terms or are otherwise breached by it or its Affiliates or Representatives, monetary damages may not be necessarily sufficient remedy. Therefore, the OBP agrees that, in addition to all other rights and remedies otherwise available to EMVO, EMVO shall be entitled to specific performance or equitable relief by way of injunction or otherwise in the event it or its Affiliates or Representatives breach or threaten to breach any of the provisions of this Agreement.
- 2.5. The OBP agrees that EMVO is under no obligation to disclose any information to the OBP at any time under this Agreement.

### **3. Permitted Disclosure**

- 3.1. The restrictions on use or disclosure of EMVO Confidential Information as defined above do not extend to information which:
- is or comes into the public domain through no breach of this Agreement;
  - is lawfully received by the OBP on a non confidential basis;
  - is independently developed by the OBP; and

- is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, the OBP give EMVO immediate notice thereof, and give EMVO reasonable time under the specific circumstances, so that it may seek a protective order or other appropriate relief, or waive compliance with the non-disclosure provisions of this Agreement. In such case, the OBP shall cooperate with EMVO, by all legal means, in order to limit the effects of the disclosure and to prevent the disclosure of any other EMVO Confidential Information.

#### **4. Disclosure to Affiliates and Representatives**

4.1. The OBP shall be entitled to disclose EMVO Confidential Information to those of its Affiliates, and the OBP's and such Affiliates' authorised officers, employees, agents and contractors (collectively referred to as the "Representatives") to whom, and to the extent to which such disclosure is necessary for the Purposes contemplated under this Agreement, provided that it:

- informs such Affiliates and Representatives of the limitations and conditions with respect to the use and disclosure of EMVO Confidential Information set forth in this Agreement;
- procure that such Affiliates and Representatives agree in writing to observe limitations and conditions as those set forth in this Agreement; with respect to the OBP's employees, it is acceptable that the OBP ensures that appropriate confidentiality undertakings are included in their employment agreement in accordance with applicable law, this without prejudice to the OBP remaining responsible for any non-compliance with confidentiality obligations under this Agreement by any of by its employees ; and
- shall be fully liable for any violation of these limitations and conditions, by any Affiliate or Representative or any other person or entity to whom the Receiving Party discloses EMVO Confidential Information, whether or not in accordance with this Agreement.

#### **5. Reproduction and Ownership**

5.1. Except to the extent necessary for the Purposes contemplated under this Agreement, the OBP undertakes not to copy, duplicate or reproduce in whole or in part, and by any mean whatsoever, EMVO Confidential

Information, except with the prior consent of EMVO.

- 5.2. The OBP acknowledges that EMVO Confidential Information shall at all times remain the exclusive property of EMVO. Moreover, the OBP recognizes that the legal and beneficial interest in the copyright and all other Intellectual Property Rights subsisting in EMVO Confidential Information belong to EMVO.
- 5.3. Unless specifically provided in this Agreement, neither the disclosure of EMVO Confidential Information nor anything herein contained shall be interpreted as giving expressly or implicitly to the OBP, any right, including but not limited to Intellectual Property Right (by license or any other mean) on the Confidential Information or any protected or protectable invention or work which might be derived therefrom directly or indirectly and the OBP shall neither claim or seek any right, including but not limited to Intellectual Property Right thereon.

**6. No obligation to enter into any subsequent agreement for participation to the On-boarding Project**

- 6.1. Absent a separate agreement between EMVO and the OBP, neither this Agreement, nor the disclosure or receipt of EMVO Confidential Information shall constitute or imply any promise or obligation whatsoever to enter into any agreement for participation in On-boarding Project of the EMVS.
- 6.2. Either Party may, at any time, terminate the discussions as to participation to the On-boarding Project and EMVO may decide to amend, suspend or terminate the On-boarding Project of the EMVS at any time.
- 6.3. Always subject to Section 6.1. above, if the OBP decides to participate in the On-boarding Project, the OBP will inform EMVO thereof, and EMVO and the OBP shall enter into an agreement for participation in the On-Boarding project of the EMVS. Unless otherwise agreed by EMVO and the OBP, the terms of this NDA shall continue to be in effect and shall make integral part of this agreement for participation in the On-boarding Project.
- 6.4. If the OBP decides not to participate in the On-boarding Project, it shall inform EMVO thereof and shall not make any further use of EMVO Confidential Information, except with EMVO's prior consent. The OBP will nevertheless remain held by the terms of this Agreement for the term thereof.



## **7. No warranty**

- 7.1. No warranty of any kind is made or given with respect to EMVO Confidential Information or use thereof, including, but not limited to, as to the accuracy or the completeness of EMVO Confidential Information. Use of any EMVO Confidential Information is at the OBP's own risks.
- 7.2. EMVO shall not be liable for any direct nor indirect damage, loss or claims, including loss of profits, loss of benefit, loss of turnover, loss of income, loss of savings, loss of contract, loss of use, loss of business or business interruption, loss of goodwill, loss of data, loss of clientele, third party's claim, or any other indirect, special, incidental or consequential damages of any kind in connection with or arising out of the use of EMVO Confidential Information disclosed hereunder, whether alleged as a breach of contract (including grave fault) or tortious conduct, negligence (including gross negligence), hidden/latent defects, even if EMVO had been advised of the possibility of such damage. Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.

## **8. Jurisdiction - Governing law**

- 8.1. This Agreement and any contractual or non contractual (including pre-contractual) matters in connection with its conclusion, validity, interpretation, enforcement, performance and termination shall be governed by and construed in accordance with the laws of Belgium.
- 8.2. Any dispute arising between the Parties arising out of or in connection with this Agreement and/or any contractual or non-contractual (including pre-contractual) matters in connection with its conclusion, validity, interpretation, enforcement, performance and termination will be submitted to the exclusive jurisdiction of the courts of Brussels.

## **9. Data protection**

- 9.1. As necessary in relation to the performance of this Agreement, EMVO may collect, store and process Personal Data about the OBP or the OBP's Representatives, in accordance with applicable data protection law. The OBP shall inform its Representatives about the processing of their Personal Data by EMVO for the above purposes, as well as about their rights of access, rectification and objection (including the right to object, at any time and free of charge, to the processing of Personal Data for direct marketing

purposes).

## 10. General provisions

- 10.1. This Agreement shall remain in force for a term of 5 years as from its Effective Date, unless extensions or stipulations are agreed between the Parties and/or arising from the future contractual relations and unless earlier terminated.
- 10.2. Notwithstanding Section 10.1, the OBP agrees to be bound unilaterally by all its obligations under this Agreement as of such Effective Date, which will then be enforceable vis-à-vis the OBP by EMVO or any third-party beneficiary as a unilateral undertaking under Belgian law, this even if this Agreement has not been countersigned by EMVO yet.
- 10.3. Failure by either the OBP or EMVO to enforce any of the provisions of this Agreement or any reaction or absence by a Party in the event of a breach by the other Party of one or more provisions of this Agreement shall not operate neither be construed as a waiver of its rights under this Agreement or under said provision(s) or preclude the further exercise of any such rights. Any waiver of a right must be express and in writing.
- 10.4. Should any provision of this Agreement be held by a court of competent jurisdiction to be illegal, invalid or otherwise unenforceable, in whole or in part, this shall neither affect nor impair the legality, validity or enforceability of the remaining provisions of this Agreement, which shall continue in full force and effect. Instead, the provision held illegal, invalid, or unenforceable shall be deemed modified to the extent necessary to render such provision enforceable, and the rights and obligations of the Parties shall be construed and enforced accordingly, preserving to the fullest permissible extent the intent and agreements of the Parties set forth herein.
- 10.5. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and respective successors.
- 10.6. Without any prejudice to Section 10.7, the OBP undertakes to notify EMVO, in writing, of any modification affecting its corporate situation, including about any (i) change of address or registered office, (ii) change of legal form, (iii) change of control, (iv) change in the legal or beneficial ownership of the company, (v) merger or consolidation, or (vi) any acquisition (in one transaction or in a series of transaction) of all or substantially all of the assets of the OBP, to the extent such modification

directly or indirectly affects or is relevant to this Agreement.

10.7. The OBP cannot transfer nor assign its rights and obligations under this Agreement to any third party, without the prior written consent of EMVO. EMVO shall be entitled to assign or novate this Agreement and/or any or all of its rights and obligations under this Agreement to any entity established to perform substantially any of the functions deemed to be performed by EMVO, by written notice to the OBP, and the OBP shall enter into such documents as are necessary for such purpose.

10.8. Notices. Any notice or other communication to be given under this Agreement shall be in writing and sent by (i) express mail; (ii) registered mail; (iii) electronic mail (SMTP) with a request for a delivery receipt; or (iv) by hand, to the other Party, at the addresses set out below, or at such other addresses as a Party may from time to time designate by written notice to the other Party:

**Notices to EMVO:**

Name: Tobias Beer

Address: Rue de la Loi 28, box 21, 1040 Brussels

E-mail: helpdesk@emvo-medicines.eu

**Notices to OBP:**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

Any such notice or other communication shall be deemed to have been made at the time and place of the earlier of its first presentation to, or reception by, the receiving Party.

10.9. Any Amendment to this Agreement, as well as any additions or omissions, can only be agreed in writing with the mutual consent of the Parties.



Con-number  
(provided by EMVO)

CP-number  
(provided by EMVO)

**In witness thereof**, without prejudice to Section 10.2 above, this Agreement has been signed in two (2) originals, each party acknowledging that it received one duly signed original.

**For EMVO**

**For the OBP**

**For the OBP**  
(second sign. if required)

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Name: Andreas Walter  
\_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: General Manager  
\_\_\_\_\_

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

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

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_