

# **OBP PARTICIPATION AGREEMENT**

## **OPERATIONAL PHASE**

**SAMPLE**



*CP-number  
(provided by EMVO)*

*CON-number  
(provided by EMVO)*

**AGREEMENT FOR PARTICIPATION OF ONBOARDING PARTNERS IN THE  
EUROPEAN MEDICINES VERIFICATION SYSTEM**

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

**EUROPEAN MEDICINES VERIFICATION ORGANIZATION**, a non-profit association with registered offices at 1000 Brussels (Belgium), Rue du Commerce 123, VAT BE 0638.801.022 RPM Brussels, represented by Andreas Walter, General Manager,  
Hereinafter referred to "**EMVO**";

**And**

*[Company Name]*

having its registered office at,

*[Street] [Number], [Zip Code] [City], [Country],*

Legal Entities' Registry or equivalent number *[Company Registration Number]*

represented herein by,

*[Authorised Representative First Name] [Authorised Representative Last Name]*

*[Authorised Representative Job Title]*

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 the 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 Delegated Regulation.

**WHEREAS**, as EMVO did not have the required know-how in the field of information technology for the implementation, development, testing and operation of the EMVS, a contract has been concluded (the "**European Hub IT Contract**") with an IT company (the "**European Hub IT Company**") in order to implement, develop, test and operate the European Hub and other components of the EMVS.

**WHEREAS**, EMVO has set the EMVS into preliminary operational mode during a ramp-up period as part of the On-boarding Project and the EMVS is now entering into full operational mode.

**WHEREAS** the OBP is willing to participate in the On-boarding Project and the EMVS Operational Phase and/or will or already has developed, implemented, used and/or operated an interface to the European Hub based on specifications provided by EMVO and/or will use or already uses the EMVO Gateway provided by EMVO in order to upload and transfer data to National Systems and query information through the European Hub under the terms and conditions set forth below.

**WHEREAS**, the Parties recognise the commercially sensitive nature of the OBP Data in the EMVS.

**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. **Addendum** means the addendum to be entered into between the Parties according to the template provided under Appendix 4 to this Agreement and containing specific provisions supplementing the provisions of this Agreement in relation to an OBP not located in the European Economic Area; the Addendum forms part of this Agreement; in case of discrepancy, the Addendum shall prevail on this Agreement.
- 1.2. **Affiliate** means, in relation to a Party, any other entity Controlling, Controlled or under common Control with the Party. "Control" and its derivatives mean either the holding, directly or indirectly, of 50 % or more than 50% ownership interest or the statutory or de facto authority to exercise a decisive influence on the appointment of the majority of directors or managers or the orientation of policy provided it is, at EMVO's own absolute discretion, sufficiently proven.
- 1.3. **Agreement** means this Agreement for the Participation in the On-boarding Project as well as in the EMVS Operational Phase of the European Medicines Verification System, and any and all

Appendices 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.

- 1.4. **Data Protection Laws** mean the General Data Protection Regulation (EU) 2016/679 ("GDPR") and any equivalent legislation in the jurisdiction where the OBP is established, including any applicable supplementing national legislation regarding the collection, use and processing of Personal Data.
- 1.5. **Delegated Regulation** means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
- 1.6. **Effective Date** means the date on which this Agreement has been signed by all the Parties, as indicated by the last signature date mentioned in the signature block at the end of the Agreement.
- 1.7. **EMVO Confidential Information** means 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 nor listed under Section 2.1 of Appendix 3 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 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 Documentation provided by EMVO to the OBP in the frame of or for the purpose of (assessing) participation to the On-boarding Project and the EMVS and/or the EMVS Operational Phase.
- 1.8. **EMVO Documentation** means any and all specifications, manuscripts, user guides, explanatory material and operating manuals, reports and other written documentation 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.

- 1.9. **EMVO Software** means 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.
- 1.10. **EMVO Gateway** means the solution provided, subject to Section 6.1, 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.
- 1.11. **EMVS Implementation Phase** means the ramp-up period for the preliminary operational mode of part of the EMVS that automatically terminates on the 8th February 2019, at 23:59:59 CET and during which:
- (i) EMVO develops, tests, implements, and operates the European Hub and each OBP develops, tests, implements and operates its OBP System respectively, and
  - (ii) EMVO and the OBP connect the European Hub and the OBP System with each other for the transmission of OBP Data to National Systems through the European Hub.
- 1.12. **EMVS Operational Phase** means the full scale (day-to-day) operational mode of the EMVS, which starts on the 9<sup>th</sup> February 2019, at 00:00 CET during which both Parties, having developed, tested, implemented and operated their respective systems (EMVO the European Hub and the OBP the OBP System) and connected them with each other, for the transmission of OBP Data to National Systems through the European Hub.
- 1.13. **End User** means any wholesaler, pharmacy or other person authorised or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation or as otherwise foreseen under applicable law.
- 1.14. **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.
- 1.15. **European Hub** designates the component of the EMVS under the responsibility of EMVO that serves as a central information and data router according to Article 32, para. 1, a) of the Delegated Regulation for the transmission of OBP Data to or from the National Systems; it is set up and managed by the EMVO.

- 1.16. **European Medicines Verification System or EMVS** means 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 authorised users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- 1.17. **Good Industry Practice** means in relation to any undertaking and any circumstances, the exercise of that degree of professionalism, skill, diligence, care, prudence, judgment, productivity, innovation, integrity and foresight which would reasonably and/or ordinarily be expected from a skilled and experienced person or an internationally recognised global market-leading company engaged in the same type of activity under the same or similar circumstances.
- 1.18. **Intellectual Property Rights** mean any or all patents, rights to inventions, utility models, registered designs, design rights, trademarks, 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 registered, registrable, patentable or not).
- 1.19. **MAH(s)** mean(s) the Marketing Authorisation Holder(s) and/or the holders of parallel import or parallel distribution licenses that operate and place medicines on the market for sale in the European Economic Area and/or Switzerland.
- 1.20. **National Medicines Verification Organisation(s)** or “**NMVO(s)**” mean(s) the non-profit legal entity (entities) that is(are) responsible to set up and manage a national and/or supranational repository(ies) in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- 1.21. **National (Medicines Verification) System or NMVS** means a national or supranational repository of the EMVS according to Article 32, para. 1, b) of the Delegated Regulation under the responsibility of one NMVO; it is connected to the European Hub and allows authorised users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- 1.22. **OBP Affiliate** means [the MAH that is] an Affiliate of the OBP, as notified by the OBP to EMVO from time to time and that has agreed in writing to be bound by and to observe all terms,

limitations and conditions set forth in this Agreement as further detailed under Section 4.6; for the purpose of this Agreement, all references to the OBP also include all OBP Affiliates.

- 1.23. **OBP Confidential Information** means any information (whether in oral, written or electronic form) belonging or relating to the OBP, its business affairs or activities, which is not in the public domain and which: (i) the OBP has marked as confidential or proprietary, (ii) the OBP has advised EMVO, orally or in writing, that is of a confidential nature, or (iii) due to its character or nature, a reasonable person in a similar position to EMVO and under similar circumstances, would treat as confidential, or (iv) consists of OBP Data (subject to limited permitted disclosure to participants to the EMVS as necessary for the purpose of the EMVS). OBP Confidential Information does not include information which (i) is or comes into the public domain through no breach of this Agreement, (ii) is lawfully received by EMVO on a non-confidential basis, (iii) is independently developed by EMVO, its officers, employees, agents or contractors, or (iv) is required by law, by court or governmental order to be disclosed, albeit to the extent and for the exclusive purpose of such disclosure, provided that, before making such disclosure, EMVO shall to the extent possible give OBP notice thereof, and give OBP reasonable time under the specific circumstances, so that OBP may seek a protective order or other appropriate relief, or waive compliance with the confidentiality provisions of this Agreement.
- 1.24. **OBP Connection Provider** means any third party IT provider, consultant or agent to which the OBP entrusts in whole or part of the development, implementation, provision, use and/or operation of the OBP Interface, subject to the conditions set forth under Section 5.3 and Appendix 1 to this Agreement.
- 1.25. **OBP Data** means any information – to be – uploaded by the OBP (on its behalf, if it is a MAH, and/or on behalf of the OBP Affiliates) 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.
- 1.26. **OBP Interface** means the solution (to be) developed, implemented, tested, used and/or operated by the OBP, at OBP's discretion, in accordance with the Software Development Kit, as may be amended from time to time by EMVO, that will allow the OBP System to interface with the European Hub to upload OBP Data to the European Hub and to perform a set of transactions.



- 1.27. **OBP Mark** means any of the trademarks, service marks, trade names, logos or other commercial or product designations (registered or not) that are used or contained in, relate to, or protect any OBP Data.
- 1.28. **OBP Representative** means an OBP's authorised officer, employee, agent, and OBP Connection Provider, who has agreed in writing to observe the limitations and conditions set forth in this Agreement; it being noted that the OBP remains fully liable for its Representative. With respect to the OBP's authorised officer, employee and agent, this obligation may notably be fulfilled by the OBP undertaking and warranting that appropriate obligations are included in its agreement(s) with its authorised officer, employee and agent, and/or in those persons' legal and/or contractual duties, this without prejudice to the OBP remaining responsible for due compliance with this Agreement by any of its authorised officers, employees and agents, and without prejudice to the requirements applying vis-à-vis OBP Connection Providers under Section 5.3 of this Agreement.
- 1.29. **OBP System** means the system for which the OBP is the system owner and holds the OBP Data for transmission to National Systems through the European Hub.
- 1.30. **On-boarding Fee** means the one-time administrative fee to be paid by the OBP in accordance with Section 8.2 and Appendix 2 to this Agreement.
- 1.31. **On-boarding Project** means the project relating to the EMVS Implementation Phase or EMVS Operational Phase, as the case may be, during 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.
- 1.32. **Personal Data** means any and all information relating to an identified or identifiable individual (or to a legal entity if protected as personal data) as defined under applicable Data Protection Laws).
- 1.33. **Purpose(s)** mean(s) the participation of the OBP in the On-boarding Project as well as in the EMVS Operational Phase, including the conditions for the grant of Rights that are necessary for the performance thereof.
- 1.34. **Qualified Person (QP)** means the person defined in Article 48 of Directive 2001/83/EC, as amended.



- 1.35. **Quality Management System** means a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives.
- 1.36. **Rights** mean the limited license and other usage rights granted by EMVO to the OBP under this Agreement, as necessary for the performance of this Agreement.
- 1.37. **Software Development Kit ("SDK")** means 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/or 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.
- 1.38. **Supplementary Fee** means the administrative fee, which is additional to the Onboarding Fee, to be paid by the OBP in accordance with Appendix 2 to this Agreement.
- 1.39. **Term** means the period of time set forth in Section 12 of this Agreement, unless this Agreement is terminated prior to the end of such period of time.
- 1.40. **Updates** mean the error corrections, minor release, modifications or enhancements to the EMVS, or any component thereof, including the European Hub, the interfaces to the manufacturers'/ parallel distributors' systems and to the National Systems, the EMVO Gateway and/or the SDK, including the EMVO Software, that EMVO may, at its sole discretion, make available to the OBP.
- 1.41. **User(s)** mean(s) any and all authorised users of the EMVS or European Hub in accordance with the EU Directive on Falsified Medicines and Delegated Regulation, including End Users, pharmaceutical manufacturers, MAHs and national governments.

## **2. Interpretation of the Agreement**

- 2.1. Section, paragraph and appendix headings shall not affect the interpretation of this Agreement.
- 2.2. Unless the context requires otherwise, words in the singular shall include the plural and vice versa, and reference to one gender shall include a reference to other genders and vice versa.
- 2.3. References to sections and appendices are to the sections and appendixes of this Agreement and references to paragraphs are to paragraphs of the relevant section.
- 2.4. Any words following the terms "include", "including", "in particular" or "for example" or any similar phrase shall be construed as illustrative and shall not limit the generality of the related general words.

## **3. Subject matter of the Agreement**

- 3.1. This Agreement establishes the contractual framework and conditions for the participation of the OBP in the On-boarding Project as well as in the EMVS Operational Phase, including the conditions for the grant of Rights that are necessary for the performance thereof.
- 3.2. It is expressly agreed that the subject matter of this Agreement is the participation of the OBP to the EMVS Operational Phase, and, as the case may be, depending on the Effective Date of this Agreement, to the On-Boarding Project.
- 3.3. For the avoidance of any doubt, during the EMVS Implementation Phase, the EMVS, or any component thereof, such as the European Hub, the EMVO Gateway or the SDK, and the On-boarding Project may be substantially amended or suspended by EMVO without any indemnity being due to the OBP.
- 3.4. This Agreement does not cover and is not in lieu of any of the OBP's and the OBP Affiliate's obligations under applicable laws regarding handling of medicines, including OBP's information, alert, and recall duties of whatever nature which the OBP shall comply with at all times.

#### **4. Grant of Rights**

- 4.1. Subject to the terms and conditions of this Agreement, including the OBP's obligation to pay the On-boarding Fee as detailed under Section 8.2 and Appendix 2, EMVO grants the OBP, and the OBP accepts, a non-exclusive, non-transferable and royalty free licence to use the Software Development Kit and the EMVO Documentation to develop the OBP Interface (if applicable), as well as to implement, test, use and operate the OBP Interface and/or, without prejudice to Section 6.1, the EMVO Gateway, in connection with the European Hub to upload and transfer OBP Data to National Systems (on its own behalf and/or on behalf of its OBP Affiliates, as the case may arise), for the whole duration of this Agreement.
- 4.2. License rights granted to the OBP are limited to those expressly granted herein. EMVO reserves all other rights.
- 4.3. Except as expressly agreed in writing between the Parties or as strictly necessary for the purpose of this Agreement, the OBP may not (i) use, copy, maintain, distribute, sell, sublicense, rent, make corrections to or modify the SDK, the EMVO Gateway, the European Hub or the EMVO Documentation; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer or otherwise translate the SDK, the EMVO Gateway, the European Hub or the

EMVO Documentation, unless to the extent the foregoing restrictions are expressly prohibited by applicable law; (iii) create derivative works based on the SDK, the EMVO Gateway, the European Hub or the EMVO Documentation; or (iv) use or sublicense the SDK, the EMVO Gateway, the European Hub or the EMVO Documentation for the benefit of a third party.

- 4.4. Subject to the terms and conditions of this Agreement, the OBP hereby grants to EMVO a limited, perpetual, non-exclusive, non-sublicensable, royalty-free and worldwide license to use the OBP Marks solely for the purposes of creating content directories or indexes as required for the performance of this Agreement and in accordance with the EU Directive on Falsified Medicines and the Delegated Regulation. The OBP reserves all other rights related to the Marks. Nothing in this Agreement shall be deemed to vest in EMVO any legal or beneficial right in the ownership of the Marks or of any other OBP's trademarks or logos.
- 4.5. The name and logo "EMVO" are registered trademarks. Nothing in this Agreement shall be deemed to vest in the OBP any legal or beneficial right in the ownership of these trademarks or of any other EMVO trademarks or logos. The OBP is not permitted to use neither to reproduce nor to authorise anyone to use or reproduce these trademarks or logos or any similar, related or analogous names or logos that would create a likelihood of confusion with EMVO's trademarks or logos in the sense of Article 9 of the EU Regulation 207/2009 of 26 February 2009, as amended, on the European Union trade mark, without the prior written consent of EMVO, which consent shall be given at the sole discretion of EMVO.

#### 4.6. *Grant of Rights and OBP Affiliates*

4.6.1. The OBP may authorise its Affiliates to benefit from its Rights under this Agreement and to participate to the On-boarding Project of the EMVS as well as to the EMVS Operational Phase, subject to the following terms and conditions, it being noted and agreed that the OBP remains fully responsible and liable vis-à-vis EMVO for any act or omission of its OBP Affiliate in the performance of this Agreement and that EMVO will be entitled to exercise and enforce all its rights and prerogatives under this Agreement directly, as it will see it appropriate at its entire discretion, vis-à-vis the OBP and/or its relevant OBP Affiliate(s) that committed the act or omission in breach of the Agreement, which will be bound jointly and severally for such purpose, this as further detailed under section 4.6:

- 4.6.1.1. the OBP Affiliate agrees in writing – by way of adhesion to this Agreement – to be bound, jointly and severally with the OBP, by and to observe all terms, limitations and conditions applying to the OBP as set forth in this Agreement;
- 4.6.1.2. the OBP Affiliate agrees in writing – by way of adhesion to this Agreement – to be bound by and to conform to all confidentiality and non-disclosure terms set forth under Section 13 and Appendix 3 to this Agreement;
- 4.6.1.3. the OBP confirms that it is duly authorised by the OBP Affiliate to perform the upload of the OBP Data on behalf of its OBP Affiliate, and that it shall only upload on the European Hub those OBP Data on behalf of its OBP Affiliate for which it is duly authorised;
- 4.6.1.4. upon request from EMVO, any OBP Affiliate shall notify EMVO of other OBPs that it authorises to upload Data on its behalf;
- 4.6.1.5. the OBP notifies EMVO about its OBP Affiliates (legal name, legal form, address of registered offices, if applicable national registration number in each market in which the OBP Affiliate operates) that wish to be authorised to benefit from the OBP's Rights under this Agreement and to participate in the On-boarding Project as well as in the EMVS Operational Phase, and that have agreed in writing to be bound by and to observe all terms, limitations and conditions set forth in this Agreement [and which OBP Data shall be uploaded by the OBP on behalf of the OBP Affiliate];
- 4.6.1.6. the OBP remains fully responsible and liable for any act or omission of its OBP Affiliates in the performance of this Agreement;
- 4.6.1.7. EMVO shall have the right, at its entire discretion, to exercise all its rights and prerogatives and to enforce any provision of this Agreement for any act or omission of the OBP Affiliates, directly vis-à-vis the OBP and/or its relevant OBP Affiliate(s) that committed the act or omission in breach of this Agreement;
- 4.6.1.8. without prejudice to other remedies: (i) in case of material default by any OBP Affiliates, EMVO reserves the right to terminate the Agreement with the OBP and (ii) in case of any default in general by any OBP Affiliates, EMVO reserves the right to request the OBP to withdraw the authorisation granted to any OBP Affiliates to participate to the On-boarding Project or to the EMVS Operational Phase and to

benefit from any of the OBP rights under this Agreement, at EMVO's discretion and without any indemnity being due to the OBP nor its OBP Affiliates; and

- 4.6.1.9. termination or expiration of this Agreement between EMVO and the OBP for whatever cause, including any attributable to EMVO, shall entail the automatic termination of any OBP Affiliates' Rights.

## **5. Rights and Obligations of the OBP**

- 5.1. The OBP undertakes to develop, implement, test, use and operate the OBP Interface and/or the EMVO Gateway in accordance with this Agreement and the SDK, including the EMVO Documentation, to be provided by EMVO, as may be amended from time to time by EMVO.
- 5.2. The OBP undertakes to pay the non-refundable On-boarding Fee as detailed under Section 8.2 and Appendix 2 to this Agreement, except if the OBP already paid the On-boarding Fee to EMVO under the Participation Agreement for the On-boarding project to the EMVS.
- 5.3. If the OBP entrusts whole or part of the development, implementation, testing and/or operation of the OBP Interface to an OBP Connection Provider or relies on a solution provided by an OBP Connection Provider for the OBP Interface, the OBP shall inform EMVO thereof and shall ensure that such OBP Connection Provider shall be of good reputation, shall comply with Good Industry Practices, and shall be subject to substantially equivalent obligations as the ones imposed on the OBP under this Agreement, including terms in favour of EMVO that are substantially equivalent to those provided under Appendix 1. The OBP shall in any event remain fully responsible for the performance of its obligations under this Agreement, including for any act or omission of the OBP Connection Provider in the performance of this Agreement. If the OBP does not conform with the terms of this Section 5.3 or the OBP Connection Provider does not, in EMVO's sole judgement, conform with terms that are substantially equivalent to those provided under Appendix 1, EMVO shall be entitled to require from the OBP that the OBP Connection Provider be dismissed at the risks, perils and expenses of the OBP.
- 5.4. The OBP hereby undertakes to develop, implement, test, use and operate the OBP Interface and/or the EMVO Gateway for the sole purpose of the performance of the On-boarding Project and the EMVS Operational Phase and for no other purposes.
- 5.5. The OBP agrees to implement such modifications, changes and Updates that EMVO may make

to the SDK, the EMVO Software, the European Hub and, subject to Section 6.1, the EMVO Gateway as they are provided from time to time by EMVO. Failure to do so may lead to issues, among others, in the functioning of the OBP System and the upload of OBP Data to the European Hub for which EMVO does not assume and explicitly disclaims any responsibility and liability and may also lead to EMVO exercising other rights and remedies available to it.

- 5.6. The OBP shall ensure that the OBP System, the OBP Interface and the EMVO Gateway are duly protected and shall implement at least the security measures set forth under the SDK. The OBP shall also ensure that no malicious software or other code is introduced into the EMVS, or any component thereof, including the European Hub or National Systems, through the OBP System, the OBP Interface or the EMVO Gateway.
- 5.7. More specifically and with respect to the EMVO Gateway and any possible creation of subaccounts by the OBP thereof and their use by a third party to upload OBP Data on behalf of the OBP, the OBP shall:
- 5.7.1 delegate such tasks to the third party in accordance with applicable legal requirements and good practices;
  - 5.7.2 for the purpose of this Agreement, the third party qualifies as an OBP Representative and shall therefore comply with all terms applying to OBP Representative under the Agreement;
  - 5.7.3 upon EMVO's request, carry out a legitimacy check of the third party (including verifying its identity, role, and legitimacy) to confirm that it meets the requirements to be granted access to, or to upload information on, the EMVS or any components thereof, in accordance with the EU Directive on Falsified Medicines and the Delegated Regulation and
  - 5.7.4 put in place specific and appropriate security procedures in accordance with applicable legal and regulatory requirements and good practices. Such procedures shall at least include the entering into of a written agreement between the OBP and, as appropriate, the OBP Affiliate and such third party, notably (i) detailing the responsibilities and obligations of each party, (ii) giving the right to the OBP/OBP Affiliate to audit the third party's compliance with its obligations, (iii) ensuring that records of data upload are kept or directly accessible by the OBP/OBP Affiliate (and competent authorities), (iv) obliging the third party to cooperate/submit to inspections carried

out by the competent authorities, and (vi) preventing the third party from subcontracting to a third party without the OBP/OBP Affiliate's authorisation (this without prejudice to further obligation that would apply to the OBP/OBP Affiliate when subcontracting certain tasks under applicable legislation).

5.8. The OBP also undertakes and warrants that:

- 5.8.1. it has all requisite power and authority to enter into this Agreement and to carry out all of its obligations under this Agreement;
- 5.8.2. access to the OBP Interface and to the EMVO Gateway shall be protected by appropriate security measures, at least the security measures set forth under the SDK, and as may be notified by EMVO to the OBP from time to time;
- 5.8.3. the OBP is responsible for maintaining the security of the OBP Interface and the confidentiality of its credentials and passwords of its account(s) (and any subaccounts) in general and in particular to connect to the European Hub through the OBP Interface or the EMVO Gateway, including for the management of secret authentication information of its users as set forth under Section 5.18 below, and is solely responsible for any activities carried out through its OBP Interface or its account (and subaccounts) on the EMVO Gateway;
- 5.8.4. only a very limited number of the OBP's Representatives shall have access to the SDK, the OBP Interface, the EMVO Gateway, the European Hub and the EMVO Documentation, as necessary for the performance of this Agreement and subject to the terms of Section 5.8;
- 5.8.5. the OBP will not – neither will any OBP Representative – attempt to circumvent any security features of the OBP Interface, the EMVO Gateway, the European Hub, the National Systems or any other components of the EMVS, and it shall not – neither will any OBP Representative – disrupt nor intercept any information or data, including data from any other manufacturer or parallel distributor, on the European Hub, National Systems or any other component of the EMVS, even though or accidental access to such information; and
- 5.8.6. OBP's Representatives are held by the same obligations as are imposed on the OBP under this Agreement;
- 5.8.7. it will only upload OBP Data on the EMVS on its behalf, if it is a MAH, and/or on



behalf of its OBP Affiliate(s) and always in accordance with the EU Directive on Falsified Medicines, the Delegated Regulation and any applicable national legislation as well as with any requirement(s) mutually agreed by the relevant national stakeholders, in particular, relating to the uploading of information in the EMVS. For the avoidance of doubt, the OBP will only upload OBP Data for an NMVS provided it has fulfilled all obligations vis-a-vis the respective NMVO that has established and manages this NMVS;

5.8.8. transfer of OBP Data from the European Hub to - and their storage in - the NMVS may only be allowed provided that the OBP (or the respective OBP Affiliate(s) that the OBP is representing) has (have) appropriate agreement(s) in place with the relevant NMVOs (subject to payment of due fees to the NMVOs);

5.8.9. it is fully responsible for the OBP Data stored in any of the National Systems, as the case may be, as well as for any damages, losses, claims or consequences arising out from OBP Data stored on the National Systems;

5.9. In the event the OBP and/or (one of) the OBP Affiliate(s) have a wholesaler license, the OBP undertakes and warrants that:

- (i) it will only perform respective wholesaler transactions of packs (including, but not limited to, verify packs, export packs from the EU) through the EU Hub for its own marketing authorisations and/or the marketing authorisations of its Affiliates;
- (ii) it is aware that the Audit Trail of the transactions performed through the EU Hub will contain the name of the OBP and not the name of the OBP Affiliate(s);
- (iii) it will not perform wholesaler transactions of packs of other OBPs and/or other OBP Affiliates;
- (iv) it will advise, as the case may be, the OBP Affiliates and ensure that they connect to the respective National System to perform wholesaler transactions.

5.9.1. The Parties agree that point (iii) above does not apply to OBPs whose OBP Affiliates are holders of parallel import or parallel distribution licenses, only in the context of their parallel import/distribution activities, in which case they can perform transactions of packs but not for wholesaler related purposes.

5.9.2. The Parties agree that point (i) above does not apply to OBPs that themselves or their OBP

Affiliates are holders of a manufacturing license, only for the purpose of processing packs used in clinical trials (including comparator products), in which case they can perform wholesaler transactions on packs that are not covered by their own or their OBP Affiliates' marketing authorisation.

- 5.10. Without any prejudice to Section 15.4, the OBP undertakes to inform, in writing, EMVO of any modification relating to its situation such as, but not limited to, change of address or registered office, as well as modification affecting its corporate situation, such as change of legal form, change of control, change in the legal or beneficial ownership of the company, merger or consolidation, or 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 the OBP's participation to the On-boarding Project, the EMVS Operational Phase and/or this Agreement.
- 5.11. The OBP shall appoint a key contact person (Single Point of Contact/SPOC) for the performance of this Agreement, as identified under Section 15.5 below.
- 5.12. Upon request by EMVO, the OBP shall report project status and progress to EMVO by e-mail in order to enable EMVO to control and steer the progress of the On-boarding Project and the EMVS Operational Phase. Information to be reported should include, amongst others:
- 5.12.1. status with OBP Interface development, implementation, testing, use and/or operation; and
- 5.12.2. issues met by the OBP in the implementation of the On-boarding Project as well as during the EMVS Operational Phase.
- 5.13. The OBP further agrees to provide EMVO, upon request, with a comprehensive and up-to-date list of all its Affiliates (including their legal name, legal form, address of registered offices, if applicable national registration number in each market in which the Affiliate operates) that qualify as MAHs and that should use the EMVS during the EMVS Operational Phase (whether or not such MAHs are participating to this On-boarding Project in accordance with Section 4.6 of this Agreement). The OBP shall inform EMVO whenever such list of MAHs has to be updated. The OBP will notify EMVO, either upon EMVO's reminder or request or on its own initiative, regarding any change in the address of the registered offices of its (new or existing) Affiliates.
- 5.14. The OBP agrees that it will have QPs certify the finished product batch as well as that the safety features as set forth in the EU Directive on Falsified Medicines are on the package.

- 5.15. The OBP shall ensure that the OBP Data have been uploaded on the EU Hub prior to release of the batch for sale or distribution.
- 5.16. The OBP shall take appropriate measures to ensure that the OBP System shall be used and operated for the whole Term of this Agreement for the Purposes, in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation and (ii) this Agreement.
- 5.17. The OBP is responsible for its own internet connection in order to be able to upload OBP Data to the European Hub, either via the OBP Interface or the EMVO Gateway.
- 5.18. Management of secret authentication information of users:  
The allocation of secret authentication information must be controlled by the OBP through a formal management process. The OBP must require its authorised users to sign a statement to keep personal secret authentication information confidential
- 5.19. Throughout the Term of the Agreement, the OBP shall obtain and maintain in effect a general liability insurance to cover its obligations under this Agreement. The OBP will not knowingly do or permit anything to be done which would make the insurance referred to hereunder void or voidable, or which would permit the insurer to reject, diminish or delay any claim under the insurance. Self-insurance of the OBP is also acceptable so far as and to the extent that the requirements set out hereunder are met and complied by the OBP.

## **6. Rights and Obligations of EMVO**

- 6.1. EMVO shall provide the OBP with the SDK and the EMVO Documentation necessary to develop, implement, test, use and operate the OBP Interface in connection with the European Hub. EMVO shall furnish the SDK and the EMVO Documentation to the OBP electronically or on media in machine-readable object code form. Moreover at least during the EMVS Implementation Phase and until 29 February 2020, EMVO shall provide the OBP with the EMVO Gateway and the parts of the EMVO Documentation necessary to develop, implement, test, use and operate the EMVO Gateway. EMVO reserves the right, throughout the Term of this Agreement, in its own right and without giving any reason and without any indemnity or other liability being due to the OBP, to review the provision of the EMVO Gateway in general and to either suspend or discontinue it or otherwise modify its terms by giving prior sufficient notice to the OBP.
- 6.2. EMVO reserves the right – but does not undertake any obligation – to make substitutions or modifications to any component of the EMVS, the European Hub, the EMVO Gateway -without

prejudice to Section 6.1, EMVO Software or the SDK, and shall inform the OBP thereof and provide Updates to the OBP, at its own discretion, it being agreed that the EMVS, or any component thereof, may be substantially changed, amended or even abandoned in the future. EMVO shall inform the OBP in advance to allow it to make the necessary changes in the OBP System.

6.3. Upon written notification from the NMVO with which the OBP and/or the OBP Affiliate is supposed to or has already entered into an agreement that this OBP (and/or the OBP Affiliate(s)) (a) has repeatedly refused to enter into a relevant agreement with such NMVO or (b) failed or refused to pay or has only partially paid the fees due to the NMVO or (c) has chosen to pay only one NMVO where multi-market packs are concerned, and is therefore in breach of its contractual obligations vis-à-vis the NMVO, EMVO will be entitled to take appropriate measures to block the upload of new OBP Data by this OBP for the requested NMVO territory. Notwithstanding the above, EMVO will not be required to restrict access to existing OBP Data that has been uploaded into the EMVS. For the avoidance of any doubt, EMVO will only block the upload as set forth hereunder provided that:

- (i) the NMVO has taken all necessary actions to address and solve the issue of non-compliance with the OBP and/or OBP Affiliate(s) on a bilateral basis as well as has informed it and/or them of the potential consequences described hereunder;
- (ii) the NMVO has taken appropriate action to inform the national competent authority of the non-compliance of the OBP and/or OBP Affiliate(s) with their contractual obligation, if such contractual basis exists or of its (their) refusal to enter into a relevant agreement with the NMVO, as the case may be, as well as of its intention to request EMVO to take the above measures to block the upload of new OBP Data;
- (iii) EMVO will request the NMVO to provide concrete evidence that demonstrates such non-compliance of the OBP and/or OBP Affiliate(s), as well as evidence that demonstrate the steps (i) and (ii) above; and
- (iv) the above right of EMVO to impose measures to block the upload of OBP Data will only and solely cover the case of non-payment of fees due by the OBP and/or OBP Affiliate(s) to the NMVO or refusal to enter into a relevant agreement and not any other breach of any contractual obligation, act and/or omission of the OBP and/or OBP Affiliate vis-à-vis the NMVO.

6.3.1 The Parties agree that, provided that the conditions above are met, EMVO is entitled to apply the above described measures at the request of an NMVO and that EMVO shall not be liable nor responsible for any damage, loss or consequences resulting therefrom. In case these measures are disputed by the OBP, this shall be solved in accordance with Section 14.2 below without any suspensive effect on the procedure described under Section 6.3.

- 6.4. EMVO shall take appropriate measures to ensure that the European Hub shall be used and operated for the whole Term of this Agreement for the Purposes, in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation and (ii) this Agreement and that it includes functionalities in line with Section 10.3 hereunder on Data ownership as well as the functionalities set out in Article 34 and 35 of the Delegated Regulation.
- 6.5. EMVO agrees to set in good faith appropriate and reasonable service levels for the European Hub approved by its governing body, to be implemented as soon as reasonably practicable and may thereafter be adapted from time to time by EMVO, notably if it appears that some service levels are not appropriate or feasible due to whatever reason.
- 6.6. EMVO shall take appropriate measures to ensure development, implementation and testing of the European Hub and, without prejudice to Section 6.1, the EMVO Gateway according to applicable best practices (e.g. GAMP 5). This includes ensuring and maintaining the systems' validated status including, in particular, keeping their specifications up-to-date.
- 6.7. EMVO shall take appropriate measures to ensure operation of the European Hub and, without prejudice to Section 6.1, the EMVO Gateway according to the service levels as set out in Section 6.5 and best practices applicable to system operations. EMVO will use its best efforts to ensure that the European Hub IT Company applies the above best practices.
- 6.8. EMVO shall take appropriate measures to establish and maintain a Quality Management System.
- 6.9. Following an audit performed on EMVO by an independent qualified third party, EMVO will provide the OBP with the final approved written audit report in due time after it becomes available to EMVO by the qualified third party.
- 6.10. Throughout the Term of the Agreement, EMVO shall obtain and maintain in effect a general liability insurance to cover its obligations under this Agreement. The OBP will not knowingly do or permit anything to be done which would make the insurance referred to hereunder void or voidable, or which would permit the insurer to reject, diminish or delay any claim under the insurance.

**7. Ownership of the EMVS, in particular the European Hub, EMVO Gateway, SDK, and the EMVO Documentation**

- 7.1. The OBP acknowledges that all components of the EMVS that belong (or will belong) to EMVO, including without limitation the European Hub, the EMVO Gateway, the SDK, and all EMVO Documentation, shall at all times remain the property of EMVO. Moreover, the OBP recognizes that the legal and beneficial interests in all Intellectual Property Rights subsisting in those components of the EMVS that belong (or will belong) to EMVO, including the European Hub, the EMVO Gateway, the SDK, and all EMVO Documentation, shall at all times remain the property of EMVO.
- 7.2. The OBP undertakes not to adapt, amend, publish, display, distribute or sub-licence or otherwise use any copies of the European Hub, the EMVO Gateway, SDK or EMVO Documentation, except as expressly permitted by this Agreement and shall ensure that OBP Representatives are made aware of and abide by all of the terms of this Agreement.
- 7.3. EMVO represents and warrants that it holds sufficient rights to grant the license under this Agreement.
- 7.4. EMVO undertakes to use its best efforts to set up the European Hub in a diligent manner and to implement state-of-the-art security measures to protect OBP Data uploaded to the European Hub for transfer to National Systems as part of the On-boarding Project and the EMVS Operational Phase from unauthorised access or interception.
- 7.5. Without prejudice to the foregoing, the OBP shall in principle be the holder of the OBP Interface and of the underlying Intellectual Property Rights (without prejudice to its contract with the OBP Connection Provider). The OBP shall, however, only be authorised to develop, implement, test, use and operate the OBP Interface for the purposes set forth – and according to the terms – of this Agreement, at the exclusion of any other purposes. The OBP undertakes not to publish, display, distribute or sub-license or otherwise use any copies of the OBP Interface except as expressly permitted by this Agreement and shall ensure that OBP Representatives are made aware of – and abide by – all of the terms of this Agreement.

**8. Costs**

- 8.1. Each Party shall bear its own costs for the entering into and performance of its rights and obligations under this Agreement.
- 8.2. Notwithstanding the preceding, the OBP shall pay the non-refundable On-boarding Fee to EMVO



in accordance with Appendix 2 to this Agreement, except if the OBP already paid the On-boarding Fee to EMVO under a duly executed Participation Agreement for the On-boarding project to the EMVS.

8.2.1 Without prejudice to the above, for every new OBP Affiliate the OBP confirms that it is duly authorised to perform the upload of the OBP Data via any appropriate communication platform as provided by EMVO (as for instance the ‘OBP portal’), it shall pay the respective On-boarding Fee in accordance with the terms of Appendix 2 to this Agreement.

- 8.3. The On-boarding Fee due by the OBP to EMVO hereunder shall be made net of any and all local taxes (including withholding, added value, stamp, excise, transfer and other taxes), and free of any set-off, counterclaim or other deduction of whatever nature (including without limitation for or on account of taxation) unless the deduction or withholding is required by law, in which case the payment to EMVO shall be increased to the extent necessary to ensure that, after the making of such deduction or withholding, EMVO receives and retains (free from any liability in respect of any such deduction or withholding other than tax on its overall net income) a sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made.
- 8.4. The EMVO Gateway will be made available for free during the EMVS Implementation Phase and may be provided upon payment of a fee during the EMVS Operational Phase but, in no case earlier than May 2019 (meaning that the provision of the EMVO Gateway will be for free until May 2019), it being agreed that such fee will be notified by EMVO to the OBP four months before its entry into force.
- 8.5. Without prejudice to EMVO’s obligations as set forth under this Agreement, the OBP acknowledges and agrees that additional fees may apply to cover any services the OBP may request from EMVO during the On-Boarding Project and/or the EMVS Operational Phase, it being agreed that EMVO shall provide a cost estimate along with the details of the respective cost categories to the OBP in advance.
- 8.6. If any fees (including, but not limited to the Onboarding Fee and the Supplementary Fee) are not paid by the OBP to EMVO when due, EMVO reserves the right to charge the OBP with late interests on such fees on a daily basis at the Belgian legal interest rate as prevailing from time to time, calculated from and including the day the fees became due for payment up to but excluding the date of payment.



## 9. Limitation of warranty and liability

### 9.1. Warranties:

- 9.1.1 Except as otherwise set forth in this Agreement, the OBP agrees that its sole remedy, in case the European Hub and the EMVO Gateway would not operate properly or according to their specifications, shall be limited, at EMVO's option to repair or replace the portion of the European Hub or the EMVO Gateway that does not comply. This warranty will apply only if the European Hub and the EMVO Gateway are used in accordance with their specifications.
- 9.1.2 Although EMVO undertakes to use its best efforts to set up the European Hub in a diligent manner and to implement state-of-the-art security measures to protect OBP Data uploaded to the European Hub for transfer to National Systems from unauthorised access or interception, there is no absolute guarantee of security. EMVO is in any event not responsible for the security and confidentiality of OBP Data on systems that are not under EMVO's control such as the OBP System, or any National System.
- 9.1.3 In the unlikely event of an interception or unauthorised access to OBP Data despite EMVO's best efforts as per Sections 7.4 and 9.1.1 above, including in case of negligence or gross negligence, EMVO shall not be liable for such interceptions or unauthorised access, or any direct, indirect, special, incidental, or consequential damages (including lost profits, loss of savings, loss of business, loss of data and third parties' claim) suffered by the OBP, even if EMVO has previously been advised of the possibility of such damages. EMVO does not warrant, neither expressly nor implicitly, that OBP Data shall be preserved from interception or unauthorised access while processed as part of the EMVS.
- 9.1.4 The foregoing are OBP's sole and exclusive remedies and are exclusive and in lieu of all other warranties, terms and conditions, including for hidden/latent defects, all of which are hereby excluded to the fullest extent permitted by law. Except for the limited warranty under 9.1 above, any and all aspects of the EMVS, the European Hub, the SDK, the EMVO Gateway and the EMVO Documentation are provided "as is" and EMVO makes no warranties, whether express or implied, or statutory regarding or relating thereto, or any materials or services furnished or provided to the OBP under this Agreement. Specifically, EMVO does not warrant that the EMVS, the European Hub, the SDK, the EMVO Gateway, the EMVO Software or the EMVO Documentation will be error and defect free (whether apparent or hidden/latent) or will perform in an uninterrupted manner, or that such errors or defects will be corrected. More specifically and

to the maximum extent allowed by law and except for the limited warranty under 9.1.1, EMVO specifically disclaims all implied guarantee and warranties, including any warranty of condition, quality, performance, satisfactory quality, merchantability or fitness for a particular purpose (even if EMVO had been informed of such purpose), including for latent or hidden defects, with respect to any part of the EMVS, the SDK, the EMVO Gateway, the European Hub, the EMVO Software and the EMVO Documentation.

9.1.5 Each of the Parties acknowledges and agrees that in entering into this Agreement, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding of any person other than as expressly mentioned in this Agreement, in the preamble or as a warranty or representation.

## 9.2. **Liability:**

**9.2.1.** Without prejudice to the foregoing, in no event will EMVO or its employees, officers, agents or subcontractors be liable for any 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 furnishing, performance or use of the EMVS or any component thereof, including the European Hub, the SDK, the EMVO Gateway, the EMVO Software or the EMVO Documentation, or any other services or assistance performed hereunder or any delay in delivery or furnishing thereof 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.

**9.2.2.** Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud or any other liability which cannot be limited or excluded under applicable law.

**9.2.3.** Except in the case of personal injury or death and without prejudice to the foregoing, EMVO's maximum aggregate liability vis-à-vis the OBP (including the OBP Affiliates) (whether in contract, law, case-law, tort or any other form of liability) for damages or loss, howsoever arising or caused, whether or not arising from EMVO's breach of contract (including grave fault) or tortious conduct, negligence (including gross negligence) or hidden/latent defects, shall in no event exceed the amount of the On-boarding Fee paid by the OBP in accordance with Appendix 2 to this Agreement at the time the event giving

rise to the claim occurred, for any and all claims arising under or in connection with - and for the whole duration of - this Agreement, subject to the limitations set out below.

9.2.4. EMVO's total cumulative and aggregate liability vis-à-vis all participants to the On-boarding Project and/or the EMVS Operational Phase, including all on-boarding partners and their Affiliates, on a collective basis, for any and all claims originating from or relating to a same event or series of connected events giving rise to EMVO's liability, will not exceed 2 million Euro per such event or series of events. By event or series of events, one shall understand an event or series of events causing one or several individual claims.

9.2.5. Participants to the On-boarding Project and/or the EMVS Operational Phase, including all on-boarding partners and their Affiliates, raising claims for the same event or series of events under the previous clause shall never be entitled to damages, inclusive of all interests, penalties, legal costs and attorney fees whatsoever, exceeding 2 million Euro in total for such claims. If any such claims are found to have merits, the damages awarded, as the case may arise, by the court(/tribunal) or pursuant to an out-of-court settlement to any claimant shall be reduced by the court(/tribunal) or automatically (*de plein droit*) so as not to exceed the result of the following formula:

Reduced damages awarded or payable to a given claimant in respect of an event or series of events =

€2,000,000 \*

(A) Damages rightfully claimed by the claimant in respect of such event or series of events (or, as the case may arise, unreduced damages awarded to the claimant by a court(/tribunal) or pursuant to an out-of-court settlement)

/ (B) Total damages rightfully claimed by all claimants in respect of such event or series of events

it being noted that (i) for the purposes of (B), damages claimed by any claimant, shall be deemed to be rightfully claimed until they would be irrevocably waived or found as not rightfully claimed by a final, non-appealable judgment or pursuant to a final out-of-court settlement, binding on EMVO and the relevant claimant, and that (ii) claimants will not be entitled to late interest or any financial penalty at charge of EMVO for the period of time during which their rights under this section will be assessed such as e.g., the time necessary to find another claim without merits and, as a result, to mitigate the

reduction of the damages awarded to other claimants.

9.2.6. Any claim shall be time barred one year after the occurrence of the event or of the latest of a series of events giving rise to it.

## **10. Regulatory, Legitimacy check, data ownership and protection**

### **10.1. Regulatory**

**10.1.1.** Each Party is fully and solely responsible for compliance with all statutory and regulatory obligations applying to its business and activities, including but not limited to anti-bribery and anti-money laundering regulations.

**10.1.2.** This Agreement is not in lieu of any information, alert, or recall duties of other obligations of whatever nature which the OBP shall comply with at all times independently of the EMVS.

**10.1.3.** It is expressly agreed that the OBP is and remains solely responsible for its OBP System and OBP Data, and for the uploading of OBP Data to the European Hub for transfer to National Systems (including for the uploading of OBP Data on behalf of the OBP Affiliate(s)).

### **10.2. Legitimacy check**

**10.2.1.** The OBP also understands and agrees that, before executing this Agreement, EMVO shall carry out a legitimacy check (including verifying the OBP's identity, role, and legitimacy) to confirm that the OBP and the OBP Affiliate(s) meet(s) the requirements to be granted access to, or to upload information on, the EMVS or any components thereof, in the sense of the EU Directive on Falsified Medicines and the Delegated Regulation.

**10.2.2.** The OBP further recognizes and agrees that EMVO's execution of this Agreement will notably be subject to successful completion of such legitimacy check.

**10.2.3.** The OBP acknowledges and agrees that the administrative costs of such legitimacy check shall be supported by the OBP and shall be included in the On-boarding Fee to be paid by the OBP in accordance with Appendix 2 for up to two (2) reviews within the same OBP's legitimacy check. In case a third or more reviews within the same legitimacy check is (are) required, the OBP will bear the administrative costs for these checks.

### **10.3. Data ownership**

10.3.1. As a principle, the data contained in the EMVS belongs to the User who generates this data when interacting with the EMVS ('whoever creates the data, owns the data'). Without any restriction whatsoever to the use of the data generated by a User's own IT system as mentioned above, access to and/or use of any data (static or dynamic) extracted from, copied from or downloaded from the EMVS for purposes outside of the scope of the Falsified Medicines Directive and its Delegated Regulation needs to be agreed by all the stakeholders owning that data on a case by case basis in compliance with relevant legislation.

10.3.2. Data generated by a User's own IT system (e.g., sales or transactional data, stock movements, pricing information, etc.) by electronic or manual means, or captured with the same, is exclusively owned and may be freely used without any restriction whatsoever by the concerned User. For the avoidance of doubt, this means that pharmacists own the data generated by their own IT system, that wholesalers own the data generated by their own IT system, and that manufacturing and/or marketing authorisation holders own the data generated by their own IT system.

#### 10.4. General data protection obligations

10.4.1. If Data include Personal Data, or if any Personal Data is otherwise collected, processed and transferred by a Party acting as controller or processor in connection to this Agreement, this Party shall comply with all its obligations, as controller, respectively as processor of such Personal Data, under applicable Data Protection Laws, and shall notably implement appropriate technical and organizational measures to protect Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised access, disclosure or transfer, misuse, and against any other unlawful forms of processing. For the purposes of this Section 10.4, 'process/processing', 'data subject', controller' and 'processor' shall have the same meaning as defined under applicable Data Protection Laws. In particular, the following provision will apply to any processing or sharing of personal data:

10.4.1.1. In relation to any Personal Data provided by one Party to the other in connection with this Agreement, such Party represents that it is allowed to share the Personal Data with the other Party in connection with this Agreement and that it has informed –and, where legally required, has obtained necessary consent

from – data subjects and competent data protection authorities in relation to the processing and sharing of their personal data in accordance with applicable Data Protection Laws.

10.4.1.2. The Parties shall not transfer Personal Data received from the other Party outside the European Economic Area to countries not recognized by the EU Commission as providing an adequate level of protection without ensuring that such transfer is covered by appropriate safeguards in accordance with applicable Data Protection Laws.

10.4.1.3. Each Party shall not process or retain Personal Data longer than necessary for the purposes set forth under this Agreement or as otherwise required or permitted under applicable Data Protection Laws.

10.4.1.4. In the event of an OBP established outside of the European Economic Area, the provisions under Appendix 4 shall apply in addition to the preceding.

10.4.1.5. Without prejudice to the preceding, if and where, in relation to the performance of the Agreement and/or as required under applicable Data Protection Laws, any Party processes personal data on behalf of the other (as data processor or sub-processor), the Parties agree that they will sign a Data Processing Addendum, which will be an Annex and inseparable part of this Agreement.

10.4.1.6. In addition and if and to the extent necessary to comply with mandatory provisions under applicable Data Protection Laws, the Parties agree that, as the case may arise, they will negotiate and agree in good faith any further amendment to the Agreement and/or to the Data Processing Addendum, that could be required in the future to comply with the applicable Data Protection Laws, in particular the General Data Protection Regulation, taking into account any interpretation, guidance or orders issued by competent EU or Member State authorities, and any national supplementing laws' provisions, relating to the Data Protection Laws.

## 10.5. Protection of Personal Data of the signatories of this Agreement

10.5.1. In accordance with the applicable Data Protection Laws, the Parties acknowledge that they will process the Personal Data of the signatory(ies) of the Agreement representing the other Party in accordance with the Data Protection Laws as data controllers for the

purposes of maintenance and execution of the contractual relationship. Therefore, the legal basis for the processing of the Personal Data of the signatories of this Agreement is the performance of this Agreement (Article 6, 1. (b) of the GDPR).

10.5.2. The Personal Data will be processed for the duration of this Agreement, it being noted that personal data may then be stored for ten (10) years after expiry of the contractual relationship for the establishment, exercise or defense of legal claims, and/or as required or permitted by applicable law.

10.5.3. The signatories of this Agreement may exercise their rights to request access to their Personal Data the relevant Party holds about them, to request the rectification or erasure of any inaccurate Personal Data, to object, under certain circumstances as described under Data Protection Laws, to the processing of their Personal Data, by writing to the addresses provided under Section 15.5 of this Agreement, accompanying a copy of their identity document and identifying the right that they wish to exercise. Under certain circumstances as described under Data Protection Laws, the signatories may also have the right to request the restriction of processing as well as the right to data portability. They are also entitled to lodge a complaint with the supervisory authority.

**10.6. Protection of Personal Data of Staff (including contact persons and representatives of the other Party such as the SPOC, legal representative, initial requester of any appropriate communication platform as provided by EMVO (as for instance the ‘OBP portal’) or other authorised users or managers of such platform)**

10.6.1. In accordance with the applicable Data Protection Laws, each Party hereby informs the other Party that, without prejudice of the preceding, it may also process the Personal Data of representatives and employees of the other Party, such as the SPOC, legal representatives, initial requester of any appropriate communication platform as provided by EMVO (as for instance the ‘OBP portal’) and other users or managers of such platform (herein referred to as "Staff") (including the name, contact details, function and account details) as data controller, for the purposes of the performance of this Agreement and maintaining and managing the contractual relationship, including invoicing and claim management as well as in order to allow efficient management of the EMVS and communication between the different stakeholders of the EMVS (in particular communication of the SPOC's contact details to the NMVOs). Therefore, the legal basis



for the processing of Personal Data shall be the performance of this Agreement (Article 6, 1. (b) of the GDPR) as well as the relevant data controller's legitimate interests not overridden by the data subjects' own interests and fundamental rights and freedoms, in particular where the processing aims at allowing efficient management and communication between the stakeholders of the EMVS (Article 6,1 (f) of the GDPR). If either Party does not provide the information mentioned above, the other Party may not be able to perform the Agreement and manage the contractual relationship with this Party

10.6.2. Personal Data will be processed for the duration of this Agreement, it being noted that Personal Data may then be stored for 10 (ten) years after expiry of the contractual relationship for the establishment, exercise or defense of legal claims, and/or as required or permitted by applicable law.

10.6.3. The Staff may exercise their rights to request access to Personal Data the relevant Party holds about them, to request the rectification or erasure of any inaccurate Personal Data, to object, under certain circumstances as described under Data Protection Laws, to the processing of their Personal Data, by writing to the address detailed above, accompanying a copy of their identity document and identifying the right that they wish to exercise. Under certain circumstances as described under Data Protection Laws, the Staff may also have the right to request the restriction of processing as well as the right to data portability. They are also entitled to lodge a complaint with the supervisory authority.

10.6.4. Each Party undertakes to have informed - and obtained the consent, where necessary - of their respective Staff to have their data disclosed to and further processed by the other Party for the above purposes and to inform them of their ability to exercise their rights as described above, in accordance with Data Protection Laws.

10.6.5. Without prejudice to the preceding, EMVO may decide to display, at its own discretion and to the extent desirable or necessary under applicable Data Protection Laws, its own privacy notices and consent forms on its website and/or on any appropriate communication platform as provided by EMVO (as for instance the 'OBP portal'), and to collect extra consent from data subjects to the processing activities that EMVO carries out exclusively for its own purposes as data controller. The Parties recognized that any use of EMVO's website and/or any appropriate communication platform as provided by

EMVO (as for instance the ‘OBP portal’) may be subject to the terms, including the privacy terms, posted thereon, in particular [EMVO’s privacy policy](#).

## **11 Force Majeure**

No Party shall be liable for any delay in performing or for failure to perform its obligations hereunder if the delay or failure results from any cause or circumstance whatsoever beyond its reasonable control, including any breach or non-performance of this Agreement by the other Party (hereinafter "event of force majeure"), provided the same arises without the fault or negligence of such Party. If an event of force majeure occurs, the date(s) for performance of the obligation affected shall be postponed for as long as is made 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 Party. Each Party shall use its reasonable endeavours to minimize the effects of any event of force majeure.

## **12 Term of the Agreement and Conditions of Termination**

12.1 This Agreement shall start upon its Effective Date, and, unless terminated earlier by any Party as set forth below, shall remain in full force and effect for an indefinite period of time.

12.2 Without prejudice to other remedies under applicable law, either Party shall be entitled to terminate the Agreement unilaterally and without indemnity at its charge for mere convenience at any time upon giving at least three (3) months prior written notice to the other.

12.3 Without prejudice to other remedies under applicable law, either Party is entitled to dissolve this Agreement forthwith, in its own right and without prior intervention of any court or arbitral body, without indemnity, by mere notification to the other Party, if (i) the latter is in breach of any material obligation under this Agreement and, (ii) the defaulting Party fails to cure such breach within thirty (30) calendar days after such cure has been demanded in writing if such breach is capable of cure.

12.4 Without prejudice to the above, EMVO is entitled to terminate this Agreement immediately, without indemnity, if the OBP (i) has become unable to pay any of its debts as they fall due; or (ii) assigns or attempts to assign or delegate its rights or duties under this Agreement in whole or in part, without the prior consent of EMVO.

12.5 Without prejudice to the above, the Agreement shall automatically expire if EMVO is no longer

in charge of operating the European Hub.

12.6 The expiration or termination of this Agreement shall not affect provisions thereof that by their terms and meaning are of a continuing nature.

### **13 Confidentiality**

13.1 With respect to EMVO Confidential Information, the OBP undertakes and agrees to conform to all confidentiality and non-disclosure terms set forth under Appendix 3 to this Agreement, which are hereby incorporated into this Agreement and makes integral part thereof, indifferently whether this Confidential Information was provided before or after the Effective Date of this Agreement.

13.2 With respect to OBP Confidential Information, EMVO agrees to maintain the confidentiality of the OBP Confidential Information and to protect it in the same manner as it protects its own proprietary and confidential information of like kind but in no case less than with reasonable care. EMVO agrees to disclose OBP Confidential Information only to those of its officers, employees, agents and contractors, including the European Hub IT Company, to whom, and to the extent such disclosure is necessary for the purposes of the implementation, testing and operation of the EMVS, or of any component thereof, including the European Hub, the EMVO Gateway, the interfaces to the OBP Systems and to the National Systems, the National Systems, etc., as contemplated under this Agreement. It is, however, expressly agreed that OBP Data that will be uploaded by the OBP into the National Systems through the European Hub may be accessible/visible to certain participants to this On-boarding Project and the EMVS as necessary for the purpose of the EMVS.

13.3 The OBP acknowledges and agrees that EMVO is authorised to communicate with its members, all parties involved in the EMVS, as well as third parties about the EMVS, its implementation, testing and operation, including about the participation of the OBP in the On-boarding Project and/or the EMVS Operational Phase and their progress. The OBP expressly authorises EMVO to announce publicly its participation in the On-boarding Project and/or the EMVS Operational Phase on the EMVO website or by any other communication means, mentioning the OBP's company name and logo. The OBP shall provide EMVO with required texts and graphics. The OBP is permitted to announce publicly its participation to the On-boarding Project and/or the EMVS Operational Phase on its websites (it being noted that any other information in relation to the On-boarding Project and/or the EMVS Operational Phase or this Agreement remains subject to the confidentiality and non-disclosure terms set forth under Appendix 3 to this Agreement),

and it being agreed that EMVO shall at all time reserve the right to require the OBP to remove any information related to the EMVS or any component thereof published by the OBP on its websites or by other communication means, and that the OBP shall conform to any such request from EMVO within 2 business days.

- 13.4 The obligations set forth under this Section 13 and in Appendix 3 to this Agreement shall remain in force for five (5) years after the termination or expiration of this Agreement for whatever cause.

#### **14 Jurisdiction - Governing law**

- 14.1 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.
- 14.2 The Parties must use their best efforts to amicably resolve any issues that may arise between them in relation to this Agreement. They must escalate any such issues to their competent levels of management, before attempting to solve their dispute according to the CEPANI Rules of Mediation ([www.cepani.be](http://www.cepani.be)). All disputes not solved by mediation within three months upon a Party's request to initiate mediation will be finally settled under the CEPANI Rules of Arbitration by one arbitrator appointed in accordance with those rules ([www.cepani.be](http://www.cepani.be)). Mediation and arbitration are conducted in Brussels and in English.

#### **15 General provisions**

- 15.1 This Agreement, together with its Appendices which form an integral part thereof, sets forth the entire agreement between the OBP and EMVO as to the subject matter hereof and supersedes and prevails over all prior discussions, proposals, agreements (such as the Agreement for Participation in On-boarding Project of the European Medicines Verification System for the EMVS Implementation Phase that may have been previously signed between the Parties), arrangements, and communications, whether oral or written, between the OBP and EMVO, except for any prior non-disclosure agreement entered into in relation to the EMVS.
- 15.2 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) neither will it preclude the further exercise of any such rights. Any waiver of a right must be express and in writing.
- 15.3 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.

- 15.4 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.
- 15.5 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 du Commerce 123, box 02, 1000 Brussels

E-mail: [helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)

**Notices to OBP:**

[SPOC First Name] [SPOC Last Name]

[Street] [Number], [Zip Code] [City], [Country]

[SPOC Email]

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 receipt by, the receiving Party.



CP-number  
(provided by EMVO)

CON-number  
(provided by EMVO)

- 15.6 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.
- 15.7 Each person signing this Agreement represents and warrants that he or she is duly authorised and has legal capacity to execute and deliver this Agreement. Each Party represents and warrants to the other that the execution and delivery of the Agreement and the performance of such Party's obligations hereunder have been duly authorised and that the Agreement is a valid and legal agreement binding on such Party and enforceable in accordance with its terms.
- 15.8 The Parties agree that their entering into the Agreement will be effective upon exchange of a scanned copy thereof via the communication platform as provided by EMVO. Either Party recognizes that such signature and exchange will be recognized equivalent, for all legal purpose, to a signed original notified to the other Party, that shall be countersigned by the other Party in the same way, and the Parties waive any and all evidentiary and/or other requirements as to the entering into the Agreement.

**In witness thereof**, 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: *[Authorised*

*Representative First Name]*

*[Authorised Representative*

*Last Name]*

Name: Andreas Walter

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Title: General Manager

Title: *[Authorised*

*Representative Job Title]*

Title:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Date:

Date:

Date:

## Appendices

### Appendix 1 – Terms in favor of EMVO to be included in the agreement with OBP Connection Provider

As per Section 5.3 of this Agreement, if the OBP entrusts whole or part of the development, implementation, testing, use or operation of the OBP Interface to an OBP Connection Provider or relies on a solution provided by an OBP Connection Provider for the OBP Interface, the OBP shall ensure that such OBP Connection Provider be subject to terms in favour of EMVO that are substantially equivalent to the terms below:

The OBP Connection Provider subscribes the following obligations both contractually in favour of the OBP and unilaterally in favour of EMVO, which is deemed to accept such stipulations upon their mere subscription by the OBP Connection Provider, and agrees that EMVO shall be considered as third party beneficiary and shall be entitled to enforce any of these provisions directly against the OBP Connection Provider, at EMVO's sole discretion:

#### 1. Non-Disclosure of Confidential Information

- 1.1. The OBP Connection Provider expressly agrees that the obligations of confidentiality contained herein shall apply and have full force and effect in respect of any and all Confidential Information disclosed to it relating to the EMVS or any component thereof, including the SDK, both before and after the date of this Agreement.
- 1.2. The OBP Connection Provider undertakes to:
  - keep the Confidential Information secret and confidential, and without limiting the foregoing, not disclose the Confidential Information to any person, other than to its OBP connection Provider Representatives in accordance with Section 3 below, except as expressly otherwise permitted by the terms of this Agreement;
  - exercise the same degree of care and protection with respect to the Confidential Information that the OBP Connection Provider exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with best care;



- only use the Confidential Information for the purpose of the development, implementation, testing, use or provision of the OBP Interface on behalf of the OBP under its agreement with the OBP, at the exclusion of any other purpose;
  - take all necessary precautions in order to prevent any unauthorised misuse, disclosure, theft or other loss of the Confidential Information, and to notify immediately the OBP and 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.
- 1.3. The OBP Connection Provider shall be liable, and shall indemnify and hold harmless the OBP and EMVO, for any damages, loss, or costs, expenses or liability arising out of or resulting from the breach by the OBP Connection Provider (or of its Representatives referred to in Section 3 to this Appendix 1) of the terms herein, as well as for any loss, theft or other unauthorised use or disclosure of Confidential Information caused by the OBP Connection Provider's or its Representatives' fault or negligence.
- 1.4. The OBP Connection Provider agrees that if any of these provisions are not performed in accordance with their respective terms or are otherwise breached by it or its Representatives, monetary damages may not be necessarily sufficient remedy. Therefore, the OBP Connection Provider agrees that, in addition to all other rights and remedies otherwise available, the OBP and/or EMVO shall be entitled to specific performance or equitable relief by way of injunction or otherwise in the event it or its Representatives breach or threaten to breach any of these provisions.
- 1.5. The OBP Connection Provider agrees that EMVO is under no obligation to disclose any information nor to provide any assistance to the OBP Connection Provider at any time.

## **2. Permitted Disclosure**

- 2.1. The restrictions on use or disclosure of 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 received legitimately by the OBP Connection Provider from a third-party on a non-confidential basis;
  - is independently developed by the OBP Connection Provider; or
  - is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, the OBP Connection Provider gives the OBP and EMVO

immediate notice thereof and give the OBP and 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. In such case, the OBP Connection Provider shall cooperate with the OBP and EMVO, by all legal means, in order to limit the effects of the disclosure and to prevent the disclosure of any other Confidential Information.

### **3. Disclosure to OBP Connection Provider Representatives**

3.1. The OBP Connection Provider shall be entitled to disclose Confidential Information to those of its authorised officers, employees and contractors (collectively referred to as the "OBP Connection Provider Representatives") to whom, and to the extent to which such disclosure is necessary for the purpose of the development of the OBP Interface on behalf of the OBP under its agreement with the OBP, provided that it:

- informs such OBP Connection Provider Representatives of the limitations and conditions with respect to the use and disclosure of the Confidential Information set forth herein;
- ensure that such OBP Connection Provider Representatives agree in writing to observe the limitations and conditions set forth herein; and
- shall be fully liable for any violation of these limitations and conditions, by any OBP Connection Provider Representative or any other person or entity to whom the OBP Connection Provider discloses Confidential Information, whether or not in accordance with these provisions.

### **4. Reproduction and Ownership**

4.1. Except to the extent necessary for the development, implementation, testing, use or operation of the OBP Interface on behalf of the OBP, the OBP Connection Provider undertakes not to copy, duplicate or reproduce in whole or in part, and by any mean whatsoever, the Confidential Information, except with the prior consent of EMVO.

4.2. The OBP Connection Provider acknowledges that the Confidential Information shall at all times remain the exclusive property of EMVO. Moreover, the OBP Connection Provider recognizes that the legal and beneficial interest in the copyright and all other Intellectual Property Rights subsisting in EMVO Confidential Information (including any component of the EMVS that belong (or will belong) to EMVO, in particular the SDK) belong (or will belong) to EMVO.

4.3. Neither the disclosure of Confidential Information nor anything herein contained shall be interpreted as giving to the OBP Connection Provider, any implied or express right, including

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 Connection Provider shall neither claim nor seek any right, including to Intellectual Property Rights thereon.

- 4.4. Subject to the terms and conditions of these provisions, the OBP Connection Provider is granted a non-exclusive non-transferable royalty-free licence to use the Software Development Kit and the EMVO Documentation for the sole purpose of developing, implementing, testing, using or operating the OBP Interface on behalf of the OBP and in accordance with the terms of the agreement between the OBP and the OBP Connection Provider.
- 4.5. License rights granted to the OBP Connection Provider are limited to those expressly granted herein. Except as expressly provided herein, the OBP Connection Provider may not (i) use, copy, maintain, distribute, sell, sublicense, rent, make corrections to or modify the SDK or EMVO Documentation, except as specifically necessary for the purpose of the development, implementation, testing, use or operation of the OBP Interface on behalf of the OBP under its agreement with the OBP; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer or otherwise translate the European Hub, SDK and the EMVO Documentation, unless to the extent the foregoing restrictions are expressly prohibited by applicable law; (iii) create derivative works based on the SDK, European Hub or the EMVO Documentation, except for the OBP Interface as necessary for the purpose of the development, implementation, testing, use or operation of the OBP Interface on behalf of the OBP under its agreement with the OBP; or (iv) use or sublicense the SDK, European Hub or the EMVO Documentation for the benefit of a third party.
- 4.6. The OBP Connection Provider agrees that, if he wishes to make any further use of the SDK, the EMVO Documentation, or re-use the Confidential Information in any manner, outside the scope of its agreement with the OBP, the OBP Connection Provider will be required to enter into a separate license agreement with EMVO, which will have no obligation to grant it.
- 4.7. The OBP Connection Provider agrees that sensitive information may be processed as part of the EMVS, or any component thereof, including the SDK, and that it shall implement all required security measures to protect them from unauthorised disclosure.

## 5. No warranty

- 5.1. The OBP Connection Provider agrees that neither EMVO nor the OBP makes or gives any warranty of any kind with respect to the Confidential Information of use thereof, including as to the accuracy or the completeness of the Confidential Information. Use of any Confidential Information is at the OBP Connection Provider's own risks and perils.
- 5.2. The OBP Connection Provider agrees that 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 Confidential Information, whether alleged as a breach of contract or any other undertaking (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.

## **6. General provisions**

- 6.1. These provisions shall remain in force for a term of five (5) years as from the effective date of the agreement between the OBP and the OBP Connection Provider, unless extensions or stipulations are agreed between the Parties and/or arising from the future contractual relations and unless earlier terminated.

## **7. Definitions**

As used in these provisions, the capitalized terms shall have the same meanings as set forth under Section 1 of the body of this Agreement.

**Appendix 2 – On-boarding Fees**

The one-time and non-refundable On-boarding Fee (excluding all taxes/VAT, if applicable) to be paid by the OBP to EMVO under this Agreement shall be calculated and invoiced by EMVO to the OBP (i) in respect of the number of MAHs the OBP represents in Europe (European Economic Area and Switzerland), (ii) in respect of the timing when the OBP shares a valid Agreement with EMVO via the respective platform EMVO has indicated and (iii) in accordance with the table below:

	Onboarding Fee
OBPs with more than 12 MAHs in Europe	45,000 €
OBPs with 6 to 12 MAHs in Europe	22,500 €
OBPs with 3 to 5 MAHs in Europe	18,000 €
OBPs with 2 MAHs in Europe	13,500 €
OBPs with 1 MAH in Europe	6,750 €

**Important Notes**

1. The Agreement will be considered valid provided all the following conditions are satisfied:
  - All pages of the Agreement have been shared with EMVO using the respective platform as per above
  - No amendments, changes or other edits have been made to the Agreement
  - The individual(s) signing the Agreement is (are) the individual(s) duly authorised to sign on behalf of the OBP and provide(s) evidence to that respect as per the requirements EMVO has set and communicated to the OBP.

2. If, during the Term of this Agreement, the OBP notifies EMVO of new MAH(s) as per Section 5.13, then the Supplementary Fee will be due and paid by the OBP to EMVO. The Supplementary Fee will be non-refundable and will be calculated and invoiced by EMVO to the OBP in accordance with the terms and conditions provided under Appendix 2 (e.g. if the addition of new MAH(s) results in the OBP falling under a higher Onboarding Fee category, then the supplementary fee will equal the difference between the previous and the new Onboarding Fee category). EMVO reserves the right to reasonably modify the Onboarding Fee from time to time throughout the Term of this Agreement and to notify the OBP thereof. In this case, the OBP acknowledges and agrees that such modification may also impact the Supplementary Fee it being agreed that the OBP will then pay to EMVO the Supplementary Fee calculated according to the Onboarding Fee as applicable at the time of notification of new MAH(s).

### **Appendix 3 – Confidentiality and Non-disclosure Terms**

#### **1. Non-Disclosure of Confidential Information**

- 1.1. 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 Appendix 3 to the 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 the Agreement.
- 1.2. 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 OBP Affiliates and OBP Representatives in accordance with Section 3 to this Appendix 3, 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.
- 1.3. 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 OPB Affiliates or OBP Representatives referred to in Section 3 to this Appendix) of the terms of this Appendix, as well as for any loss, theft or other unauthorised use or disclosure of EMVO Confidential Information caused by the OBP or OBP Affiliates' or OBP Representatives' fault or negligence.
- 1.4. The OBP agrees that if any of the provisions of this Appendix are not performed in accordance with their respective terms or are otherwise breached by it or OBP Affiliates or OBP 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 OBP Affiliates or OBP Representatives breach or threaten to breach any of the provisions of this Appendix.
- 1.5. The OBP agrees that EMVO is under no obligation to disclose any information to the OBP at any time under this Appendix and the Agreement, unless otherwise expressly provided hereunder.

## **2. Permitted Disclosure**

- 2.1. 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 Appendix;
  - 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 gives EMVO immediate notice thereof, and gives 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 Appendix. 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.

### **3. Disclosure to OBP Affiliates and OBP Representatives**

3.1. The OBP shall be entitled to disclose EMVO Confidential Information to those of OBP Affiliates and OBP 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 OBP Affiliates and OBP Representatives of the limitations and conditions with respect to the use and disclosure of EMVO Confidential Information set forth in this Appendix;
- ensures that such OBP Affiliates – by way of adhesion to this Agreement – and OBP Representatives agree in writing to observe limitations and conditions as those set forth in this Appendix; 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 Appendix by any of its employees ; and
- shall be fully liable for any violation of these limitations and conditions, by any OBP Affiliate or OBP Representative or any other person or entity to whom the Receiving Party discloses Confidential Information, whether or not in accordance with this Agreement.

### **4. Reproduction and Ownership**

4.1. Except to the extent necessary for the purposes contemplated under the 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.

4.2. 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.

- 4.3. Unless specifically provided in the 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 EMVO 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.

## **5. No warranty**

- 5.1. 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 the EMVO Confidential Information. Use of any EMVO Confidential Information is at the OBP's own risks.
- 5.2. 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.

## **6. General provisions**

- 6.1. Notwithstanding the Effective Date of the Agreement, the OBP agrees to be bound unilaterally by all its obligations under this Appendix as of the date of signature of the Agreement by the OBP, 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 the Agreement has not been countersigned by EMVO yet.

**Appendix 4 – Addendum only applicable to non-EEA OBPs.<sup>1</sup>**

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

**EUROPEAN MEDICINES VERIFICATION ORGANIZATION**, a non-profit association with registered offices at 1000 Brussels (Belgium), Rue du Commerce 123, VAT BE 0638.801.022 RPM Brussels, represented by Andreas Walter, General Manager,

Hereinafter referred to "**EMVO**";

**And**

*[Company Name]*

having its registered office at,

*[Street] [Number], [Zip Code] [City], [Country],*

Legal Entities' Registry or equivalent number *[Company Registration Number]*

represented herein by,

*[Authorised Representative First Name] [Authorised Representative Last Name]*

*[Authorised Representative Job Title]*

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** this Addendum forms part of the Agreement for Participation of the Onboarding Partners in the European Medicines Verification System entered into between the Parties (the "**Agreement**") to which it is attached and is only valid provided that it is signed together with the Agreement.

<sup>1</sup> A non-EEA OBP is the OBP not established within the European Economic Area (e.g. Switzerland, United States, Israel, Australia etc). Only the OBPs established outside the European Economic Area are required to sign this Appendix 4 of the Participation Agreement and comply with the provisions hereunder.

**WHEREAS** the Parties wish to supplement and/or amend the Agreement with the provisions below with respect to the specific situation of an OBP not established within the European Economic Area (“**non-EEA OBP**”).

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

- 1.1 Without prejudice to Sections 4.6 and 10.4, if a non-EEA OBP is appointed by the OBP Affiliate(s) to carry out the upload of OBP Data on their behalf, the following terms and conditions shall apply:
  - 1.1.1 both the non-EEA OBP and the OBP Affiliate(s) will be bound by a duly executed written agreement in accordance with applicable legal requirements and good practice, without prejudice to the OBP Affiliates remaining fully responsible for compliance with all obligations under this Agreement (including this Addendum) and the Delegated Regulation;
  - 1.1.2 the OBP Affiliate(s) agree(s) in writing – by way of adhesion to this Agreement, which will be performed by the OBP Affiliate signing a letter of adhesion – to be bound, jointly and severally with the non-EEA OBP, by and to observe all terms, limitations and conditions applying to the non-EEA OBP as set forth in this Agreement and Addendum;
  - 1.1.3 in case the appointment of the non-EEA OBP triggers any transfer of personal data outside the European Economic Area, both parties shall implement appropriate safeguards and take appropriate technical and organizational measures to ensure that such processing and transfer comply with Data Protection Laws (including, as the case may arise, informing and obtaining the consent of any non-EEA OBP Representatives to the processing and transfer of their personal data outside the EEA in countries that may not be recognized by the European Commission as providing an adequate level of protection of personal data); and
  - 1.1.4 the non-EEA OBP shall keep records of Data upload, shall make them immediately accessible by the OBP Affiliate(s) (and therefore the national competent authorities), and shall provide all necessary assistance and submit to inspections carried out by the national competent authorities upon request.
- 1.2 EMVO shall actively monitor, regularly audit and, where applicable, take steps to enforce the compliance by imposing specific requirements in terms of quality and security of Personal Data and of the Data upload process, and the availability of information and records for EMVO, the OBP Affiliate(s) and the national competent authorities.



CP-number  
(provided by EMVO)

CON-number  
(provided by EMVO)

1.3 The Parties agree that all audit, reporting, legitimacy checks, data security and confidentiality, access by national competent authorities and other obligations as provided under Article 36 and 37 of the Delegated Regulation as well as this Agreement will remain in full force and effect hereunder.

1.4 The Parties agree that their entering into the Agreement will be effective upon exchange of a scanned copy thereof via the communication platform as provided by EMVO. Either Party recognizes that such signature and exchange will be recognized equivalent, for all legal purpose, to a signed original notified to the other Party, that shall be countersigned by the other Party in the same way, and the Parties waive any and all evidentiary and/or other requirements as to the entering into the Agreement.

**In witness thereof**, 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: *[Authorised*

*Representative First Name]*

*[Authorised Representative*

*Last Name]*

\_\_\_\_\_

Name: Andreas Walter

Name:

\_\_\_\_\_

Title: General Manager

Title: *[Authorised*

*Representative Job Title]*

Title:

\_\_\_\_\_

Date:

Date:

Date:

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