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

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

**EUROPEAN MEDICINES VERIFICATION ORGANIZATION**, a non-profit association with registered offices at 1040 Brussels (Belgium), Rue de la Loi 28, VAT BE 0638.801.022 RPM Brussels, represented by Andreas Walter, EMVO General Manager, Hereinafter referred to "**EMVO**";

**and**

[**FILL IN COMPANY NAME AND LEGAL FORM** \_\_\_\_\_],  
having \_\_\_\_\_ its \_\_\_\_\_ registered \_\_\_\_\_ office \_\_\_\_\_ at  
[*place* \_\_\_\_\_]  
\_\_\_\_\_,  
Legal Entities' Registry or equivalent number [*number* \_\_\_\_\_],  
represented herein by [*name* \_\_\_\_\_], [*function* \_\_\_\_\_],  
hereinafter referred to as the "**On-boarding Partner**" or "**OBP**";

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

**Preamble**

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

**WHEREAS**, EMVO and key stakeholders in the supply chain of medicinal products in Europe are collaborating to develop the European Medicines Verification System (EMVS) in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

**WHEREAS**, as EMVO does not have the required know-how in the field of information technology for the implementation, development, testing and operation of the EMVS, a contract was 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 intends to set the EMVS into preliminary operational mode on a limited scale as part of the On-boarding Project.

**WHEREAS**, as part of the On-boarding Project, the OBP will develop, implement, use and/or operate an interface to the European Hub based on specifications provided by EMVO and/or will use the EMVO Gateway provided by EMVO.

**WHEREAS**, the OBP is willing to participate to the On-boarding Project, and to develop, implement, test, use and/or operate an OBP Interface to the European Hub, and/or use the EMVO Gateway provided by EMVO, in order to upload and transfer data to National Systems through the European Hub under the terms and conditions set forth below.

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

**1. Definitions**

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

- 1.1. **Affiliate** shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).
- 1.2. **Agreement** shall mean this Agreement for the Participation in the On-boarding Project 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.
- 1.3. **Delegated Regulation** shall mean the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
- 1.4. **Effective Date** means the date on which this Agreement 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.
- 1.5. **EMVO Confidential Information** shall mean any information (whether in oral, written or electronic form) belonging or relating to EMVO, its business affairs or activities which is not in the public domain and which: (i) EMVO has marked as confidential or proprietary, (ii) EMVO, orally or in writing, has advised the OBP is of a confidential nature, (iii) due to its character or nature, a reasonable person in a similar position to the OBP 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.
- 1.6. **EMVO Documentation** shall mean 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.
- 1.7. **EMVO Software** shall mean any and all computer software program(s) to be provided by EMVO, or on behalf of EMVO, to the OBP in object code form in any form or media, in the frame of or in connection with this Agreement, and all Updates to such program, as well as the relevant sections of the EMVO Documentation.

- 1.8. **EMVO Gateway** shall mean the solution provided by EMVO that will allow the OBP to upload OBP Data to the European Hub and to perform a set of transactions, e.g., to verify a pack or to obtain a report, during the On-boarding Project.
- 1.9. **EU Directive on Falsified Medicines** shall mean Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.
- 1.10. **European Hub** designates the component of the EMVS under the responsibility of the EMVO that serves as a central information and data router for the transmission of OBP Data to or from the National Systems; it is set up and managed by the EMVO.
- 1.11. **European Medicines Verification System or EMVS** shall mean the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems and allows authorized users to verify the authenticity of medicinal products.
- 1.12. **Intellectual Property Rights** shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, 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 registrable, patentable or not).
- 1.13. **MAH(s)** shall mean the Marketing Authorization Holder(s) that operate and place medicines on the market for sale in the European Economic Area and/or Switzerland.
- 1.14. **National (Medicines Verification) System or NMVS** shall mean a national or supranational repository of the EMVS under the responsibility of one national medicines verification organisation; it is connected to the European Hub and allows authorized users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- 1.15. **OBP Affiliate** shall mean an Affiliate of the OBP, as notified by the OBP to EMVO from time to time, that has agreed in writing to be bound by and to observe all terms, limitations and conditions set forth in this Agreement, 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; for the purpose of this Agreement, references to the OBP also include all OBP Affiliates that are authorized to benefit from the OBP's rights under this Agreement and to participate to the On-boarding Project, as notified by the OBP to EMVO from time to time, in accordance with Section 4.6 of this Agreement.
- 1.16. **OBP Confidential Information** shall mean 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 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 this On-boarding Project 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.

- 1.17. **OBP Connection Provider** shall mean a third party contractor engaged by the OBP to assist 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.
- 1.18. **OBP Data** shall mean any information – to be – uploaded by the OBP to the European Hub via the OBP Interface or via the EMVO Gateway for transfer to National Systems, as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation (in particular its Article 33, para. 2), irrespective of whether or not these include Personal Data.
- 1.19. **OBP Interface** shall mean the solution (either through a system-to-system direct connection or through a gateway provided by an OBP Connection Provider) to be developed, implemented, tested, used and/or operated by the OBP, at OBP discretion, in accordance with the Software Development Kit, as may be amended from time to time by EMVO, that will allow connecting the OBP System to the European Hub to upload OBP Data to the European Hub and to perform a set of transactions.
- 1.20. **OBP Mark** shall mean 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.
- 1.21. **OBP Representative** shall mean 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 authorized 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 authorized 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 authorized officers, employees and agents, and without prejudice to the requirements applying vis-à-vis OBP Connection Providers under Section 5.3 of this Agreement.
- 1.22. **OBP System** shall mean the system that is owned by the OBP and holds the OBP Data for transmission to National Systems through the European Hub.
- 1.23. **On-boarding Fee** shall mean the one-time administrative fee to be paid by the OBP in accordance with Appendix 2 to this Agreement.
- 1.24. **On-boarding Project** means the limited scale and preliminary operational mode of part of the European Medicines Verification System under which the OBP shall be entitled to (i) use the EMVO Gateway and/or (ii) develop, implement, test, use and/or operate an OBP Interface to the European Hub in accordance with the Software Development Kit provided by EMVO, for the transfer of OBP Data to National Systems through the European Hub.

- 1.25. **Personal Data** shall mean any and all information relating to an identified or identifiable individual (or to a legal entity if protected as personal data under applicable data protection law).
- 1.26. **Rights** shall 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.
- 1.27. **Software Development Kit ("SDK")** shall mean all EMVO Software, specifications and EMVO Documentation provided by EMVO to the OBP in any form or media, for the development, implementation, testing, use and/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.
- 1.28. **Updates** shall 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 that EMVO may, at its sole discretion, make available to the OBP.

## **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, including the conditions for the grant of Rights that are necessary for the performance of the On-boarding Project.
- 3.2. It is expressly agreed that the subject matter of this Agreement is the participation of the OBP to the limited scale and preliminary operation of certain part(s) of the EMVS, which is still being designed, developed and tested and could therefore be substantially amended or even abandoned. 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, suspended or even terminated in the future by EMVO without any indemnity being due to the OBP. Besides, EMVO does not give any warranty that the EMVS, or any component thereof, will ever enter into full scale (day-to-day) operational mode.
- 3.3. This Agreement does not cover and is not in lieu of any of the OBP'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 independently of the EMVS.
- 3.4. This Agreement does not cover the use by the OBP for full scale (day-to-day) operational mode of the EMVS or any National Systems, which shall, as the case may arise and if implemented, be covered by a distinct agreement, unless otherwise agreed in writing by the Parties in accordance with Section 15.6 below.

#### **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 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 the EMVO Gateway in connection with the European Hub to upload and transfer OBP Data to National Systems, 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, non-exclusive, non sublicenseable, 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 the On-boarding Project. This license shall automatically expire upon expiration or termination of this Agreement for whatever cause, except as otherwise agreed between the Parties. 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 authorize 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. The OBP may authorize its Affiliates to benefit from its Rights under this Agreement and to participate to the On-boarding Project of the EMVS, subject to the following terms and conditions:
- 4.6.1. 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;
- 4.6.2. 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;

- 4.6.3. 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 authorized to benefit from the OBP's Rights under this Agreement and to participate in the On-boarding Project, and that have agreed in writing to be bound by and to observe all terms, limitations and conditions set forth in this Agreement;
- 4.6.4. the OBP remains fully responsible and liable for any act or omission of its OBP Affiliates in the performance of this Agreement;
- 4.6.5. 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;
- 4.6.6. in case of default by any OBP Affiliates, without prejudice to other remedies, EMVO reserves the right to terminate the Agreement with the OBP or to request the OBP to withdraw the authorization granted to any OBP Affiliates to participate to the On-boarding Project 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
- 4.6.7. 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. 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 to be provided by EMVO, as may be amended from time to time by EMVO.
- 5.2. The OBP undertakes to pay the On-boarding Fee as detailed under Appendix 2 to this Agreement.
- 5.3. If the OBP entrusts whole or part of the development, implementation, testing 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 shall be of good reputation, shall comply with best industry practice, and shall be subject to the same obligations as imposed on the OBP under this Agreement. Without prejudice to the preceding, the OBP shall require the OBP Connection Provider to agree on the terms in favour of EMVO provided under Appendix 1, unless EMVO confirms in writing (either individually to the OBP or collectively by publishing or posting a list of OBP Connection Providers, e.g., on EMVO's website) that the OBP Connection Provider already subscribed equivalent obligations. 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 the terms 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. If the OBP entrusts whole or part of the development, implementation, testing, operation or provision of the OBP Interface to an OBP Connection Provider that has entered into a licence agreement for use of the SDK with EMVO, the OBP shall notify EMVO thereof, and consents

that such OBP Connection Provider shall communicate to EMVO the name of the OBP for which it develops, implements, tests, operates or provides the OBP Interface.

- 5.5. 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 for no other purposes.
- 5.6. The OBP agrees to implement promptly such modifications and changes that EMVO may make to the SDK during the On-boarding Project as they are provided from time to time by EMVO.
- 5.7. 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.
- 5.8. The OBP also undertakes and warrants that:
  - 5.8.1. 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;
  - 5.8.2. 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;
  - 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) 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 5.14 below, and is solely responsible for any activities carried out through its OBP Interface or its account on the EMVO Gateway;
  - 5.8.4. 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 through or accidental access to such information; and
  - 5.8.5. OBP's Representatives are held by the same obligations as are imposed on the OBP under this Agreement.
- 5.9. Without any prejudice to Section 15.4, the OBP undertakes to inform, in writing, EMVO of any modification relating to its situation (modification of equipment, 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 and/or this Agreement.
- 5.10. 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.



- 5.11. The OBP shall report key facts, project status and project progress to EMVO by e-mail in order to enable EMVO to control and steer the progress of the On-boarding Project. Information to be reported should include, amongst others:
- 5.11.1. status with OBP Interface development, implementation, testing, use and/or operation;  
and
- 5.11.2. issues met by the OBP in the implementation of the On-boarding Project.
- 5.12. 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 in its operational phase as of 9 February 2019 (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.
- 5.13. 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.
- 5.14. Management of secret authentication information of users:
- Control: The allocation of secret authentication information must be controlled by the OBP through a formal management process. The OBP must require its authorized users to sign a statement to keep personal secret authentication information confidential and to keep group (i.e. shared) secret authentication information solely within the members of the group.

## **6. Obligations of EMVO**

- 6.1. EMVO shall provide the OBP with the EMVO Gateway, the SDK and the EMVO Documentation necessary to develop, implement, test, use and operate the EMVO Gateway and 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.
- 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 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 and that EMVO does not guarantee that the EMVS, or any component thereof, will ever enter into full scale (day-to-day) operational mode at any stage.

## **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 from unauthorized 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 authorized 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 On-boarding Fee to EMVO in accordance with 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.

## **9. Limitation of warranty and liability**

- 9.1. The OBP agrees and acknowledges that this On-boarding Project constitutes a limited scale preliminary operational mode of part of the EMVS implementation, that the OBP participates to this On-boarding Project at its own costs and risks, and that EMVO therefore does not guarantee that this On-boarding Project will – and shall not be liable in case it does not – result in an effective full scale (day-to-day) operational mode system.
- 9.2. Except as otherwise set forth in this Agreement, the OBP also agrees that its sole remedy, in case the EMVS or any aspect thereof, including the European Hub, the EMVO Gateway, the SDK and/or the EMVO Documentation or the OBP Interface would not operate properly or according to their specifications, shall be to cease any use thereof and to terminate its participation in the On-boarding Project, without indemnities at charge of EMVO.
- 9.3. 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 unauthorized 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, neither on the OBP System, nor on any National Systems, that are

not under EMVO's control.

- 9.4. In the unlikely event of an interception or unauthorized access to OBP Data despite EMVO's best efforts as per Sections 7.4 and 9.3 above, including in case of negligence or gross negligence, EMVO shall not be liable for such interceptions or unauthorized 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 unauthorized access while processed as part of the EMVS.
- 9.5. 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. 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 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 and the OBP is solely responsible for all costs and expenses associated with rectification, repair or damage caused by such errors or defects.
- 9.6. To the maximum extent allowed by law, 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 and the EMVO Documentation.
- 9.7. 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.
- 9.8. 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 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.
- 9.9. Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.
- 9.10. 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 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.

- 9.11. EMVO's total cumulative and aggregate liability vis-à-vis all participants to the On-boarding Project, 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.
- 9.12. Participants to the On-boarding Project, 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.

- 9.13. 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 and data protection

- 10.1. Each Party is fully and solely responsible for compliance with all statutory and regulatory obligations applying to its business and activities.
- 10.2. 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.
- 10.3. 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. If OBP Data include Personal Data, which is presumed not to occur, the OBP shall comply with

all its obligations, as controller of such Personal Data, under any and all applicable data protection and privacy laws. If required under applicable data protection laws, the OBP shall make all necessary notifications and will obtain all necessary authorization from competent data protection authorities for the contemplated data collection, processing and transfer.

- 10.4. 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 meets 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 Delegated Regulation.
- 10.5. The OBP further recognizes and agrees that EMVO's execution of this Agreement will notably be subject to successful completion of such legitimacy check.
- 10.6. 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.
- 10.7. As necessary in relation to the performance of this Agreement, including for the completion of the legitimacy check as foreseen under the previous section, EMVO may collect, store and process Personal Data about the OBP or the OBP's Representatives, in accordance with applicable data protection law. The OBP shall inform OBP Representatives about the processing of their Personal Data by EMVO for the above purposes, as well as about their rights of access, rectification and objection (including the right to object, at any time and free of charge, to the processing of Personal Data for direct marketing purposes).

## **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 automatically expire (without any prior notice) on 8 February 2019 at 24h00. At least 6 months prior to the expiration of this Agreement and provided that EMVO is still in capacity to perform and operate the European Hub in accordance with the EU Directive on Falsified Medicines and Delegated Regulation, EMVO shall provide the OBP with a template agreement in order to cover the operational phase of the EMVS. The Parties shall aim at – and shall use their best efforts in good faith to – enter into such agreement to cover the operational phase of the EMVS as early as possible and at least three months before the expiration of this Agreement, to be effective as of 9 February 2019 at 00h00 in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.
- 12.2. 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 30 days 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, (i) if the European Hub IT Contract between EMVO and the European Hub IT Company is terminated or expires for whatever reason, or (ii) if and when the On-boarding Project is terminated and/or the EMVS enters into full scale operational mode, or if EMVO is no longer in capacity to perform or operate the European Hub for whatever reason.
- 12.5. 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 manufacturers'/parallel distributors' 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 authorized 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 its progress. The OBP expressly authorizes EMVO to announce publicly its participation in the On-boarding Project 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 on its websites (it being noted that any other information in relation to the On-boarding Project 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 24 hours.
- 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. Any dispute arising between the Parties out of or in connection with this Agreement and/or any contractual or non-contractual (including pre-contractual) matters in connection with its conclusion, validity, interpretation, enforcement, performance and termination will be submitted to the exclusive jurisdiction of the courts of Brussels.

#### **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 all prior discussions, proposals, agreements, 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 neither 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 de la Loi 28, box 21, 1040 Brussels

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



CP-number  
(provided by EMVO)

CON-number  
(provided by EMVO)

**Notices to OBP:**

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
E-mail: \_\_\_\_\_

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

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.

**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: Andreas Walter

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

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

Title: General Manager

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 require the OBP Connection Provider to agree on the following terms in favour of EMVO:

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 Article 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 Article 3) of the terms herein, as well as for any loss, theft or other unauthorized 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 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;
  - procure 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 except 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 very 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 unauthorized 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 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 following capitalized terms shall have the meanings set forth below:

- 7.1. **Confidential Information** shall mean any information (whether in oral, written or electronic form) belonging or relating to EMVO, its business affairs or activities which is not in the public domain, which 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, as well as any component thereof including the European Hub, the interfaces to the manufacturers'/parallel distributors' systems, the Software Development Kit and the EMVO Gateway, and any underlying EMVO Software and EMVO Documentation.
- 7.2. **EMVO Documentation** shall mean any and all specifications, manuscripts, user guides, explanatory material and operating manuals, whether in electronic form or hard copy, as EMVO may in its discretion provide 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.
- 7.3. **EMVO Software** shall mean any and all computer software program(s) to be provided to the OBP Connection Provider in object code form in any form or media, in the frame of or in connection with these provisions, and all Updates to such program, as well as the relevant sections of the Documentation.
- 7.4. **European Hub** designates the component of the EMVS under the responsibility of the EMVO that serves as a central information and data router for the transmission of OBP Data to or from the National Systems; it is set up and managed by the EMVO.
- 7.5. **European Medicines Verification System ("EMVS")** shall mean the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National (Blueprint) Systems and allows authorized users to verify the authenticity of medicines.
- 7.6. **European Medicines Verification Organisation ("EMVO")** means the non-profit legal entity established to set up and manage the European Hub in accordance with EU Directive on Falsified Medicines and Delegated Regulation.
- 7.7. **EMVO Gateway** shall mean the solution provided by EMVO that will allow the OBP to upload OBP Data to the European Hub and to perform a set of transactions, e.g., to verify a pack or to obtain a report during the On-boarding Project.
- 7.8. **Intellectual Property Rights** shall 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 registrable, patentable or not).

- 7.9. **OBP Interface** shall mean the solution (either through a system-to-system direct connection or a gateway provided by an OBP Connection Provider) to be developed, implemented, tested, used and/or operated by the OBP Connection Provider on behalf of the OBP in accordance with the Software Development Kit and the EMVO Documentation, as may be amended from time to time by EMVO, that will allow connecting the OBP System to the European Hub to upload OBP Data to the European Hub and to perform a set of transactions.
- 7.10. **On-boarding Project** means the limited scale preliminary operational mode of part of the European Medicines Verification System under which the OBP will be entitled to (i) use the EMVO Gateway and/or (ii) develop, implement, test, use and/or operate the 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.
- 7.11. **Software Development Kit ("SDK")** shall mean all EMVO Software, specifications and EMVO Documentation provided by EMVO to the Receiving Party in any form or media, for the development, implementation, testing, use and operation of the OBP Interface and/or EMVO Gateway in connection with the European Hub, as may be amended by EMVO from time to time.

SAMPLE



*CP-number*  
*(provided by EMVO)*

*CON-number*  
*(provided by EMVO)*

**Appendix 2 – On-boarding Fees**

The one-time 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 in respect of the number of MAHs of the OBP in Europe (European Economic Area and Switzerland), in accordance with the table below:

	On-boarding Fee
OBPs with more than 12 MAHs in Europe	20,000 €
OBPs with 6 to 12 MAHs in Europe	10,000 €
OBPs with 3 to 5 MAHs in Europe	8,000 €
OBPs with 2 MAHs in Europe	6,000 €
OBPs with 1 MAH in Europe	3,000 €

SAMPLE

## 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 Article 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 OBP Affiliates or OBP Representatives referred to in Article 3 to this Appendix) of the terms of this Appendix, as well as for any loss, theft or other unauthorized 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.

## 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;
- procure 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.