

Contract Number:  
EMVO

SP Number:  
EMVO

**LICENCE AGREEMENT FOR USE OF THE SDK BY OBP CONNECTION PROVIDER**

**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, represented by Andreas Walter, EMVO Director General, Hereinafter referred to "**EMVO**" ;

**and**

[ company name and legal form \_\_\_\_\_ ],  
having its registered office at  
[ street, number \_\_\_\_\_ ]  
[ zip code, city \_\_\_\_\_ ]  
[ country \_\_\_\_\_ ],  
Legal Entities' Registry or equivalent number [ \_\_\_\_\_ ],  
represented herein by [ name \_\_\_\_\_ ], [ function \_\_\_\_\_ ],  
hereinafter referred to as the "**On-boarding Partner Connection Provider**" or "**OBP Connection Provider**" ;

EMVO and the OBP Connection Provider 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 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, in particular the European Hub, 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 that have entered into an Agreement for Participation in the On-boarding Project with EMVO will develop, implement, use and/or operate their own interface to the European Hub (the OBP Interface) based on specifications provided by EMVO and/or will use the EMVO Gateway provided by EMVO.

**WHEREAS**, the OBP Connection Provider is a provider of IT solutions of good reputation and complies with best industry practices.

**WHEREAS**, the OBP Connection Provider is willing to receive the Software Development Kit and, as the case may arise, to use it to develop standardized solution(s) for the development, distribution and provision of OBP Interface(s) subject to the terms and conditions set forth in this Agreement.

**WHEREAS**, EMVO is willing to provide a copy of the Software Development Kit to the OBP Connection Provider as necessary for the OBP Connection Provider to develop and propose such standardized solution(s) for the OBP Interface(s) under the terms and conditions of this Agreement.

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

#### **1. Definitions**

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

- 1.1. **Affiliate** shall mean, in relation to a Party, any company or incorporated body that controls or is directly or indirectly controlled by such Party. For the purposes of this definition, “control” means ownership of more than fifty percent (50%) – and/or the right to exercise the vote of 50% (fifty percent) or more – of all the voting shares or the ability to appoint the majority of the directors.
- 1.2. **Agreement** shall mean this License Agreement for use of the SDK by OBP Connection Provider, 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 Connection Provider is of a confidential nature, (iii) due to its character or nature, a reasonable person in a similar position to the OBP Connection Provider 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, 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.

- 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 Connection Provider from time to time, for or in connection with the development, implementation, use, testing 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 Connection Provider 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 OBPs 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 EMVO that serves as a central information and data router for the transmission of OBP Data to or from the National Systems; it is set up and managed by EMVO.
- 1.11. **European Hub Test System** shall mean the test environment of the European Hub where Standardized Solution(s) may be tested by the OBP Connection Provider in order to verify that such Solutions(s) will allow OBPs to use and operate their OBP Interface in connection with the European Hub to upload and transfer OBP Data to the National Systems.
- 1.12. **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 medicines.
- 1.13. **Intellectual Property Rights** shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, trade marks, service marks, author rights, copyrights, neighbouring rights and related rights, database rights, trade and business names, domain names, know-how, trade secrets, confidential information, patterns, drawings, rights in computer software, proprietary marketing materials, and any and all other intellectual or industrial property rights in all their patrimonial and moral aspects, as well as any application therefor, anywhere in the world (whether registrable, patentable or not).
- 1.14. **National (Medicines verification) System or NVMS** 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 Connection Provider Confidential Information** shall mean any information (whether in oral, written or electronic form) belonging or relating to the OBP Connection Provider, its business affairs or activities, which is not in the public domain and which: (i) the OBP Connection Provider has marked as confidential or proprietary, (ii) the OBP Connection Provider 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.
- 1.16. **On-boarding Partner or OBP** shall mean a party that has entered into an Agreement for Participation in On-boarding Project of the European Medicines Verification System with EMVO.
- 1.17. **OBP Data** shall mean any information – to be – uploaded by the OBP to the European Hub via the OBP Interface or, as the case may arise, via the EMVO Gateway for transmission 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.
- 1.18. **OBP Interface** shall mean the solution (either through a system-to-system direct connection or through a gateway provided by the 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.
- 1.19. **OBP Connection Provider Representative** shall mean an authorised officer, employee, agent of 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 Connection Provider remains fully liable for its Representative.
- 1.20. **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.
- 1.21. **On-boarding Project** means the limited scale preliminary operational mode of part of the European Medicines Verification System under which OBPs will be entitled to (i) use the EMVO Gateway and/or (ii) develop, implement test, use and/or operate the OBP Interface(s) 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.
- 1.22. **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).
- 1.23. **Rights** shall mean the limited license and other usage rights granted by EMVO to the OBP Connection Provider under this Agreement, as necessary for the performance of this Agreement.
- 1.24. **Software Development Kit ("SDK")** shall mean all EMVO Software, specifications, and EMVO Documentation provided by EMVO to the OBP Connection Provider 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.

1.25. **Standardized Solution(s) or Solution(s)** shall mean the standardized solution(s) to serve as OBP Interface(s) that the OBP Connection Provider will develop, test, distribute and provide in accordance with the terms of this Agreement, and, as the case may arise, specific agreement(s) to be entered into between the OBP Connection Provider and OBP(s).

1.26. **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 (as the case may arise) and/or the SDK that EMVO may, at its sole discretion, make available to the OBP Connection Provider.

## 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 under which EMVO will disclose the SDK, EMVO Documentation and other EMVO Confidential Information to the OBP Connection Provider, and grant it a limited license thereon to allow the OBP Connection Provider to develop, as the case may arise, the Standardized Solution(s), to test such Solution(s) with the European Hub Test System, and to distribute and provide such Solution(s) subject to the terms and conditions set forth in this Agreement.

3.2. It is expressly agreed that the EMVS, including all components thereof, 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 SDK, and the On-boarding Project may be substantially amended, suspended or even terminated in the future without any indemnity being due by EMVO to the OBP Connection Provider or to its Representatives. 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. It is expressly agreed that the OBP Connection Provider is under no obligation to develop nor to commercialize Standardized Solution(s). In case the OBP Connection Provider decides not to develop such Standardized Solution(s), the OBP Connection Provider shall cease any use of and return the SDK, EMVO Documentation and any other EMVO Confidential Information to EMVO at EMVO's first demand, and shall delete any copy thereof it would have taken. In such case, the OBP Connection Provider undertakes to refrain from using in whatever manner any information, including EMVO Confidential Information, it would have learned in connection with this Agreement or in relation to the EMVS or any component thereof, including the European Hub, the EMVO Gateway, the SDK or the EMVO Documentation.

3.4. It is expressly agreed that any Solution(s) developed and distributed/provided by the OBP Connection Provider will only be allowed to interface an OBP System with the EMVS or any

part thereof subject to EMVO's prior authorization, which shall be granted at EMVO's sole discretion, and that nothing obliges EMVO to grant such authorization.

- 3.5. It is expressly agreed that this Agreement is non exclusive and that EMVO may have provided – and retains the right to provide – the SDK, the EMVO Documentation and any other EMVO Confidential Information, to any other OBP Connection Provider it has determined or would determine in its discretion for the development of similar or other solutions in relation to the EMVS or any component thereof.

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

- 4.1. Subject to the terms and conditions of this Agreement, EMVO grants the OBP Connection Provider, and the OBP Connection Provider accepts, a non exclusive, non transferable and royalty-free licence to use the Software Development Kit and the EMVO Documentation to develop the Standardized Solution(s), to test such Solution(s) with the European Hub Test System, and to distribute and provide such Solution(s) subject to the terms and conditions set forth in this Agreement, for the whole duration of this Agreement.
- 4.2. The OBP Connection Provider shall be authorized to test its Standardized Solution(s) with the European Hub Test System in order to verify that such Solution(s) will allow OBPs to use and operate their OBP Interface in connection with the European Hub to upload and transfer OBP Data to National Systems. The OBP Connection Provider shall be granted limited access to the European Hub Test System for the sole purpose of testing its Standardized Solution(s), at its own costs, it being agreed that the time, duration and modalities of such testing shall be mutually agreed between the Parties upon reasonable prior notice from the OBP Connection Provider. The OBP Connection Provider shall be fully liable towards EMVO for any damage caused by or in connection with such testing. For the avoidance of doubt, it is expressly agreed that the OBP Connection Provider shall only be authorized to test its Standardized Solution(s) for interfacing OBP Systems with the European Hub Test System.
- 4.3. License rights granted to the OBP Connection Provider are limited to those expressly granted herein. EMVO reserves all other rights. Neither the disclosure of EMVO Confidential Information nor anything herein contained shall be interpreted as giving to the OBP Connection Provider, any implied or express right, or any including 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 Connection Provider shall neither claim nor seek any right, including to Intellectual Property Rights thereon.
- 4.4. Except as expressly agreed in writing between the Parties or as strictly necessary for the performance of this Agreement, including for the purpose of the development, implementation, testing, use or operation of the Standardized Solution(s), the OBP Connection Provider may not (i) use, copy, maintain, distribute, sell, sublicense, rent, make corrections to or modify the SDK, the European Hub or the EMVO Documentation; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer or otherwise translate the SDK, 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 European Hub or the EMVO Documentation, or (iv) use or sublicense the SDK, the European Hub or the EMVO Documentation for the benefit of any third party (other than the OBPs).
- 4.5. The OBP Connection Provider agrees that, if he wishes to make any further use of the SDK, the EMVO Documentation, or re-use the EMVO Confidential Information in any manner, outside

the scope of its agreement with an 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.

- 4.6. The name and logo of "EMVO" are registered trade marks. Nothing in this Agreement shall be deemed to vest in the OBP Connection Provider any legal or beneficial right in the ownership of these trade mark or of any other EMVO trade marks, trade names or logos. The OBP Connection Provider is not permitted to use neither to reproduce nor authorize anyone to use or reproduce these trade marks, trade names and logos or any similar, related or analogous names or logos that would create a likelihood of confusion with EMVO's 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.

#### **5. Obligations of the OBP Connection Provider**

- 5.1. In order to be able to connect to the European Hub and test its Standardized Solution(s) with the European Hub Test System, the OBP Connection Provider will have to enter into a support contract with the European Hub IT Company (the "Support Contract"). All costs related to this Support Contract and the support services to be provided by the European Hub IT Company to the OBP Connection Provider will be at charge of the OBP Connection Provider. If the OBP Connection Provider requires any further assistance from the IT Company who developed the European Hub, SDK and the EMVO Documentation on behalf of EMVO, the OBP Connection Provider shall request the relevant information or assistance and/or services at its own costs (as the case may arise, subject to EMVO's prior consent if this includes any EMVO Confidential Information), it being acknowledged and agreed that the European Hub IT Company is free to provide such assistance or services and that the OBP Connection Provider shall in any case be solely responsible for all costs related to the assistance and services provided by the European Hub IT Company to the OBP Connection Provider.
- 5.2. The OBP Connection Provider undertakes to develop, implement and test the Standardized Solution(s) for OBP Interface in accordance with the SDK and the EMVO Documentation to be provided by EMVO in accordance with Appendix 1, as may be amended from time to time by EMVO.
- 5.3. The OBP Connection Provider hereby undertakes to use the SDK and the EMVO Documentation for the sole purpose of developing and testing the Standardized Solution(s) in accordance with the terms and conditions set forth in this Agreement.
- 5.4. The OBP Connection Provider agrees to implement promptly such modifications and changes that EMVO may make to the SDK as they are provided by EMVO.
- 5.5. 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. The OBP Connection Provider further undertakes not to store on an insecure place any elements of or relating to the European Hub, the European Hub Test System, the EMVO Gateway, SDK or EMVO Documentation, or any other EMVO's Confidential Information,
- 5.6. The OBP Connection Provider shall ensure that the Standardized Solution(s) that it develops and provides to OBPs, and the corresponding OBP Interface, is/are duly protected and shall integrate at least the security measures set forth under the SDK. The OBP Connection Provider shall also ensure that no malicious software or other code is introduced in the

Standardized Solution(s), the OBP Interface, nor in any component of the EMVS through the OBP Interface.

- 5.7. The OBP Connection Provider also undertakes and warrants that:
- 5.7.1. access to the OBP Interface shall be protected by appropriate security measures set forth under the SDK, and as may be notified by EMVO to the OBP Connection Provider from time to time;
  - 5.7.2. only a very limited number of the OBP Connection Provider's Representatives shall have access to the SDK, the EMVO Documentation or any other EMVO Confidential Information;
  - 5.7.3. the OBP Connection Provider and its Representatives shall by no means try to access, change or delete data processed in the frame of the EMVS; and
  - 5.7.4. OBP Connection Provider's Representatives are held by the same obligations as are imposed on the OBP Connection Provider under this Agreement.
- 5.8. The OBP Connection Provider 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 Connection Provider,...).
- 5.9. The OBP Connection Provider shall appoint a key contact person for the performance of this Agreement, as identified under Section 15.5 below.
- 5.10. The OBP Connection Provider shall report to EMVO as to the status of development and provision of the Standardized Solution(s).
- 5.11. The OBP Connection Provider shall communicate to EMVO the name of the OBP(s) for which it develops, implements, tests, operates or provides an OBP Interface.
- 6. Obligations of EMVO**
- 6.1. EMVO shall provide the OBP Connection Provider with the SDK and the EMVO Documentation electronically or on media in machine-readable object code form, in accordance with Appendix 1.
- 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 SDK and the EMVO Documentation, and shall inform the OBP Connection Provider thereof and provide Updates to the OBP Connection Provider, 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, European Hub, SDK, Documentation and EMVO Confidential Information**
- 7.1. The OBP Connection Provider acknowledges that all components of the EMVS that belong (or will belong) to EMVO, including without limitation the European Hub, the European Hub Test System, the EMVO Gateway, the SDK and all EMVO Documentation, as well as EMVO Confidential Information, shall at all times remain the property of EMVO. Moreover, the OBP

Connection Provider 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 without limitation the European Hub, the European Hub Test System, the EMVO Gateway, the SDK, and all EMVO Documentation, as well as EMVO Confidential Information, shall at all time remain the property of EMVO.

- 7.2. The OBP Connection Provider undertakes not to copy, duplicate or reproduce, in whole or in part, neither to adapt, amend, publish, display, distribute or sub-license or otherwise use any copies of the European Hub, the European Hub Test System, the EMVO Gateway, SDK or EMVO Documentation, or any other EMVO's Confidential Information, except as expressly permitted by this Agreement and shall ensure that OBP Connection Provider Representatives are made aware of and abide by all of the terms of this Agreement. Upon termination of this Agreement, the OBP Connection Provider undertakes that it and OBP Connection Provider Representatives shall cease any use thereof for whatever purpose.
- 7.3. EMVO represents and warrants that it holds sufficient rights to grant the license herein under this Agreement.
- 7.4. Without prejudice to the foregoing, and subject to the terms of the specific agreement to be entered into between the OBP Connection Provider and an OBP for the development of an OBP Interface, the OBP Connection Provider shall in principle be the holder of the Standardized Solution(s) and of the underlying Intellectual Property Rights that it develops, it being agreed that all pre-existing Intellectual Property Rights in any component of the EMVS that belong (or will belong) to EMVO, including without limitation the European Hub, the European Hub Test System, the EMVO Gateway, the SDK and all EMVO Documentation, (will) remain the sole property of EMVO, which grants a limited license thereof to the OBP Connection Provider in accordance with the terms of this Agreement. It is expressly agreed that the OBP Connection Provider shall only be authorized to develop, use and provide the Standardized Solution(s) for the purposes set forth in – and subject to the terms of – this Agreement, at the exclusion of any other purposes. The OBP Connection Provider acknowledges and agrees that, when distributing or providing such Standardized Solution(s), it shall remain subject to the confidentiality undertakings and all other obligations set forth in this Agreement (except vis-à-vis OBPs). In particular and notwithstanding anything to the contrary in this Agreement, no EMVO Confidential Information may be disclosed by the OBP Connection Provider to third parties (except OBPs) as part or in connection with the distribution or provision of its Standardized Solutions, except with EMVO's prior written authorization.

## **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. The OBP Connection Provider will, however, bear all costs for the development, testing and provision of its Standardized Solution(s).
- 8.2. It is expressly agreed that the Rights granted to the OBP Connection Provider under this Agreement are provided free of charge, and represent the counterpart of the exclusions of warranty and liabilities below.

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

- 9.1. The OBP Connection Provider agrees and acknowledges that the On-boarding Project constitutes a limited scale preliminary operational mode of part of the EMVS implementation, that the OBP Connection Provider will develop the Standardized Solution(s) at its own costs

and risks, and that EMVO therefore does not guarantee that the On-boarding Project will result in an effective full scale (day-to-day) operational mode system.

- 9.2. No warranty of any kind is made or given with respect to EMVO Confidential Information or any use thereof, including, but not limited to, as to the accuracy or the completeness of the EMVO Confidential Information. Use of EMVO Confidential Information is at the OBP Connection Provider's own risks and perils. 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, 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.
- 9.3. The OBP Connection Provider agrees and acknowledges that it enters into this Agreement and that it shall use the SDK and EMVO Documentation to develop, test and propose its Standardized Solution(s) at its own costs, risks and perils, and that EMVO does not guarantee that – and shall not be liable in case – the EMVS never results in an effective full scale (day-to-day) operational mode system; it being noted that authorization to interface any OBP System with the European Hub is granted at EMVO's sole discretion.
- 9.4. Except as otherwise set forth in this Agreement, the OBP Connection Provider also agrees that its sole remedy, in case the EMVS or any component thereof, including the European Hub, the European Hub Test System, the SDK and/or the EMVO Documentation, would not operate properly or according to their specifications, shall be to cease any use thereof and to terminate this Agreement, without indemnities at charge of EMVO.
- 9.5. The foregoing are OBP Connection Provider's sole and exclusive remedies and are exclusive and in lieu of all other warranties, terms and conditions, including but not limited 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 European Hub Test System, the SDK, and the EMVO Documentation is provided “as is” and EMVO makes no warranties, whether express or implied, or statutory regarding or relating thereto, neither regarding any materials or assistance (if any) furnished or provided to the OBP Connection Provider under this Agreement. Specifically, EMVO does not warrant that the EMVS, the European Hub, the SDK 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 Connection Provider 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 without limitation, 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 European Hub, the European Hub Test System, the SDK, and the EMVO Documentation, or any EMVO Confidential Information.
- 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 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 furnishing, performance or use of the EMVS or any component thereof, including the European Hub, the European Hub Test System, the SDK or the EMVO Documentation, use of any EMVO Confidential Information, or any assistance provided hereunder (if any), 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. Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.
- 9.9. 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 Connection Provider (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), hidden/latent defects, shall in no event exceed 1,000 Euro for any and all claims arising out of or in connection with this Agreement.
- 9.10. 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 and Right of refusal**

- 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. The OBP Connection Provider also understands and agrees that, if at any point, EMVO has any reasonable reason to consider that the OBP Connection Provider does not meet the conditions set forth in this Agreement or the security requirements to be granted access to the EMVS or any components thereof (in particular the European Hub Test System), EMVO may refuse or interrupt such access to the OBP Connection Provider without any prior notice.

## **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 (including its Representatives). 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 become effective as of its Effective Date and shall continue thereafter for an indefinite term, unless terminated by any Party as set forth below.

- 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, (ii) if and when the On-boarding Project is terminated and/or the EMVS enters into full scale operational mode, or (iii) if EMVO is no longer in capacity to perform or operate the European Hub for whatever reason.
- 12.5. Upon termination or expiration of this Agreement for whatever cause, the OBP Connection Provider will:
- 12.5.1. promptly return to EMVO or destroy (at EMVO's sole discretion) all originals and copies of all documents and files, whether in electronic or hard copy, containing EMVO Documentation and EMVO Confidential Information that are in the possession or under the control of the OBP Connection Provider or its Representatives;
  - 12.5.2. permanently remove all EMVO Documentation and EMVO Confidential Information from any computer, disk or other device containing Confidential Information; and
  - 12.5.3. if so requested by EMVO, provide a certificate confirming due compliance with the obligations contained under this Section 12.5.
- 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.
- 12.7. It is expressly agreed that the restrictions as to the use, distribution, provision, commercialization or sale of Standardized Solution(s) shall survive for 5 (five) years after the termination or expiration of this Agreement for whatever cause and that the OBP Connection Provider shall not be allowed to provide/commercialize or sell such Standardized Solution(s) after termination of this Agreement.

### **13. Confidentiality**

- 13.1. 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 EMVO Confidential Information, including EMVO Confidential Information disclosed to it or learned by it relating to the EMVS or any component thereof, both before and after the execution of this Agreement.
- 13.2. The OBP Connection Provider undertakes to:
- keep EMVO Confidential Information secret and confidential, and without limiting the foregoing, not disclose EMVO Confidential Information to any person, other than the OBP Connection Provider Representatives in accordance with Section 13.3 below, except with

EMVO's specific prior written consent, or as expressly otherwise permitted by the terms of this Agreement;

- exercise the same degree of care and protection with respect to EMVO 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 EMVO Confidential Information for the purpose of the development of the Standardized Solution(s) and to distribute or provide it/them in accordance with the terms and conditions set forth in this Agreement, at the exclusion of any other purpose;
  - 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.
- 13.3. The OBP Connection Provider shall be entitled to disclose EMVO Confidential Information to the OBP Connection Provider Representatives to whom, and to the extent to which such disclosure is strictly necessary for performance of this Agreement, provided that it:
- informs such OBP Connection Provider Representatives of the limitations and conditions with respect to the use and disclosure of EMVO Confidential Information set forth in this Agreement;
  - procures that such OBP Connection Provider Representatives agree in writing to observe the limitations and conditions set forth in this Agreement; 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 it discloses Confidential Information, whether or not in accordance with this Agreement.
- 13.4. The OBP Connection Provider 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 Connection Provider (or of the OBP Connection Provider Representatives) of the terms herein, as well as for any loss, theft or other unauthorized use or disclosure of EMVO Confidential Information caused by the OBP Connection Provider or the OBP Connection Provider Representatives' fault or negligence.
- 13.5. EMVO shall maintain the confidentiality of the OBP Connection Provider Confidential Information and agrees 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 Connection Provider 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 Project and implementation, testing and operation of the EMVS, or of any component thereof, including the European Hub, the EMVO Gateway, the SDKs, the National Systems, etc., as contemplated under this Agreement.
- 13.6. The restrictions on use or disclosure of EMVO Confidential Information and of OBP Connection Provider 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 one Party from a third-party on a non confidential basis;

- is independently developed by that Party; or
  - is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, the required Party gives the other Party immediate notice thereof, and gives the other Party 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 Parties shall cooperate with each other, by all legal means, in order to limit the effects of the disclosure and to prevent the disclosure of any other EMVO Confidential Information and OBP Connection Provider Confidential Information.
- 13.7. The OBP Connection Provider acknowledges and agrees that EMVO is authorized to communicate with its members, all parties involved in the EMVS, including OBPs, as well as third parties about the EMVS, its implementation, testing and operation, including about this Agreement with the OBP Connection Provider. Any public announcement as to the OBP Connection Provider developing Standardized Solution(s) shall be mutually agreed by the Parties and the OBP Connection Provider shall provide EMVO with texts and graphics as required by EMVO. EMVO is also authorized to maintain and publish a list of OBP Connection Providers (and OBP Connection Provider Representatives) that have entered into a License Agreement for OBP Connection Provider with EMVO.
- 13.8. The Parties agree that if any of these provisions of this Section 13 are not performed in accordance with their respective terms or are otherwise breached, monetary damages may not necessarily be sufficient remedy. Therefore, the Parties agree that, in addition to all other rights and remedies otherwise available to it, each Party shall be entitled to specific performance or equitable relief by way of injunction or otherwise in the event the other Party or its Representatives breach or threaten to breach any of these provisions.
- 13.9. EMVO reserves the right to make the SDK, the EMVO Documentation and any other EMVO Confidential Information public at any time as it deems appropriate.
- 13.10. It is expressly agreed that the restrictions as to the use of EMVO Confidential Information, in particular the SDK, the EMVO Documentation, or any other information relating to the EMVS or any components thereof and their development, testing and operation, shall survive the termination or expiration of this Agreement for whatever cause and that OBP Connection Provider shall not be allowed to use them in whatever manner in the frame or for the purpose of any further project, and this for a period of [5] years after the termination or expiration of this Agreement for whatever cause.
- 13.11. 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.
- 13.12. The obligations set forth under this Section 13 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 arising out of or in connection with this Agreement and/or any contractual or non-contractual (including pre-contractual) matters in connection with

its conclusion, validity, interpretation, enforcement, performance and termination will be submitted to the exclusive jurisdiction of the courts of Brussels.

## 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 Connection Provider 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 Connection provider and EMVO.
- 15.2. Failure by either the OBP Connection Provider 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 in the court's opinion 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 Connection Provider cannot transfer nor assign its rights and obligations under this Agreement to any third party (including OBP Connection Provider Affiliates and Representatives), whether voluntarily, by operation of law, change of control, or otherwise, without the prior written consent of EMVO. For the purposes of this Agreement, any change of control, merger, consolidation, or acquisition of all or substantially all of the assets of the OBP Connection Provider shall be deemed an assignment. Any purported assignment or other action in violation of this Section 15.4 shall be void; and shall give EMVO the right to terminate this Agreement forthwith, in its own right and without prior intervention of any court or arbitral body, without indemnity, by mere notification to the OBP Connection Provider. 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 third party, by written notice to the OBP Connection provider, and the OBP Connection Provider shall enter into such documents as are necessary for such purpose. This Agreement shall bind and inure to the benefit of the parties and their respective successors and permitted assignees.
- 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, 1040 Brussels

E-mail: helpdesk@emvo-medicines.eu

**Notices to OBP Connection Provider:**

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) original copies, each party acknowledging that it received one duly signed copy.

**For EMVO**

**For the OBP  
Connection Provider**

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

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

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

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

Name: Andreas Walter

Name: name

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

Title: General Manager

Title: function

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

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

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

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

## Appendix

### Appendix 1 – Provision of the Software Development Kit and Documentation

The Parties agree that the Software Development Kit, including the specifications and security requirements for the OBP Interface, as well as the EMVO Documentation, shall be made available by EMVO to the OBP Connection Provider, electronically or on media in machine-readable object code form, upon receipt by EMVO of this Agreement signed by the Parties.

The OBP Connection Provider shall acknowledge receipt of the complete SDK and the EMVO Documentation within 7 days as of the OBP Connection Provider being notified of their availability. If the OBP Connection Provider does not send such acknowledgement of receipt to EMVO within the said period, the OBP Connection Provider shall be deemed to have received the complete SDK and Documentation.

Updates or amendments to the SDK and EMVO Documentation shall be made available from time to time by EMVO to the OBP Connection Provider.

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