

## EVI Terms of Use

### Version update: November 2019

By using the European Medicines Verification System Information (EVI) tool ('EVI'), you and, if applicable, the entity you represent (collectively, "you" or "your") acknowledge that you have read and that you understand, accept and agree to be bound by the following terms and conditions for the use of the EVI ("**Terms of Use**" or "**Terms**").

You further acknowledge and agree that EMVO may modify, amend or supplement these Terms of Use from time to time upon notification. Please make sure that you always refer to the latest version of these Terms in effect. The most current version of the Terms will supersede all prior versions and by using the EVI after publication of modifications of these Terms, you agree to be bound by and to the full extent by the most current version of the Terms of Use, as revised and published.

The latest version is always available for download on the EMVO website. This document, which includes by reference the [EVI user guidance document](#), is placed on the EVI webpage and is also available in the Documents Overview of the Knowledge Database on the EMVO website.

#### 1. Definitions

- "Delegated Regulation" means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
- "Downtime" means the type of interruption of the EVI whereby a system is not available (down). It is envisaged that communication with this system will not be possible for the duration of the published entry.
- "European Medicines Verification Organisation" or "EMVO" means the non-profit legal entity that is responsible to set up and manage a central information and data router ('hub') in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- "European Medicines Verification System" or "EMVS" means the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems, and allows the End Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
- "EU Directive on Falsified Medicines" means Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, as well as, where appropriate, the relevant implementing national laws in the relevant EEA Member States.
- "EVI subscribers" means any individual or entity, whether they be a user of the EMVS or not, subscribing to the EVI to be informed about the status of the EMVS systems.
- "Information" means any information or guidance relating to the operation of an EMVS system figuring on the EVI, either being a Known Issue, a Downtime or Maintenance, which is not used to communicate malfunctions of any of the EMVS systems.
- "Known Issue" means the type of interruption of the EVI whereby some functionalities of an EMVS system may not be functioning as intended some of the time for the duration of the published entry.
- "National Medicines Verification Organisation(s)" or "NMVO(s)" mean(s) the non-profit legal entity (entities) that is(are) responsible to set up and manage a national and/or

supranational repository(ies) in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

## 2. Ownership and Grant of License

Subject to the Terms of Use, EMVO hereby grants to you, and you hereby accept, a nonexclusive, nontransferable, non-sublicenseable, revocable license to hold an account within EVI and use the EVI solely in accordance with these Terms. All rights not expressly granted to you under these Terms are reserved to EMVO. Other than as expressly provided for in these Terms, you expressly acknowledge and agree that any and all rights, titles, and interests in and to the EVI remain the sole and exclusive property of EMVO. EMVO retains all ownership rights to any concepts, ideas, methods, methodologies, procedures, processes, know-how, techniques, models, templates, user interfaces and screen designs contained in the EVI.

## 3. Use and Restrictions on Use

You agree that you will be assigned only one account within the EVI via which you will be able to create entries in order to inform the EVI Subscribers about any Known Issue, Downtime, Maintenance or any other Information regarding your EMVS system as soon as this appears or comes into your knowledge. You also agree that you will create entries solely for your own EMVS system(s) or the EMVS system(s) you manage and not for any other EMVS system(s) (including but not limited to the systems managed by other NMVOs or/and EMVO).

Moreover, you acknowledge and agree that once you create an entry on the EVI, this entry will be automatically published and relevant notifications will be sent to the EVI Subscribers informing them about such entry. This means that any entries you will create along with the related information you will provide will immediately be made publicly available.

It is highly recommended that as soon as an issue impacting your EMVS system is discovered, an entry is published on the EVI in order to inform the EVI Subscribers thereof for as long as your investigation of the root cause of the issue lasts. You agree to update this entry as soon as the root cause is identified along with any Information or additional information on any corrective actions taken or to be taken as well as respective timelines.

You agree that you will not use the EVI in any manner or for any purpose that violates any law or regulation, including but not limited to the intellectual property rights, personal data regulation, the EU Directive on Falsified Medicines and the Delegated Regulation or in any manner inconsistent with these Terms of Use.

More specifically, you will not publish any entries, material or other information that contains vulgar, profane, abusive or hateful language, inflammatory attacks of a personal, racial or religious nature, or expressions of bigotry, racism, discrimination or hate. The above also includes any entry the content of which is defamatory, threatening, disparaging, grossly inflammatory, false, misleading, deceptive, fraudulent, inaccurate, unfair, contains gross exaggeration or unsubstantiated claims, is unreasonably harmful or offensive to any individual or EMVO, contains any actionable statement, or tends to mislead or reflect unfairly on any other person, business or entity.

You will not yourself or any other third party: (a) modify, decode, decompile, disassemble, reverse engineer or otherwise translate the software behind the EVI in whole or in part; (b) write or develop any derivative software or any other software program based upon the EVI; (c) use the EVI to provide services to third parties; (d) sublicense the use of your EVI account; (e) provide, disclose, divulge or make available to, or permit use of your EVI account by any third party; (f) disable or modify any licensing control features of the EVI; or (g) directly or indirectly attempt to do any of the foregoing.

#### 4. Maintenance

The EVI may periodically be updated with tools, improvements, third party applications or general updates to correct errors, fix bugs or to otherwise improve and enhance its features and performance. EMVO may also, at its own discretion, change or discontinue the EVI, in whole or in part, including but not limited to, any feature or aspect of it.

#### 5. Passwords and Security

You are responsible for maintaining the confidentiality of your username and password and for ensuring that your username and password is used only by you. You agree to notify EMVO immediately of any unauthorized use of your data, account, usernames and passwords, or of any other breach of security with respect to the EVI of which you are aware.

You acknowledge that, notwithstanding security precautions deployed by EMVO, the use of, or connection to, the Internet provides the opportunity for unauthorized third parties to circumvent such precautions and illegally gain access to the EVI. Both EMVO and you agree to take all commercially reasonable precautions to protect the security of data transmitted over or stored in any system connected to or accessible via the Internet in connection with use of the EVI.

#### 6. Privacy and Personal data

By using the EVI, you agree to EMVO processing your personal data in accordance with its Privacy Policy available on the EMVO Website.

#### 7. Liabilities, Warranties and Limitations

You are solely and exclusively responsible for creating entries on the EVI and publishing Information or other material thereon in accordance with these Terms of Use. Moreover, you agree that you are solely responsible for the entries you publish on the EVI and their content as well as for ensuring that any Known Issue, Downtime or other Information affecting your EMVS system is reflected on the EVI. EMVO warrants that it will at all times employ all commercially available methodologies, technologies and other means to prevent introduction, and it will not intentionally introduce, into your devices, software or network, any virus, worm, "back door," Trojan Horse, or similar harmful codes.

The warranties set forth hereunder will apply only if: (a) your use of the EVI has been at all times in accordance with the Terms of Use, (b) no modification, alteration or addition has been made to the EVI by parties other than EMVO, (c) you have not breached these Terms, and (d) to the extent applicable, you promptly notify EMVO of the existence and nature of any defect and provide reasonable assistance and access to resolve such defect.

EXCEPT AS SPECIFICALLY SET FORTH HEREUNDER, THE EVI IS PROVIDED "AS IS". TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EMVO DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT THE EVI IS FIT FOR A PARTICULAR PURPOSE, TITLE, MERCHANTABILITY, DATA LOSS, NON-INTERFERENCE WITH OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS, OR THE ACCURACY, RELIABILITY, QUALITY OR CONTENT IN OR LINKED TO THE EVI. EMVO DOES NOT WARRANT THAT THE EVI IS SECURE, FREE FROM BUGS, VIRUSES, INTERRUPTION, ERRORS, THEFT OR DESTRUCTION. EMVO DOES NOT WARRANT ACCESS TO THE INTERNET OR TO ANY OTHER SERVICE, CONTENT OR DATA TRANSMITTED THROUGH THE EVI. EMVO DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES THAT YOUR USE OF THE EVI WILL ENSURE COMPLIANCE WITH ANY LEGAL OBLIGATIONS OR LAWS OR REGULATIONS. YOU ARE SOLELY RESPONSIBLE FOR ENSURING THAT YOUR USE OF THE SYSTEM IS IN ACCORDANCE WITH APPLICABLE LAW, INCLUDING, BUT NOT LIMITED, TO THE EU DIRECTIVE ON FALSIFIED MEDICINES AND THE DELEGATED REGULATION.

IN NO EVENT WILL EITHER EMVO OR YOU BE LIABLE FOR ANY EXEMPLARY, INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR ARISING OUT OF THESE TERMS OR THE PERFORMANCE OR USE OF THE EVI OR ANY SERVICES PERFORMED HEREUNDER, WHETHER ALLEGED AS A BREACH OF CONTRACT OR TORTIOUS CONDUCT, INCLUDING NEGLIGENCE, EVEN IF HAVING BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE EXCLUSIONS AND LIMITATIONS SET FORTH IN THIS SECTION SHALL NOT APPLY IN CASE OF WILLFUL MISCONDUCT OF EITHER PARTY.

**8. Third Party Software**

To the extent any third-party software is incorporated in or required by the EVI, EMVO shall be responsible for obtaining licenses for such software.

**9. Governing Law and Jurisdiction**

These Terms of Use shall be governed by Belgian law and be subject to the exclusive jurisdiction of the Belgian courts of Brussels.