THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

TERMS AND CONDITIONS

This agreement is between your organisation ("You" or the "IT Service Provider") and the **Κυπριακός Οργανισμός Επαλήθευσης Φαρμάκων** (Κ.Ο.Ε.Φ.), a company limited by guarantee, with its registered office at 2 Sophouli Str., The Chanteclair House, 9th floor, 1096 Nicosia, Cyprus, with registration number HE 365968 ("NCP").

Either hereafter referred to as a "Party", or together as the "Parties".

These general terms and conditions ("Terms") apply to the connection, access to and use of the NCP National System, which is operated by the NCP. Please read these Terms carefully before accessing the NCP National System in any manner. By accepting these Terms, You confirm that they constitute a legally binding agreement between You and the NCP that governs Your connection, access to and use of the NCP National System.

The NCP licenses use of the NCP National System, and other components of the EMVS, to the IT Service Provider subject to these Terms. The NCP does not sell the NCP National System nor any component of the EMVS to the IT Service Provider and the NCP (or its licensors) remain the owners of the NCP National System and any component of the EMVS at all times.

The IT Service Provider shall be provided with a copy of these Terms for future reference.

Now, therefore, in consideration of the mutual agreements, provisions and covenants contained in these Terms, and for other good and lawful consideration, including the sum of EUR 1 (which includes any applicable taxes), the receipt and sufficiency of which are hereby acknowledged by the NCP, the Parties hereto, intending to be legally bound, hereby agree as follows:

ACCEPTANCE OF THESE GENERAL TERMS AND CONDITIONS

1.1 By connecting, accessing and using the NCP National System or by clicking 'I Accept' during the connection process, You acknowledge that You have read, understood and agree to be bound by these Terms and that your electronic acceptation will be recognized as equivalent, for all legal purposes, to a signed version of these Terms.

1.2 If You are operating under one (or more) legal entity(ies), (each) such legal entity must agree and be bound by these Terms. You must notify the NCP if this is the case, so that appropriate wider arrangements may be made. Where entering into these Terms on behalf of a company, organization, association or other legal entity, You hereby agree – and declare and represent – that You are entitled, have the legal capacity and are duly authorised to represent and bind such

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

company, organization, association or other legal entity, and that such company, organization, association You represent (hereinafter, collectively, the "IT Service Provider") agrees to be bound by these Terms.

If You do not accept these Terms, You are not authorized to connect, to access or to use the NCP National System.

1. PURPOSE OF THESE TERMS

1.1. The purpose of these Terms is to set out the respective rights and obligations of the NCP and the IT Service Provider with respect to the connection, access to and use of the NCP National System by the IT Service Provider to create and deliver the interface between the User's system and the NCP NMVS in order to verify the authenticity of, and to decommission, the unique identifier of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation (the "Purpose").

1.2. It is expressly agreed that EMVO and the NMVOs develop and operate the EMVS, including the European Hub and the National Systems, in view of the verification of the authenticity and the decommissioning of the unique identifiers of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation, to be operational by 8 February 2019, at 23:59:59 CET at the latest. The EMVS, including the European Hub and National Systems, is therefore still being designed, developed and tested and could therefore be substantially amended, without any indemnity being due to the IT Service Provider.

2. GRANT OF RIGHTS TO THE IT SERVICE PROVIDER

2.1. Subject to the IT Service Provider's agreement to and continued compliance with these Terms, the NCP hereby grants to the IT Service Provider a limited, revocable, non-exclusive, non-transferable, personal license right to connect, to access to and to use the NCP National System, solely for the Purpose, in accordance with the EU Directive on Falsified Medicines and the Delegated Regulation.

2.2. License rights granted to the IT Service Provider are limited to those expressly granted herein. The NCP (and its respective licensors) reserve all other rights.

3. LICENCE RESTRICTIONS

3.1. Except as expressly agreed in writing herein or as provided in these Terms or as necessary for the Purpose, the IT Service Provider may not (i) use, copy, maintain, distribute, sell, publish, display, sublicense, rent, make corrections to, or modify the NCP National System nor any

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

component thereof; (ii) modify, adapt, decompile, disassemble, reverse assemble, reverse compile, reverse engineer, or otherwise translate the NCP National System or any component thereof, unless to the extent the foregoing restrictions are expressly prohibited by applicable law; (iii) use or sublicense use of the National System or any component thereof for the benefit of a third party, and more generally, for any purpose other than the Purpose, (iv) store, access or transmit information or data on the NCP National System, or any other component of the EMVS, that is inaccurate or that has not been legally obtained or that is in violation of any other applicable Intellectual Property Right, or that is in violation of the EU Directive on Falsified Medicines or Delegated Regulation.

3.2. If, at any time, the NCP has reasonable and objective grounds to believe that the (further) connection, access to or use of the NCP National System by the IT Service Provider:

3.2.1. immediately and substantially endangers the security or functioning of the NCP National System or the EMVS (in whole or in part), the NCP is entitled to immediately and without prior notice block or disconnect the IT Service Provider from the NCP National System; it is hereby agreed that the NCP shall inform the IT Service Provider about such measure and the reasons thereof as soon as possible, and that the connection of the IT Service Provider to the NCP National System shall be re-established as soon as possible when there is no longer any immediate and substantial danger to the security or functioning of the NCP National System or part of the EMVS; or

3.2.2. is in breach of these Terms but does not immediately and substantially endanger the security or functioning of the NCP National System or the EMVS (in whole or in part), the NCP is entitled to block or disconnect the IT Service Provider from the NCP National System (and may then exercise its further rights in accordance with these Terms), provided that, if such breach is capable of cure, the IT Service Provider failed to cure the breach within ninety (90) calendar days (or such shorter period where justified) after such cure has been demanded in writing by the NCP.

3.3. If, at any time, the IT Service Provider has reasonable and objective grounds to believe that the (further) connection, access to or use of the NCP National System immediately and substantially endangers the security of the IT Service Provider, the IT Service Provider may block or disconnect from the NCP National System, it being agreed that the IT Service Provider shall inform the NCP about such measure and the reasons thereof at the IT Service Provider's earliest

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

convenience, and that the connection of the IT Service Provider shall be re-established as soon as there is no longer any immediate and substantial danger to the security of the IT Service Provider..

4. OBLIGATIONS OF THE IT SERVICE PROVIDER

4.1. The IT Service Provider undertakes to connect, to access to and to use the NCP National System (serving the Territory in which the IT Service Provider is authorized or entitled) to create and deliver the interface between the User's system and the NCP NMVS in order to verify the authenticity of, and to decommission, the unique identifier of medicinal products in accordance with these Terms and the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

4.2. The IT Service Provider warrants that:

4.2.1. the IT Service Provider is responsible for maintaining the security of its system and the confidentiality of its credentials and passwords to connect to the NCP National System, and is solely responsible for any activities carried out through its connection and on its system, including for the correctness and accuracy of any information or Data uploaded or generated by the IT Service Provider on the NCP National System;

4.2.2. the IT Service Provider's own system and any connection or access by the IT Service Provider to the NCP National System shall be protected by appropriate security measures, as necessary to protect against unauthorized access, interception, disruption or other Security Breach, including the security measures as notified by the NCP to the IT Service Provider from time to time; and

4.2.3. the IT Service Provider shall notify the NCP of any Security Breach as soon as it becomes aware of such Security Breach and shall take all necessary measures to mitigate such Security Breach, in so far as this is possible.

4.3. In any case, the IT Service Provider must not (i) use the NCP National System in any unlawful manner, for any unlawful purpose, or in any manner inconsistent with these Terms or the EU Directive on Falsified Medicines and Delegated Regulation, or act fraudulently or maliciously, for example, by hacking into or inserting malicious code, including viruses, or inaccurate, false or harmful data into the NCP National System; (ii) infringe any Intellectual Property Rights relating to the NCP National System, or those of any third party in relation to the use of the NCP National System, or (iii) use the NCP National System in a way that could damage, disable, overburden, impair or

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

compromise the NCP National System or interfere with other Users.

4.4. The IT Service Provider may authorize its IT Service Provider Representatives to benefit from its rights under these Terms and to connect, to access to and to use the NCP National System on behalf of the IT Service Provider as necessary for the Purpose, subject to the following conditions:

4.4.1. the IT Service Provider Representative is informed of and is bound by and required to observe all terms, limitations and conditions applying to the IT Service Provider as set forth in these Terms;

4.4.2. the IT Service Provider remains fully responsible and liable for any act or omission of its Representative(s);

4.4.3. without prejudice to other remedies, in case of material breach of these Terms by the IT Service Provider Representative, the NCP reserves the right to require the IT Service Provider to suspend or withdraw the authorization granted to the said Representative in accordance with this Section 4.4, without any indemnity being due to the IT Service Provider; and

4.4.4. it is expressly agreed that, as far as the IT Service Provider's employees are concerned, the provisions under this Section 4.4 shall be sufficiently met provided that such employees are duly informed about these Terms and have a duty to observe them as per their employment agreement with the IT Service Provider, and the IT Service Provider remains fully responsible and liable for its employees, their actions and any inappropriate use of the EMVS.

4.5. The IT Service Provider hereby agrees to execute, within 7 working days, any changes to its interface between the User's system and the NCP National System that may be indicated by the NCP, and to follow all relevant instructions that the NCP may provide to this effect.

5. OBLIGATIONS OF THE NCP

5.1. The NCP shall take appropriate measures to ensure that the NCP National System shall be developed, implemented, tested and operated for the whole period of time set forth in Section 11.1 of these Terms in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation, and (ii) these Terms.

5.2. The NCP National System shall satisfy all conditions as set forth under Article 35, para. 1 of the Delegated Regulation, including without limitation:

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

5.2.1. it shall allow the reliable electronic identification and authentication of individual packs of medicinal products by the User, in accordance with the requirements of the Delegated Regulation;

5.2.2. it shall have application programming interfaces able to transfer and exchange data with the software used by the User and, where applicable, national competent authorities;

5.2.3. when the User queries the NCP National System for the purposes of verification of authenticity and decommissioning of a unique identifier, the response time of the NCP National System, not considering the speed of the internet connection, shall be lower than 300 milliseconds in at least 95 % of queries; the NCP National System performance shall allow the User to operate without significant delay; and

5.2.4. in the exceptional case of a failure of the User's own software, the NCP National System shall include graphical user interfaces providing direct access to it to the User verified in accordance with Section 5.3.3 below, for the purposes of verifying the authenticity of the unique identifier and decommissioning it.

5.3. Without prejudice to the generality of the above, the NCP undertakes:

5.3.1. to use its best efforts to set up the NCP National System in a diligent manner and shall take appropriate measures so that the NCP National System and Data on the NCP National System be protected by appropriate security measures, including against unauthorized access, interception or disruption;

5.3.2. to use its diligent efforts so that no malicious software, malware or other code is introduced into the EMVS, or any component thereof, through its NCP National System;

5.3.3. in accordance with Article 37, para. 1, b) of the Delegated Regulation, to put in place security procedures ensuring that only Users whose identity, role and legitimacy has been verified can access the NCP National System or upload Data to the NCP National System;

5.3.4. in accordance with Article 36, para. 1, b) of the Delegated Regulation, the NCP National System shall provide for the triggering of an alert in the system and in the terminal where the verification of the authenticity of a unique identifier is taking place when such verification fails to confirm that the unique identifier is authentic, shall continuously monitor the NCP National System for events alerting to potential incidents of falsification and provide for immediate investigation of all potential incidents of falsification

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

flagged in the system as required under the Delegated Regulation;

5.3.5. in accordance with Article 36, para. 1, g) of the Delegated Regulation and without prejudice to Article 35, para. 1, h) thereof and Section 5.3.1 above, the NCP National System shall allow the access by verified wholesalers to the list of wholesalers referred to in Article 33 para. 2, h) of the Delegated Regulation (i.e. wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorization on his behalf), for the purpose of determining whether they have to verify the unique identifier of a given medicinal product in accordance with the EU Directive on Falsified Medicines and Delegated Regulation;

5.3.6. to appoint a key contact point for the performance of these Terms; and

5.3.7. to support the IT Service Provider and provide it with access to all relevant material and documentation and framework for training, in order to allow the IT Service Provider to connect to the NCP National System for the Purpose.

6. INTERNAL AUDIT BY THE NCP

6.1. **Internal audit by the NCP.** The NCP shall carry out regular audits, by appropriate means, of its own compliance with the requirements under the Delegated Regulation (in particular all technical and organizational security aspects relating to the set-up and the operation of the NCP National System), as required under the Falsified Medicines Directive, Delegated Regulation and these Terms.

7. INTELLECTUAL PROPERTY RIGHTS

7.1. The IT Service Provider acknowledges and agrees that all rights, titles and interests to, and all underlying Intellectual Property Rights in the NCP National System, including any application programming interfaces and graphical user interfaces, or any other component of the EMVS, anywhere in the world, belong to the NCP, respectively EMVO, and are licensed (not sold) to the IT Service Provider. The IT Service Provider has no rights in, or to, the NCP National System, including any application programming interfaces and graphical user interfaces, or any component of the EMVS, other than the right to use them for the Purpose in accordance with these Terms and the Falsified Medicines Directive and Delegated Regulation.

7.2. The NCP represents that it holds sufficient right, title and interest in and to the NCP National System to grant the license herein under

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

these Terms.

8. DATA PROTECTION AND OWNERSHIP

8.1. In accordance with Article 35, para. 1, h) of the Delegated Regulation, the structure of the NCP National System shall be such as to guarantee the protection of Personal Data and information of a commercially confidential nature and the ownership and confidentiality of the data generated when the User and/or the IT Service Provider interacts with it, in accordance with Article 38 of the Delegated Regulation.

8.2. Your contact details will be used by the NCP to communicate to You information and updates relating to the NCP National System.

9. CONFIDENTIALITY

9.1. The NCP and the IT Service Provider, each with respect to Confidential Information received from the other Party, undertakes to:

9.1.1. take all necessary precautions to prevent the other Party's Confidential Information in its possession, custody or control from being copied, stolen or otherwise misappropriated;

9.1.2. keep the other Party's Confidential Information secret and confidential, and without limiting the foregoing, not disclose such Confidential Information to any person, except as expressly otherwise permitted by these Terms or the Falsified Medicines Directive and Delegated Regulation;

9.1.3. exercise the same degree of care and protection with respect to the other Party's Confidential Information that it exercises with respect to its own proprietary and confidential information of same kind, but in no case less than with best care;

9.1.4. only use the other Party's Confidential Information for the Purpose or as otherwise provided under the Falsified Medicines Directive and Delegated Regulation, at the exclusion of any other purpose;

9.1.5. 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 other Party upon becoming aware of the same and take all necessary measures in order to reduce the effects of such unauthorized misuse, disclosure, theft or other loss.

9.2. The restrictions on use or disclosure of Confidential Information as defined above do not extend to information which:

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

9.2.1. is or comes into the public domain through no breach of these Terms;

9.2.2. will be lawfully received by the other Party on a non-confidential basis after the Effective Date or has been lawfully received by the NCP or the IT Service Provider on a non-confidential basis prior to the Effective Date from a third party;

9.2.3. is independently developed by the NCP or the IT Service Provider;

9.2.4. is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, the NCP or the IT Service Provider, if permitted, gives the other Party immediate notice thereof, and give 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 of these Terms. In such case, the NCP or the IT Service Provider shall cooperate with the other Party, by all legal means, in order to limit the effects of the disclosure and to prevent the disclosure of any other Confidential Information; and

9.2.5. is to be disclosed as necessary for the Purpose.

10. LIMITATION OF WARRANTY AND LIABILITY

10.1. **Disclaimer of warranty.** Except as otherwise provided in these Terms, the NCP's National System is provided “as is”, and, the NCP makes no warranties, whether express or implied, or statutory regarding or relating thereto. Specifically, without prejudice to the NCP’s obligations under the EU Directive on Falsified Medicines and Delegated Regulation, the NCP does not warrant that the NCP National System will be error and defect free (whether apparent or hidden/latent) or will perform in an uninterrupted manner.

10.2. To the maximum extent allowed by law, the NCP specifically disclaims all implied guarantees and warranties, including any warranty of condition, quality, performance, satisfactory quality, merchantability or fitness for a particular purpose (even if the NCP had been informed of such purpose), including for latent or hidden defects, with respect to any part of the NCP National System.

10.3. **Exclusion of Indirect Damages.** Without prejudice to Sections 10.1 and 10.2 above, neither Party shall be liable for any claims, proceedings, damages, expenses, costs and losses that are indirect or consequential, including 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,

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

loss of clientele, third party's claim, or any other indirect, special, incidental or consequential damages of any kind ("Indirect Damages") whether based on a contractual breach, tort (including negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable, in connection with or arising out of access to or use of the NCP National System.

10.4. In addition, without prejudice to the NCP's obligations under the EU Directive on Falsified Medicines and Delegated Regulation, the NCP shall not be held responsible or liable vis-à-vis the IT Service Provider or the User for any damage or prejudice caused by third parties accessing, uploading or downloading Data in, to or from the European Hub (e.g., manufacturers or parallel distributors or other NMVOs and their IT Service Providers), including any direct or indirect consequences of inaccurate, incomplete or corrupted data, or any malicious software, malware or other code transferred, uploaded or downloaded through the NCP National System by such third parties.

10.5. **Liability Cap.** The NCP's maximum aggregate liability vis-à-vis the IT Service Provider or the User arising out of, or in connection with these Terms, for damages, howsoever arising or caused, whether or not arising from breach of contract or tortious conduct, negligence, hidden/latent defects, shall in no event exceed EUR 500.

10.6. **Exclusion.** Nothing in these Terms will exclude or limit the Parties' liability:

10.6.1. for fraud or wilful misconduct;

10.6.2. for death or personal injury arising from the Party's negligence or that of its Representatives;

10.6.3. breach of the anti-bribery legislation; and

10.6.4. any other liability which cannot be limited or excluded under applicable law.

10.7. **Losses suffered by other Users of the NCP National System**. The Parties acknowledge and agree that any losses suffered by any other IT service providers or Users of the NCP National System in connection with these Terms will be deemed to be actual losses suffered by the NCP under these Terms, and the NCP will be entitled to recover such losses directly against the IT Service Provider in accordance with this Section 10.

11. TERM AND TERMINATION

11.1. The initial period of time of these Terms is of 12 months as of the Effective Date but not exceeding the EMVS Implementation Phase.

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

After the initial period of time, these Terms will be tacitly renewed for additional periods of time of 12 months each, unless either party objects to such renewal by sending a notice in writing to the other at least ninety 90 days prior to the renewal date.

11.2. Without prejudice to other remedies under applicable law, either Party is entitled to dissolve these Terms 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 these Terms and, (ii) the defaulting Party fails to cure such breach within ninety (90) calendar days after such cure has been demanded in writing if such breach is capable of cure.

11.3. Without prejudice to the above, the NCP is entitled to terminate these Terms immediately, without indemnity, (i) if the contract between EMVO and the NCP for the use of the European Hub by the NCP is terminated or expires for whatever reason, or (ii) if the IT Service Provider is no longer contracted by the relevant User in relation to the Purpose.

11.4. The expiration or termination of these Terms shall not affect provisions thereof that by their terms and meaning are of a continuing nature, in accordance with Section 13.4 below.

12. CHANGES AND UPDATES TO THE NCP National System

12.1. The NCP may apply updates, changes and/or modifications to the NCP National System at any time in accordance with the following during the EMVS Implementation Phase.

12.2. Relevant Artifacts

For the EMVS Implementation Phase, the [SDK/API] and the updates or amendments to the [SDK/API] shall be provided from time to time by the NCP to the IT Service Provider in accordance with the following:

12.2.1. copy of the [SDK/API] documentation – [Document reference to be inserted] in electronic form.

12.3. Communication of the [SDK/API]

The [SDK/API] will be communicated by means of email to the [contact point] named by the IT Service Provider, with copy to the email address notified by the IT Service Provider to the NCP, and copy to the NCP Helpdesk for record.

12.4. Release Management

Any updates and changes to these Artifacts follow a specific release management process similar to ITIL V3 or newer. The release

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

management distinguishes between Emergency Fix, Minor Release and Major Release.

(i) Emergency Fix

An Emergency Fix is used to correct urgent errors in the NMVS or the interfaces. Threats to data security, data integrity or system security are explicitly considered as urgent errors. Emergency Fixes typically include hot fixes and/or bug fixes. Due to the nature of the threats that should be fended off, time is a crucial factor. Therefore, Emergency Fixes can be applied prior to distributing the [SDK/API]. Nevertheless, the relevant connected parties should be informed as soon as possible about the Emergency Fix. Given the nature of the system described, backward compatibility is an essential aspect of any change including emergency changes.

(ii) Minor Release

A Minor Release is used to bundle a set of smaller improvements, corrections and/or known bugs. Typically, a Minor Release does not include changes of interfaces. If such changes are included, they are backward compatible. Minor Releases will be distributed at least 30 calendar days prior to becoming effective.

(iii) Major Release

A Major Release is used to roll out new functionality and/or processes. Backward is not necessary. After a transitional period, a Major Release completely replaces the former Major Release. Major Releases will be distributed at least sixty (60) calendar days prior to becoming effective.

12.5. If the deployment or installation of such updates, changes and/or modifications to the NCP National System imply a (temporary) restriction or interruption of the IT Service Provider's access to parts or all of the NCP National System, the NCP shall provide the IT Service Provider with reasonable prior notice that allows to mitigate the impact and shall take all diligent efforts to minimize any restriction or interruption.

12.6. All updates, changes or modifications shall be the sole property of the NCP.

12.7. All maintenance, repair work, alterations, updates, changes and modifications of any nature whatsoever to the NCP National System shall be done at the NCP's discretion, subject to Section 12.1 above.

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

13. GENERAL PROVISIONS

13.1. The IT Service Provider may not assign these Terms, in whole or in part, without the NCP's prior written consent and any attempted assignment in violation of this provision shall be null and void. The NCP may assign any these Terms without the IT Service Provider's consent at any time, it being agreed that the NCP shall inform the IT Service Provider about such assignment.

13.2. The IT Service Provider must supply all necessary facilities, utilities and equipment necessary to use and access the NCP National System, or any other component of the EMVS, including appropriate computer equipment and Internet connections, at the IT Service Provider's sole risk and expense.

13.3. The IT Service Provider must report the incidents he/she witnessed in relation with the use and access to the NCP National System, or any other component of the EMVS, to the NCP and respond to any request for information from the NCP in a timely manner.

13.4. The provisions of these Terms which by their nature should survive termination, including without limitation Sections 9, 10 and 11 shall remain in force for a term of 5 years as from the Effective Date of these Terms, unless extensions or stipulations are agreed between the NCP and the IT Service Provider and/or arising from the future contractual relations and unless earlier terminated.

13.5. Upon termination of these Terms, the IT Service Provider must destroy all copies of the NCP National System, any other component of the EMVS and related documentation in his/her possession, (if any), and provide an affidavit to that effect, except where the retention of such copies is necessary for the IT Service Provider to comply with its obligations under the EU Directive on Falsified Medicines and Delegated Regulation or under applicable law, in which case the IT Service Provider shall inform the NCP of such legal obligation and the basis thereof and shall keep all these copies securely.

13.6. Choice of law and jurisdiction

These Terms and any contractual or non-contractual (including pre-contractual) matters in connection with their conclusion, validity, interpretation, enforcement, performance and termination shall be governed by and construed in accordance with the laws of the Republic of Cyprus.

Any dispute between the parties arising out of or in connection with these Terms and/or their conclusion, validity, interpretation, enforcement, performance and termination shall be submitted to and finally decided by the courts of the Republic of Cyprus.

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

14. DEFINITIONS

As used in these provisions, the following capitalized terms shall have the meanings set forth below:

14.1. **Confidential Information** shall mean

(i) all information of any nature whatsoever (including, but not limited to, all data, trade secrets, know-how, business information, plans, reports, analyses, studies, drawings, designs, models, concepts, ideas, discoveries, techniques, sketches, tools, computer programs, flow charts, processes, timetables, specifications and technical and quality standards (such as draft and signed contracts, business and/or financial records, samples, correspondence, presentations)),

on whatever support and in whatever form, format, or medium (including, but not limited to, written, oral, graphic, electronic, html pages, pictures, audio, video),

that a disclosing party discloses to the receiving party, or to which the receiving party obtains access, and that relates to the EMVS, its development, implementation, testing or operation, including but not limited to respective information of EMVO members, NCP members, third parties involved in the development, implementation, testing or operation of the NCP National System and of IT Service Providers or any User;

(ii) all Data;

(iii) all information and software for or related to the NCP National System (including the NCP National System interface); and

(iv) any information which, if not otherwise described above, is designated by the disclosing party as confidential or is of such a nature that a reasonable person would believe it to be confidential.

14.2. **Data** shall mean any information uploaded, processed, transferred, generated or stored on or through the EMVS as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation (in particular its Article 33, para. 2), irrespective of whether such Data are stored in the European Hub or a National System and whether or not these include Personal Data.

14.3. **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

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

products for human use.

14.4. **Effective Date** shall mean the date of last signature below (which may be an electronic signature).

14.5. **EMVS Implementation Phase** shall mean the ramp-up period for the limited scale and preliminary operational mode of part of the EMVS that shall automatically terminate on the 8th February 2019, at 23:59:59 CET.

14.6. **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, as well as, where appropriate, the relevant implementing national laws in the relevant EEA Member States.

14.7. **European Hub** designate the component of the EMVS under the responsibility of EMVO that serves as a central information and data router according to Article 32, para. 1, a) of the Delegated Regulation for the transmission of Data to and from the National Systems; it is set up and managed by EMVO.

14.8. **European Medicines Verification Organisation or "EMVO"** shall mean 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.

14.9. **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 the Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

14.10. **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[1], trade and business names, domain names, know-how, rights in computer software, proprietary marketing materials, trade secrets, and any and all other intellectual or industrial property rights in all their patrimonial and moral aspects, as well as any application therefore, anywhere in the world (whether registered or not).

[1] including sui generis database rights resulting from Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

14.11. **IT Service Provider** means the service provider contracted by the User, to deliver the interface between the User's system and the NCP NMVS.

14.12. **IT Service Provider Representative** shall mean any IT Service Provider's authorised director, officer, employee or agent, as well as any business or operating unit within the IT Service Provider, which has no distinct legal personality.

14.13. **National Medicines Verification Organisation(s)** or "**NMVO(s)**" mean the non-profit legal entity (entities) established in the Union 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.

14.14. **National (Medicines Verification) System** or "**NMVS**" shall mean a national or supranational repository of the EMVS according to Article 32, para. 1, b) of the Delegated Regulation under the responsibility of one NMVO; it is connected to the European Hub and allows the Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

14.15. **NCP [or National Contract Partner]** shall mean the National Medicines Verification Organization, which is a Party to these Terms.

14.16. **NCP National (Medicines Verification) System** or **"NCP NMVS"** shall mean the National Medicines Verification System that is under the responsibility of the NCP.

14.17. **NCP Representative** shall mean a NCP's authorised director, officer, employee, agent, or NCP IT company.

14.18. **Personal Data** shall mean any and all information relating to an identified or identifiable individual as defined under the Data Protection Directive 95/46/EC, as will be repealed by the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 once it comes into effect on 25 May 2018, and national laws implementing the Data Protection Directive as applicable.

14.19. **Security Breach** shall mean any event that endangers the security or the functioning of the EMVS, including but not limited to any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or unauthorized access to Data or (other) Confidential Information, as well as the unauthorized upload of data or the upload of illegitimate data on the EMVS.

14.20. **Terms** shall mean the Terms entered into between the NCP and the IT Service Provider relating to the use and access by the IT Service Provider to the NCP National System for the purpose of creating and

THE CHANTECLAIR HOUSE
2 SOPHOULIS STREET, 9TH FLOOR
NICOSIA 1096, CYPRUS
P.O. BOX 21646, CY1511 NICOSIA
TEL: +357 22676060
FAX: +357 22676061
EMAIL: artouros@ldlaw.com.cy
WEB: www.koef.org.cy

delivering the interface between the User's system and the NCP NMVS.

14.21. **Territory** shall mean the European Economic Area and Switzerland.

14.22. **User(s)** shall mean any authorized user, of the EMVS or National System as referred to under the EU Directive on Falsified Medicines and the Delegated Regulation.