TERMS AND CONDITIONS

FOR THE USE OF THE NCP NATIONAL SYSTEM BY END USER

INTRODUCTION

These general terms and conditions (the "**Terms**") apply to the connection, access to and use of the NCP National System.

The NCP National System has been established by NoMVO, with its registered office at Essendropsgate 3, 8.floor, 0368 Oslo, Norway, and registered with the Norwegian company registration no. 918 320 989, under article 35, para. 1, b) of the Delegated Regulation.

In accordance with the Cooperation Agreement for the Operation of the EMVS between NoMVO and EMVO, NoMVO has delegated the set-up, operation and management of the NCP National System to NoMVeC AS, with its registered office at Essendropsgate 3, 8.floor, 0368 Oslo, Norway, and registered with the Norwegian company registration no. 818 142 382, ("**NoMVeC**"). NoMVO and NoMVeC are hereinafter jointly referred to as the "**NCP**".

Please read these Terms carefully before accessing or using the NCP National System in any manner. By accepting these Terms, you (hereinafter, "**You**" or the "**End User**") 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 End User subject to these Terms. The NCP does not sell the NCP National System nor any component of the EMVS to the End User and the NCP (or its licensors) remain the owners of the NCP National System and any component of the EMVS at all times.

For Pharmacies that are connecting to the NCP National System through a certificate switching server and have issued a power of attorney to DIFA to act on their respective behalf in connection with the NMVS, Appendix 1 will apply as an integrated part of these Terms. In the event of a conflict between the provisions of the main body of the Terms and Appendix 1, Appendix 1 shall prevail with the exception of sections, 3, 4.3, 6.3.5, 9 and 10.

The End User is invited to print 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 valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, hereby agree as follows:

1. ACCEPTANCE OF THESE GENERAL TERMS AND CONDITIONS

By connecting, accessing and using the NCP National System and by signing this agreement, You acknowledge that You have read, understood and consent to be bound by these Terms and that your electronic acceptation will be recognized equivalent, for all legal purposes, to a signed version of these Terms.

If You are operating under one (or more) legal entity(ies), (each) such legal entity must agree and be bound by these Terms. 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 and have the legal capacity to represent and bind such company, organization, association or other legal entity, and that such company, organization,

association You represent (hereinafter, collectively, the "**End User**") consents to be bound by these Terms.

If You (on behalf of the End User) do not accept these Terms, the End User is not authorized to connect, to access nor to use the NCP National System.

2. PURPOSE OF THESE TERMS

2.1. The purpose of these Terms is to set the respective rights and obligations of the NCP and the End User with respect to the connection, access to and use of the NCP National System by the End User 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**").

3. GRANT OF RIGHTS TO THE END USER

3.1. Subject to the End User's agreement to and continued compliance with these Terms, the NCP hereby grants to the End User 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.

3.2. License rights granted to the End User are limited to those expressly granted herein. The NCP (and its respective licensors) reserves all other rights.

4. LICENCE RESTRICTIONS

4.1. Except as expressly agreed in writing herein or as provided in these Terms or as necessary for the Purpose, the End User may not (i) use, copy, maintain, distribute, sell, publish, display, sublicense, rent, make corrections to, or modify the NCP National System nor any 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 Falsified Medicines Directive or Delegated Regulation.

4.2. 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 End User:

4.2.1. 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 disconnect the End User from the NCP National System, it being agreed that the NCP shall inform the End User about such measure and the reasons thereof as soon as possible, and that the connection of the End User 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; and

4.2.2. 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 disconnect the End User 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 End User 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.

4.3. If, at any time, the End User has reasonable and objective grounds to believe that the (further) connection, access to or use of the NCP National System immediately and substantially endanger the security of the End User, the End User may disconnect from the NCP National System, it being agreed that the End User shall inform the NCP about such measure and the reasons thereof at the End User's earliest convenience, and that the connection of the End User shall be re-established as soon as there is no longer any immediate and substantial danger to the security of the End User. This is without prejudice to End User's unilateral decision to disconnect from the NCP National System at any time (this without prejudice to the End User's obligations under the EU Directive on Falsified Medicines and Delegated Regulation).

4.4. The Parties shall fully cooperate so that any disconnection as foreseen under Sections 4.2 and 4.3 is only used as a last resort.

5. OBLIGATIONS OF THE END USER

5.1. The End User undertakes to connect, to access to and to use the NCP National System (serving the territory in which the End User is authorized or entitled) to verify the authenticity of the unique identifier of medicinal products and decommission the unique identifier in accordance with these Terms and all its obligations under the EU Directive on Falsified Medicines and the Delegated Regulation.

5.2. The End User warrants that:

5.2.1. the End User 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/account and on its system, including for the correctness and accuracy of any information or Data uploaded or generated by the End User on the NCP National System;

5.2.2. the End User's own system and any connection or access by the End User 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 End User from time to time; and

5.2.3. the End User 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.

5.3. In any case, the End User 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 Falsified Directive 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 compromise the NCP National System or interfere with other Users.

5.4. (Bulk) verifications can only be performed by End Users in respect of products under their physical control. Decommissioning of unique identifiers by End Users can only be performed by or after verifying and scanning individual packs under their physical control and in hand.

5.5. The End User may authorize its End User 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 End User as necessary for the Purpose, subject to the following conditions:

5.5.1. the End User Representative is informed of and is bound by and required to observe all terms, limitations and conditions applying to the End User as set forth in these Terms;

5.5.2. the End User remains fully responsible and liable for any act or omission of its Representative(s);

5.5.3. without prejudice to other remedies, in case of material breach of these Terms by the End User Representative, the NCP reserves the right to require the End User to suspend or withdraw the authorization granted to the said Representative in accordance with this Section 5.4, without any indemnity being due to the End User; and

5.5.4. it is expressly agreed that, as far as the End User's employees are concerned, the provisions under this Section 5.4 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 End User, and the End User remains fully responsible and liable for its employees, their actions and any inappropriate use of the NCP National System.

6. OBLIGATIONS OF THE NCP

6.1. 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 12.1 of these Terms in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation, and (ii) these Terms.

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

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

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

6.2.3. when the End 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 End User to operate without significant delay; and

6.2.4. in the exceptional case of a failure of the End User's own software, the NCP National System shall include graphical user interfaces providing direct access to it to the End User verified in accordance with Section 6.3.3 below, for the purposes of verifying the authenticity of the unique identifier and decommissioning it.

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

6.3.1. 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;

6.3.2. 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;

6.3.3. 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;

6.3.4. 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 flagged in the system as required under the Delegated Regulation;

6.3.5. in accordance with Article 36, para. 1, g) of the Delegated Regulation and without prejudice to Article 35, para. 1, h) thereof and Section 6.3.1 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 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;

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

6.3.7. to support the End User and provide access to all relevant material and documentation and framework for training, in order to allow the End User to connect to the NCP National System for the Purpose.

7. INTERNAL AUDIT BY THE NCP

7.1. **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.

8. INTELLECTUAL PROPERTY RIGHTS

8.1. The End User 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 End User. The End User 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.

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

9. DATA PROTECTION AND OWNERSHIP

9.1. 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 End User interacts with it, in accordance with Article 38 of the Delegated Regulation, as described below.

9.2. As a principle, the Data contained in the EMVS belongs to the User who generates this Data when interacting with the EMVS ('whoever creates the Data, owns the Data'). The EMVS shall hold the following data components:

9.2.1. Static data (i.e., the information listed under Article 33, para. 2 of the Delegated Regulation); and

9.2.2. Dynamic data i.e.,:

9.2.2.1. the status of the unique identifier, i.e., active or de-commissioned. In case of 'de-commissioned' unique identifier, dynamic data also includes the detail, e.g. dispensed, recalled, stolen, etc.; and

9.2.2.2. changes to the complete record ("**Audit Trail**") as referred to in Article 35, para. 1, g) of the Delegated Regulation, which contains a record of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations.

9.3. As per the principle outlined above, dynamic data and static data contained in the EMVS belong to the operator who generates the Data when interacting with the system. This information must not be accessible for any other party, with exception of the static data

and the information on the status of a unique identifier for the sole purpose of verification (Article 38, para. 1 of the Delegated Regulation) and without prejudice to the right of access by national competent authorities as provided for under Article 39 of the Delegated Regulation.

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

9.5. Without any restriction whatsoever to the use of the data generated by an End User's own IT system as mentioned above, access to and/or use of any Data (static or dynamic) extracted from, copied from or downloaded from the EMVS for purposes outside of the scope of the Falsified Medicines Directive and Delegated Regulation needs to be agreed by all the stakeholders owning that Data on a case-by-case basis in compliance with relevant legislation.

9.6. In accordance with Article 35, para. 1, g) of the Delegated Regulation, the NCP National System shall maintain an Audit Trail of all operations concerning a unique identifier, of the Users performing those operations and the nature of the operations. The NCP shall not access the Audit Trail stored on its NCP National System and the Data contained therein without the written agreement of the legitimate data owners (determined in accordance with Sections 9.1 to 9.5 above), except for the purpose of investigating potential incidents of falsification flagged in the EMVS in accordance with Article 36 b), Article 37 d) and Article 38.2 of the Delegated Regulation or for the purpose of granting access to the national competent authorities in accordance with Article 39 of the Delegated Regulation or for the purpose of maintenance, repair work or other alterations to the NCP National System as evidentially and essentially necessary for its operation.

9.6.1. The access to and the use of the data contained in the Audit Trail shall be strictly limited to these purposes it being noted that the NCP Representative that will conduct the operation of accessing the Audit Trail will be restricted on a need-to-know basis as necessary for the above purposes provided that the NCP informs its Representative of the restrictions as to the access and use of the data contained in the Audit Trail and ensures that its Representative is bound by a confidentiality undertaking or obligations of confidence which protect the data contained in the Audit Trail to at least the extent that it is protected under these Terms.

9.7. The NCP shall only grant access to its NCP National System and the Data contained therein to competent authorities for its territory for the purposes set forth under Article 39 of the Delegated Regulation and in so far as they concern the NCP's own territory (which may cover multiple countries in the case of a supranational repository) unless otherwise required under the EU Directive on Falsified Medicines and Delegated Regulation, or under relevant legislation applicable to the NCP.

9.8. In the instances of competent authority access referred to under Section 9.7, except where data are accessed for the purpose of investigation (Article 39 of the Delegated Regulation) or where explicitly prohibited by law or not foreseen under applicable

legislation, the owner of the Data contained in the NCP National System may request to be informed about access to its data by national competent authorities. The NCP should confirm with the national competent authorities that such information may be provided. The modalities for the provision of this information – including the delay for the provision of the information - are to be defined by the NCP at its discretion in line with any guidance provided by the national competent authorities, i.e. the respective reporting capabilities, their development, use and the associated cost allocations are to be decided at national level.

10. CONFIDENTIALITY

10.1. The NCP and the End User, each with respect to Confidential Information received from the other Party, undertakes to:

10.1.1. 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;

10.1.2. 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;

10.1.3. 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;

10.1.4. 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;

10.1.5. 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.

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

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

10.2.2. 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 End User on a non-confidential basis prior to the Effective Date from a third party;

10.2.3. is independently developed by the NCP or the End User;

10.2.4. is required by law, by court or governmental order to be disclosed, provided that before making such disclosure, the NCP or the End User, 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 End User 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

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

10.3. The NCP shall take appropriate measures in relation to the protection of the identity of the End Users, without prejudice to the NCP's obligation to take appropriate measures to ensure that its NCP National System shall be used and operated for the whole Term of this Agreement for the Purposes, in accordance with (i) the EU Directive on Falsified Medicines and Delegated Regulation and (ii) this Agreement.

11. LIMITATION OF WARRANTY AND LIABILITY

11.1. **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 Falsified Medicines Directive 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.

11.2. 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.

11.3. **Exclusion of Indirect Damages.** Without prejudice to Sections 11.1 and 11.2 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 opportunity, 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 ("**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.

11.4. In addition, without prejudice to the NCP's obligations under the EU Falsified Medicines Directive and Delegated Regulation, the NCP shall not be held responsible or liable vis-à-vis the End 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 End Users), 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.

11.5. **Liability Cap.** The NCP's maximum aggregate liability vis-à-vis the End 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 20.000 (twenty thousand euros). The End User's maximum aggregate liability arising out of, or in connection with these Terms, for damages, howsoever arising or caused, whether or not arising from the End User's breach of contract or tortious conduct, negligence, hidden/latent defects shall in no event exceed EUR 20.000 (twenty thousand euros). In no event shall the NCP's liability hereunder for breach caused by EMVO's breach of the cooperation agreement between the NCP and EMVO, exceed the limitations of liability of EMVO towards the NCP under the cooperation agreement.

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

11.6.1. for fraud or wilful misconduct;

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

11.6.3. breach of the anti-bribery legislation; and

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

11.7. **Losses suffered by other Users of the NCP National System**. The Parties acknowledge and agree that any losses suffered by any other 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 End User in accordance with this Section 11.

12. TERM AND TERMINATION

12.1. These Terms shall come into force upon its Effective Date and is concluded for an indefinite term. Either Party may terminate these Terms by ninety (90) days' written notice.

12.2. 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.

12.3. 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 End User is no longer authorised or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and Delegated Regulation.

12.4. 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 14.4 below.

13. CHANGES AND UPDATES TO THE NCP National System

13.1. 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 Operational Phase.

13.2. Relevant Artifacts

For the EMVS Operational 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 End User in accordance with the following:

13.2.1. copy of the SDK/API documentation – FD-002 Implementation Guideline NMVS in electronic form. (This document and others are available through the NMVS Software supplier portal or by contacting the NCP.)

13.3. Communication of the SDK/API

The SDK/API will be communicated by means of email to the a contact point named by the End User, with copy to the email address notified by the End User to the NCP, and copy to the NCP Helpdesk for record.

13.4. Release Management

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

13.5. 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 End User's access to parts or all of the NCP National System, the NCP shall provide the End User with reasonable prior notice that allows to mitigate the impact and shall take all diligent efforts to minimize any restriction or interruption.

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

13.7. 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 13.1 above.

14. GENERAL PROVISIONS

14.1. The End User 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 End User's consent at any time, it being agreed that the NCP shall inform the End User about such assignment and the reasons thereof at the NCP's earliest convenience.

14.2. The End User 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 End User's sole risk and expense.

14.3. The End User must first report the incidents it witnessed in relation with the use and access to the NCP National System or any other component of the EMVS to their respective IT software provider.

14.4. The provisions of these Terms which by their nature should survive termination, including without limitation Sections 8, 9, 10, 11 and 14.6 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 End User and/or arising from the future contractual relations and unless earlier terminated.

14.5. Upon termination of these Terms, the End User must destroy or delete all copies software (including installation files and documentations) and access tokens or credentials relating to the NCP National System, any other component of the EMVS and related documentation in his/her possession, (if any), except where the retention of such material or information is necessary for the End User to comply with its obligations under the EU Directive on Falsified Medicines and Delegated Regulation or under applicable law, in which case the End User shall inform the NCP of such legal obligation and the basis thereof and shall keep all copies of such material and information securely.

14.6. 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 Norway.

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 decided by Oslo District Court (No. "Oslo tingrett").

15. DEFINITIONS

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

15.1. **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 End Users;

(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.

15.2. **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.

15.3. **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.

15.4. **Effective Date** shall mean the date on which the End User accepts these Terms in accordance with Section above.

15.5. **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.

15.6. **EMVS Operational Phase** means the full scale (day-to-day) operational mode of the EMVS, which starts on the 9th February 2019, at 00:00 CET and which is governed by this Agreement.

15.7. **End User Representative** shall mean any End User's authorised director, officer or employee

15.8. **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.

15.9. **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.

15.10. **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.

15.11. **European Medicines Verification System or "EMVS"** shall mean the European system for medicines verification to be set up and managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems and allows 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.

15.12. **Intellectual Property Rights** shall mean any or all patents, rights to inventions, utility models, registered designs, design rights, trademarks, service marks, author rights, copyrights, neighbouring rights and related rights, database rights[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).

15.13. **ITIL V3** shall mean the third version of the Information Technology Infrastructure Library, a globally recognized collection of best practices for managing information technology.

15.14. **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.

15.15. **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

[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.

Regulation under the responsibility of one NMVO; it is connected to the European Hub 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.

15.16. **NCP or National Contract Partner** shall mean the National Medicines Verification Organization, including NoMVeC, which is a Party to these Terms.

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

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

15.19. **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.

15.20. **SDK/API** shall mean the technical documentation to establish the connection and the interactions between the End User and the NCP National System available for the End User (or a third party as indicated by it) on the development portal provided by the NCP.

15.21. **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.

15.22. **Terms** shall mean the Terms entered into between the NCP and the End User relating to the use and access by the End User to the NCP National System for the purpose of verifying the authenticity of medicinal products bearing the unique identifier in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

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

For the End User

Signature :

Name: TERJE WISTNES

Title: GENERAL MANAGER DIFA

Date: 8/2/19.

For the NCP

Signature :

Name: Kai Mjaanes

Title: General Manager NoMVeC AS

Date: 8/2/19

Oppsigelsestid for sluttbrukeravtale

Denne avtalen er et tillegg til avtale om «TERMS AND CONDITIONS FOR THE USE OF THE NCP NATIONAL SYSTEM BY END USER» som er inngått 8. februar 2019.

Avtalepartene er innforstått med at det skal utarbeides vedlegg som ikke foreligger i endelig form ved avtaleinngåelse, og har derfor avtalt at inntil det er enighet om innhold i vedleggene kan den inngåtte avtalen sies opp på 7 dagers varsel, uavhengig av hva som er angitt i artikkel 12 «Term and Termination».

Oslo, 8. februar 2019

For End User

Terje Wistner
Daglig Leder, Difa

For NCP

Kai Mjaanes
Daglig Leder NoMVO/Nomvec AS