Appendix 1 – Special provisions for End Users represented by [DIFA]

1 INTRODUCTION

This Appendix 1 to the Terms contains special provisions and guidelines applicable for pharmacies (the "**Pharmacies**") that have authorized DIFA AS ("**DIFA**") to represent them in relation to the NCP and in matters relating to the NCP National System (as evidenced by written documentation provided to the NCP). This Appendix 1 applies in addition to the Terms for the Pharmacies.

The NCP is responsible for the establishment, operation and maintenance of the NCP National System, as set out in the EU Directive on Falsified Medicines and its Delegated Regulation and as covered in the EMVO URS each in accordance with the EU Directive on Falsified Medicines and its Delegated Regulation (the "**Blueprint Arrangements**"). The NCP will facilitate the connection of the Pharmacies (as End Users) to the NCP National System and the connection of the NCP National System to the European Hub.

The NCP has entered into an agreement with Arvato Systems GmbH (the "**NCP IT Company**") whereby the NCP IT Company shall operate and maintain the NCP National System and the connection with the European Hub on behalf of the NCP (the "**National Blueprint Agreement**").

The Pharmacies are required to connect to the NCP National System and connection between the Pharmacies and the NCP National System will be facilitated through the National Pharmacy Portal ("the **NPP**"), which is owned and operated by DIFA. Each Pharmacy has entered into an agreement with DIFA (the "**NPP Agreement**") whereby the Pharmacies are given access to the NPP and DIFA has undertaken to facilitate and manage the technical interface and connection between the NPP and the NCP National System.

DIFA's role in relation to the NCP National System is limited to acting as a duly authorized centralized intermediary between the NCP and the Pharmacies, and DIFA will not be an End User or otherwise enter into any contractual arrangement with the NCP in relation to the NCP National System. DIFA shall however be entitled to invoke the rights granted to it as the Pharmacies' authorized representative in this Appendix 1, and to generally act on behalf of the Pharmacies in relation to any matters pertaining to the NCP National System or the Terms, excepts as may be explicitly set out herein.

The parties recognize that the proper functioning and availability of the NCP National System is of great importance to the Pharmacies and the distribution of pharmaceuticals in Norway, and that errors and interruptions in the NCP National System could have material adverse consequences.

The purpose of this Appendix 1 is to establish certain governance principles to ensure that the Pharmacies can connect to the NCP National System through the NPP, and to facilitate a cooperation between the NCP and DIFA in relation to the NCP National System to ensure predictability, transparency, connectivity and interoperability in relation to the Pharmacies' use of the NCP National System, and to set up a governance and cooperation model between the NCP and DIFA.

2 CONTACT PERSONS

Nomvec AS	**Difa AS**
Kai Mjaanes	Ingar Dahl
kai@nomvec.no (e), 91161650 (m)	ingar.dahl@apotek.no (e), 97076155 (m)
General Manager	General Manager

3 ROUTINES FOR CONNECTION OF NEW USERS AND DISCONNECTION OF END USERS

The Pharmacies shall be verified and connected to the NCP National System in accordance with the procedures set by NoMVO.

4 PRINCIPLES FOR GOVERNANCE AND MEETINGS BETWEEN NCP AND DIFA

4.1 Principles for governance

The NCP and DIFA shall cooperate in good faith with the objective of ensuring adequate interoperability, transparency, security and service levels with respect to the Pharmacies' connection to the NCP National System.

4.2 Meetings

The NCP and DIFA shall establish a joint working group which shall meet regularly to discuss matters that are relevant for the Pharmacies in relation to the NCP National System. Working group meetings shall be held at least once every six months. DIFA and the NCP shall use reasonable endeavours to ensure that their respective contact persons and other relevant personnel participate in such meetings.

Both DIFA and the NCP may request an extraordinary working group meeting with 5 working days' written notice, if required to resolve or discuss urgent matters. The requesting party shall provide an agenda for such meeting, identifying in reasonable detail the rationale behind the request, resources that should participate in the meeting and other matters of significance to the matter(s) to be dealt with.

DIFA shall host and be responsible for arranging the Working group meetings unless otherwise agreed with the NCP. Invitations shall be sent to the NCP's contact person with at least one month's notice, except for extraordinary working group meetings. The parties shall endeavour to agree on an agenda for each meeting in advance.

5 PRINCIPLES FOR INFORMATION SHARING AND REPORTING

The NCP shall through continuous dialogue and meetings with DIFA make reasonable efforts to provide DIFA with information about the operations and maintenance of the NCP National System which DIFA may reasonably request, or as otherwise required by this appendix, in order to facilitate secure and efficient connection and interoperability between the NCP National System and the NPP at all times.

Nothing in this Appendix 1 shall be construed such as to grant the Pharmacies the right to receive any information (i) revealing data in violation of other end user's rights as further described in Clause 10 of the End User Agreement, and/or (ii) in violation of the EU Directive on Falsified Medicines, the Delegated Regulation and any applicable mandatory laws or contractual obligations (such as anti-trust laws, data protection legislation or confidentiality obligations).

Without prejudice to any other obligations of the NCP, the following principles shall apply for information sharing:

- The NCP shall share system availability and performance reports received from the NCP IT Company, within reasonable time from the NCP's receipt of such, and at least once per month.
- DIFA shall share system availability and performance reports from the NPP insofar as such reports concern the NCP National System, within reasonable time from the NCP's receipt of such, and at least once per month.

- The NCP and DIFA shall share all incident reports for incidents that have affected the Pharmacies' use of the NCP National System, without undue delay after having produced or received the same.

The details, format and frequency of such reporting shall be agreed separately between the NCP and DIFA.

6 CHANGE MANAGEMENT

Changes to the NCP National System is governed by clause 13 of the Terms, except as otherwise set out in this Appendix 1.

The Parties may agree to cooperate in initiatives to make changes to the NCP National System, through discussions with EMVO, stakeholders or national authorities, conf. section 11 of this Appendix 1.

DIFA shall act as the Pharmacies' contact point in all matters pertaining to changes to the NCP National System in accordance with clause 13, and all communication with the Pharmacy (in its capacity as End User) with respect to such changes shall be between the NCP and DIFA, on behalf of the Pharmacies.

Changes to the NCP National System that are initiated by or otherwise within the control of the NCP shall be notified to the Pharmacies prior to such changes being implemented.To the extent that such changes are likely to impact the connection or interoperability between the NPP and the NCP National System (the "**Relevant Changes**"), the NCP shall, to the extent commercially, technically and legally viable, confer with DIFA prior to executing any final Change Order, so that the parties can discuss the effect of any Relevant Changes on the connection or interoperability of the NPP with the NCP National System before the Relevant Changes are implemented or otherwise effectuated.

The NCP shall notify DIFA of any actual or planned Relevant Changes to the NCP National System that are outside the control of the NCP (including, where applicable, changes to the EMVS and/or the URS), without undue delay after becoming aware of such Relevant Changes. The NCP and DIFA (on behalf of the Pharmacies) shall in good faith discuss and keep each other updated on any planned changes and change requests concerning the URS, the EMVS, the NPP or any other NMVS (whether initiated by stakeholder organizations, EMVO or EU or governmental authorities), for the purpose of ensuring that such changes do not adversely affect the operation of the NCP National System, the NPP or the distribution of pharmaceuticals in Norway.

DIFA shall notify the NCP of any changes to the NPP which may affect the connection or interoperability of the NPP with the NCP National System, so that the parties can discuss the effect of any such change on the connection or interoperability of the NPP with the NCP National System before the Relevant Changes are implemented or otherwise effectuated.

The NCP and DIFA shall cooperate in good faith to establish test environments and carry out adequate testing to verify all Relevant Changes and changes to the NCP prior to such changes being put into operation.

7 AVAILABILITY OF THE NCP NATIONAL SYSTEM

Pursuant to the National Blueprint Agreement, the NCP IT Company has undertaken to operate and maintain the NCP National System in accordance with the service levels set out in part V, section 4.1 and 9.1.9 of the URS (as amended from time to time) and as further described in the

Service Level Matrix and Service Level Descriptions attached hereto as Annex 1 ("**URS Service Level Requirements**").

Subject to the limitations set out in clause 11 of the Terms, the NCP shall ensure that the NCP National System fulfils the URS Service Level Requirements, through proactive measures and engagement with the NCP IT Company.

Service levels will be measured in accordance with the URS. The NCP will share system availability and performance reports received from the NCP IT Company under the National Blueprint Agreement, within reasonable time upon receipt of such and at least once per month.

8 SECURITY AND CONFIDENTIALITY

The NCP shall procure that the NCP IT Company complies with the information security policies and other security policies set out in the National Blueprint Agreement and the Delegated Regulation, including the security policies and procedures set out in Annex 2 hereto.

The NCP shall, in cooperation with DIFA establish routines for monitoring the NCP IT Company's compliance with its obligations pertaining to confidentiality and access to data, data breach and information security, and the NCP shall be responsible for implementing such routines. Subject to limitations set out in applicable laws, the NCP shall on request provide DIFA with access to reports on how data from the Pharmacies is processed and accessed in the NCP National System and/or the EMVS.

Without prejudice to each Pharmacy's ownership rights to its own Data, the NCP acknowledges that it is of high importance to the Pharmacies that the Data is kept confidential and only used for the specific purposes set out in the Delegated Regulation. The NCP is responsible for keeping the Data confidential in accordance with the Terms [and the Delegated Regulation, including that the NCP IT Company complies with the same. The NCP shall procure that the NCP IT Supplier issues a declaration to the Pharmacies, which shall be approved by DIFA, where the NCP IT Supplier agrees to comply with all such confidentiality obligations and restrictions on use. In the event of an actual or suspected breach of confidentiality obligations of the NCP and/or the NCP IT Company, the NCP shall immediately notify DIFA and shall take all steps reasonable required to remedy such breach.

9 INCIDENT MANAGEMENT

Incidents relating to the NCP National System that are reasonably relevant to the Pharmacies' connection to the NCP National System ("**Relevant Incidents**") shall be handled in accordance with the following:

- Any incidents discovered by the Pharmacies and DIFA shall be reported [in accordance with the URS Service Level Requirements. The NCP and DIFA shall cooperate in good faith to establish a suitable interface and technical solution for reporting of Relevant Incidents.
- Incidents shall be classified in accordance with the URS part V, section 9.1.8. The NCP shall provide reasonable assistance in classifying Relevant Incidents.
- Until appropriate reporting routines have been agreed and implemented, the NCP shall immediately forward all reports to and from the NCP IT Company in connection with Relevant Incidents, and shall procure that the NCP IT Company complies with the response times set out in the URS Service Level Requirements. The NCP shall follow up

with the NCP IT Company to ensure that DIFA receives all necessary status updates regarding the resolution of any Relevant Incidents.

- The NCP and DIFA shall cooperate in good faith and shall upon request provide each other with reasonable assistance in relation to error investigations, analysis and corrections of defects and incidents within the NCP National System and the Pharmacies' own systems (including the NPP). If it can be documented that the defects and/or incidents in the a party's systems were not caused by defects in the other party's system, the first party shall cover the other party's easonable documented costs incurred in connection with such assistance.

10 DIFA'S AUDIT RIGHTS

10.1 Audit rights

The NCP's right to audit the NCP IT Company and the NCP National System is set out in article 17 (Audit and Record Retention) of the Blueprint Agreement. In order to provide transparency and visibility around the NCP's and the NCP IT Company's compliance with the National Blueprint Agreement and the EU Directive on Falsified Medicines, the NCP shall grant DIFA the right to participate, as an observer, in the audit activities conducted by the NCP under the National Blueprint Agreement. Any such participation shall always be subject to any restrictions under applicable laws and instructions from EU or governmental bodies. DIFA shall receive reasonable advance notice of any such audits. DIFA shall receive a copy of the report from any audits conducted under the National Blueprint Agreement, insofar as it relates to the processing of the Data from the Pharmacies, and notwithstanding its own participation in the audit. The Pharmacies' participation shall be at the cost of the Pharmacies. The NCP shall use reasonable endeavours to comply with the Pharmacies' reasonable requests for the NCP to exercise its audit rights under the National Blueprint Agreement. The Pharmacies shall compensate the NCP for all documented reasonable costs and expenses incurred in connection with carrying out audit activities requested by the Pharmacies.

10.2 Access to NCP IT Company

If the NCP does not wish to or is not able to exercise its audit rights under the National Blueprint Agreement, the NCP shall at the request of DIFA (on behalf of the Pharmacies) allow DIFA (on behalf of the Pharmacies) to carry out audit activities directly with the NCP IT Company as the NCP's representative in accordance with the provisions and limitations of the Blueprint Agreement. The NCP shall ensure that the NCP IT Company is notified of such appointment. The NCP shall receive a copy of the report and any other documentation from any audits conducted by DIFA as the NCP's representative.

11 ALIGNMENT WITH NATIONAL REQUIREMENTS

The NCP acknowledges that certain system availability and information security requirements applicable to the NCP National System, which have been agreed pursuant to centralized negotiations between stakeholders at European level (and reflected in the URS), may not fully meet the national legal requirements to which the Pharmacies are subject (the "**National Requirements**").

Acknowledging the benefits which may be achieved through consistency between National Requirements and the requirements set out in the Agreement and the Blueprint Arrangements:

- The NCP and DIFA will cooperate in good faith to identify and discuss what discrepancies, inconsistencies and other challenges there are between the Blueprint

Arrangements and the National Requirements, in order to identify the need for changes to the Blueprint Arrangements (as applicable to Norway), and to agree on what changes should be prioritized and how with respect to Norway and the Pharmacies (the "**Common Goals**").

- The NCP and DIFA will cooperate in good faith to engage in discussions with EMVO, other NMVOs and stakeholders, including applicable Norwegian authorities, with the objective of changing the National Requirements and/or the Blueprint Arrangements so that the National Requirements and the rights and obligations of the parties set out herein are materially aligned.

The costs associated with implementing changes as a result of the above shall be discussed and agreed between the Parties in each case, however both the NCP and DIFA shall bear their own costs in negotiating the above.

* * *

These Terms have been prepared in 2 (two) originals, of which each Party has received one.

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For the End User	**For the NCP**
Difa AS	NoMVeC AS
Signature: 	Signature: 
Name: Ingar Dahl	Name: Kai Mjaanes
Title: General Manager Difa AS	Title: General Manager NoMVeC AS
Date: 8/5-2019	Date: 8/5/19