Registration Form – the Norwegian NMVS Program

Company details		
Company name:		
Company registration number and address		
Contact details of the Company for alert investigation purposes	Phone:	E-mail:
Contact details of the Company for commercial and administrative purposes	Phone:	E-mail:
Signature and date:		
Name and title in capital letters:		

The Company represents the following marketing authorization holders in Norway (Listing of several marketing authorization holders is possible)	
Company name:	Company registration number:
Company name:	Company registration number:
Company name:	Company registration number:
Company name:	Company registration number:

Invoicing information	
Name	
Address	
VAT number	

Line for Nomvec signature (if requested):_____

JAN 2025

TERMS & CONDITIONS

These Terms & Conditions governs the relationship between:

(1) **Nomvec AS**, a company registration number 818 142 382 ("**Nomvec**"); and

(2) The Company entity set out in the Registration Form on the cover page (the "**Company**");

with respect to the Company's participation in the Norwegian NMVS Program (the "**Program**")

Nomvec and the Company are together referred to as the "**Parties**" and individually as a "**Party**".

1 DEFINITIONS

"Company" means the Company entity set out in the Registration Form on the cover page;

"**Confidential Information**" means any and all technical and/or commercial information and other material of a Party relating to, without limitations, its business, business plans, financial details, customers, partners, intellectual property, facilities, products, techniques and/or processes whether in oral, written or electronic form, that is specifically marked or otherwise communicated as being confidential at the time of disclosure or reasonably should be understood as being confidential.

"**Delegated Regulation**" means the Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, including the implementing Norwegian law and/or regulation;

"**Directive**" means the Directive on Falsified Medicines 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, including the relevant implementing Norwegian laws and regulations, as applicable;

"**Effective Date**" means the signature date set out by the Company on the Registration Form.

"**European Medicines Verification Organisation**" or "**EMVO**", means the non-profit legal entity established to set up and manage the European Hub in accordance with the Directive and Delegated Regulation;

"**European Medicines Verification System**" or "**EMVS**" means the European system for medicines verification set up and managed in accordance with Chapter VII of the Delegated Regulation. The EMVS consists of the European Hub and the National Systems and allows the wholesalers and retailers to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

"**European Hub**" means the component of the EMVS under the responsibility of EMVO that serves as a central information and data router for the transmission of Data to and from the National Systems;

"**National (Medicines Verification) System**" or "**NMVS**" means a national medicines verification system that is connected to the European Hub and allows the wholesalers and retailers to verify the authenticity of medicinal products in accordance with the provisions of the Directive and the Delegated Regulation;

"**Norwegian NMVS**" means the national medicines verification system which is to be developed, implemented, operated and maintained in Norway.

"**Norwegian NMVS Program**" or "**Program**" means this document established for the purposes described in Section 2 of these Terms & Conditions.

"**MAH**" means the Company as well as other holders of marketing authorization(s) for a medicinal product with effect on the territory of Norway. MAH also includes parallel importers of medicinal products in Norway, and other entities allowed to act legally in Norway as an MAH;

"**Nomvec AS**" or "**Nomvec**" is the private limited company responsible for the development, implementation and operation of the Norwegian NMVS on behalf of NoMVO.

"**NoMVO**" is the National Medicines Verification Organization of Norway, i.e. the non-profit legal entity established in accordance with the Delegated Regulation.

"**Registration Form"** means the cover page of this document, completed and signed by the Company.

2 SUBJECT MATTER OF THE TERMS & CONDITIONS

In the application of the Directive and the Delegated Regulation, A National Medicines Verification System will be established in Norway. The Norwegian NMVS will be part of the European Medicines Verification System, and will be developed, implemented and maintained by Nomvec. The Norwegian NMVS will be operational by 8 February 2019 in accordance with the Directive and the Delegated Regulation.

Pursuant to the Directive and the Delegated Regulation, the costs of the development, implementation, operation and maintenance of the NMVS shall be borne by marketing authorization holders for medicinal products in the relevant market. Therefore, the Company, together with other MAHs, is responsible for the aforementioned costs for the Norwegian NMVS.

The Parties have therefore agreed to enter into the Program where Nomvec will be responsible for the development, implementation, operation and maintenance of the Norwegian NMVS and the Company will bear its share of the costs for the foregoing and the financing of Nomvec on the Terms & Conditions set out herein.

3 OBLIGATIONS OF NOMVEC

Nomvec agrees and undertakes to:

(i) Develop, implement, operate and maintain the Norwegian NMVS in accordance with the Directive and Delegated Regulation;

(ii) Protect the Norwegian NMVS, including the access thereto, by good industry practice security measures.

(iii) Use its reasonable efforts so that no malicious software, malware or other code is introduced into the Norwegian NMVS.

(iv) Implement into the Norwegian NMVS such updates as EMVO may require in accordance with the agreement entered into between Nomvec and EMVO.

(v) only give access to the Norwegian NMVS to authorized users in accordance with the Directive and Delegated Regulation, and to national competent authorities in accordance with Article 39 of the Delegated Regulation.

4 PAYMENT

4.1 Fees and costs

The Company shall be responsible for costs as set out in the Directive and the Delegated Regulation and subsequent amendments, currently comprising:

(i) The administrative costs for Nomvec,

(ii) The costs for developing, implementing, operating and maintaining the Norwegian NMVS,

(iii) The costs for connecting the Norwegian NMVS to the European Hub.

As of 2025 the yearly fee will be calculated as the sum of:

- A flat fee of NOK 31.500 per. MAH
- A variable revenue based fee*.

*) The revenue based fee will be set at the start of the year based on the previous year's sales. Projections for next years fee will be published on the Nomvec web site. As sales we will use the reported (actual) sales (aka. GIP) for the previous year as reported to the NCA. If the actual sales have not been reported or made available, Nomvec will use the sales data as reported from the pharmacies (aka. AIP) for the company.

New entrant MAHs will be charged a one time entrant fee of NOK 15.000.

The Company acknowledges and agrees that both Nomvec and NoMVO are non-profit entities, set up as a vehicle for each MAHs compliance with the Directive and Delegated Regulation. Thus, the Company agrees that the fees set out in the Registration Form are estimates, that might change inter alia due to the number of MAHs participating, cost increases from EMVO or if the costs for developing, implementing, operating and maintaining the Norwegian NMVS increase. Nomvec has the right, at any time during the Program to adjust the fees set out in Registration Form. Nomvec will publish changes to the fees in advance on www.nomvec.no.

4.2 Payment terms

All fees which shall be paid by the Company are set out in Registration Form. Unless otherwise specified in the Registration Form, all fees are exclusive of any taxes and duties, including inter alia value added tax, withholding tax and similar taxes and duties, which the Company shall be responsible for paying. All fees are quoted in Norwegian kroner.

Payment shall be made within thirty (30) calendar days of the invoice date.

If the Customer fails to make payment by the agreed time, the Contractor shall be entitled to claim interest on any overdue amount, pursuant to the Act No. 100 of 17 December 1976 relating to Interest on Overdue Payments, etc. (Late Payment Interest Act).

The Company's invoicing address or electronic invoicing details are set out in the Registration Form. The Company shall inform Nomvec immediately in case of any changes in its invoicing address.

If the fees are paid by the Company on behalf of several MAHs, the Company shall in any case remain solely responsible and liable for the payment of the fees under this Program.

5 PROPRIETARY RIGHTS

All intellectual property rights related to the Norwegian NMVS and the EMVS shall be owned by Nomvec, NoMVO and EMVO unless owned by their service providers. The Company and the users of the Norwegian NMVS and the EMVS will not obtain any intellectual property rights to the Norwegian NMVS or EMVS.

6 CONFIDENTIAL INFORMATION

Each Party guarantees that all information of a confidential nature received from the other Party or their advisors before, during and after the conclusion of the Program shall remain confidential.

Each Party may disclose the other Party's Confidential Information to its affiliates, employees or subcontractors on a need to know basis for the purpose of this Program and under at least as stringent confidentiality obligations as set out in this Section 6.

The confidentiality obligations set out in this Section 6 do not apply to material and information that (i) is generally available or otherwise public without the receiving Party being in breach of these Terms & Conditions; (ii) the receiving Party has received from a third party without breach of confidentiality; (iii) was in the possession of the receiving Party without confidentiality obligation prior to receiving the information from disclosing Party; or (iv) the receiving Party has independently developed without using the information or material received from the disclosing Party. The obligations under this Section 6 will remain in force after termination of this Program.

7 LIABILITY

Both Parties agree that Nomvec shall not be liable towards the Company or any third party under or in connection with this Program or its Termination, in contract, pre-contract, tort or otherwise, for any

(i) Economic loss (including loss of revenues, profits, contracts, business or anticipated savings);

(ii) Any loss of goodwill or reputation;

(iii) Any damage direct or indirect;

unless Nomvec or anyone for whom it is responsible for has acted with gross negligence or willful misconduct for which liability cannot be limited by law.

The aforesaid losses include any special, indirect, incidental, statutory, punitive or consequential losses or damages as well as any losses or damages caused by interruption of operations.

8 TERM AND TERMINATION

This Program shall commence on the Effective Date and remain effective unless terminated as provided herein.

Since this Program covers the execution of compulsory legal provisions as set out in the Directive and the Delegated Regulation, both Parties understand and agree that this Program in principal

only may be terminated when the Company no longer acts as a MAH in Norway or when the applicable legislation ceases to apply to either the Company or Nomvec.

Notwithstanding the above, either Party may terminate the Program if the other Party commits a material breach and does not cure such breach within 15 (fifteen) days written notice. Nomvec shall also be entitled to terminate the Program if the agreement between Nomvec/NoMVO and EMVO for the connection of the Norwegian NMVS and the European Hub is terminated for any reason.

In the event of termination, the Company will have no rights whatsoever to be refunded of the already paid fees (neither as a whole nor pro rata).

9 ASSIGNMENT

The Parties are not entitled to assign or otherwise transfer any of its rights or obligations under this Program without the other Party's prior written consent, which may not be unreasonably withheld.

Notwithstanding the above, Nomvec may assign or otherwise transfer any of its rights or obligations under this Program to NoMVO. Nomvec shall notify the Company of such assignment or transfer.

10 ENTIRE AGREEMENT

This Program and the documents referred to herein constitute the entire agreement between the Parties relating to the subject matter of this Program and supersede all prior expressions of intent or undertakings, representations, negotiations, agreements or understandings, written or oral, between the Parties relating to the subject matter of this Program.

11 GOVERNING LAW AND DISPUTE RESOLUTION

This Program and the legal relationship between the Parties shall be governed by Norwegian law.

Any dispute, controversy or claim arising out of or in connection with this Program, or the breach, termination or invalidity thereof, shall be finally settled by arbitration in accordance with the Rules of the Arbitration and Dispute Resolution Institute of the Oslo Chamber of Commerce in force at any time.

* * *