PARTICIPATION AGREEMENT 2.0

This Participation Agreement ("Agreement") by and between Dansk Medicin Verifikation Organisation ApS, ("DMVO"), a corporation organized under the laws of Denmark having a place of business at Lersø Parkallé 101, 2100 København Ø, Denmark and registered with the Danish Business Authority under CVR-no. 38 22 92 65, and INSERT NAME, ("Company") a INSERT COUNTRY corporation having a principal place of business at INSERT ADDRESS and registered under company registration number INSERT NUMBER, is entered into as of the date last written below ("the Effective Date"). Both hereafter referred to as a "Party", and together as the "Parties".

A. WHEREAS, the DMVO is established to set up and manage the Danish Medicines Verification System or DMVS in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

B. WHEREAS, the DMVO concluded an agreement (the National Blueprint Agreement) with the National System IT Company in order to implement, develop, test and operate the DMVS and its interfaces with other systems.

C. WHEREAS, the costs of the development, implementation,operation and the maintenance of the DMVS and all related activities shall be born, by Marketing Authorization Holders (MAHs) for medicinal products in the relevant market.

D. WHEREAS, the DMVO must conclude an Agreement with Company on a non-exclusive basis to co-finance the set-up costs of the DMVS and all other expenses to maintain and operate the DMVS.

E. WHEREAS, it is a pre-condition for entering into this Agreement that there has been signed an additional Agreement with EMVO regarding the upload of product data into the European Hub.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties agree as follows:

1.0 Definitions

1.1 Definitions. In this Agreement the Definitions are set out in Exhibit A ("Definitions"),unless the context otherwise requires.

2.0 Scope.

2.1 Financing the DMVS. This Agreement sets forth the terms and conditions for payment of the applicable fees that Company (including Company on behalf of the MAHs it represents) must pay to co-finance the DMVS.

3.0 Fee Schedule, Payment and Registration Form.

3.1 Fee Schedule. Fees shall be those specified in DMVO's fee schedule in Exhibit B. All stated prices are exclusive of any taxes, fees and duties or other amounts, however designated, and including without limitation value added and withholding taxes which are levied or based upon such charges, or upon this Agreement. Company shall pay any taxes related to products or services purchased or licensed pursuant to this Agreement, or Company shall present an exemption certificate acceptable to the taxing authorities. Applicable taxes shall be billed as a separate item on the invoice, to the extent practical. DMVO may change fees annually by issuance of a revised fee schedule in Exhibit B or other announcement of a change in fee. Subject to and expressly conditioned upon compliance with the terms and conditions of this Agreement the EU Directive on Falsified Medicines

and the Delegated Regulation, including the obligation for Company to pay the applicable fees set forth in the Fee Schedule in Exhibit B, DMVO grants Company and the MAHs Company represents a non-exclusive, non-transferable, non-sublicensable, personal license to make use of the DMVS to process Data. The DMVO has set up the DMVS and will subsequently maintain and operate the DMVS based on such fees. If the Company represents Marketing Authorization Holders/ MAHs for medical products within the Danish territory, the applicable fees will be charged according to the number of MAHs. Under no circumstances will anything in this Agreement be construed as granting, by implication, estoppel or otherwise, a license to any system technology or proprietary right belonging to the other party other than as expressly set forth under this Agreement.

3.2 Payment. Unless otherwise stated in the Agreement the payment term shall be net thirty (30) days from the date of invoice. All payments shall be made in Euro. Any sum not paid by Company, when due, shall bear interest until paid at a rate of 1.5% per month (18% per annum) or the maximum rate permitted by law, whichever is less. If at any time, Company is delinquent in the payment of any invoice, or is otherwise in breach of this Agreement, DMVO shall i) notify the Danish Medicines Agency of the non-fulfilment of the Company's obligation under Article 31 paragraph 5 of the Delegated Regulation and ii) reserve the right to suspend the Company and the MAHs it represents access to the DMVS until the due fulfilment of the payment obligation. All fees are exclusive of any taxes, fees and duties or other amounts, however designated, and including without limitation value added and withholding taxes which are levied or based upon such charges, or upon this Agreement. Any taxes related to this Agreement shall be paid by Company unless Company can present an exemption certificate acceptable to the taxing authorities. Applicable taxes shall be billed as a separate item on the invoice, to the extent possible. If fees are paid by a third party on behalf of Company, the Company shall in any case remain solely responsible and liable for the compliance with the Agreement, including but not limited to the EU Directive on Falsified Medicines and Delegated Regulation. This also applies where Company represents other MAHs.

3.3 Registration Form. The Company must ensure that the invoicing address and other contact information specified in the registration form in Exhibit C is correct and up to date. Should the address, other contact information or number of MAHs change, it is the responsibility of the Company to inform the DMVO in writing by immediately sending a new updated and signed Exhibit C as an addendum to this Agreement. If the contact information in Exhibit D changes, the Parties must inform the other Party in writing.

3.4 All Fees are non-reimbursable. Except as otherwise decided by the DMVO board all amounts paid by the Company are definitely acquired by the DMVO and are non-reimbursable.

3.5 Each Party shall bear its own costs. Each party shall bear its own costs for the entering into and performance of its rights and obligations under this Agreement.

4.0 Costs, Loans & Other Activities.

4.1 MAH(s) whom Company represents. Company shall pay the applicable fee as set forth in the fee schedule mentioned in Exhibit B to DMVO under this Agreement. Company hereby guarantees the performance by such MAH(s) of the financial and other contractual obligations set forth in this Agreement and represents and warrants that it is empowered to enter into this Agreement on behalf the MAH(s) mentioned in exhibit C and to bind (and does so bind) such MAH(s) to the terms and conditions of this Agreement. Company may require certain of the listed MAH(s) to execute an agreement with DMVO such that the legal relationship shall be between DMVO and the MAH(s). Any breach by Company or by MAH(s) which Company represents of this Agreement, shall entitle DMVO to terminate this Agreement pursuant to Section 8. The limits of liability set forth in this Agreement shall be deemed an aggregate limit of liability, not per MAH, regardless of whether a MAH has executed a separate Agreement with DMVO.

4.2 Payment of Outstanding Costs. In the event that the implementation of the EU Directive on Falsified Medicines as a whole or the development of the DMVS more specifically would be postponed, all development activities and ramp-up activities may need to be amended, suspended or even terminated. The Parties understand that, in such case, the incurred costs and accepted but still outstanding invoices addressed to DMVO need to be paid. The potential costs and/or penalties to be

paid to the National System IT Company will be provisioned as well as the cost for the salaries and lay-off costs of the personnel, freelancers and/or third party consultants on the payroll of the DMVO or any outstanding loans. Both Parties understand and agree that such additional costs may result in additional invoices by DMVO to Company.

5.0 Indemnification

5.1 The DMVS may be substantially amended, suspended, or even terminated by the DMVO without any indemnity being due to Company or MAH(s).

6.0 Limited Warranty and Limitation of Liability.

6.1 DMVO does not warrant that the DMVS will be error-free or will operate without interruption. Company's exclusive remedy for breach of this section 6.1 shall be to notify DMVO of the problem, in which event DMVO shall use reasonable efforts to correct such problem or provide a work-around.

6.2 DMVO shall not be liable for actions of EMVO and of the persons to whom access to the DMVS and the EMVS has been provided. DMVO shall not be liable for the content, integrity, or completeness of the Data in the DMVS or the EMVS and for such Data being up to date.

6.3 The aggregate total liability of DMVO and its suppliers under or in connection with this Agreement or otherwise, whether in contract, tort or otherwise, shall be limited to money paid to DMVO under this Agreement in the twelve (12) month period prior to the event or circumstances giving rise to the liability.

7.0 Consequential Damages Waiver.

7.1 Except for statutory limitations, in no event shall DMVO or its suppliers be liable for any special, incidental or consequential damages, or lost revenue or profits, or lost or damaged Data, or any indirect damages, whether arising in contract, tort (including negligence), or otherwise.

8.0 Term and Termination.

8.1 Since this Agreement covers the execution of compulsory legal provisions (mentioned in the EU Directive on Falsified Medicines, Delegated Regulation and possible other legislation) this Agreement shall be effective upon the Effective Date and shall remain in force unless otherwise terminated as provided herein.

8.2 This Agreement may be terminated immediately by either party through written notice to the other Party if the Company no longer acts as MAH in the Danish market or represents 3rd party MAHs. In such case, the Company will have no rights whatsoever to be refunded of the already paid fees (neither in whole nor pro rata).

8.3 This Agreement may be terminated if the applicable legislation ceases to apply to the undersigned Company or the DMVO. Safe for Section 4.2, the board of directors of DMVO has the sole and exclusive right to decide on whether to refund any remaining funds, and to decide on the modalities of a potential refund (including timing and proportion). Such potential refund will be paid on a pro rata basis of all amounts paid by the Company and other eligible parties that are still active in Denmark at the time of the decision by the DMVO board.

8.4 DMVO will have the right to terminate the Agreement without any liability to Company (or the MAHs which Company represents), if the agreement between EMVO and DMVO, for the use of the European Hub is terminated for any reason.

8.5 This Agreement may be terminated with immediate effect by written notice by the non-defaulting Party in the event that the other Party commits a material breach of this Agreement and fails

to remedy such breach within thirty (30) days after having been given written notice in respect thereof.

8.6 The rights and obligations of the parties contained in Sections 5, 6, 7, 8, 9 and 10 will survive any expiration or termination of this Agreement.

9.0 Confidential Information.

9.1 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 Agreement shall remain confidential.

9.2 The obligations of confidentiality set forth herein shall not apply to information which (a) has entered the public domain except where such entry is the result of Company's or MAH(s) which Company represents breach of this Agreement; (b) prior to disclosure hereunder was already rightfully in Company's possession; or (c) subsequent to disclosure hereunder is obtained by Company or MAH on a non-confidential basis from a third party who has the right to disclose such information to Company or MAH. Neither party shall disclose, advertise, or publish the terms and conditions of this Agreement without the prior written consent of the other party. Any press release or publication regarding this Agreement is subject to prior review and written approval of the parties.

10.0 General Terms and Conditions.

10.1 Assignment. Neither party may assign this Agreement or any interest or rights granted hereunder to any third party without the prior written consent of the other party. A change of control or reorganization of either party pursuant to a merger, sale of assets or stock will be deemed to be an assignment under this Agreement. This Agreement will terminate immediately upon occurrence of any prohibited assignment.

10.2 Relationship of Parties. The parties are independent contractors under this Agreement and no other relationship is intended, including a Membership, franchise, joint venture, agency, employer/employee, fiduciary or other special relationship. Neither party will act in a manner which expresses or implies a relationship other than that of independent contractor. Neither party has the right or authority to, and will not, assume or create any obligation of any nature whatsoever on behalf of the other party or bind the other party in any respect whatsoever.

10.3 Notices. Any notice required or permitted to be given by either party under this Agreement will be in writing and will be delivered to the persons identified, and at the addresses specified, in the Notice section of Exhibit D attached hereto or as otherwise agreed in writing.

10.4 Governing Law. This Agreement and any action related thereto will be governed, controlled, interpreted and defined by and under the Laws of Denmark and any dispute shall be subject to the exclusive jurisdiction of the Danish courts, without regard to the conflicts of laws provisions thereof, provided that either party shall at all times have the right to commence proceedings in any other court of its choice of appropriate jurisdiction to obtain injunctive relief for protection of intellectual property proprietary rights or Data.

10.5 No Waiver. Failure by either party to enforce any provision of this Agreement will not be deemed a waiver of future enforcement of that or any other provision. Any waiver, amendment, or other modification of any provision of this Agreement will be effective only if in writing and signed by the parties.

10.6 Entire Agreement. This Agreement, including all exhibits which are incorporated herein by reference, constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes and replaces all prior and contemporaneous understandings or agreements, written or oral, regarding such subject matter. No modification or attempted modification of this Agreement will be effective unless agreed to in writing by both DMVO and Company. Both Parties agree

that when European legislation regarding by example the EU Directive on Falsified Medicines and guidelines lead to extra responsibilities, an addendum to this Agreement will need to be entered into which will outline in more detail all rights and obligations of both Parties with regard to the subject matter of this Agreement. Such addendum will not jeopardize the rights of the DMVO with regard to the stipulations on the flat fee payment as mentioned in the fee schedule in Exhibit B. Furthermore, the parties agree to update or amend this Agreement, if necessary due to revised agreements between EMVO and DMVO or DMVO and National IT Service Provider.

10.7 Exhibits. If there is a discrepancy between the main body of this Agreement and the Exhibits, the main body of this Agreement prevails.

10.8 Signatures. This Agreement has been drawn up and executed in two (2) identical copies (which may also be electronic including electronic signatures) of which each Party has received one (1) copy.

Dansk Medicin Verifikation Organisation ApS ("DMVO")	_____ ("Company")
By:	By:
Name:	Name:
Title:	Title:
Date:	E-mail:
	Date:

EXHIBIT A
DEFINITIONS

1. Definitions

As used in this Agreement, the following capitalized terms shall have the meanings set forth below:

1.1. **Agreement** shall mean this Agreement for the financing of the Danish Medicines Verification System, and any and all Exhibits attached thereto, as well as any other document expressly incorporated into this Agreement. A mere reference to another document shall not constitute an explicit incorporation.

1.2 **Company** is the legal entity listed on the front page of this Agreement. Company can have multiple MAHs for which they pay the applicable fee(s) . In addition, Company can represent Marketing Authorization Holders (MAH) on behalf of which it will pay the applicable fees. In the latter case, DMVO may at its option request either: i) a co-signed Agreement between MAH, Company and DMVO such that the legal relationship shall be between DMVO, Company and MAH; and/or ii) proof of Company being authorized to represent MAH in the form of an power of attorney in fact (in Danish fuldmagt) However Company guarantees the performance by such MAH(s) of the financial and other contractual obligations set forth in this Agreement and represents and warrants that it is empowered to enter into this Agreement on behalf of MAH(s) mentioned in exhibit C and to bind (and does so bind) such MAH(s) to the terms and conditions of this Agreement also in situations where DMVO does not request such power of attorney.

1.3. **Danish (Medicines Verification) System or DMVS** or **National (Medicines Verification) System or NMVS** shall mean a national or supranational repository of the EMVS under the responsibility of one national medicines verification organisation; it is connected to the European Hub and allows authorized users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.

1.4. **Data** shall mean information uploaded, processed, transferred, generated or stored in the EMVS or the DMVS as set out in the EU Directive on Falsified Medicines and the Delegated regulation (in particular its Article 33, paragraph 2).

1.5. **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 as amended from time to time.

1.6. **DMVO** shall mean Dansk Medicin Verifikation Organisation ApS.

1.7. **DMVS** shall have the meaning set forth in 1.4 above.

1.8. **Effective Date** shall mean the date on which this Agreement has been signed by both Parties, as indicated by the last signature date mentioned in the signature block at the end of the Agreement.

1.9. **EMVO** shall mean the European Medicines Verification Organisation.

1.10. **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 amended from time to time.

1.11. **European Hub** designates the component of the EMVS under the responsibility of the EMVO that serves as a central information and data router for the transmission of data to or

from the National Systems; it is set up and managed by the EMVO.

1.12. 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 authorized users to verify the authenticity of medicinal products.

1.13. MAH(s) shall mean the Marketing Authorization Holder(s) that operate and place prescriptive medicines on the market for sale in Denmark. Each MAH markets at least one product within the Danish territory.

1.14. National System IT Company shall mean the IT company that is developing and operating the DMVS on behalf of the DMVO subject the separate agreement.

EXHIBIT B
FEE SCHEDULE

Company will fill in and sign this Agreement with a view to pay the fees mentioned in this Exhibit B.

The DMVO has the right to, at any time during the term of this Agreement, increase the fees, if for example but not limited to the National System IT Company or EMVO increases its fees or charges additional fees from DMVO or if the fees related to the development, testing, implementation, operation, maintenance or update of the DMVO increases due to any other reason. Likewise, Company acknowledges that the fees set out in Exhibit B are estimates and may change once the budget and number of participating Companies with market authorizations in Denmark are confirmed. DMVO may in accordance with Section 3.1 change fees annually by issuance of a revised fee schedule in Exhibit B or other announcement of a change in fee. The Fee (excluding all taxes/VAT, if applicable) to be paid by the Company per MAH under this Agreement shall be calculated and invoiced by DMVO to the Company in accordance with below:

To cover the implementation costs of DMVO during the period from 2016 to 8th february 2019, and especially but not limited to the investment in and setup of the IT system to run the DMVS, a one-off registration fee must be paid by all participating Companies and Representatives who have a market authorization in Denmark as per February 9, 2019.

The one-off registration fee amount to EUR 20,000 (VAT excl.) per MAH.

A. Annual flat fee contribution (Component A)

An annual flat fee contribution will be payable by Company. The annual flat fee will be charged per market authorization holder to cover inter alia, the annual costs of the operation and further development of the DMVS, costs inherited from the European Medicines Verification Organization and all necessary and legally compulsory activities of the DMVO.

The level of the annual flat fee contribution will be based on actual cost of running the DMVO short and long term. Both Parties agree that the amount of the yearly flat fee (IT-cost and operational cost of DMVO divided by number of MAH's) may fluctuate from time to time.

In line with the European Medicines Verification Organization recommendation, DMVO has decided for an annual flat fee contribution to be paid by the Company. The payment deadline for the annual flat fee contribution is January 15 each year.

EXHIBIT C
REGISTRATION AND INVOICING INFORMATION

Company must ensure that the invoicing address and other contact information specified in the below registration form is correct and up to date during the term of the contract. Company shall fill in one of form for Company and one form for each of the MAHs that Company represents and pays for in the danish market. Should the address, other contact information or number of MAHs change, it is the responsibility of Company to inform the DMVO immediately by sending a new updated and signed Exhibit C to the DMVO. It is specifically agreed that the invoice from DMVO will not be raised against a purchase order number from Company. If the data in the below tables are incorrect or not updated then all costs related to the re-issuance of invoices will be born by Company.

Invoicing details for Company

Registration and Invoicing information for Company Please fill in one form per market authorization	
Company Name	
Address	
Company Registration No.	
VAT No.	

List of MAHs which Company represents in Denmark

DMVO may at its option request either i) a co-signed Agreement between MAH, Company and DMVO such that the legal relationship shall be between DMVO, Company and MAH; ii) proof that Company is authorized to sign this Agreement on behalf of MAH in the form of a power of attorney in fact (in Danish fuldmagt); or iii) such other documentation as the DMVO see fit.

Company is the representative of the following MAHs in Denmark and will pay the applicable fee for the below mentioned MAHs:

Company represents the following MAH no. 1 in Denmark	
Name	
Address	
Company Registration No.	

Company represents the following MAH no. 2 in Denmark	
Name	
Address	
Company Registration No.	

Company represents the following MAH no. 3 in Denmark	
Name	
Address	
Company Registration No.	

EXHIBIT D
CONTACT INFORMATION FOR NOTICES

NOTICE CONTACT:

DMVO
_____
_____
_____
_____

phone: _____

email: _____

Company
_____
_____
_____
_____

phone: _____

email: _____