MEMORANDUM OF CO-OPERATION
PILOT STAGE OF FMD PROJECT

concluded by and between

Národní organizací pro ověřování pravosti léčiv, z.s.

Registered office: Pobřežní 620/3, Karlín, 186 00 Prague 8

Registered number: 05851742

Association entered in the associations' register maintained by the Municipal Court in Prague under file ref. L 67982

and

Entities from the Ranks of Manufacturers, Distributors and Pharmacies Participating in the Pilot Stage of the FMD Project

(hereinafter each of them is referred to individually as a "Party to the Pilot Stage of the FMD Project")

(Národní organizace pro ověřování pravosti léčiv, z.s., and Participants in the Pilot Stage of the FMD Project are hereinafter referred to as the "Contracting Parties")

on the Pilot Stage of the FMD Project in the Czech Republic

……. 2017

Definitions

European repository – will be linked to domestic and regional data repositories and will serve as a verification platform enabling the verification of the authenticity of medicines anywhere in the supplier chain in the European Economic Area. This European repository and domestic repositories are jointly also called the "**European Medicines Verification System (EMVS)**" or the "**System**".

FMD – An abbreviation for the Falsified Medicines Directive, as the umbrella term for the introduction of duties resulting from the Directive and the Implementing Regulation.

Medicinal Product – a medicinal product that must be equipped with safety features in accordance with the Directive (see below) and related acts in delegated powers adopted in accordance with the Directive (in particular the Implementing Regulation, see below) in the Czech Republic.

NOOL or the **Association** – Národní organizace pro ověřování pravosti léčiv, z.s. – A Czech non-profit legal entity established by its ordinary founding members for the purpose of ensuring the protection of the legal supply chain from fake medicinal products by creating and administering a domestic data repository that will be connected to the European repository. The European repository, which will be linked to domestic and regional data repositories, will serve as a verification platform enabling the verification of the authenticity of Medicinal Products anywhere in the supplier chain in the European Economic Area.

NMVS – National Medicines Verification System – a system comprising a domestic repository connected to the European data repository and serving as a platform for verifying the authenticity of Medicinal Products in the Czech Republic.

Verification – a check that the Medicinal Product exists in the national database with the same data stated on the 2D matrix code on the packaging.

Implementing Regulation – Commission Delegated Regulation (EU) 2016/161 of 2 October 2015, supplementing Directive 2001/83/EC of the European Parliament and of the Council and laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

Directive – Directive 2011/62/EU of the European Parliament and of the Council 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.

Contracting Parties – for the purposes of this memorandum the contracting parties shall be understood to be NOOL and entities from the ranks of manufacturers, medicine distributors and pharmacies.

I. Introduction

The purpose of this document is to set out in writing and familiarise the Contracting Parties with the basic mechanism of co-operation between entities voluntarily involved in the pilot stage of the FMD project and with the conditions for participation in it concerning Verification of the authenticity of Medicinal Products in the Czech Republic (hereinafter the "**Pilot Stage of the Project**").

The Contracting Parties involved in the Pilot Stage of the Project are aware that their participation in the Pilot Stage of the Project is free of charge, without a claim for remuneration or the reimbursement of any costs they incur in connection with their participation in the Pilot Stage of the Project.

II. Basic Conditions of Operation between Contracting Parties during Pilot Stage of Project

The basic duty of each of the Contracting Parties is to provide active co-operation during the Pilot Stage of the Project in accordance with individual steps and deadlines that arise during the preparation of the Pilot Stage of the Project and that will be specified in ongoing fashion.

With regard to the deadlines and conditions resulting from the Directive and the Implementing Regulation it is necessary to ensure the full functionality of the NMVS by 9 February 2019, so the Parties to this Memorandum, guided by an attempt to verify the functionality of the NMVS from this date and ensure compliance with the duties resulting from the Directive and the Implementing Regulation at the level of all entities that connect to the System, agree to co-operate with each other when preparing and implementing the Pilot Stage of the Project.

A participant in the FMD pilot project undertakes to provide NOOL with the maximum co-operation that can justly be required of it in the Pilot Stage of the Project and undertakes that as of the launch of the Pilot Stage of the Project it will have arranged all the necessary requisites for connection to the System, where NOOL undertakes to notify the party to the FMD pilot project a sufficient time in advance before the launch of the Pilot Stage of the Project of the precise extent and specifications of such necessary requisites.

NOOL undertakes that it will provide participants in the Pilot Stage of the Project with all co-operation that is requested from it when preparing the Pilot Stage of the Project and ensuring the necessary technical measures.

III. Handling of Confidential Information

1. The Contracting Parties undertake to ensure the confidentiality of information received as a part of the negotiation and signature of this memorandum and obtained during the Pilot Stage of the Project and not use such information for purposes other than those expressly agreed.

2. Compliance with this obligation will not be required in the event that either of the Contracting Parties, based on the law or based on a decision of a court body or other government body, is obligated to provide information concerning the Memorandum on Co-operation to such body or third party.

IV. Concluding Provisions

1. All changes and modifications hereto, including the end of this memorandum's validity, must be in the form of written, numbered amendments signed by the Contracting Parties.

2. This memorandum comes into force and effect on the day it is signed by the last of the Contracting Parties to sign, but no earlier than the day it is approved by the Association's board of directors at one of its meetings.

3. The Contracting Parties are aware that this Memorandum of Co-operation is not legally binding on the Contracting Parties, its purpose is only to set out and familiarise the Contracting Parties with the basic mechanism of co-operation between entities involved in the Pilot Stage of the Project and with the conditions of participation in it, all for the Verification of the authenticity of Medicinal Products in the Czech Republic.

Prague, on _____2017

_____

Mgr. Jakub Dvořáček, MHA

Chairman of the Board of Directors

_____

Mgr. Martin Mátl

Deputy Chairman of the Board of Directors

for **Národní organizace pro ověřování pravosti léčiv, z.s.**

Prague, on _____2017

_____

for the company [*]