

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE MEDICINES PATENT POOL FOUNDATION
AND
NATIONAL MEDICAL PRODUCTS ADMINISTRATION**

This Memorandum of Understanding (“MOU”) is made as of October 2018 by and between the Medicines Patent Pool Foundation (“MPP”), a not-for-profit corporation organised under the laws of Switzerland, whose business headquarters is located at Rue de Varembe 7, 1202 Geneva, Switzerland, and the National Medical Products Administration (“NMPA”) with a principal address at #26 Xuanwumen Xiadajie, Xicheng District, Beijing China, 10053, which are referred to collectively as the “Parties” and individually as a “Party”.

Background:

MPP is committed to improving the health of people living with HIV, hepatitis C and tuberculosis in low- and middle-income countries (LMICs) by increasing access to quality, safe, efficacious, and affordable medicines by facilitating access to intellectual property, development of appropriate drug formulations needed in LMICs, and bringing to market in LMICs novel medicines and technologies.

NMPA is set up directly under the State Council of People’s Republic of China to strengthen the supervision and administration, and to improve the safety and quality of drugs, medical devices and cosmetics.

MPP has in recent years licensed multiple HIV medicines to pharmaceutical companies in China for manufacturing in China and supplying to LMICs. Such companies will require a Certificate of Pharmaceutical Product (COPP) issued by the NMPA in order to obtain regulatory approval from respective drug regulators in other LMICs and export HIV medicines to those LMICs.

The Parties are interested to ensure that MPP’s Chinese licensees are able to obtain COPPs from NMPA for drugs for which these companies hold voluntary licences, and are willing to collaborate with each other to facilitate the issuance of COPPs, involving exchange of information, under the terms of this Memorandum of

Understanding (MOU).

To that end, the Parties have agreed upon a framework of collaboration (the “Collaboration”) as follows:

(1) Description of the Collaboration

a. The therapy areas covered by the Collaboration will be the therapy areas in which MPP works, which currently comprise HIV, viral hepatitis and tuberculosis and may be expanded from time to time.

b. The COPPs issued by the NMPA under this Collaboration will be available only to those manufacturers and manufacturing sites that have Chinese GMP certificate.

c. In furtherance of the Collaboration, the MPP will:

i. Share with the NMPA:

Information on, and the identity of, its licensees in China with details of drugs licensed and formulations under development, updated as and when necessary.

Copies of licence agreements with Chinese manufacturers.

ii. When its Chinese licensees are ready to apply to NMPA for a COPP, issue Certification Letters to its licensees for submission to the NMPA per the attached format (Annex 1) confirming the existence and validity of the licence agreement.

iii. Obtain authorization of its licensees to carry out the above activities.

d. In furtherance of the Collaboration, the NMPA will promptly issue COPPs, in the format prescribed by the World Health Organization, to qualified Chinese manufacturers pursuant to this MoU.

(2) Funding. There is no intention or commitment to exchange funds under the Collaboration. Each Party will respectively bear its own expenses, costs, risks, and liabilities arising from each Party’s obligations and efforts under this MOU.

(3) Disclosure. NMPA acknowledges that this MOU, in accordance with MPP policy, will be made publicly available on MPP’s website and by other appropriate means.

(4) Term and Termination. This MOU shall remain valid for five years and shall be automatically extended every five years unless either Party notifies the other Party of its wish to terminate it.

IN WITNESS WHEREOF, the Parties, each acting through their duly authorized representatives, have caused this MOU to be signed in their names and delivered as of this ____ of _____ 2018.

THE MEDICINES PATENT POOL FOUNDATION

BY: Charles Gore

Name: Charles Gore

Title: Executive Director

Date: 30.10.2018

NATIONAL MEDICAL PRODUCTS ADMINISTRATION

BY: 袁林

Name: YUAN Lin

Title: Director General, Department of Drug Regulation

Date:

Certification Letter

(On MPP Letterhead)

To Whom It May Concern:

This is to attest that [X] is an authorized licensee of the Medicines Patent Pool (MPP) for the manufacture and sale of API and finished formulations containing [Y]. A copy of the executed licence agreement is enclosed and can also be found on MPP's website here: [weblink]. The licensee remains in good standing.

The MPP also understands that the licensee intends to manufacture [Y] at [site] and has obtained a Chinese Good Manufacturing Practices Certificate (enclosed) for this site from relevant authorities in China. The licensee [has filed/intends to file] for WHO pre-qualification/Tentative Approval from USFDA.

Your prompt attention to the issuance of a Certificate of Pharmaceutical Product by the National Medical Products Administration would be greatly appreciated.

The Medicines Patent Pool Foundation

Authorised Signatory

Date:

Place:

Enclosed: copy of licence agreement between [X] and Medicines Patent Pool for [Y]