MoU

Badan POM RI dengan NCEMMDME

REPUBLIK INDONESIA

MEMORANDUM OF UNDERSTANDING BETWEEN THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA AND THE REPUBLICAN STATE-OWNED ENTERPRISE ON THE RIGHT OF ECONOMIC MAINTAINING "NATIONAL CENTER FOR EXPERTISE OF MEDICINES, MEDICAL DEVICES AND MEDICAL EQUIPMENT" OF THE MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT OF THE REPUBLIC OF KAZAKHSTAN CONCERNING BILATERAL COOPERATION ON MEDICINES

The National Agency for Drug and Food Control of the Republic of Indonesia and the Republican State-owned Enterprise on the Right of Economic Maintaining "National Center for Expertise of Medicines, Medical Devices and Medical Equipment" of the Ministry of Health and Social Development of the Republic of Kazakhstan, hereinafter referred to as the "Parties",

DESIRING to strengthen friendship and cooperation existing between the two countries,

INTENDING to promote the benefits of mutual interest in the field of controlling the safety, efficacy and quality of the medicines,

STRIVING for effective cooperation in the field of expertise of medicines and quality control and to ensure the protection of public health,

PURSUANT TO the prevailing laws and regulation of the two countries,

HAVE AGREED to the following:

ARTICLE 1
OBJECTIVE

The objective of this Memorandum of Understanding (hereinafter referred to as "the MoU") is to create and consolidate bilateral cooperation in the field of providing safety, efficacy, and quality control of the medicines.

ARTICLE 2
SCOPE OF COOPERATION

The Parties implement bilateral cooperation, envisaged by this MoU in the following areas:

1. Exchange of information regarding law, regulations, standards and other relevant policies related to medicines;
2. Exchange of experience in improving the procedure for evaluation of medicines, as well as exchange of information on the product/medicines registration requirements of the current legislation of the Parties;
3. Capacity building activities, including workshops, training and research;
4. Exchange of information in Pharmacovigilance issues;
5. Publications (the publication of articles in scientific journals of the Parties, co-authorship, the exchange of scientific and educational publications and materials, etc.);
6. Participation in scientific and practical conferences, symposiums, seminars and fora organized by the Parties;
7. Exchange of experts, best practices, methodologies, research by appointments of the Parties;
8. Information exchange on plans for committing international congresses, conferences and other similar events on request of scientific and medical societies and other organizations of the Parties.

ARTICLE 3
IMPLEMENTATION

In order to implement the MoU, the Parties agreed to conclude a Plan of Action for a period of 2 (two) years. The Plan of Action will be defined by specific items of cooperation, financial aspects, and other necessary implementation arrangements. Monitoring and evaluation for the implementation of the Plan of Action will be done by Parties periodically.

ARTICLE 4
FINANCIAL ARRANGEMENT

1. This MoU does not impose on the Parties any financial obligations.
2. Each Party will bear the expenses related to the implementation of this MoU, unless mutually agreed otherwise.

ARTICLE 5
CONFIDENTIALITY

1. The Parties shall maintain confidentiality of all technical information and knowledge required in the performance of this MoU and shall use this information only for the purpose intended by this MoU.
2. If either of the Party wishes to disclose confidential data and/or information resulting from cooperation activities under this MoU to any third Party, the disclosing Party must obtain prior written consent from other Party before any disclosure can be made.

ARTICLE 6
COPYRIGHT AND RELATED RIGHTS

1. The Parties will ensure the protection of copyright and related rights in respect of all subject matters under this MoU in accordance with their own

laws and the international agreements to which the two countries are Parties.

2. The ownership and utilization of any copyright and related rights resulting from cooperation under this MoU will be set out in specific arrangements between the Parties or other entities involved in the specific areas of cooperation. Such arrangements will take into full consideration the equitable distribution of ownership based on the contributions of the Parties or other entities.

ARTICLE 7
AMENDMENT AND REVIEW

The Parties may review or amend any part of this MoU by mutual written consent at any time. Such revisions or amendments will come into effect upon signature by both Parties, or as otherwise mutually determined by the Parties and shall form as an integral part of this MoU.

ARTICLE 8
SETTLEMENT OF DIFFERENCES

The Parties will resolve any differences concerning the interpretation and/or implementation of this MoU amicably through consultations or negotiations.

ARTICLE 9
ENTRY INTO FORCE, DURATION AND TERMINATION

1. This MoU shall enter into force on the date of its signing;
2. This MoU shall remain in force for a period of 3 (three) years and may be renewed for subsequent period of 3 (three) years, unless it is denounced in writing by either Party, 6 (six) months prior to the intended date of termination of this MoU.

The Memorandum of Understanding i signed in Almaty on November 2, 2016 in eight originals, two in Indonesian, two in Kazakh, two in Russian and two in English lenguages, each version being equaly authentic. In case of divergence of interpretation, the English version shall prevail.

For The National Agency for Drug and Food Control of the Republic of Indonesia

Dr. Ir. Penny K. Lukito, MCP
Chairperson

For the RSE on REM "National Center for Expertise of Medicines, Medical Devices and Medical Equipment" of the Ministry of Health and Social Development of the Republic of Kazakhstan

Aigul Yedigeyevna Shoranova
Director General