MEMORANDUM OF UNDERSTANDING
On Cooperation in the Field of Regulatory Affairs
Between
THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA
AND
THE NATIONAL DRUG AUTHORITY OF UGANDA

The Ministry of Food and Drug Safety of the Republic of Korea(hereinafter referred to as the "MFDS") and the National Drug Authority of Uganda(hereinafter referred to as the "NDA")(hereinafter jointly referred to as the "Sides"),

DESIRING to promote cooperation between the two countries in the field of drug regulatory affairs relating to drugs and medical devices;

INTENDING to develop a mechanism for facilitating achievement of the common missions of the two Sides,

Have reached the following understanding:

Paragraph 1 DEFINITIONS

In this Memorandum of Understanding(hereinafter referred to as the "MOU"), the following definitions will apply:

a) "Information" includes all information in paper or electronic format and may include both registered and unregistered product information relating to human drugs (including biopharmaceuticals, herbal/traditional medicines, and

narcotics), and information relating to clinical trials, bio equivalence inspections, good manufacturing practices (GMP), and medical devices;

b) "Confidential Information" means information in written, graphic or other tangible form that is clearly identified as confidential at the time of or within thirty (30) days of disclosure, or which by the nature or type of information should reasonably be regarded a s confidential. It also includes documents or information obtained or used in conjunction with any business or any contract, agreement or information directly or indirectly connected with any party, including but not limited to trade secrets, intellectual and industrial property, drawings, specifications, analysis reports, feasibility studies, or information whatsoever relating directly or indirectly to such party or the business of such party.

Confidential Information does not include any information which the receiving Side who wishes to disclose such information can demonstrate:

(i) was in the public domain at the time of disclosure or use;
(ii) entered the public domain through no action of such receiving Side;
(iii) is independently developed by such receiving Side's personnel not privy to the disclosure of confidential information
(iv) is or has been lawfully disclosed to such receiving Side, or any affiliate, by a third party without obligation of confidentiality upon such receiving Side; or
(v) is disclosed in response to a valid order by a court or governmental body;

provided, however, that such receiving Side will promptly provide the providing Side with prior written notice of any process seeking such an order to enable the providing Side to seek a protective order or otherwise prevent disclosure or use and will assist the providing Side, at the providing Side's expense, in obtaining such protective order.

Paragraph 2 OBJECTIVES OF THE MOU

The objectives of this MOU are:

a) to facilitate sharing of information between the Sides for the basis of

mutual benefit;

b) to exchange information relating to drugs registration and GMP inspection processes that are undertaken by either Side's drugs regulatory agency;

c) to share information relating to strategies for enhancing post market surveillance and pharmaco-vigiliance, including information on the detection of counterfeit drugs or illicit drugs for human use;

d) to collaborate in the area of the regulation of clinical trials of drugs and medical devices;

e) to undertake training of or providing technical assistance to either Side's employees in particular areas that are identified and jointly decided upon by the Sides;

f) to collaborate and share information and best practices in the regulation of medical devices;

g) to share information regarding bio equivalence and Good Clinical Practice inspections;

h) to collaborate and share information relating Quality Management Systems in either Side.

Paragraph 3 CONFIDENTIALITY

Each Side will:

a) hold in confidence all confidential Information disclosed to it by the other Side;

b) not disclose the confidential information to any other person except as authorized herein;

c) use the confidential information only for the purposes of this MOU;

d) limit the use and access to such confidential information to the receiving Side's employees and consultants who need to know such confidential Information for the purposes of this MOU,;

e) receive, store, transmit, use and treat such confidential Information with at least the same degree of care and protection as it would use with respect to its own confidential materials. Each Side will require any other person that has access to such confidential information to comply with the commitments set forth herein.

Paragraph 4 INTELLECTUAL PROPERTY

a) Each Side will own all copyright, database rights and other intellectual property rights (the "IPR") which arise in connection with the collection, processing of or other use of information by that Side pursuant to this MOU.

b) Except as set out in this MOU, each Side will be and remain the owner of all IPR which are owned or controlled by that Side.

Paragraph 5 NON-BINDING

a) This MOU will be implemented within the framework of national laws and regulations of the Sides subject to the availability of their financial resources.

b) This MOU represents the understanding reached by the Side and does not impose any legally binding obligations under national or international law.

Paragraph 6 NOTICES

Any written notice will be delivered through the authorised representative herein

named through post, personal delivery or by any other acceptable and verifiable means of communication.

All notices shall be addressed as follows: -

In the case of the Ministry of Food and Drug Safety:

Minister
Ministry of Food and Drug Safety
Osong Health Technology Administration
Complex, 187, Osongsaengmyeong 2-ro,
Osong-eup, Cheongwon-gun,
Chungcheongbuk-do, 363-700, Korea

In the case of the National Drug Authority:

Executive Secretary / Registrar
National Drug Authority
Plot 46/48 Lumumba Avenue.
P. O. Box 23096 Kampala,Uganda

Paragraph 7 DISPUTE RESOLUTION

Any disputes arising from interpretation and/or implementation of this MOU will be resolved amicably through consultation between the Sides.

Paragraph 8 OTHER PROVISION

a) Neither Side may assign, transfer or delegate any portion of this MOU without the express written consent of the other Side.

b) If any provision of this MOU is to any extent invalid or illegal the validity of the remaining provisions will not in any way be affected or impaired.

c) Each Side will bear its own costs arising from cooperation under this MOU, unless otherwise jointly decided in advance by the Sides.

Paragraph 9 AMENDMENTS

This MOU may be amended by mutual written consent of the Sides.

Paragraph 10 ENTRY INTO EFFECT, DURATION AND TERMINATION

The MOU will come into effect on the date of its signature and will remain effective for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless either Side notifies the other Side in writing of its intention to terminate the MOU six (6) months in advance.

Signed in duplicate in Osong, Republic of Korea, on June 13th 2013, in the Korean and English, each text being equally valid. In case of any divergence of interpretation, the English will prevail.

For the **Ministry of Food and Drug Safety** **of the Republic of Korea**	**For the** **National Drug Authority of Uganda**
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