



**MUTUAL CONFIDENTIALITY ARRANGEMENT AND COMMITMENT NOT
TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY AND
BETWEEN THE MINISTRY OF FOOD AND DRUG SAFETY OF THE
REPUBLIC OF KOREA AND THE WORLD HEALTH ORGANIZATION,
ACTING THROUGH ITS DEPARTMENT OF ESSENTIAL MEDICINES AND
HEALTH PRODUCTS**

Whereas the Ministry of Food and Drug Safety of the Republic of Korea (MFDS) and World Health Organization (WHO), acting through its Department of Essential Medicines and Health Products (EMP) wish to enable the exchange of specific scientific and technical information related to the safety, quality, efficacy and post-authorization follow-up of medical products (including medicines, biopharmaceuticals, vaccines and medical devices) for human use that come within their respective responsibilities, for the purpose of coordinating and facilitating respectively MFDS's regulatory activities, and WHO/EMP's prequalification and medical product (including medicines, biopharmaceuticals, vaccines and medical devices) safety activities, as well as each Party's regulatory or prequalification (as the case may be) activities concerning medical products in the context of preparing for or responding to either an actual or potential public health crisis or an actual or potential public health emergency of international concern ("the Purpose").

Whereas the Disclosing Party will advise the Receiving Party of the non-public, proprietary or confidential nature of the information it intends to disclose, at the time of disclosure. In addition, the Disclosing Party will mark the information in question as confidential, or in the case of oral disclosure, will confirm the non-public, proprietary or confidential nature of the information to the Receiving Party in writing within 15 (fifteen) calendar days after oral disclosure. Any information of the type described in the previous paragraph and designated by MFDS or WHO/EMP, as the case may be, as non-public, proprietary or confidential as aforesaid is hereinafter referred to as "Information".

Whereas MFDS and WHO/EMP each affirm that they have the authority to protect Information from public disclosure.

Therefore, MFDS and WHO/EMP each agree that in accepting Information as Receiving Party from the other as Disclosing Party, they shall abide by the following:

- (a) The Information disclosed by one Party ("the Disclosing Party") shall be treated by the Party receiving such Information ("the Receiving Party") as strictly confidential. The Receiving Party shall use such Information only for the Purpose and shall make no other use thereof unless and until a further agreement is executed with the Disclosing Party and, where appropriate; the owner of the Information in question permits such other use thereof. In connection with the foregoing, the Receiving Party shall restrict access to Information received from the Disclosing Party hereunder strictly to those persons within its organization (i.e., MFDS or



WHO/EMP, as the case may be) who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement. For the avoidance of doubt and for purposes of this Arrangement "persons within its organization" shall, for WHO/EMP, include WHO/EMP employees, experts, temporary advisers, consultants and contractors (provided always, of course, that such employees, experts, temporary advisers, consultants and contractors have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement).

- (b) The Receiving Party will not publicly disclose Information from the Disclosing Party without the prior written consent of the Disclosing Party, and (where the Disclosing Party is not the owner of the Information), the written authorization of the owner of such Information, or a written statement from the Disclosing Party that the Information is no longer subject to the obligations contained herein.
- (c) Nothing in this Arrangement shall prevent the Disclosing Party from disclosing its own Information to any third party.
- (d) Nothing in this Arrangement shall be construed as a grant to the Receiving Party of any rights to the Information.
- (e) The Receiving Party undertakes to maintain the Information received from the Disclosing Party in confidence. In this regard, the Receiving Party shall take all reasonable measures to ensure that the Information shall not be used for any purpose other than the Purpose, and shall only be disclosed to persons within its organization who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement.
- (f) The obligations of confidentiality and restrictions on use referred to above shall not apply to any part of the Information which the Receiving Party is clearly able to, and does, demonstrate to the Disclosing Party:
 - (i) was lawfully in its possession and known to it (without any obligation of confidentiality) prior to disclosure by the Disclosing Party (as evidenced by written records or other competent proof); or
 - (ii) was in the public domain or the subject of public knowledge at the time of disclosure by the Disclosing Party; or
 - (iii) becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Party; or
 - (iv) becomes available to the Receiving Party from a third party not in breach of a legal obligation of confidentiality; or



- (v) was subsequently and independently developed by or on behalf of the Receiving Party without access to the Information of the Disclosing Party.
- (g) In addition, the Receiving Party shall be permitted to disclose Information received hereunder as may be strictly required by order of competent legislative or judicial authorities to which it is directly subject, provided that the Receiving Party shall:
 - (i) immediately notify the Disclosing Party in writing of any effort made to obtain Information of the Disclosing Party by such order, and provide adequate opportunity to the Disclosing Party to object to, or restrict, such disclosure or request confidential treatment thereof; and
 - (ii) take all reasonable measures in an effort to ensure that the Information in question will be disclosed to such competent legislative or judicial authorities in a manner that protects such Information from public disclosure.
- (h) Upon completion of the Purpose, each Party shall, upon written request from the other Party, promptly return to the other Party, or destroy, all of the Information received from the other Party, except that each Party may retain one copy of the Information in its confidential files for archival purposes only.
- (i) Any notice to be given under this Arrangement shall be deemed to be sufficiently given for all purposes if successfully transmitted by facsimile and confirmed by mail, or if sent by registered mail or recorded delivery post (postage prepaid) addressed to the Party to be notified at the following address:

If to WHO/EMP:

Attn: Head, Regulation of Medicines and other Health Technologies (RHT)
20, Avenue Appia
1211 Geneva 27
Switzerland
Tel. + 41 22 791 55 31
Fax. + 41 22 791 47 30

If to MFDS:

Attn: International Cooperation Office
Osong Health Technology Administration Complex
187, Osongsaengmyeong2(i)-ro
Osong-eup, Heungduk-gu, Cheongju-si, Chungcheongbuk-do
Republic of Korea
Tel. + 82 43 719 1557
Fax. + 82 43 719 1550



Ministry of Food and
Drug Safety



World Health
Organization

- (j) This Arrangement constitutes the entire understanding of the Parties hereto with respect to the subject matter hereof and shall not be modified except by mutual agreement in writing.
- (k) The Receiving Party will promptly inform the Disclosing Party of any circumstances or changes that would affect its ability to honour the commitments in this Arrangement.
- (l) Nothing in or relating to this Arrangement shall imply an obligation on the part of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO under any national or international law, convention or agreement.
- (m) Any dispute relating to the interpretation or application of this Arrangement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the parties agree to negotiate in good faith to find another means of finally settling the dispute.

Agreed and accepted
on behalf of MFDS:

Agreed and accepted
on behalf of WHO/EMP:

Signature: 양진영

Signature: Le Hill

Name: Mr Jin-young Yang
Title: Director General for Planning
and Coordination

Name: Dr Suzanne Hill
Title: Director
Department of Essential
Medicines and Health Products

Date: May 26. 2017

Date: May 30 2017