Ministry of Health, Labour and Welfare

Pharmaceuticals and Medical Devices Agency

Interlaken; 13th October, 2016

Dear Dr. Marie-Paul Kieny

Whereas the Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the one side, and the Department of Essential Medicines and Health Products (EMP) of the World Health Organization (WHO) on the other side (hereinafter referred to individually as the "Participant" and collectively as the "Participants") have recognised a need for an exchange of letters to enable the exchange of specific scientific and technical information and documents related to the safety, quality, efficacy and post-authorization follow-up of medical products for human use that come within their respective responsibilities, i.e. for the purpose of coordinating and facilitating respectively MHLW's and PMDA's regulatory activities, and WHO/EMP's prequalification, medical product safety activities, as well as each Participant'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 in this connection each Participant may (as "the Disclosing Participant") disclose to the other Participant (as "the Receiving Participant") certain information relating to its aforesaid activities that it considers non-public, confidential or proprietary to it or participants collaborating with it.

Whereas the aforesaid information may include confidential product and/or commercial information; trade secret information; personal privacy information; law enforcement information, and/or internal, pre-decisional information.

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

Whereas the MHLW and PMDA, and WHO/EMP will disclose Information to each other solely for the Purpose.

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

Therefore, the MHLW and PMDA, and WHO/EMP will each abide by the following in accepting Information as Receiving Participant from the other as Disclosing Participant:

(a) This Letter will not compel either Participant to disclose any Information to the other Participant.

(b) The Information disclosed by one Participant ("the Disclosing Participant") will be treated by the Participant receiving such Information ("the Receiving Participant") as strictly confidential. The Receiving Participant will use such Information only for the Purpose and will make no other use thereof unless and until the Disclosing Participant and/or where appropriate, the owner of the Information in question consents to such other use in writing. In connection with the foregoing, the Receiving Participant will restrict access to Information received from the Disclosing Participant hereunder strictly to those persons within its organization (i.e., the MHLW and PMDA or WHO/EMP, as the case may be) who have a need to know for the Purpose and are bound by similar conditions of confidentiality and restrictions on use in respect of the Information as contained in this Letter. For the avoidance of doubt and for purposes of this Letter "persons within its organization" will, for WHO, include WHO experts and temporary advisers (provided always, of course, that such experts and temporary advisers have a need to know for the Purpose and are bound by similar conditions of confidentiality and restrictions on use in respect of the Information as contained in this Letter).

(c) The Receiving Participant will not publicly disclose Information from the Disclosing Participant without the prior written consent of the Disclosing Participant, or the written authorization of the owner of such Information, or the written authorization from the individual who is the subject of the personal privacy Information, or a written statement from the Disclosing Participant that the Information is no longer subject to the conditions contained herein.

(d) Nothing in this Letter will prevent the Disclosing Participant from disclosing its own Information to any third party.

(e) Nothing in this Letter will be construed as a grant to the Receiving Participant of any rights to the Information.

(f) The Receiving Participant will maintain the Information received from the Disclosing Participant in confidence. In this regard, the Receiving Participant will take all reasonable measures to ensure that the Information will not be used for any purpose other than the Purpose, and will only be disclosed to persons within its organization who have a need to know for the Purpose and are bound by similar

conditions of confidentiality and restrictions on use in respect of the Information as contained in this Letter.

(g) The above mentioned conditions of confidentiality and restrictions on use in respect of the Information will not apply to any part of the Information which the Receiving Participant is clearly able to, and does, demonstrate to the Disclosing Participant:

(i) was lawfully in its possession and known to it (without any such conditions) prior to disclosure by the Disclosing Participant (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 Participant; or
(iii) becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Participant; or
(iv) becomes available to the Receiving Participant from a third party not in breach of any conditions of confidentiality ; or
(v) was subsequently and independently developed by or on behalf of the Receiving Participant without access to the Information of the Disclosing Participant.

(h) In addition, the Receiving Participant will 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 Participant will:

(i) immediately notify the Disclosing Participant in writing of any effort made to obtain Information of the Disclosing Participant by such order, and provide adequate opportunity to the Disclosing Participant 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.

(i) Upon completion of the Purpose, each Participant will, upon written request from the other Participant, promptly return to the other Participant, or destroy, all of the Information received from the other Participant, except that each Participant may retain one copy of the Information in its confidential files for archival purposes only.

(j) Any notice to be given under this Letter will 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 Participant to be notified at the following address:

If to MHLW/PMDA:

1. Office of International Regulatory Affairs
   Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare (MHLW)
1-2-2 Kasumigaseki, Chiyoda, Tokyo, 100-8916, Japan
Tel. +81 3 3595 2431
Fax. +81 3 3597 9535

2. Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)
Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda,
Tokyo, 100-0013, Japan
Tel. +81 3 3506 9456
Fax. +81 3 3506 9572

If to WHO/EMP:
Department of Essential Medicines and Health Products
Attn: Head, Regulation of Heath Products and Technologies (RHT)
20, avenue Appia
1211 Geneva 27
Switzerland
Tel. + 41 22 791 38 81
Fax. + 41 22 791 48 36

(k) This Letter is not an international treaty. It is an administrative document between the Government of Japan and WHO. This Letter will not be modified except by mutual consent in writing.

(l) The Receiving Participant will promptly inform the Disclosing Participant of any circumstances or changes that would affect its ability to honour the commitments in this Letter.

(m) Nothing in or relating to this Letter will be deemed to constitute a waiver of any of the privileges and immunities of WHO under any national or international law, convention or agreement and/or as submitting WHO to any national court jurisdiction.

(n) In the unlikely event that any difference will arise in the interpretation of this Letter, the matter will be submitted to the Director, Office of International Regulatory Affairs of the MHLW and to the Director, Office of the General-Director of the World Health Organization, who will settle the question personally and jointly or through their duly authorized representatives.

We look forward to implementing the cooperative relationship allowing for the sharing of information and to continuing cooperative activities to further enhance the relationship between the MHLW and the PMDA and WHO/EMP in the best interest of public health.

Yours sincerely,

Accepted by and on behalf of Ministry of Health, Labour and Welfare:

Signature:

Name: Toshihiko Takeda
Title: Director General, Pharmaceutical Safety and Environmental Health Bureau
Date:

Accepted by and on behalf of Pharmaceuticals and Medical Devices Agency:

Signature:

Name: Tatsuya Kondo
Title: Chief Executive
Date: