

**MUTUAL CONFIDENTIALITY  
ARRANGEMENT AND COMMITMENT  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY AND BETWEEN  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
AND  
THE WORLD HEALTH ORGANIZATION**

Whereas as part and in the course of the discussions between the United States Food and Drug Administration (FDA) and the World Health Organization, through its Department of Essential Medicines and Health Products (WHO/EMP), aimed at coordinating and facilitating communications between FDA and WHO/EMP 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, each party may (as "the Disclosing Party") disclose to the other party (as "the Receiving Party") certain information relating to its aforesaid activities that it considers non-public, confidential or proprietary to it or parties collaborating with it.

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

Any information of the type described in the previous paragraph and designated by FDA or WHO/EMP, as the case may be, as non-public, proprietary or confidential as aforesaid is hereinafter referred to as "Information."

Whereas FDA and WHO/EMP are willing to disclose Information to each other for the sole purpose of undertaking discussions aimed at coordinating and facilitating FDA and WHO communications 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 (hereinafter referred to as "the Purpose").

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

Therefore, FDA and WHO/EMP each agree that any disclosure of Information by one Party to the other will be subject to the following terms and conditions:

- a. Any Information which is supplied in written or other tangible form shall be clearly identified as subject to this Arrangement. Any Information which is disclosed in oral form shall be confirmed in written summary form within fifteen (15) days from the date of oral disclosure by the Disclosing Party.

- b. The Information disclosed by the Disclosing Party shall be treated by 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/or, where appropriate, the owner of the Information in question permits such other use(s) 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., FDA or WHO, 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 include: FDA officials and employees, contractors; FDA Commissioned State Officials and Special Government Employees; and WHO employees, experts, temporary advisors, consultants and contractors.
- c. The Receiving Party will not publicly disclose Information from the Disclosing Party without the prior written consent of the Disclosing Party, or (where the Disclosing Party is not the owner of the Information) 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 Party that the Information is no longer subject to the obligations contained herein.
- d. Nothing in this Arrangement shall prevent the Disclosing Party from disclosing its own Information to any third party.
- e. Nothing in this Arrangement shall be construed as a grant to the Receiving Party of any rights to the Information.
- f. 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 (as defined above) and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement.
- g. 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.
- h. 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 is it 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,  
(provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or to submit WHO to any national court jurisdiction).
- i. Upon completion of the Purpose and in the absence of any further written agreement between the Parties, each Party shall cease all use, shall make no further use of the Information disclosed to it hereunder, and 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 to determine any continuing obligations hereunder.
  - j. 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:

**WHO/EMP:**

World Health Organization  
Director, Department of Essential Medicines and Health Products  
20 Avenue Appia  
1211 Geneva 27  
Switzerland  
Fax. + 41 22 791 4167....

**FDA:**

Associate Commissioner for International Programs  
Office of International Programs  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
United States of America  
Tel. +1 301 796 4600  
Fax. +1 301 595 7937

- k. 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.
- l. 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.

- m. 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.
- n. In the unlikely event that any difference shall arise in the interpretation or application of this Arrangement, the matter shall be submitted to the Director of the Office of Global Health Affairs within the U.S. Department of Health and Human Services and to the Assistant Director-General responsible for General Management of the World Health Organization, who will settle the question personally and jointly or through their duly authorized representatives.

**Signed on Behalf of FDA**

---/S/---

**Name:** Howard Sklarberg, J.D.

**Title:** Deputy Commissioner for Global  
Regulatory Operations and Policy

United States Food and Drug  
Administration

Date: 8/25/2014

**Signed on Behalf of WHO**

---/S/---

**Name:** Dr Kees De Joncheere

**Title:** Director,  
Department of Essential Medicines and Health  
Products

World Health Organization

Date: 15.08.2014