Joint Declaration
on the Exchange of Confidential Information
between
the Ministry of Food and Drug Safety
of the Republic of Korea
and
the Federal
Institute for Drugs and Medical Devices – BfArM

Introduction

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Federal Institute for Drugs and Medical Devices (BfArM) of the Federal Republic of Germany (hereinafter referred to as the "Participants");

Being the regulatory authorities of their respective countries responsible for the testing, marketing authorization and other regulatory mechanisms regarding medicinal products (including biological products) and medical devices intended for administration to or use by human beings, which have undergone clinical trials, and which are marketed, distributed, manufactured or assembled in the Republic of Korea and/or in the Federal Republic of Germany

Jointly declare as follows:

1. The Participants will exchange information, documents and information regarding medicinal products and medical devices, subject to the observance of data protection requirements and in compliance with the national laws pursuant to which such laws was established.

2. The Participants hold the view that occasionally circumstances may arise in which it is mutually beneficial to exchange information and experience concerning medical devices or the guarantee of the safety, quality and efficacy of medicinal products intended for human use, which are under clinical trials, and are authorized for marketing or the licensing of which is being examined, both in the Republic of Korea and in the Federal Republic of Germany.

3. The Participants will cooperate to facilitate the exchange of confidential documents and non-public information. By virtue of this Joint Declaration, cooperation will be established and stipulated, specifying which kinds of information the Participants may share and on what basis. The expression "confidential documents or non-public information" means arbitrary documents or information which is not in the public domain, which is in the possession of one Participant and which that Participant treats as confidential in accordance with its pertinent national laws.

4. In particular, in the case of COVID-19 and future pandemics, the Participants share critical information on in vitro diagnostic medical devices such as diagnostic test kits for accurate diagnosis of the

infections, or syringes that are used together with therapeutic agents or the vaccines, thermometers, and so forth, in a situation where the importance of the medical devices are emphasized, the Participants promptly share technical information on regulations, approvals (or products) that are related to infectious diseases, which has a potential ripple effect.

5. The kinds of information which may be shared by the Participants may include, *inter alia,* but are not restricted to:

(a) data that one Participant has gathered from the distribution of a product, the safety and efficacy of which it is concerned about, and which is manufactured or distributed in the territory of the other Participant;

(b) information about impairments of quality or recalls by one Participant with respect to medicinal products and medical devices which were manufactured or are distributed in the other Participant's territory;

(c) information included in files, concerning the registration and/or its subsequent amendment by one Participant, which are of interest to the public health of the other Participant to whom they are forwarded; and

(d) information from investigative reports conducted by one Participant which are of relevance to the public health of the other Participant to whom they are forwarded.

(e) Experiences such as decision making criteria or other relevant matters acquired by the Participants while reviewing products

or considering product-related policies (it may be shared in various forms such as in-person, written, virtual meetings or workshops)

6. The Participants, their staff members or representatives may, at their own discretion, restrict the extent to which the above information is shared, especially if its disclosure or exchange has an adverse impact on the economic interests of third parties, represents an infringement on the commitment to protect confidentiality or data, reveals a business secret or is contrary to the public interest or the interest of the other Participant. In some cases, the exchange of information within the scope of this Joint Declaration may be subject to the prior approval of the enterprises or persons involved.

7. The Participants consider it to be an essential element of this Joint Declaration that confidential information made available by one Participant to the other will continue to be classified as confidential, and, as far as this is possible and complies with the applicable law, the receiving Participant will treat the exchanged information as confidential.

8. The Participants are aware that some of the information made available by one Participant to the other may include non-public information as well as information not intended for being forwarded according to the applicable law and jurisdiction of the Participant affected, such as confidential information, sensitive economic data, business secrets, personal data or information on

pending lawsuits, which cannot be made public according to the applicable law of the Participant forwarding the information. This non-public information will be shared on the basis of mutual trust and the Participants will attach fundamental importance to ensuring its confidentiality. The Participants will notify each other of the non-public status of information as soon as it is shared.

9. The Participants recognize that circumstances may arise in which a Participant which received confidential information has to take measures for the protection of public health as a result of this information, possibly making it necessary to forward this information in whole in part to other agencies. In this case, the receiving Participant will forward such information only upon prior consultation with the other Participant.

10. The Participants share the view that, if the forwarding of information (including non-public information received from the other Participant) is requested by order of a court, by parliamentary decision or another decision covered by legislation, the Participant will have to make this information available to the body or person making the request. If this request is made with respect to non-public information that was received by the other Participant, the Participant who received this instruction will immediately inform the requesting body or person and take all possible measures so that the information is forwarded in a form which is protected against public dissemination.

11. Joint Declaration is not intended to create any legally binding obligations.

12. Any differences arising from the interpretation or implementation of this Joint Declaration will be resolved through consultations between the Participants.

13. This Joint Declaration will come into effect on the date of signature. It will replace any pertinent prior joint declarations between the Participants and will remain in effect until one Participant gives written notice, at least thirty (30) days in advance, to the other that it wishes to terminate this Joint Declaration.

14. The Participants may jointly decide in writing to amend this Joint Declaration or to terminate its effectiveness any time.

15. The person in charge of the MoU and its contact point is as follows.
    1) MFDS: Office of International Affairs, e-mail: intmfds@korea.kr
    2) BfArM: International Liaison Office and Conferences, e-mail: P21@bfarm.de

SIGNED in duplicate in English, both copies being equally valid.

FOR THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA	FOR THE FEDERAL INSTITUTE FOR DRUGS AND MEDICAL DEVICES OF THE FEDERAL REPUBLIC OF GERMANY
J. S Kim	Karl Broich
Date: Nov. 17. 2021	Date: Nov. 17, 2021
Place: Bonn	Place: Bonn