

Joint Declaration of Cooperation
between
The German Federal Institute for Drugs and Medical Devices
(BfArM)
and
The Taiwan Food and Drug Administration (TFDA)

Introduction

The German Federal Institute for Drugs and Medical Devices (BfArM), which established within the portfolio of the Federal Ministry of Health of the Federal Republic of Germany and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare (hereinafter referred to as the "Participants");

Being the competent national authorities of their respective countries responsible for the testing, marketing authorization and other regulatory mechanisms regarding medicinal 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 Taiwan and/or in the Federal Republic of Germany;

Jointly declare as follows:

1. The Participants will exchange information and documents regarding medicinal products and medical devices, subject to related data protection requirements and in compliance with the national laws pursuant to which such laws were established.
2. The Participants hold the view that occasionally circumstances may arise in which it is mutually beneficial to exchange information concerning medical devices or the guarantee of the safety, quality and efficacy of medicinal products intended for human use, which are under clinical trials, are authorized for marketing or the licensing of which is being examined, both in Taiwan and in 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 documents¹ 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. 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.

5. 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.

¹ In order to articulate the characteristic of documents, which is subject to exchange between TFDA and BfArM, "confidential"

6. 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.
7. 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.
8. The Participants recognize that circumstances may arise in which a Participant which receives 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 or in part to other agencies. In this case, the receiving Participant will forward such information only upon prior consultation with the other Participant.
9. 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.

10. Joint Declaration is not intended to create any legally binding obligations.²
11. Any differences arising from the interpretation or implementation of this Joint Declaration will be resolved through consultations between the Participants.³
12. 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.
13. The Participants may jointly decide in writing to amend this Joint Declaration or to terminate its effectiveness any time.

SIGNED in duplicate in the Chinese, German and English languages, all texts being equally valid. In case of any divergence of interpretation of this Joint Declaration, the English text will prevail.

FOR The German Federal Institute for
Drugs and Medical Devices (BfArM)

FOR The Taiwan Food and Drug
Administration (TFDA)



Prof. Dr. Karl Broich
President

Yu-Mei, Chiang
Director-General

Date: Oct 13, 2015
Place: Berlin

Date: June 16 2015
Place: Taipei

² As this Joint Declaration has no legal binding and obligation, this clause was added

³ As it has not indicated how to resolve any conflict that may arise in terms of the interpretation or implementation of this Joint Declaration, this clause was added.