法規名稱：CONFIDENTIALITY MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE FOOD AND DRUG ADMINISTRATION OF TAIWAN AND THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

簽訂日期：民國 101 年 12 月 18 日

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Introduction:

1. The Food and Drug Administration (FDA) of Taiwan and the Medicines and Healthcare products Regulatory Agency of the United Kingdom of Great Britain and Northern Ireland (UK) (the MHRA), are the regulatory authorities (collectively, the Participants) with responsibility in their respective countries/territories for the authorisation, granting, renewal, variation, suspension, and revocation of licences, certificates, or other regulatory mechanisms relating to those medicinal products and medical devices for human use which are clinically investigated, marketed, supplied, manufactured, or assembled in the UK and Taiwan respectively.
2. The FDA acknowledges that the MHRA is authorized, subject to relevant data protection requirements, to exchange information and documentation relating to medicinal products and medical devices in accordance with the domestic laws under which it is constituted.
3. The Participants consider that from time to time circumstances will arise where sharing information held by one regulatory authority will assist the other regulatory authority in carrying out its regulatory functions in relation to medical devices or to ensure the safety, quality, and efficacy of medicinal products for human use which are under clinical investigation, authorised for marketing, or under review for marketing authorisation in both the UK and Taiwan.
4. The FDA will co-operate with the MHRA to facilitate the sharing between the FDA and the MHRA of otherwise non-public documents and information for the purposes of assisting the

FDA in carrying out its functions. This MOU sets out a co-operation framework for the information which the FDA and the MHRA may share with each other and the basis upon which they may share it. Non-public documents or information means any document or information not in the public domain that is held by a Participant and is treated as confidential by that Participant in accordance with the domestic laws applicable to the Participant.

5. In this Confidentiality MOU, the term "medicinal products for human use" excludes all medicinal products subject to evaluation or authorised by the European Medicines Agency (EMA) under the centralised procedure as well as medicinal products authorised at national level by European Union Member States that are subject to official European Union arbitration and referrals.

Information that may be shared between the MHRA and the FDA:

6. The type of information that may be shared between the regulatory authorities includes, but is not limited to:
   I. Post-authorisation pharmacovigilance data held by one Participant which raises safety concerns about a product manufactured or distributed in the territory of the other authority.
   II. Information on quality defect or product recalls held by one Participant in relation to medicinal products and medical devices which are distributed or have been manufactured in the territory of the other Participant.
   III. Information contained in marketing authorisation applications and applications to vary a marketing authorisation received by one Participant which are of significant public health interest to the other Participant to which they are disclosed.
   IV. Information contained in reports on inspections done by one Participant which are of significant public health interest to the other Participant to which they are

disclosed.

7. The Participants, their officials or representatives, may in their absolute discretion limit the scope of the above information, particularly if its dissemination or exchange may harm the commercial interests of a third party, breach a duty of confidence or privacy attaching to the information, disclose a trade secret, or be contrary to the public interest or the interests of the Participant. In some cases, exchange of information under this understanding may be subject to prior consent from the companies or individuals concerned.

The basis on which this information is shared between the FDA and the MHRA:

8. The Participants recognise that it is an essential element of this MOU that confidential information emanating from one Participant to the other will continue to be treated as such by the receiving Participant, and that so far as practicable and to the extent permitted by its respective laws, the receiving Participant will keep the information exchanged confidential.
9. The FDA acknowledges that some of the information it will receive from MHRA may include non-public information exempt from public disclosure under the relevant laws and regulations of the UK, such as confidential information, commercially sensitive information, trade secrets, personal information, law enforcement information, or internal pre-decisional information. The FDA understands that this non-public information is shared in confidence with it, and that the MHRA considers it critical that the FDA maintain the confidentiality of this information. The FDA understands that the MHRA will advise the FDA of the non-public status of the information at the time that the information is shared.
10. The FDA understands that the MHRA affirms that the MHRA has the authority to protect such non-public information

provided to it (including its officials and representatives) by the FDA, and that it will protect such information as information not to be disclosed by it under the UK Freedom of Information Act. The FDA considers it crucial that such non-public information should not be disclosed without the consent of the FDA and that disclosure made without such consent could endanger the relations between the Participants and seriously jeopardise any further scientific and regulatory interactions between the FDA and the MHRA.

11. The FDA understands that the MHRA is of the view that the disclosure by the FDA of any non public information provided to it (including its officials and representatives) by MHRA could seriously jeopardise any further scientific and regulatory interactions between the FDA and the MHRA and would prejudice the relations between the MHRA and the FDA. The FDA understands that the MHRA considers that it is crucial that this non-public information is protected from disclosure and that the condition of sharing this non-public information with the FDA is that it be held in strict confidence by the FDA.
12. The FDA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the MHRA and will take all practicable steps to protect any such non-public information from disclosure unless the owner of the information has provided written authorisation to make the information public or, unless in relation to the information requested, the MHRA informs the FDA that it no longer considers the information to be non-public or that it no longer considers that disclosure of the non-public information will harm relations between the MHRA and the FDA or if the non-public information is required to be released under applicable local law.
13. Within 5 working days of receiving from the FDA a third party request for disclosure, the MHRA will inform the FDA

as to whether the MHRA remains of the view that the requested disclosure should not be made and that if made it will breach a confidence and/or endanger relations between the Participants.

14. On each occasion where the FDA receives a request from a third party for disclosure to that third party of non-public information received from the MHRA, the FDA will consult with the MHRA on that requested disclosure and understands that the MHRA will respond to the FDA as per paragraph 13.
15. On each occasion when the MHRA receives a request from a third party for disclosure to that third party of non-public information received from the FDA, the FDA understands that MHRA will consult with the FDA on that requested disclosure, and the FDA will provide the MHRA with its position on whether or not that non-public information should be disclosed within 5 working days of receiving from the MHRA any third party request for disclosure.
16. The Participants recognise that there may be occasions when the Participant with whom confidential information is shared may as a result of receiving that information need to take measures to protect public health which may necessitate sharing some or all of such confidential information with certain other agencies. In those circumstances the Participants will only decide to share the information in consultation with the other Participant.
17. Both the MHRA and the FDA recognise that if requests for information in their possession (including otherwise non-public information received from the other Participant) are demanded by judicial, parliamentary order or other order issued under law, the Participant will have to surrender the information to the court, legislature, or person concerned. If such an order is received for otherwise non-public information received from the other Participant, the Participant under order to produce the information will inform the requestor immediately and will take all measures

open to it to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

Duration, change, and termination of Memorandum of Understanding:

18. This MOU will come into effect on signature. It is intended to replace any previous similar understandings between the Participants and will continue in effect until terminated by either Participant on 30 days written notice to the other Participant or if mutually decided by the Participants at any time.
19. The Participants may amend this MOU at any time by mutual decision in writing.

Jaw-Jou Kang, Ph.D.
Director General
Food and Drug Administration

(Signed on 18/12/12 in duplicate in the English language)