

法規名稱：CONFIDENTIALITY AGREEMENT BETWEEN THE TAIWAN FOOD AND DRUG ADMINISTRATION OF MINISTRY OF HEALTH AND WELFARE AND THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTHCARE OF THE COUNCIL OF EUROPE

簽訂日期：民國 103 年 05 月 12 日

生效日期：民國 103 年 05 月 12 日

The Taiwan Food and Drug Administration of Ministry of Health and Welfare (TFDA) and the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), hereinafter referred to as "the Parties", share the common goal of protecting public health and safety by ensuring the quality and safety of Substances for Pharmaceutical Use, i.e. Active Pharmaceutical Ingredients (API) and Excipients that are used in the production or preparation of medicinal products.

The Parties will co-operate as follows to facilitate the sharing of information related to the quality and manufacture of substances for pharmaceutical use and in particular Active Pharmaceutical Ingredients (APIs) of common interest, including non-public and proprietary information.

1. The information to be shared by EDQM includes:

- (a) information on negative actions taken on Certificates of suitability to the monographs of the European Pharmacopoeia (CEPs), or applications for CEPs in the context of the EDQM inspection programme, which includes details of the reasons for GMP non-compliance for the companies inspected by EDQM;
- (b) information on negative actions taken on CEPs, or applications for CEPs, as a consequence of a failure from the holder or intended holder to meet the requirements of the Certification procedure;
- (c) upon request from TFDA, information on inspections of manufacturers of pharmaceutical substances carried out by EDQM (typically inspections reports);
- (d) upon request from TFDA, to help the assessment of licensing applications referring to a CEP, and subject to prior

- agreement of the holder of the CEP, evaluation reports for CEP applications;
- (e) information on new technical guidance.
2. The information to be shared by TFDA includes:
- (a) upon request from EDQM, information on inspections of manufacturers of pharmaceutical substances carried out by TFDA on the Taiwanese territory or elsewhere, typically information on outcomes of inspections or inspection reports;
- (b) information on new technical guidance or changes in regulation.
3. Parties understand that some of the information they receive from each other may include non-public information exempt from public disclosure under the applicable laws and regulations, including each Party's internal rules, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information or internal operational information. Both Parties understand that this non-public information is shared in confidence, and that it is critical that the confidentiality of the information is maintained.
4. Both Parties shall inform each other of the non-public status of the information at the time that the information is shared. They shall guarantee confidentiality in accordance with the applicable laws and regulations, including their own internal rules.
5. TFDA and EDQM note that this Agreement relating to the exchange of information:
- (a) does not affect the authority of the Parties to carry out their regulatory responsibilities;
- (b) does not create any obligation to share information and that each Party may decline to provide information to the other Party.
6. Any disputes or disagreements with respect to the interpretation or implementation of this Agreement shall be

resolved amicably by good faith negotiations between the Parties.

7. This Agreement is to enter into force on the date of the latter signature. Either Party may terminate this Agreement at any time by giving a three month written notice to the other Party.
8. This Agreement may be amended through negotiations by the Parties.

This Agreement is signed in duplicate in English.

Taiwan Food and Drug
Administration of
Ministry of Health and
Welfare

European Directorate
for the Quality of
Medicines and
HealthCare of the
Council of Europe

Dr. Ming-Kung Yeh
Director-General

Dr. Susanne Keitel
Director

Date: 2014. 05. 12
Place: Taipei

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