法規名稱：MEMORANDUM OF UNDERSTANDING BETWEEN THE TAIWAN FOOD AND DRUG ADMINISTRATION AND THE EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE NETWORK FOR VACCINES FOR HUMAN USE AND MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD AND PLASMA AS REPRESENTED BY THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTHCARE OF THE COUNCIL OF EUROPE REGARDING PARTICIPATION IN ACTIVITES OF THE EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE NETWORK FOR VACCINES FOR HUMAN USE AND MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD AND PLASMA
簽訂日期：民國 108 年 11 月 20 日
生效日期：民國 108 年 12 月 04 日

The EU Official Control Authority Batch Release (OCABR) Network for vaccines for human use and medicinal products derived from human blood and plasma as represented by the European Directorate of the Quality of Medicines and HealthCare (EDQM) of the Council of Europe, is hereinafter referred to as ‘the Human OCABR Network’

The Taiwan Food and Drug Administration is hereinafter referred to as TFDA.

The TFDA and the Human OCABR Network are hereinafter jointly referred to as ‘the Participants’.

Recognising that the Participants share a common goal to protect health and safety by assessing the quality of vaccines for human use and medicinal products derived from human blood and plasma (Biological Medicinal Products) through physical analysis of batches of these Biological Medicinal Products.

Recalling that the TFDA is an observer of the European Pharmacopoeia Commission and officially recognises the European Pharmacopoeia as a standard and that they are an associate member of the General European OMCL Network (GEON) and share in common the principles of the GEON and comply with the GEON definition of an Official Medicines Control Laboratory (OMCL);

The Participants have reached the following understanding:
I.PURPOSE
1) This Memorandum of Understanding (MOU) establishes an arrangement between TFDA and the Human OCABR Network for collaboration and exchange of information related to the evaluation of batches of Biological Medicinal Products as conducted by the Human OCABR Network and as conducted by TFDA during the course of their regulatory activity.
2) This MOU does not modify existing cooperative activities nor

does it preclude entering into separate arrangements for specific activities that can be handled more efficiently by special arrangements.

II. A) DEFINITIONS

Biological Medicinal Products: In the context of this document means vaccines and sera for human use and medicinal products derived from human blood and plasma which are subject to OCABR.

Mutually recognised partner: In the context of this document refers to countries which have signed a formal legal agreement with the EU which includes batch release activity e.g a Mutual Recognition Agreement or Agreement on Conformity Assessment and Acceptance of Industrial Products.

Official Control Authority Batch Release: a codified system in the EU for control of biological medicinal products batch by batch before they are placed on the market as defined in EU Directive 2001/83/EC as amended by 2004/27/EC and detailed in the current Administrative Procedure for OCABR in the EU.

Official Medicines Control Laboratory: an independent laboratory which carries out analytical analysis of medicinal products which fits the definition of an OMCL in the current Terms of Reference of the General OMCL Network.

Outside partners: Organisations or countries outside of the Human OCABR network, its Mutually Recognised partners and/or MOU partners.

II. B) ABBREVIATIONS

COE: Council of Europe

EDQM: European Directorate of the Quality of Medicines and HealthCare

EU: European Union

GEON: General European OMCL Network

MOU: Memorandum of Understanding

OCABR: Official Control Authority Batch Release

OMCL: Official Medicines Control Laboratory

III. SCOPE

The following outlines the agreed scope of the exchange.

Part A: Exchange of Information

A.1 The Human OCABR network will:

1) Allow TFDA to participate in the blood, vaccine and common OCABR sessions of the Human OCABR Network annual meeting.
2) Provide TFDA with timely access to annual reports of OCABR blood and vaccine activity from the network prior to the annual meeting in accordance with the EU Administrative Procedure for OCABR and to all documents distributed to participants at such a meeting.
3) Provide notice to TFDA of confidential information relating to the status of a batch of medicinal product derived from

human blood and plasma and vaccines, such as OCABR notice of non-compliance or withdrawal from parallel testing, when it arises, using the information exchange tools in the EU Administrative Procedure for OCABR (e.g. Annexes IIe, VI, VII and VIII). As a result it will include TFDA as an observer in Annex III blood/vaccine contacts of the EU Administrative Procedure for OCABR.

4) Provide TFDA with access to internal procedures and documents of the Human OCABR network.

A.2 TFDA will:

1. Agree, in attending the annual meeting of OCABR blood, vaccine and common sessions, to limit its involvement to comment on the meeting documents or material provided to all participants; that it will not have any decision-making capacity nor right to vote respecting the adoption of documents or other forms of information provided for that purpose; and that it will not have the right to vote in elections for members of the Advisory Group.
2. Provide, in advance of the annual meeting of the Human OCABR network, a report on its activity concerning medicinal products derived from human blood and plasma and vaccines similar to the OCABR activity including technical details on batches tested using the annual report format (Annex V of the EU Administrative Procedure for OCABR) as far as possible.
3. Provide notice to the Human OCABR network of confidential information regarding the status of batches of medicinal products derived from human blood or plasma and vaccines, when there are concerns related to quality, as the information becomes available. If appropriate, the information exchange tools in the EU Administrative Procedure for OCABR (e.g. Annexes VI and VII) should be used.
4. Provide the Human OCABR network with access to internal procedures and documents of their batch release related activity as needed.

Part B: Use of Information

1) The information shared or exchanged will only be used for the purposes of this MOU and in the context of batch control activity for the OMCLs/National regulatory authority(ies) and related activity concerning license assessment and inspection activity by the control authorities.
2) Information exchanged under this MOU may contain confidential information exempt from public disclosure under the laws and regulations of Taiwan (R.O.C) and the Council of Europe/European Union Member States. Information that is exempt from public disclosure will only be shared according to the procedures and policies of the Participants as permitted by their respective laws and regulations. Neither TFDA nor the Human OCABR Network will divulge confidential

information including but not limited to trade secret information and personal information to outside partners without the consent of the provider of such information.

IV. ROLES

1) The Participants acknowledge that the administration of this MOU, including management of issues arising from the application of the MOU and the evaluation and communication of the application of the MOU, will rest with the administrator of each Participant. Administrators will be：
   a) For the Human OCABR Network, the person holding the position of Director EDQM; and
   b) For TFDA, the person holding the position of Director General
2) The Participants acknowledge that written requests for information and documentation should be made to the identified contact person for each Participant. The contact person will carry out the day-to-day operations and monitor the application of the MOU. The contact person will be:
   a) For the Human OCABR Network, the person holding the position of Head of the Department for Biological Standardisation, OMCL Network and HealthCare or the Deputy Head; and
   b) For TFDA, the person holding the position of section chief
3) The Participants acknowledge that they will establish a mechanism for communication on an annual or as needed basis as a means of facilitating the application and functioning of this MOU.
4) The Participants acknowledge that they will notify each other of changes in their respective legislation, regulations, operational practices, policies and procedures relating to matters covered by this MOU which might impact on their ability to cooperate as intended by this MOU.
5) The Participants acknowledge that if any information or documentation is provided to the other, it will be free of charge.

V. COMMENCEMENT, REVIEW, AMENDMENT AND TERMINATION

1) This MOU will come into effect 10 working days after it is signed by the last Participant.
2) The MOU will be reviewed yearly by the OCABR Advisory Group on the occasion of the first OCABR Advisory group meeting after the annual meeting of a given year.
3) The MOU may be amended at any time with the written consent of the Participants. Any such amendment will come into effect on the date determined by the Participants.
4) Either Participant may terminate this MOU by written notice to the other Participant. The MOU will then terminate 30 calendar days after receipt of the notice to terminate.

Signed in duplicate on 23/09/19 in Strasbourg, France(initials)

Signed in duplicate on 20/11/19 in Taipei, Taiwan(initials)

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Dr. Shou-Mei Wu	Dr. Susanne Keitel
Director General Taiwan Food and Drug Administration	Director The European Directorate for the Quality of Medicines and HealthCare of the Council of Europe for the Human OCABR Network