PREFACE

OCABR Network Human Biologicals Guidelines and Procedures

These procedures and guidelines have been elaborated by a panel of experts from various OMCLs under the aegis of the EDQM and endorsed by the plenary network of Official Control Authority Batch Release laboratories after public enquiry where appropriate. The procedures are to be used for application of Official Control Authority Batch Release in the EU/EEA within the prescriptions outlined in article 114 of Directive 2001/83/EC, as amended by Directive 2004/27/EC. The product specific guidelines take into account the current state of the art in methodology and techniques for the quality control of blood derived medicinal products and vaccines as detailed in the Marketing Authorisation applications which, as indicated in the annex 1 of 2001/83/EC (amended by 2003/63/EC), shall include reference to the European Pharmacopoeia and therefore wherever appropriate they are based on the monographs, general chapters and methods in the European Pharmacopoeia. They are intended to be used by manufacturers and OMCLs for the Official Control Authority Batch Release of blood derived medicinal products and vaccines for human use as appropriate and are applicable as noted on each cover page. Revisions must first pass through a system of consultation and approval by the appropriate authorities before being applied. A form for requesting changes to existing guidelines is available in the guideline table on the EDQM website (http://www.edqm.eu/en/Human-OCABR-Guidelines-1530.html) and can be downloaded for use. Requests for change should be substantiated with supportive data or background information as appropriate.

The complete set of guidelines and procedures is now available exclusively on the EDQM website (http://www.edqm.eu/en/Human-OCABR-Guidelines-1530.html). They should be applied by users in the context of the Rules Governing Medicines in Europe, published by the EU Commission, Directorate General for Health and Consumers (http://ec.europa.eu/health/documents/eudralex/index_en.htm).

We wish to remind the readers/users that all EU Member States and the EEA partners, may decide to apply Official Control Authority Batch Release in accordance with article 114 of Directive 2001/83/EC, as amended by Directive 2004/27/EC. As of 1 July 2013 this also

includes Croatia. All the procedures and guidelines for the running of OCABR throughout the network apply equally to all Member States and as such, where applied, Official Control Authority Batch Release is mutually recognised throughout the full EU territory.

It is also recalled that since June 1st, 2002 any Official Control Authority Batch Release Certificate issued in the EU/EEA for a batch of product released following the procedures and product specific guidelines outlined here will also be valid in Switzerland in application of the Mutual Recognition Agreement (MRA) between that country and the EU (Chapter 15 of Annex 1).

Reciprocally, Official Control Authority Batch Release performed in Switzerland according to their specific procedure and resulting in issue of a Batch Release Certificate with reference to the MRA will be recognised within the EU/EEA. Detailed information can be obtained at www.swissmedic.ch.

Furthermore, an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with Israel came into effect on 19 January 2013. With respect to OCABR this agreement will initially cover the field of human vaccines only. In this context mutual recognition of results obtained through applying the EU regulation, procedures and guidance on OCABR will be applicable between Israel and EU/EEA Member States.

NOTE TO USERS

OCABR Network Human Biologicals Guidelines and Procedures

All guidelines and procedures are now available exclusively on the EDQM website (http://www.edqm.eu/en/Human-OCABR-Guidelines-1530.html). The complete list is presented in a table from which the files may be downloaded. The table indicates the date of entry into force of the relevant document and the last date on which the website was updated in relation to the document. A package containing all of the documents is also available for download at the same location.

The guidelines will be updated on an on-going basis as needed. New and revised versions will be placed on the website within one month of their date of entry into force. Users are encouraged to visit the site regularly to ensure they are using the most recent versions.

Highlights on recent addition and revision updates can be found in the right side bar of the same page.

Each individual guideline is clearly identified on the title page. For continuity and transparency previous guideline names and other editorial information are provided.

ADMINISTRATIVE PROCEDURE

The Administrative Procedure clearly outlines the steps to be followed by OMCLs and MAHs for the application of Official Control Authority Batch Release. It contains a number of annexes with templates for communication between MAHs and OMCLs and between OMCLs.

Annex I	Template for a model letter from a competent authority to the marketing authorisation holder as regards official control authority batch release within EC
Annex IIA	EU Official Control Authority Batch Release Certificate For Immunological Products
Annex IIB	EU Official Control Authority Batch Release Certificate For Medicinal Products Derived From Human Blood Or Plasma
Annex IIC	EU Official Control Authority Batch Release Certificate Of Approval For Monovalent Bulk Of Poliomyelitis Vaccine (Oral)
Annex IID	EU Official Control Authority Batch Release Certificate Of Approval For Plasma Pools
Annex IIE	EU Administrative Procedure for the Official Control Authority Batch Release: General Model For Non-Compliance/Failure

Annex IIF	EU Official Control Authority Batch Release Certificate For Ancillary Medicinal Products Derived From Human Blood Or Plasma In A Medical Device
Annex IIG	EU Official Control Authority Batch Release Certificate Of Approval For Monovalent Pneumococcal Polysaccharide Bulk Conjugates
Annex III	Contact persons for results & questions concerning EU/EEA Official Control Authority Batch Release
Annex IV	Marketing information form, model for manufacturers
Annex V	Model format and content of annual reports for the network for OCABR of human biological medicinal products
Annex VI	Model letter for confidential rapid information exchange with OCABR Network members
Annex VII	Model letter for batch release procedural information
Annex VIII	Notification of Nullification of Certificate

Users are reminded that Annex III, the list of official contacts for OCABR, is continuously updated as soon as changes in contact details are made known to EDQM. The most recent contact details for the network of EU/EEA and MRA partners are found separately on the EDQM website (http://www.edqm.eu/en/human-biologicals-611.html). It is advised to regularly check the update status to ensure that users have the most recent contact details.

PRODUCT SPECIFIC GUIDELINES

Product specific guidelines outline tests to be performed by the OMCL for OCABR and indicate the samples that should be provided by the MAH in order that the testing may be carried out.

The model protocol, present in all guidelines, is provided for use by the manufacturer. It is meant to help ensure complete and harmonised protocol submission. An attempt has been made to list all appropriate production steps and controls as required by the Marketing Authorisation and the relevant monograph(s) of the Ph Eur. It is possible however that a protocol for a specific product may differ in detail from the model provided. The essential point is that all relevant details demonstrating compliance with the Marketing Authorisation and the Ph Eur monograph(s) (where existing) for a particular product should be given in the protocol submitted by the manufacturer. This is explained clearly in section 3 of all guidelines.

To complete the set of references for OCABR to match the current market situation new guidelines are added and existing ones revised as needed. All recent additions and revisions are highlighted in the right side bar of the web page.

OTHER RELATED PROCEDURES

In the context of Article 58 of CEC Council Regulation 726/204 a procedure has been developed through a close collaboration between the WHO, EDQM and the EMA to facilitate the possibility of certification of batches by European OMCLs for biologicals destined to 3rd (non EU) countries. The procedure is presented here for information for potential users.