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EMA Pre- / Post-Authorization Procedural Advice for Users of the Centralized Procedure

13 November 2023 – the EMA updated guidance on pre-/post-authorization for users of the centralized procedure.

Updates:

3.3.6. How should I submit an Active Substance Master File (ASMF)?

Human Medicines Division - Active Substance Master File (ASMF)

1.4. How shall I present and submit my Type IA/ IAIN Variation(s)?

5.4. What procedure number will be given to grouped variation applications?

6.3. What pre-submission steps will apply to a work sharing procedure?

Human Medicines Division - Type IA Rev 106

What EMA Publishes and When: Guide to Information on Human Medicines Evaluated by EMA

13 November 2023 – the EMA published the guide to information on human medicines evaluated by EMA.

This guide describes the different types of information the Agency currently publishes for both centrally and non-centrally authorized medicines, as well as publication times and location on EMA's website. It aims to help stakeholders know what kind of information to expect on medicines undergoing evaluations and other regulatory procedures.

Read more online

Biosimilars in the EU: Information Guide for Healthcare Professionals

13 November 2023 – the EMA published an Information Guide prepared jointly by the European Medicines Agency and the European Commission on the use and implementation of biosimilars for healthcare professionals.

This guide has been prepared with the important objective of providing healthcare professionals with reference information on both the science and regulation underpinning the use of biosimilars.

Information Guide

Clinical Trials Information System (CTIS) — Sponsor Handbook

10 November 2023 – the EMA published v3.03 of the CTIS Sponsor Handbook.

This Handbook addresses key questions on CTIS and provides a compilation and references to key guidance, technical information, recommendations, training materials, and supportive documentation to facilitate the submission and assessment of CTAs and additional information during the lifecycle of a trial.

Read more online

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CTIS Newsflash

10 November 2023 – the EMA published the latest CTIS newsflash.

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

Read more online

Guidance on Good Manufacturing Practice and Good Distribution Practice: Questions and Answers

9 November 2023 – the EMA published updated Q&A on GMP and GDP. Guidance

The guidance provided by the working group in the form of questions and answers (Q&As) provides additional interpretation of the European Union (EU) GMP guidelines and GDP guidelines published by the European Commission.

Read more online

Questions and Answers on Data Requirements when Transitioning to Low Global Warming Potential (LGWP) Propellants in Oral Pressurized Metered Dose Inhalers

8 November 2023 – the EMA published updated Q&A guidance on data requirements when transitioning to LGWP in oral pressurized metered dose inhalers.

This questions and answers document aims at providing advice regarding data requirements for such replacements. It applies to all medicinal products irrespective of the legal basis for marketing authorization.

Read more online

First Electronic Product Information (ePI) Published for Selected Human Medicines

8 November 2023 – the EMA announced the first ePI published for selected human medicines.

The Heads of Medicines Agencies (HMA), the European Commission (EC) and EMA have published for the first time, electronic product information (ePI) for selected human medicines harmonized across the European Union (EU).

The product information of a medicine includes its summary of product characteristics, labelling and package leaflet.

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CTIS Training Information

7 November 2023 – the EMA published updated guidance on a variety of CTIS trainings as well as an upcoming webinar and updated Clinical Study Reports Quick Guide.

FAQs--How to Create, Submit and Withdraw a CTA

FAQs--How to Create, Submit and Withdraw a CTA

Clinical Trials Information System (CTIS) Bitesize Talk

CTIS Webinar

Quick Guide—Clinical Study Reports

Updated Quick Guide

Guideline on the Clinical Requirements for Non-Replacement Therapy in Hemophilia A and B

31 October 2023 – the EMA published the draft scientific guideline on clinical requirements for non-replacement therapy in hemophilia A and B.

This guideline describes the main clinical data needed to support an application for a marketing authorization for non-replacement therapy for use in prevention of bleeding in patients with hemophilia A and/or hemophilia B.

Read more online

Concept Paper on the Revision of the Non-Clinical and Clinical Module of the Influenza Vaccines Guideline

31 October 2023 – the EMA published the draft concept paper on the revision of the non-clinical and clinical module of the influenza vaccines guideline.

Overall, there is some degree of urgency to revise the guideline on non-clinical and clinical development of influenza vaccines. In particular, to add sections relevant to the development of mRNA-based influenza vaccines and to reflect on how lessons learned from the COVID-19 pandemic could be relevant to the development of influenza vaccines, including those intended only for pandemic usage.

Read more online

Draft Revised Consolidated 3-year Work Plan for the Methodology Working Party (MWP)

31 October 2023 – the EMA published the draft revised consolidated 3-year work plan for the MWP.

The Methodology Working Party aims to leverage the cross-disciplinary expertise to support methodological innovation in global drug development and support advice and interpretation of complex methodology across (clinical) drug development.

Read more online

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Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA

26 October 2023 – the EMA published the reflection paper on ethical and GCP aspects of clinical trials conducted outside of the EU/EEA and submitted in marketing authorization applications to the EU regulatory authorities.

The scope of this Reflection Paper is to clarify the practical application of requirements for clinical trials conducted outside of the EU/EEA and submitted in Marketing Authorization Applications to the EMA (through the centralised procedure) or to National competent Authorities (through decentralised, mutual recognition, or national procedures). The Paper sets up practical steps to be undertaken during the provision of guidance and advice in the medicine development phase and during the evaluation of Marketing Authorization Applications.

Read more online

Appendix on Disclosure Rules, to the "Functional Specifications for the EU Portal and EU Database to be Audited - EMA/42176/2014"

26 October 2023 – the EMA published the appendix on disclosure rules in the EU clinical trial portal and database.

The key instrument to ensure transparency of clinical trials is the EU clinical trial portal and database that will be used for submission and maintenance of clinical trial applications and authorizations within the EU. This Appendix sets out rules and criteria for the application of the exceptions in relation to the disclosure provisions of the European Clinical Trial Regulation.

Read more online

Draft Proposal for an Addendum, on Transparency, to the "Functional Specifications for the EU Portal and EU Database to be audited - EMA/42176/2014"

26 October 2023 – the EMA published the draft proposal for an addendum on transparency in the EU clinical trial portal and database.

This consultation document sets out proposals and options on the application of the exceptions in relation to the transparency provisions of the European Clinical Trial Regulation.

Section 6 and the part of Table 2 Section 4.3 will be revised following the consultation and added to the "Functional specifications for the EU portal and EU database" as an addendum.

Read more online

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Public Consultation on Implementation of Transparency Requirements of the European Clinical Trial Regulation

26 October 2023 – the EMA published the updated Q&A guidance on public consultation on implementation of transparency requirements of the European clinical trial regulation.

The document now open for consultation describes how it is proposed to implement the transparency requirements of the European Clinical Trial Regulation, and when and which information on clinical trials conducted in the EU should be made public.

Read more online

Procedural Advice for Post-Orphan Medicinal Product Designation Activities

20 October 2023 – the EMA published Rev. 14 of the guidance on post-orphan medicinal product designation activities for sponsors.

This guideline covers detailed information and procedures applicable to orphan designated products:

1. Incentives
2. Annual reports
3. Transfer of orphan designation
4. Change of sponsor's name or address
5. Amendment of designated condition
6. Marketing authorisation application
7. Removal of orphan designation
8. Review of the period of market exclusivity of orphan medicinal products.

Read more online

Procedural Advice for Orphan Medicinal Product Designation

20 October 2023 – the EMA published Rev. 13 of the guidance on procedural advice for orphan medicinal product designation for sponsors

In examining an application for orphan medicinal product designation, the COMP will focus on determining whether the sponsor has established that the designation criteria are met. All orphan applications should be created and submitted via the IRIS portal, which also contains the relevant procedural advice.

Read more online

Position Statement on DNA and Host Cell Protein Impurities, Routine Testing Versus Validation Studies

19 October 2023 – the EMA published updated scientific guideline on DNA and host cell protein impurities, routine testing versus validation studies.

The "validation approach" appears to be an acceptable way, in most cases, to approach the question of residual host cell DNA.

This position is not as readily applicable for host cell proteins (HCP) impurities where a "case by case" review is proposed.

It is noteworthy that in any case, processes and procedures should undergo periodic critical re- evaluation to ensure that they remain capable of achieving the intended results.

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COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers

7 November 2023 – the FDA issued guidance on COVID container closure system and component changes for industry.

FDA is issuing this guidance to collate recommendations for appropriate reporting category and the content of post approval change submissions across numerous FDA guidance documents. This guidance does not apply to CCS types other than glass vials and stoppers.

Read more online

Real-Time Oncology Review (RTOR)

7 November 2023 – the FDA issued the guidance on real-time oncology review.

The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected new drug applications (NDAs) and biologics license applications (BLAs) with oncology indications for review under Real-Time Oncology Review (RTOR).

Read more online

Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments Using Item Response Theory

6 November 2023 – the FDA issued guidance on the submission of clinical outcome assessment data using item response theory.

This document provides technical specifications for the submission of clinical outcome assessment (COA) data that use Item Response Theory (IRT) and supplements the FDA Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development (PFDD) Methodological Guidance Series.

Read more online

Submitting Patient-Reported Outcome Data in Cancer Clinical Trials

6 November 2023 – the FDA issued guidance on the submission of patient-reported outcome data in cancer clinical trials.

This document provides technical specifications for submitting patient-reported outcome (PRO) data collected in cancer clinical trials to support a marketing application for a medical product in oncology, where a PRO is a type of clinical outcome assessment (COA) used to collect patient experience data.

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Enforcement Policy for Clinical Electronic Thermometers

3 November 2023 – the FDA published the final guidance on enforcement policy for clinical electronic thermometers.

FDA is issuing this guidance to provide clarification on its enforcement policies and premarket review expectations for clinical electronic thermometers at the conclusion of the COVID-19 public health emergency.

Read more online

Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices

3 November 2023 – the FDA published guidance on how to request a review of a denial of export certificates for certain devices.

This guidance describes the information that the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), in collaboration with the Office of Regulatory Affairs (ORA), will provide to a person whose request for a Certificate to Foreign Government (CFG) for a device is denied, and the process for seeking review of such a denial. Although CFG-NEs apply to devices not exported from the United States, the processes referenced below also apply to CFG-NEs, pursuant to section 801(e)(4)(F)(iv) of the FD&C Act, unless otherwise specified.

Read more online

Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions

2 November 2023 – the FDA published guidance on the enforcement policy for certain supplements for PMA or HDE submissions.

The FDA is issuing this guidance to describe FDA's general recommendations for limited modifications to devices required to have an approved PMA or HDE to help address manufacturing limitations or supply chain disruptions. FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health.

Read more online

Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities

26 October 2023 – the FDA published draft guidance on remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities. Submit comments by 26 December 2023.

FDA is issuing this guidance to describe how we request and conduct voluntary remote interactive evaluations at facilities where drugs are manufactured, processed, packed, compounded, or held, and at drug facilities covered under FDA's bioresearch monitoring (BIMO) program.

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Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products

24 October 2023 – the FDA published draft Q&A guidance on communications from firms to HCPs regarding scientific information on unapproved uses of approved/cleared medical products. Submit comments by 24 December 2023.

This revised draft guidance, when finalized, will provide FDA's current thinking on common questions regarding certain communications by firms to health care providers (HCPs) of scientific information on unapproved use(s) (SIUU) of approved/cleared medical products.

Read more online

Topical Dermatologic Corticosteroids: In Vivo Bioequivalence

24 October 2023 – the FDA published draft guidance on topical dermatologic corticosteroids in vivo bioequivalence.

This guidance is intended to assist applicants who submit abbreviated new drug applications (ANDAs) for topical dermatologic corticosteroid products of all potency groups hereinafter referred to as topical corticosteroids. This guidance describes recommendations for in vivo studies to demonstrate the bioequivalence of topical corticosteroids.

Read more online

Development and Licensure of Vaccines to Prevent COVID-19

19 October 2023 – the FDA published the final guidance on development and licensure of vaccines to prevent COVID-19.

FDA is issuing this guidance to assist sponsors in the clinical development and licensure of vaccines for the prevention of Coronavirus Disease 2019 (COVID-19) which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Read more online

Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies

19 October 2023 – the FDA published the final guidance on the voluntary consensus standards recognition program for regenerative medicine therapies.

This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate.

Read more online

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Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring

19 October 2023 – the FDA published the final guidance for non-invasive remote monitoring devices used to support patient monitoring.

FDA is issuing this guidance to foster the availability of certain non-invasive remote monitoring devices that can help eliminate unnecessary patient contact and ease burdens on hospitals, other health care facilities, and health care professionals, which are experiencing high demands.

Read more online

Benefit-Risk Assessment for New Drug and Biological Products

17 October 2023 – the FDA published the final guidance on benefit-risk assessment for new drug and biological products.

The intent of this guidance is to clarify for drug sponsors and other stakeholders how considerations about a drug's benefits, risks, and risk management options factor into certain premarket and postmarket regulatory decisions that the Food and Drug Administration (FDA or Agency) makes about new drug applications (NDAs) submitted under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as well as biologics license applications (BLAs) submitted under section 351(a) of the Public Health Service Act (PHS Act).

Read more online

Diabetic Foot Infections: Developing Drugs for Treatment

17 October 2023 – the FDA published draft guidance on developing drugs for treatment of diabetic foot infections. Submit comments by 18 December 2023.

The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of diabetic foot infections (DFIs) without concomitant bone and joint involvement.

Read more online

Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements

17 October 2023 – the FDA published the final guidance on blood and blood component donation suitability, donor eligibility and source plasma quarantine hold requirements.

This guidance addresses certain requirements that apply to blood establishments that collect blood and blood components, including Source Plasma.

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MHRA

Regulating Medicines and Medical Devices

Access Consortium

6 November 2023 – the MHRA provided the latest updates from the Access Consortium.

The most recent update includes details on the Access Consortium's Advanced Therapy Medicinal Products Working Group.

Read more online

Software and Artificial Intelligence (AI) as a Medical Device

25 October 2023 – the MHRA published updated guidance on software and AI as a medical device.

This guidance provides information for manufacturers, healthcare organisations and professionals, researchers, and patients & public on Software as a Medical Device (SaMD), including Artificial Intelligence as a Medical Device (AIaMD).

The latest update added the MHRA, FDA and Health Canada's 5 guiding principles for the use of PCCPs to the AI section.

Read more online

Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles

24 October 2023 – the MHRA published the guiding principles for the use of predetermined change control plans for machine learning-enabled medical devices.

In this document, FDA, Health Canada, and MHRA jointly identified 5 guiding principles for predetermined change control plans. These principles draw upon the overarching GMLP guiding principles, in particular principle 10, which states that deployed models are monitored for performance and re-training risks are managed.

Read more online

Apply for a License to Market a Medicine in the UK

19 October 2023 – the MHRA published the updated guidance on the application of a market license of a medicine in the UK.

The most recent update added the following:

- Checklist and abstract for bioequivalence studies and/or biowaivers
- Checklist for product information', for established active substance MAAs within scope.

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Clinical Trials for Medicines: Apply for Authorization in the UK

12 October 2023 – the MHRA updated the guidance on how to apply for a clinical trial in the UK.

The New Notification Scheme enables a more streamlined and risk-proportionate approach to processing Clinical Trial Authorizations (CTA) for "initial" applications and only applies to Phase 4 and certain Phase 3 clinical trials deemed to be of lower risk and does not include CTA applications for first in human (FIH), Phase 1 or Phase 2, or amendments at this time.

Read more online

International Recognition Procedure

3 October 2023 – the MHRA published updated guidance on how to use the new procedure for medicinal licensing applications.

The MHRA has created a new international recognition route for medicines utilizing pre-existing approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States. This new framework will support patients in the UK with expedited access to safe and effective medicines that have been approved by trusted regulatory partners. From 1 January 2024, international recognition will sit alongside the MHRA's current national procedures.

The latest updates includes additional guidance on the Eligibility Checker and submitting your Marketing Authorisation application, IRP Product Lifecycle & eCTD guidance for MAs and Lifecycle.

Read more online

Risk Management (Signalmanagement, PSURs, RMPs/RMP summaries)

8 November 2023 – the Swissmedic published updated guidance on RMP ICHE2E information for submission HMP

The guidance document "RMP ICH E2E Information for submission HMP" has been fully revised. The most important change concerns the obligation to submit RMPs, which now only applies to first authorization applications for new active substances and their indication extensions.

The changes take effect on 1 November 2023.

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Swissmedic Confirmed as a World Health Organization (WHO) Listed Authority

1 November 2023 – the Swissmedic announced the WHO listed Swissmedic as a WHO listed authority on 30th October 2023.

The WHO listed Swissmedic as a WHO Listed Authority (WLA) on 30th October 2023. Regulatory authorities that are listed as WLAs comply with international standards and practices and have been assessed by the WHO. In this way, the World Health Organization aims to ensure that only safe, effective and high-quality medicinal products are on the market worldwide.

Read more online

Amendment to the Medical Device Ordinance (MedDO)

1 November 2023 – the Swissmedic published the implementation guides of the revisions to the MedDO.

The Federal Council has decided to amend the Medical Devices Ordinance (MedDO) to improve the safety of products without an intended medical purpose (media release dated 29 September 2023). Switzerland has adapted its MedDO for these products in line with the EU requirements (Implementing Regulation 2023/1194) taking into account the new transitional periods. The required amendments to the MedDO have been approved and will enter into force on 1 November 2023.

Read more online

Changes to the Guidance Document, *Mobile Technologies* and the Related Form

1 October 2023 – the Swissmedic published changes to the guidance document, *Mobile technologies* and its related form.

Training documents according to the most recently approved RMP are now considered to be "information required by therapeutic products legislation." The form has been amended accordingly. The materials to be submitted for other training materials classified as "additional information" have been clarified. The revised *Mobile technologies* guidance document and form are valid with effect from 1 October 2023.

Read more online

Modifications to Guidance Document, *Formal Requirements*

1 October 2023 – the Swissmedic published clarification on submission via eDOK and eCTD for co-marketing medicinal products.

Submission of complete identical document sets for eDOK and eCTD has been clarified with regard to co-marketing medicinal products. In addition, the submission deadline for variations without assessment after implementation for VMPs has been extended from a maximum of 1 month to a maximum of 60 calendar days. The revised guidance document *Formal requirements* is valid with effect from 1 October 2023.

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