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Compilation of Union Procedures on Inspections and Exchange of Information

15 September 2023 – the EMA published rev. 19.1 of the compilation of union procedures on inspections and exchange of information,

The Compilation is a tool for facilitating co-operation between the GMP and GDP inspectorates of the Member States and a means of achieving harmonization. The procedures within it provide the basis for national procedures that form part of the national GMP inspectorates' quality systems.

Read more online

Guideline on Clinical Investigation of Medicinal Products in the Treatment of Depression

15 September 2023 – the EMA published rev. 2 of the draft guideline on clinical investigation of medicinal products in the treatment of depression,

The present document should be considered as general guidance on the development of medicinal products for acute and long-term treatment of Major Depressive Disorder (MDD).

The update specifically addresses:

- Several aspects for trial designs in difficult to treat patients (partial responders or non-responders to treatment) including the definition and identification of those patients, the role of augmentation and combination strategies
- Clinical development requirements for new rapid acting therapies
- Issues to consider for the development of psychedelic medications and the new paradigm of psychedelic associated psychotherapy in the field of MDD
- Clinical development requirements to target sub-domains of depression
- Requirements for clinical trials in children and adolescents and possible extrapolation from adult data
- Gender and drug metabolism differences in patient populations

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Guidance on Pediatric Submissions

14 September 2023 – the EMA published rev. 6 on pediatric submissions via the Syncplicity web client.

The following guidance outlines the main steps to take to prepare for submission, and a list of documents required for the main types of paediatric submissions.

This document should be read in conjunction with other relevant guidance on content available on the EMA website, such as the *European Commission Guideline*; *Paediatric Medicines; Paediatric investigation plans: questions and answers*; and the *Paediatric Regulation.*

Read more online

Questions and Answers on Labeling Flexibilities for COVID- 19 Vaccines

12 September 2023 – the EMA published rev. 4 of Q&A guidance on labeling flexibilities for COVID-19 vaccines.

The flexibilities discussed in this document take into account the preparedness work of COVID-19 vaccine developers and the associated logistics of early printing packaging activities. The ultimate goal is to facilitate the large scale and rapid deployment of COVID-19 vaccines for EU citizens within the existing legal framework.

Read more online

Glomerular Filtration Rate (GFR) Slope as a Validated Surrogate Endpoint for RCT in Chronic Kidney Disease (CKD)

6 September 2023 – the EMA published the guidelines on GFR slope as a validated surrogate endpoint in RCT for CKD.

Draft Qualification Opinion for GFR Slope as a Surrogate Endpoint in RCT for CKD

Initial Qualification Procedure - List of Issues

Frequently Asked Questions about Parallel Distribution

6 September 2023 – the EMA published updated Q&A guidance on parallel distribution.

The following questions have been revised or added:

- 1.7. What to do when my organization details have changed?
- 4.1. What is the validity of the notice for parallel distribution and can it be revoked, suspended or annulled?
- 5.3. What is the scope of a bulk change?
- 5.4. How to submit a bulk change?
- 5.5. What is an annual update?

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CTIS Bitesize Talk: Part I-only applications and Part II-requirements in CTIS

1 September 2023 – the EMA published the online CTIS presentation regarding applications and requirements.

This bitesize talk on CTIS provides an opportunity for sponsors to learn how to prepare for a Part I-only initial application when planning a clinical trial and how to complete the initial *Part I-only application* to satisfy the *Part II requirements* in the Clinical Trials Information System (CTIS).

Read more online

Meeting Report – Multi-stakeholder Workshop on ICH E6(R3) – Public Consultation

29 August 2023 – the EMA published the 13 July 2023 meeting report of a multi-stakeholder workshop on ICH E6(R3).

The workshop engaged all stakeholders of ICH E6 R3, including but not limited to, patients, healthcare professionals, assessors, inspectors, industry and academia.

Read more online

EVVET – EVWEB User Manual

24 August 2023 – the EMA updated the EVWEB user manual.

This user manual is part of the official documentation prepared to support the use of the Surveillance Web reporting tool EVVET3-EVWEB. The first 8 chapters will explain how the application works; the last chapter will give an example and guide the user through all the needed steps to submit a report.

Read more online

Concept Paper on the Development of a Reflection Paper on Modern Manufacturing Techniques Used for Herbal Preparations

17 August 2023 – the EMA published the concept paper on developing a Reflection Paper on modern manufacturing techniques used for herbal preparations.

This document addresses the need for the development of a reflection paper related to modern methods/technologies used in the manufacturing of herbal preparations, and seeks the participation of interested parties in providing examples and comments on current manufacturing techniques.

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Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices

September 2023 – the European Commission published v, 3 of the manual on borderline and classification for medical devices.

The aspects concerning the borderline between medical devices and other types of products, also known as qualification of a product, are generally governed by Article 4 Regulatory status of products of the MDR and the corresponding Article 3 of the IVDR. Borderline cases are those for which it is not clear from the outset whether a given product is a medical device, or an in vitro diagnostic medical device (IVD), or not.

Read more online

Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989

15 September 2023 – the FDA published the final guidance on annual status report information for submitting postmarketing requirements and commitments using forms FDA 3988 and FDA 3989.

This guidance describes the purpose and content of Form FDA 3988, Transmittal of PMR/PMC Submissions for Drugs and Biologics, and Form FDA 3989, PMR/PMC Annual Status Report for Drugs and Biologics; when to use these forms; and how to submit these forms. Submission of completed Form FDA 3989 will meet the annual status reporting requirements for postmarketing studies or clinical trials described in section 506B of the FD&C Act and its implementing regulations.

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Medical Devices with Indications Associated with Weight Loss – Clinical and Non-Clinical Study, Benefit-Risk Considerations and Recommendations

15 September 2023 – the FDA published draft guidance on clinical and non-clinical study design for medical devices with indications associated with weight loss. Submit comments by 14 November 2023.

Clinical Study and Benefit-Risk Considerations

Non-Clinical Recommendations

Breakthrough Devices Program

14 September 2023 – the FDA published the final guidance on breakthrough devices program.

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Read more online

Clinical Pharmacology Considerations for Peptide Drug Products

11 September 2023 – the FDA published draft guidance on clinical pharmacology considerations for peptide drug products. Submit comments by 12 November 2023.

This guidance provides recommendations to assist industry in the development of peptide drug products. Specifically, this guidance, when finalized, will describe the FDA's current thinking regarding the impact of clinical pharmacology considerations, including hepatic impairment, drug-drug interactions (DDIs), QTc prolongation risk, and immunogenicity risk on a peptide drug product's pharmacokinetics (PK), safety, and efficacy.

Read more online

Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products

11 September 2023 – the FDA published the final guidance on IRB review of individual patient expanded access submissions for investigational drugs and biological products.

This guidance provides recommendations to institutional review boards (IRBs) and clinical investigators regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfil its obligations under 21 CFR part 56.

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Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"

8 September 2023 – the FDA published the final guidance on the use of ISO 10993-1.

This guidance provides updated information on the use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to support applications to FDA.

Read more online

Application of Human Factors Engineering Principles for Combination Products: Questions and Answers

7 September 2023 – the FDA published the final Q&A guidance on application of human factors engineering principles for combination products.

This document contains questions and answers for industry and FDA staff on the application of human factors engineering (HFE) principles to the development of combination products as defined under 21 CFR part 3.

Read more online

Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

7 September 2023 – the FDA published draft guidance on selecting a predicate device to support a premarket notification submission. Submit comments by 6 December 2023.

FDA developed this document to provide guidance to industry and FDA staff about best practices in selecting a predicate device for premarket notification [510(k)] submissions. Specifically, this guidance recommends four (4) best practices to employ when selecting a predicate device used to support a 510(k) submission. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process.

Read more online

Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

7 September 2023 – the FDA published the draft guidance on recommendations for the use of clinical data in premarket notification submissions. Submit comments by 6 December 2023.

FDA is issuing this draft guidance to provide current thinking on the use of clinical data in 510(k) submissions to enhance the predictability, consistency, and transparency of the 510(k) Program.

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Post-Warning Letter Meetings Under GDUFA

5 September 2023 – the FDA published draft guidance on post-warning letter meetings under GDUFA. Submit comments by 6 November 2023.

This guidance specifically describes the process in the Generic Drug User Fee Amendments (GDUFA) III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility's ongoing remediation efforts to current good manufacturing practice (CGMP) deficiencies described in a warning letter, how to prepare and submit a complete meeting request package, and how FDA intends to conduct the Post-Warning Letter Meeting.

Read more online

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies

1 September 2023 – the FDA published the revised final guidance on wholesale distributor verification requirement for saleable returned drug product and dispenser verification requirements.

This revised guidance explains that FDA intends to extend for an additional year (from November 27, 2023, to November 27, 2024), the enforcement policies described in the guidance entitled "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product-Compliance Policies," published in the *Federal Register* on October 23, 2020 (the 2020 Compliance Policies).

Read more online

Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products

30 August 2023 – the FDA published final guidance on the use of RWD and RWE in regulatory decision making.

FDA is issuing this guidance as part of its RWE Program to satisfy, in part, the mandate under section 505F of the FD&C Act to issue guidance about the use of RWE to help support approval of a new indication for a drug already approved under section 505(c) of the FD&C Act or to help support post approval study requirements.

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Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act

30 August 2023 – the FDA published final guidance on the requirements for enhanced drug distribution security at the package level.

This guidance is intended to assist supply chain stakeholders, particularly trading partners, with requirements for enhanced drug distribution security at the package level under section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54). Requirements for enhanced drug distribution security, commonly referred to as the "enhanced system," go into effect on November 27, 2023.

Read more online

Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies

28 August 2023 – the FDA published final guidance on the enforcement of requirements for the interoperable, electronic, package level product tracing.

This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that will go into effect on November 27, 2023.

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MHRA

Regulating Medicines and Medical Devices

Marketing Authorization Application Submission Dates for 150-days National and European Commission Decision Reliance Procedures

12 September 2023 – the MHRA published updated guidance on submission dates and how the submissions using the EC decision reliance procedure work.

The MHRA will operate a 150-day Assessment route for high-quality marketing authorization applications (MAAs).

Table of Submission Dates was updated.

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Medicines: Apply for a Parallel Import License

12 September 2023 – the MHRA published updated guidance on the application for a parallel import licence for medicines.

The UK parallel import licensing scheme lets a medicine authorized in a European Economic Area (EEA) Member State be marketed in the UK, as long as the imported product has no therapeutic difference from the cross-referenced UK product.

Updated MR-DC product list as of 7 September 2023.

Read more online

MORE Registrations and Submissions

24 August 2023 – the MHRA published updated guidance on using the MORE platform for registrations and submissions.

Updated registration guide to include definition of 'Workspace'.

MORE Registrations - User Reference Guide

Updated Submissions guidance to reflect: Update to screenshots, guidance for draft reports and auto-population of submitter fields.

MORE Submissions - User Reference Guide

Nitrosamines Impurities in Medicines

24 August 2023 – the MHRA published guidance on nitrosamines impurities in medicines.

This guidance is to help medicine manufacturers meet safe limits on levels of nitrosamine impurities in medicines.

Read more online

swissmedic 20 years 2002 - 2022

Changes to the Guidance Document: Temporary Authorization of Human Medicinal Products

15 September 2023 – the Swissmedic published revised guidance on the temporary authorization of human medicinal products.

Swissmedic considers the following to be "authorized": 1) medicinal products that have been authorized in the procedure according to Art. 11 TPA with complete documentation, and 2) medicinal products that have been converted from a temporary authorization to an authorization with special conditions (completed documentation) according to Art. 21a para. 2 TPLO.

The revised guidance document is valid as of 15 September 2023.

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SwissGMDP Database

10 September 2023 – the Swissmedic announced that Swissmedic is establishing a SwissGMDP database, similar to the EMA's EudraGMDP database.

This database will list the GMP and GDP certificates of all companies in Switzerland with a valid establishment licence issued by Swissmedic. The certificates in the SwissGMDP database will include all authorised activities, i.e., unlike EudraGMDP, the GDP activities and Switzerland-specific GMP activities of Swiss companies will also be listed in the certificates.

Read more online

Update of Federal Laws on Human Research and Data Protection in Switzerland

1 September 2023 – the Swiss Federal Council published updated federal laws on human research in Switzerland, effective 1 September 2023, a sampling of which are linked below.

812.213 Medical Devices Ordinance (MedDO)

812.219 Ordinance on In Vitro Diagnostic Medical Devices (IvDO)

810.112.2 Reproductive Medicine Ordinance (RMO)

810.30 Federal Act on Research involving Human Beings (Human Research Act, HRA)

235.1 Federal Act on Data Protection (Data Protection Act, FADP)

Guidelines on Requirements and Deadlines for Applications for Company Authorizations

23 August 2023 – the Danish Medicines Agency published the guidelines on the requirements and deadlines for applications for company authorizations.

These guidelines describe the requirements and deadlines for applications for company authorizations. The handling of medicines, euphoriant substances, cannabis bulk and cannabis intermediate products as well as the conduct of toxicological and pharmacological tests (non-clinical tests) must only take place upon authorization from the Danish Medicines Agency.

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