Procedural Advice – Extended Assessment Time for Initial Marketing Authorization Applications of 90 Days

On 25 February 2022 the EMA published the extended assessment time for initial marketing authorization applications.

For the majority of scientific evaluations of centralized marketing authorization applications, the rapporteurs and their supporting assessment teams will have in-depth scientific knowledge and experience in the relevant scientific areas. However, in order to provide the highest level of relevant expertise, it is occasionally necessary to seek expertise from outside the allocated assessment teams, which can be a time consuming process, in particular if such a request occurs ad-hoc. In order to facilitate the assessment by the CVMP in such cases, Regulation (EU) 2019/6 has introduced a provision to exceptionally extend the standard timeframe for an initial assessment procedure by a maximum of 90 days in cases where particular expertise is required.

This document outlines the criteria for such “particular expertise”, as well as the procedural steps to take into account when deciding on the use of such additional time.

Read the pdf

NMPA Guidance on Preparation of Pharmacovigilance System Master File (PSMF)

On 25 February 2022 the Center for Drug Reevaluation of Chinese NMPA published the notification on PSMF preparation guidance.

The Good Pharmacovigilance Practice (GVP) requires a drug marketing authorization holder (MAH) to create and maintain the pharmacovigilance system master file (PSMF). The PSMF is a description of the MAH's pharmacovigilance system and activities, which should be consistent with the current pharmacovigilance system and activities, and continue to meet relevant laws, regulations and practical work needs.

By creating and maintaining the PSMF, the MAH should ensure the compliance of the pharmacovigilance system, ensure that the pharmacovigilance system operates as required, be able to detect the defects and other risk information of the pharmacovigilance system in

time, and ensure the integrity of the pharmacovigilance activities, orderly development and continuous improvement of the pharmacovigilance system.

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Patient-Focused Drug Development: Methods to Identify What Is Important to Patients

On 25 February 2022 the FDA published the final guidance for Industry, FDA staff and other stakeholders.

This guidance (Guidance 2) is the second in a series of four methodological patient-focused drug development (PFDD) guidance documents that FDA is developing to describe in a stepwise manner how stakeholders (patients, researchers, medical product developers and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making.

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European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance

On 24 February 2022 the EMA published the updated guidance for scientific advice or protocol assistance procedures.

This guidance document addresses a number of questions that users of the scientific advice or protocol assistance procedures may have. It provides an overview of the procedure to obtain scientific advice or protocol assistance and gives guidance to Applicants in preparing their request. This guidance document also explains the scope and nature of scientific advice and protocol assistance. It will enable Applicants to submit requests which are in line with Scientific Advice Working Party (SAWP) requirements and which can be validated and evaluated quickly and efficiently.

Read the pdf

Updated EudraVigilance – EVWEB User Manual

On 23 February 2022 the EMA published version 1.6 of the EVWEB web reporting tool.

This user manual is part of the official documentation prepared by the European Medicines Agency (EMA) to support the use of the EudraVigilance Web reporting tool EVWEB. The user manual consists of 5 chapters:

Chapter 1 presents a comprehensive overview of the EVWEB application and should be read before the other chapters. It contains basic information regarding the structure, functions and use of EVWEB, which applies to all other sections and needs to be understood before moving on to the more advanced aspects of the system.

Chapter 2 describes the creation and transmission of Safety and Acknowledgement messages, as well as the functions available in the WEB Trader, ICSRs, Post and Workspace screens.

Chapter 3 explains the integration of MedDRA in EVWEB and how to query the system for specific MedDRA terms.

Chapter 4 provides an insight into the administration tools available in EVWEB.

Chapter 5 lists the abbreviations and acronyms, along with their descriptions, introduced in this user manual.

Read the pdf

FDA Issues Proposal to Amend Medical Device Quality System Regulations

On 23 February 2022 the FDA issued an amendment proposal for medical device regulation. Comments on the proposed rule may be submitted until 24 May 2022. Comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 are accepted until 25 March 2022.

FDA is proposing to amend the device current good manufacturing practice requirements of the Quality System (QS) regulation (21 CFR Part 820) primarily to incorporate the international consensus standard for medical device manufacturers set by the International Organization for Standardization (ISO)- ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.

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Eudralex Volume 4 – EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use

On 21 February 2022 the European Commission published Annex 21 of Eudralex Volume 4 EU guideline for GMP.

This Annex summarizes the GMP requirements applicable to a Manufacturing Import Authorization (MIA) holder, when importing medicinal products (human, investigational and veterinary) from outside the EU/EEA. The guidance in the main chapters and other annexes of the Guide to Good Manufacturing Practice for Medicinal Products ("the EU GMP Guide") also apply, as appropriate, for other GMP activities carried out and should be consulted for supplementary guidance. Medicinal products that enter the EU/EEA with the intention of export only and that are not processed in any form nor released for placing on the EU/EEA market, are not covered by this Annex.

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Updated Clinical Pharmacology and Pharmacokinetics: Questions and Answers

On 16 February 2022 the EMA published updated Q&A guidance on expectations for bootstrapping to calculate the 90% confidence interval for the f2 similarity factor.

Q&A section 3.11 describes expectations for conducting and reporting bootstrap methodology. The use of two-sided 90% confidence interval of f2 is the recommended methodology for dissolution comparison when highly variable conditions occur, since the

use of f2 could be highly influenced by the experimental dissolution data and might not represent the population (true) f2.

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WSQMS Homepage Mar 20, 2022

Updated EMA Q&A: Good Clinical Practice (GCP)

On 15 March 2022 the EMA updated the GCP Q&A guidance.

EMA has updated the following Q&A on GCP:

- IMPs in bioavailability and bioequivalence: Question 3

- GCP matters: Questions 1-3, 8, 11, 14, 15

- Records of study subject data relating to clinical trials: Question 2

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EudraVigilance – EVWEB User Manual

On 15 March 2022 the EMA updated section 5.1 of the EVWEB reporting tool user manual.

This user manual is part of the official documentation prepared by the European Medicines Agency (EMA) to support the use of the EudraVigilance Web reporting tool EVWEB.

The user manual consists of 5 chapters.

Chapter 1: presents a comprehensive overview of the EVWEB application and should be read before the other chapters. It contains basic information regarding the structure, functions and use of EVWEB, which applies to all other sections and needs to be understood before moving on to the more advanced aspects of the system.

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Read the pdf

Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products

On 15 March 2022 the FDA published draft guidance for industry.

Chimeric antigen receptor (CAR) T cell products are human gene therapy products in which the T cell specificity is genetically modified to enable recognition of a desired target antigen for therapeutic purposes. This guidance is intended to assist sponsors, including industry and academic sponsors, developing CAR T cell products. In this guidance, we, FDA, provide CAR T cell specific recommendations regarding chemistry, manufacturing, and control (CMC), pharmacology and toxicology, and clinical study design.

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Human Gene Therapy Products Incorporating Human Genome Editing

On 15 March 2022 the FDA published draft guidance for industry.

In this guidance, we, FDA, are providing recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, this guidance provides recommendations regarding information that should be provided in an Investigational New Drug (IND) application in order to assess the safety and quality of the investigational GE product, as required in Title 21 of the Code of Federal Regulations 312.23 (21 CFR 312.23). This includes information on product design, product manufacturing, product testing, preclinical safety assessment, and clinical trial design.

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Updated Guidelines on Good Pharmacovigilance Practices (GVP)

On 14 March 2022 the EMA issued an introductory cover note updating the release of Addendum III of Module XVI on pregnancy prevention programs for public consultation.

This guidance on good pharmacovigilance practices (GVP) is organized into two types of chapters, namely Modules on pharmacovigilance processes and Product- or Population-Specific Considerations.

Today, a public consultation is launched for Addendum III of Module XVI on pregnancy prevention programs and other pregnancy-specific risk minimization measures. This new guidance defines the elements of a pregnancy prevention program and provides for deciding when such program is needed or other risk minimization measures are considered appropriate to avoid adverse pregnancy outcomes due to use of medicines and to preserve health of both the mother and the child.

Read the pdf

Compliance Monitor Process (Part 1) – An Introduction

On 11 March 2022 the MHRA Inspectorate Blog published part one of a two-part series on the Compliance Monitor Process.

From April 2022, the MHRA will begin a pilot program for GMP and GDP remediation supervision by eligible consultants acting as Compliance Monitors (CM). The CM will work with the company to deliver actions identified in a Compliance Protocol (CP), that has been agreed with the MHRA. High-level updates on progress against the CP will be communicated to the MHRA at a pre-agreed frequency (provision of additional detail will be by exception against the CP requirements).

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Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions

On 11 March 2022 the FDA published the final guidance for industry.

The purpose of this document is to state that the Food and Drug Administration (FDA, we, or the Agency), at this time and based on our current understanding of the risks, does not intend to enforce certain regulatory requirements as they currently apply to certain entities and/or activities. The applicable requirements are established in our regulations entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (21 CFR Part 507); "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR Part 117); "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (21 CFR Part 1, Subpart L (FSVP)); "Mitigation Strategies to Protect Food Against Intentional Adulteration" (21 CFR Part 121); and "Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption" (21 CFR Part 112).

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Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

On 9 March 2022 the FDA published draft guidance for industry. Comments may be submitted until 9 May 2022.

This revised draft guidance applies to the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, this draft guidance covers the statutory verification system requirements that include the quarantine and investigation of a product determined to be suspect and the quarantine and disposition of a product determined to be illegitimate. It also addresses the requirement for notification to the FDA of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser after a suspect product investigation because it is determined that the product is not an illegitimate product. Finally, this draft guidance addresses the requirement for responding to requests for verification and processing saleable returns.

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Unique Identification Number (CHRN – Swiss Single Registration Number)

On 3 March 2022 the Swissmedic updated the guidance on the unique Swiss Single Registration Number for medical devices.

The Swiss Single Registration Number (CHRN) is a unique identification number that Swissmedic assigns to Swiss manufacturers, authorized representatives and importers upon request. The CHRN is used to unambiguously identify a manufacturer, authorized representative or importer.

Until the MRA (Mutual Recognition Agreement) is updated, Swissmedic is unable to assign a European Single Registration Number (SRN) via EUDAMED for economic operators who are domiciled in Switzerland. To mitigate the consequences of this loss of information and to continue to ensure market surveillance in Switzerland, it is necessary for manufacturers, authorized representatives and importers domiciled in Switzerland to register once with Swissmedic.

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Inclusion of Older Adults in Cancer Clinical Trials

On 2 March 2022 the FDA published the final guidance for industry.

This guidance provides recommendations regarding the inclusion of older adult patients in clinical trials of drugs for the treatment of cancer. For the purpose of this final guidance, older adults are those age 65 years and older. The final guidance emphasizes the particular importance of including adults over age 75 years in cancer clinical trials. Specifically, this final guidance includes recommendations for including an adequate representation of older adults in cancer clinical trials to better enable evaluation of the benefit-risk profile of cancer drugs in this population.

Read more online

Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics

On 1 March 2022 the FDA published the final guidance for industry.

The purpose of this guidance is to provide advice to sponsors regarding the design and conduct of first-in-human (FIH) clinical trials intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs. These are trial designs that employ multiple, concurrently accruing subject cohorts, where individual cohorts assess different aspects of the safety, pharmacokinetics, and antitumor activity of the drug product.

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Pre-Launch Activities Importation Requests (PLAIR)

On 1 March 2022 the FDA published the final guidance on the PLAIR for industry.

This guidance finalizes and updates the draft guidance of the same title issued on July 24, 2013. This guidance finalizes FDA's approach for overseeing requests regarding the importation of unapproved finished dosage form drug products by applicants preparing products for market launch based on anticipated approval of a pending new drug application (NDA) or an abbreviated new drug application (ANDA). This guidance also applies to biologics licensing applications (BLAs) regulated by the Center for Drug Evaluation and Research. This guidance further describes the procedures for making these requests and FDA's actions on such requests. Finalizing this policy will help increase efficiencies in ensuring timely access to drug products upon approval.

Read more online

Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics Guidance for Industry

On 1 March 2022 the FDA published the final guidance for industry.

This guidance provides recommendations to sponsors of drugs or biologics for the treatment of cancer regarding the design and conduct of clinical trials intended to simultaneously evaluate more than one investigational drug and/or more than one cancer type within the same overall trial structure (master protocols) in adult and pediatric cancers. In general, the recommended phase 2 dose (RP2D) should have been established for an investigational drug or drugs evaluated in a master protocol.

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Should you be interested in a partnership where you will add your personal or your company's technical and professional expertise, please contact any of the Partners as a starting point of a dialogue or write an e-Mail to info@wsqms.com.

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