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EMA's Response to the Covid-19 Pandemic: Putting People's Health First

10 August 2023 – the EMA published its response to the COVID-19 pandemic.

This paper focuses on various aspects in relation to EMA ́s response to the pandemic, such as EMA ́s level of preparedness to deal with public health crisis situations before the start of the pandemic, actions taken during the course of the pandemic to address changing circumstances/ unforeseen developments, as well as additional demands requiring EMA to go beyond its formal legal remit.

Read more online

Mandate, Objective and Rules of Procedure for the Non-Clinical and New Approach Methodologies European Specialized Expert Community (NC NAMs ESEC)

9 August 2023 – the EMA published guidance on the mandate, objective and rules of procedure for the European Specialized Expert Community.

The objective of the Non-Clinical and New Approach Methodologies European Specialized Expert Community (NC NAMs ESEC) is to provide a platform of information sharing and communication on the topics that are of relevance to the community and to support the delivery of the non-clinical domain workplan.

Read more online

Clinical Data Publication (CDP)

9 August 2023 – the EMA published updated Q&A guidance on CDP for medicinal products for human use (Policy 0070).

The aim of this document is to provide Applicants/MAHs with the information they need to navigate the CDP process – to identify, redact/anonymize and submit documents.

Read more online

Authorization Advice for Users of the Centralized Procedure

31 July 2023 – the EMA published updated guidance on pre- and post- authorization procedural advice for users of the centralized procedure.

Pre-authorization procedural advice

Post-authorization procedural advice

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Obtaining and Maintaining a Scientific Opinion on a Medicine for Use Outside the European Union

31 July 2023 – the EMA published updated guidance on how to obtain and maintain a scientific opinion on medicine used outside the EU.

The EMA provides guidance on obtaining and maintaining a scientific opinion under the 'EU-M4all' procedure (previously known as Article 58) on high priority human medicines intended for markets outside of the EU.

The pre-submission requirements and evaluation procedure for the EU-M4all procedure are similar to the centralized marketing authorization procedure.

Applicants may apply in parallel for an EU marketing authorization under the centralized procedure and an opinion under EU-M4all for their medicine to be used outside the EU.

Read more online

Certification Procedures for Micro-, Small- and Medium-sized Enterprises (SMEs)

31 July 2023 – the EMA published updated guidance on how to apply for the certification procedures for SMEs.

The EMA's Committee for Advanced Therapies (CAT) provides a certification procedure for advanced therapy medicinal products (ATMPs) under development by SMEs. This is an opportunity for SMEs to get an assessment of the data they have generated and check that they are on the right track for successful development.

Read more online

Obtaining an EU Marketing Authorization, Step-by-Step

31 July 2023 – the EMA published updated guidance on how to obtain an EU marketing authorization.

The EMA is responsible for the scientific evaluation of applications for centralized marketing authorizations in the EU. This authorization procedure allows pharmaceutical companies to submit a single marketing authorization application to EMA and to market the medicine and make it available to patients and healthcare professionals throughout the European Economic Area on the basis of a single marketing authorization.

Read more online

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Questions & Answers – Practical Arrangements on the Companion Diagnostics Consultation Procedure to the European Medicines Agency by Notified Bodies

31 July 2023 – the EMA published Q&A guidance on a consultation procedure for a companion diagnostic.

Please notify the Agency of the intention to submit an application for an initial consultation on companion diagnostic by sending "a letter of intent" at least three months in advance of the expected date of submission.

Please send "the letter of intent" by raising a ticket via EMA Service Desk, selecting the tab "Business Services," category "Human Regulatory." The subcategory to be selected is "Pre-Submission Phase - Human," followed by the sub-option: "Companion Diagnostics Request."

If you do not have an EMA Account, please create it via the EMA Account Management portal.

Read more online

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

25 July 2023 – the EMA published updated Q&A guidance on GMP and GDP.

The following sections were added:

- EU GMP guide part I: Basic requirements for medicinal products: Chapter 7: Outsourced activities
- Questions and answers on remote batch certification / confirmation by the qualified person (QP) - NEW July 2023
- Question and answer on residency of the qualified person (QP) - NEW July 2023

Read more online

Report of the EMA/ETF Workshop on Lessons Learned on Clinical Trials in Public Health Emergencies

25 July 2023 – the EMA published the EMA/ETF workshop report on lessons learned on clinical trials in public health emergencies.

Lessons learned from the COVID-19 and Mpox public health emergencies of international Concern have highlighted the need to improve the way Clinical Trials (CTs) are set up and conducted in the EU during crisis times to ensure that sufficient evidence is rapidly gathered from adequately sized clinical trials across multiple Member States to support rapid access to treatments and vaccines.

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Concept Paper on the Revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies

21 July 2023 – the EMA published the concept paper on the revision of the guideline on radiopharmaceuticals based on monoclonal antibodies.

The current Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies (Eudralex 3AQ21a) was last revised in May 1991. An in-depth revision is now considered necessary to update the guideline to the current state-of-the-art, addressing novel developments and regulatory requirements.

The revision of the guideline will reflect the latest developments of radiopharmaceuticals based on monoclonal antibodies and will provide recommendations regarding quality and non-clinical aspects of these products.

Read more online

ICH M7(R2) Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

19 July 2023 – the EMA published the ICH M7(R2) Scientific Guideline and Q&A as well as an Addendum outlining application principles for calculating compound-specific acceptable intakes for M7(R2).

This guideline emphasizes considerations of both safety and quality risk management in establishing levels of mutagenic impurities that are expected to pose negligible carcinogenic risk. It outlines recommendations for assessment and control of mutagenic impurities that reside or are reasonably expected to reside in final drug substance or product, taking into consideration the intended conditions of human use.

- ICH M7(R2) Scientific Guideline
- ICH M7(R2) Q&A
- ICH M7(R2) Addendum

Reflection Paper on the Use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle

19 July 2023 – the EMA published the draft reflection paper on the use of AI in the medicinal product lifecycle.

This reflection paper provides considerations on the use of AI and ML in the lifecycle of medicinal products, including medicinal products development, authorization, and post-authorization. Given the rapid development in this field, the aim of this reflection paper is to reflect on the scientific principles that are relevant for regulatory evaluation when these emerging technologies are applied to support safe and effective development and use of medicines.

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Guidance for the Transition of Clinical Trials from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR)

19 July 2023 – the European Commission (EC) published the guidance for the transition of clinical trials from the CTD to the CTR.

This Guidance reflects the agreement reached by CTAG Contact Points and supersedes the chapter 11 of the Q&A on the application of the CTR (version 6.4).

These questions and answer provide information on the type of clinical trials that sponsors have to transfer to CTIS, on the timeline and on the content of the application for mono- and multinational trials.

Clinical trials will be considered regulated by CTR when they will be authorized under the CTR by a first Member State on the basis of a transition application.

Read more online

ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation

18 July 2023 – the EMA announced the availability of the video recording for the multi-stakeholder workshop on ICH E6 R3 public consultation.

As part of the Accelerating Clinical Trials in the EU (ACT EU) multi-annual workplan 2022-2026, and acknowledging the important role of ICH E6 as the global regulator guideline for GCP, a multi-stakeholder workshop on ICH E6 R3 public consultation is being organized by ACT EU Priority Action 4 (PA4).

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

Read more online

EMA's Individual Stakeholder Database: Patients, Consumers, Healthcare Professionals and Academia

17 July 2023 – the EMA published FAQs on the EMA's individual stakeholder database.

The database's main purpose is to identify patients, consumers, healthcare professionals and academia to participate in EMA activities. In addition, those registering will receive information in their area of interest.

Read more online

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Informed Consent Guidance for IRBs, Clinical Investigators and Sponsors

15 August 2023 – the FDA published the final guidance on Informed Consent.

This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors in complying with FDA's informed consent regulations for clinical investigations. This guidance supersedes FDA's guidance entitled "A Guide to Informed Consent," issued in September 1998, and finalizes FDA's draft guidance entitled "Informed Consent Information Sheet," issued in July 2014. This document is structured to first present general guidance on FDA's regulatory requirements for informed consent and a discussion of the roles of IRBs, clinical investigators, sponsors, and FDA related to informed consent, followed by a series of frequently asked questions.

Read more online

Classification Categories for Certain Supplements Under BsUFA III

11 August 2023 – the FDA published draft guidance on classification categories for certain supplements under BsUFA III. Submit comments by 10 October 2023.

This guidance provides recommendations for applicants and FDA review staff on classification categories A, B, C, D, E, and F for original and resubmitted prior approval supplements (hereafter referred to as *PAS or supplements*) submitted to approved applications under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)).

Read more online

Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products

11 August 2023 – the FDA published draft guidance on formal meetings between the FDA and sponsors or applicants of BsUFA products. Submit comments by 10 October 2023.

This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

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Off-The-Shelf Software Use in Medical Devices

11 August 2023 – the FDA published the final guidance on off-the-shelf software use in medical devices.

This guidance document provides information regarding the recommended documentation sponsors should include in a premarket submission for FDA's evaluation of off-the-shelf (OTS) software used in a medical device. This guidance describes information that would be typically generated and documented during software development, verification, and validation.

Read more online

Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products

10 August 2023 – the FDA published draft guidance on postmarketing approaches to obtain data on underrepresented populations. Submit comments by 10 October 2023.

The purpose of this draft guidance is to describe FDA requirements and provide recommendations for obtaining safety and effectiveness information on drug and biological products, when appropriate, in the postmarketing setting in historically under-represented patient populations in clinical trials.

Read more online

FDA Works Through ICH to Support Global Drug Development: Creating Harmonized Technical Standards Through Guidelines

10 August 2023 – the FDA announced its support of global drug development by working with ICH to create harmonized technical standards guidelines.

International regulatory harmonization is increasingly important given the complex, global and diverse nature of pharmaceutical industry operations. Different regulatory authorities often have different scientific and regulatory requirements that drug developers need to meet for product approval. This can lead to duplication of effort, increased costs and time for the developer to bring the product to market, and slower patient access. To address this challenge, FDA engages with other regulatory and industry stakeholders worldwide to harmonize regulatory requirements across regions.

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QTc Information in Human Prescription Drug and Biological Product Labeling

8 August 2023 – the FDA published draft guidance on incorporating QTc interval prolongation-related information. Submit comments by 10 October 2023.

This guidance is intended to assist applicants with incorporating QTc interval prolongation-related information into the labeling of non-antiarrhythmic human prescription drug and biological products. This guidance provides recommendations to help ensure that clinically relevant information on QTc interval prolongation is included in and distributed appropriately across sections of labeling, in accordance with regulatory requirements for the content and format of human prescription drug labeling.

Read more online

Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs)

7 August 2023 – the FDA published the final guidance on recommended acceptable intake limits for NDSRIs.

This guidance provides applicants and manufacturers of drugs, including prescription and over-the-counter (OTC) drug products, with a recommended framework for predicting the mutagenic and carcinogenic potential of NDSRIs that could be present in drug products and recommends acceptable intake (AI) limits for NDSRIs.

Read more online

Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

4 August 2023 – the FDA published the final guidance on waivers, exceptions, and exemptions from the requirements of section 582 of the federal FD&C act.

This guidance describes the process an authorized trading partner or other stakeholder should use to request a waiver, exception, or exemption from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as well as the factors FDA intends to consider when evaluating such requests from an authorized trading partner or other stakeholder, and when determining FDA-initiated exceptions and exemptions.

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Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals (ARV) for the Treatment or Prevention of HIV-1 Under PEPFAR (President's Emergency Plan for AIDS Relief)

1 August 2023 – the FDA published draft guidance on fixed-combinations and single-entity versions of previously approved antiretrovirals for the treatment or prevention of HIV–1. Submit comments by 1 November 2023.

This guidance provides recommendations for applications for single-entity (SE) antiretroviral (ARV) and fixed-combination (FC) ARV drug products for the treatment or prevention of human immunodeficiency virus-1 (HIV-1 or HIV) infection that are intended for distribution outside of the United States under PEPFAR). Specifically, this guidance addresses versions of previously approved SE and FC ARV drug products and FC ARV drug products for which the individual drug product components of the combination are already FDA-approved (i.e., for which substantial evidence of safety and efficacy of the specific individual drug product components or combination already exists).

Read more online

Assessing User Fees Under the Biosimilar User Fee Amendments (BsUFA) of 2022

31 July 2023 – the FDA published the final guidance on assessing user fees under the BsUFA of 2022.

This guidance describes the types of user fees authorized by BsUFA III, how FDA determines which products are subject to a fee, and FDA's policies regarding exceptions and waivers. This guidance also describes the process for submitting payments to FDA and the consequences for failing to pay BsUFA fees, and the process for requesting reconsideration if FDA denies a request for a waiver or return of user fees.

Read more online

Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder (OUD)

28 July 2023 – the FDA published draft guidance on clinical considerations for studies of devices intended to treat OUD. Submit comments by 26 October 2023.

This draft guidance provides recommendations for the design of pivotal clinical studies for devices intended to treat OUD and used to support marketing submissions. These recommendations are applicable to the design and development of clinical studies to provide a reasonable assurance of safety and effectiveness for a device intended to treat OUD.

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CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality

26 July 2023 – the FDA published the final guidance on CDER's program for recognized voluntary consensus standards related to pharmaceutical quality.

This guidance describes a program at FDA's Center for Drug Evaluation and Research (CDER) to make public a comprehensive listing of recognized voluntary consensus standards related to pharmaceutical quality. FDA's participation in the development and use of technical voluntary consensus standards has been integral to the execution of FDA's mission. For example, FDA has used such standards to develop and/or evaluate performance characteristics of dosage forms, testing methodologies, manufacturing practices, product standards, scientific protocols, ingredient specifications, labeling of drug products, and other technical or policy criteria.

Read more online

Qualification of Medical Device Development Tools

17 July 2023 – the FDA published the final guidance on qualification of medical device development tools.

This guidance describes a voluntary program for the qualification of medical device development tools (MDDTs) for use in the evaluation of devices regulated by CDRH. Specifically, this guidance describes the framework for voluntary proposal and qualification of an MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, considerations for qualification, and the contents of a qualification package.

Read more online

MHRA

Regulating Medicines and Medical Devices

Medicines: Marketing Authorization Holders' Submission of Nitrosamine Risk Evaluation, Risk Assessment and Confirmatory Testing

9 August 2023 – the MHRA published updated guidance on the MAH's submission of nitrosamine risk management.

MAHs should work with manufacturers of API and finished products in order to review the API and finished product manufacturing processes in light of the arrangements for preventing nitrosamine formation as well as contamination or cross-contamination. This should take into account their knowledge of the manufacturing processes as well as the potential sources of nitrosamine impurities.

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July 2023 update: Clarification regarding the recent CMDh Q&A update (version 16) is provided.

Read more online

Register Medical Devices to Place on the Market

3 August 2023 – the MHRA published updated guidance on how to register medical devices to place on the market.

All medical devices, including IVDs, custom-made devices and systems or procedure packs, must be registered with the MHRA before they can be placed on the market in Great Britain (England, Wales and Scotland).

August 2023 update: Account Management Reference Guide & Device Registration Reference Guide.

Read more online

Labeling and Packaging of Medicinal Products for Human Use Following Agreement of the Windsor Framework

28 July 2023 – the MHRA published the guidance on the implementation of labelling and packaging requirements for medicinal products for human use under the Windsor Framework.

This guidance is designed to provide information on the implementation of labelling and packaging requirements for medicinal products for human use under the Windsor Framework.

The Windsor Framework sets out the long-term arrangements for the supply of medicines into Northern Ireland. It will ensure that medicines can be approved and licensed on a UK-wide basis by the Medicines and Healthcare products Regulatory Agency (MHRA) and provides for the disapplication of European Union (EU) Falsified Medicines Directive (FMD) requirements for medicines marketed and supplied in Northern Ireland.

To preclude onward movement of these medicines into any part of the European Union (EU), while ensuring medicines use the same packaging and labelling across the UK, all medicines on the UK market must be labelled as 'UK Only.'

These measures will begin 1 January 2025.

Read more online

Renewing Marketing Authorizations for Medicines

28 July 2023 – the MHRA published updated guidance on how to renew marketing authorizations for products granted through different routes and at different times.

All holders of existing marketing authorizations (MAs), or applicants for Mas with applications submitted by 1 January 2021 and under review within a decentralized or mutual recognition procedure with UK as a CMS will have a choice on how to manage their marketing authorizations/applications.

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July 2023 update: guidance on renewal applications to reflect changes to the submission requirements for products within the mutual recognition/decentralized procedures (MR/DCP).

Read more online

Implementation of the Future Regulations

27 July 2023 – the MHRA published the updated guidance on implementation of future regulations for medical devices in the UK.

The government intends to introduce regulations in future that will implement a substantial reform of the current regulatory framework for medical devices in the UK.

This guidance has been updated to reflect that the government is now aiming for core aspects of the future regime for medical devices to apply from 1 July 2025.

In addition, the World Trade Organisation (WTO) published notification of the draft Post-market Surveillance Requirements Statutory Instrument (PMS SI) on 26 July 2023. WTO members have 60 days to submit comments to the Department of International Trade.

Read more online

Guidance on the Regulation of In Vitro Diagnostic Medical Devices in Great Britain

17 July 2023 – the MHRA published updated guidance on legislation in relation to in vitro diagnostic medical devices.

This document outlines the current controls on the sale and supply of in vitro diagnostic (IVD) medical devices and explains the main features of Part IV of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

This guidance is specific to in vitro diagnostic devices placed on the market in Great Britain (England, Wales and Scotland) only.

Read more online

Swissmedic Gains Accreditation for GMP/GDP Inspections in the Field of ATMPs

9 August 2023 – the Swissmedic announced that Swissmedic gains accreditation for GMP/GDP inspections in the field of ATMPs.

Swissmedic carries out inspections to verify compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). These quality standards are important guidelines in ensuring the quality of medicinal products. Inspection bodies that carry out these inspections in Switzerland must hold the legally prescribed ISO 17020 accreditation.

In particular, this accreditation confirms the existence of a functioning quality management system and the expertise of the inspectors.

Read more online

Mutual Recognition Agreement between Switzerland and the USA on the Manufacturing Practice for Medicinal Products Takes Effect

27 July 2023 – the Swissmedic published the MRA in principle of inspections by Swissmedic and the FDA.

The Mutual Recognition Agreement (MRA) between Switzerland and the United States in the area of Good Manufacturing Practice (GMP) for medicinal products signed in January has entered into force with effect from 27 July 2023. In principle each country thus accepts the inspections carried out by the other's regulatory authority (Swissmedic or FDA, as the case may be).

Read more online

Active Medical Devices

9 August 2023 – the Australian Therapeutic Goods Administration (TGA) published updated guidance on active medical devices.

Active medical devices are a subset of devices that use energy to operate. This document includes guidance on the requirements that specifically apply to these devices.

Read more online

Regulation of Software Based Medical Devices

8 August 2023 – the Australian TGA published the updated guidance on regulation of software based medical devices.

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets requirements, and thus indicate how manufacturers and sponsors can comply.

These documents are currently in draft, and updates and clarifications will be included as required. Feedback on the guidance is always welcome, please send any comments to digital.devices@tga.gov.au.

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Pharmacovigilance Obligations of Medicine Sponsors – Frequently Asked Questions

1 August 2023 – the Australian TGA published updated guidance and FAQs on the pharmacovigilance obligations and responsibilities of medicine sponsors.

This guidance sets out the pharmacovigilance responsibilities of sponsors of medicines included on the Australian Register of Therapeutic Goods (ARTG) and regulated by the TGA. It outlines the mandatory reporting requirements and offers recommendations on pharmacovigilance best practice.

PV Responsibilities of Medicine Sponsors

PV Obligation FAQs of Medicine Sponsors

Points to Consider for Informed Consent Using Electromagnetic Means in Clinical Trials and Post-marketing Clinical Trials

4 August 2023 – the Japanese PMDA published guidance on obtaining informed consent using electromagnetic means prior to conducting clinical trails.

In consideration of the recent progress of information and communication technology and subsequent decentralization and improved efficiency of clinical trials by utilizing this technology, we provide the points to consider for conducting informed consent procedures using documents displayed and presented by electromagnetic means, video calls, etc. in the Annex. Please fully inform these points to the related business operators under your administration, medical institutions, etc.

Read more online

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