


## Procedural Advice for Post-Orphan Medicinal Product Designation Activities

On 30 September 2022 the EMA published revision 13 on guidance for post-orphan designated products 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 authorization application

6.1 Review of the maintenance of orphan medicinal product designation at the time of marketing authorization application

6.2 Review of the maintenance of orphan medicinal product designation at the time of extending the therapeutic indication post-authorization

7. Removal of orphan designation

8. Review of the period of market exclusivity of orphan medicinal products.

Read the pdf

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## Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions

On 28 September 2022 the FDA published final guidance for industry and FDA staff.

This guidance document provides FDA's recommendations on clinical performance assessments to support premarket notification (510(k)) submissions for computer-assisted detection (CADe) devices applied to radiology images and radiology device data. This guidance applies to CADe devices, including when a CADe device is part of a combined system, such as the detection portion of combined computer-aided detection and diagnostic devices. The recommendations are intended to promote consistency and facilitate efficient review of clinical performance assessments in CADe 510(k) submissions.

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## Clinical Decision Support Software

**On 28 September 2022 the FDA published the final guidance on the scope of oversight of clinical decision support software.**

This final guidance clarifies FDA's thinking expressed in the September 2019 Draft Guidance and focuses on clarifying the types of clinical decision support (CDS) software functions that are excluded from the definition of device by the criteria in section 520(o)(1)(E) of the FD&C Act ("Non-Device CDS criteria"). The final guidance further clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a device, including those that are intended for use by patients or caregivers.

Read more online

## Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions

**On 28 September 2022 the FDA published the final guidance on premarket notification submissions for computer-assisted detection devices for industry and FDA staff.**

This guidance document provides FDA's recommendations regarding premarket notification (510(k)) submissions for computer-assisted detection (CADe) devices applied to radiology images and radiology device data. This guidance applies to CADe devices, including those marketed as a complete package with a review workstation, or as an add-on software embedded within imaging equipment, as an image review platform, or other imaging accessory equipment. The recommendations are intended to promote consistency and facilitate efficient review of 510(k) submissions for CADe devices.

Read more online

## Display Devices for Diagnostic Radiology

**On 28 September 2022 the FDA published the final guidance on premarket notification submissions for display devices for industry and FDA staff.**

This guidance document provides FDA's recommendations regarding premarket notification (510(k)) submissions for display devices intended for use in diagnostic radiology. This guidance applies to display devices intended for diagnostic radiology as identified by their classification regulation (21 CFR 892.2050) and product codes. This includes display devices for diagnostic radiology that may be referred to as soft-copy display or medical grade

monitors. The recommendations are intended to promote consistency and facilitate efficient review of display devices.

Read more online

## Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

**On 28 September 2022 the FDA published the final guidance on regulatory oversight to certain medical devices for industry and FDA staff.**

FDA is issuing this guidance to communicate how the Agency intends to apply its regulatory oversight to medical device data systems (MDDS), medical image storage devices, and medical image communication devices.

Read more online

## Policy for Device Software Functions and Mobile Medical Applications

**On 28 September 2022 the FDA published the final guidance on the regulatory oversight to certain software for industry and FDA staff.**

FDA is issuing this guidance to communicate how the Agency intends to apply its regulatory oversight to certain software, including device software functions and mobile medical applications (MMAs) intended for use on mobile platforms or on general-purpose computing platforms.

Read more online

## Checking Process of Mock-Ups and Specimens of Outer/Immediate Labeling and Package Leaflets of Human Medicinal Products in the Centralized Procedure

**On 28 September 2022 the EMA published the guidance on checking process of mock-ups and specimens.**

Since February 2007 the EMA has been operating an extensive checking process of the marketing-authorization holder's (MAH) printed packaging materials for outer and immediate labelling of centrally authorized medicinal products as well as of the printed package leaflet ('mock-ups and specimens'). This document presents the proposed revision1 of the current checking process for human medicinal products and provides further details on its practical implementation.

Read the pdf

## Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

**On 27 September 2022 the FDA published updated guidance for developers and FDA staff.**

The policies in this guidance are intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act). FDA continues to assess the evolving situation and intends to update this guidance as appropriate.

Read more online

## Providing Over-the-Counter Monograph Submissions in Electronic Format

**On 27 September 2022 the FDA published the draft guidance. Submit comments by 28 November 2022.**

This guidance provides information on providing electronic submissions to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance is intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format.

Read more online

## Good Clinical Practice for Clinical Trials

**On 27 September 2022 the MHRA published the updated guidance on GCP for clinical trials.**

This document provides guidance on how to show MHRA you're meeting good clinical practice (GCP) standards and what to expect from an inspection. The CAPA guidance PDF was also updated.

Read more online

## Update - EudraLex - Volume 10 - Clinical trials guidelines - Questions and Answers Document - Regulation (EU) 536/2014 – Version 6.2 (September 2022)

**On 26 September 2022 the European Commission published the updated Q&A document on clinical trials regulation EU 536/2014, version 6.2.**

The aim of this document is to provide general guidance on the implementation of the CTR. This document sets out frequently-asked 'questions and answers' regarding the implementation of the rules on clinical trials. All updates to this questions and answers document are presented and discussed within the “Expert group on clinical trials” and reflects the view of the group. This group is chaired by the Commission and is composed of representatives of all EU Member States and EEA contracting parties.

Read more online

## Ethical Considerations for Clinical Investigations of Medical Products Involving Children

**On 26 September 2022 the FDA published the draft guidance for industry, sponsors and IRBs.**

Clinical investigations in children are essential for obtaining data on the safety and effectiveness of drugs, biological products, and medical devices in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective. Children are a vulnerable population who cannot consent for themselves and who therefore are afforded additional safeguards when participating in a clinical investigation. Such safeguards are an essential requirement for the initiation and conduct of pediatric investigations as part of a medical product development program. This guidance describes the FDA's current thinking regarding ethical considerations for clinical investigations of medical products in children.

Read more online

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## FAQs: How to Create, Submit and Withdraw a Clinical Trial Application — CTIS Training Program - Module 10

**On 23 September 2022 the EMA published version 1.3 of the updated FAQs guidance on how to create, submit and withdraw a clinical trial application.**

This FAQs provide answers to questions regarding the creation and submission of Initial CTAs, the creation and submission of Substantial modifications CTAs, the creation and submission of Additional MSC CTAs and non-substantial modifications.

Read the pdf

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## IRIS Guide for Applicants

**On 23 September 2022 the EMA published version 2.12 of the IRIS guide on how to create and submit scientific applications, for industry and individual applicants.**

This guide has been produced to show applicants how to use the IRIS platform to prepare and submit an application and/or data for a scientific procedure (orphan designation application, scientific advice, ITF briefing meeting requests, marketing status reports, inspections and veterinary signal management) and related activities.

Read the pdf

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## Electronic Submission Template for Medical Device 510(k) Submissions

**On 22 September 2022 the FDA published the final guidance for industry and FDA staff.**

This guidance provides the further standards for the submission of premarket notification (510(k)) submissions by electronic format, a timetable for establishment of these standards, and criteria for waivers of and exemptions from the requirements to meet a statutory requirement.

Read more online

## How to Obtain a Covered Product Authorization

**On 21 September 2022 the FDA published the draft guidance for industry. Submit comments by 21 November 2022.**

This guidance describes how eligible product developers can obtain a Covered Product Authorization (CPA) from FDA under the law widely known as the CREATES Act (referred to herein as CREATES or the CREATES Act). The CREATES Act provides a pathway for eligible product developers to obtain access to the product samples they need to fulfill testing and other regulatory requirements to support their applications.

Read more online

## Notify the MHRA about a Clinical Investigation for a Medical Device

**On 21 September 2022 the MHRA published the updated guidance on notification of clinical investigation for medical devices.**

This document provides guidance on how to notify the MHRA of the intention to carry out a clinical investigation for medical devices. The section 'Quarterly Summary Reports' was newly added.

Read more online

## The Northern Ireland MHRA Authorized Route (NIMAR)

**On 20 September 2022 the MHRA published the updated NIMAR guidance.**

This document provides guidance for key stakeholders in the medicines supply chain to facilitate their use of the NIMAR regulatory route for the continued supply of GB licensed medicines to NI. The section on 'Advertising and promotions' to NIMAR guidance was newly added.

Read more online

## Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Oligonucleotides

**On 16 September 2022 the EMA published the draft guidance for consultation from 20 September 2022 to 20 December 2022.**

This concept paper addresses the need to establish a Guideline on the Development and Manufacture of Synthetic Oligonucleotides. The number of clinical trial applications for human products and marketing authorization applications for synthetic oligonucleotides for both human and veterinary products has significantly increased over the last few years.

Read the pdf

## Questions and Answers on Labeling Flexibilities for COVID-19 Vaccines

**On 16 September 2022 the EMA published the Q&A guidance on labeling flexibilities for COVID-19 vaccines.**

The EMA together with the Member States, in the context of the Quality Review of Documents (QRD) group, have developed this Questions and Answers (Q&A) document with the aim to provide operational guidance on labelling flexibilities for COVID-19 vaccines.

Read the pdf

### Interested in a Partnership with Widler & Schiemann AG?

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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WSQMS Homepage Oct 20, 2022

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

**14 October 2022 — EMA published rev. 14 guidance for applicants seeking scientific advice and protocol assistance.**

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.

Read the pdf

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## Digital Application Dataset Integration (DADI) eAF Training Webinars (26 July 2022 & 2 September 2022)

**12 October 2022 — EMA published the Q&A guidance on the recent DADI eAF webinars**

The Digital Application Dataset Integration (DADI) Network project will replace PDF electronic application forms (eAF) used for regulatory submissions with web-forms in a new dedicated portal, making the future form-filling and submission-handling process more efficient.

Read the pdf

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## EMA IRIS Industry Training for GVP Inspections: Questions & Answers

**11 October 2022 — EMA published the Q&A guidance on IRIS industry training for GVP inspections.**

Following the go-live of IRIS for Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections, EMA is adding GVP Inspections to the IRIS platform with an expected go-live in Q3 2022. This training details the GVP Inspections business process using IRIS, highlighting changes and answering questions from industry users.

Read the pdf

## EMA Account Management Training Session Presentation

**11 October 2022 — EMA published the presentation shown at the account management training session.**

EMA's Account Management portal is the gateway to using EMA applications such as IRIS, electronic application forms (eAF), EudraVigilance, the Clinical Trials Information System and Union Product Database. The following issues were addressed:

- Possible roles are unclear to potential users
- Mandatory documents required as part of the registration process are unclear
- High waiting times and rejections
- Multiple log-ins required

Read the pdf

## IRIS Guide for Applicants

**10 October 2022 — EMA published version 2.13 of the IRIS guide for applicants.**

This guide has been produced to show applicants how to use the IRIS platform to prepare and submit an application and/or data for a scientific procedure and related activities. Section 4. Scientific Advice was updated.

Read the pdf

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

**10 October 2022 — EMA published updated Q&A guidance on GCP.**

Section B. GCP matters: Question 16 was added: Is the monitoring of bioequivalence clinical trials mandatory?

Read more online

## Data Quality Framework for EU Medicines Regulation

**10 October 2022 — EMA published the draft data quality framework for the public consultation until 18 November 2022.**

This document is the first release of the EU data quality framework for medicines regulation and addresses high level principles and procedures that apply across the European Medicines Regulatory Network (EMRN)'s regulatory activities. This framework provides general considerations on data quality that are relevant for regulatory decision making, definitions for data dimensions and sub-dimensions, as well as their characterization and related metrics. It provides an analysis of what data quality actions and metrics can be put in place in different scenarios and introduces a maturity model to drive the evolution of automation to support data-driven regulatory decision making.

Read the pdf

## ICH Guideline S1B(R1) on Testing for Carcinogenicity of Pharmaceuticals

10 October 2022 — EMA published the ICH guideline S1B1(R1) – Step 5.

This document provides guidance on approaches for evaluating the carcinogenic potential of pharmaceuticals.

Read the pdf

## Reflection Paper on the Use of Interactive Response Technologies (Interactive Voice/Web Response Systems) in Clinical Trials, with Particular Emphasis on the Handling of Expiry Dates

5 October 2022 — EMA published the updated reflection paper on the use of IRT.

This paper seeks to provide guidance on what national competent authorities (NCAs) expect from such systems and in particular their use for handling of the expiry date of the Investigational Medicinal Product (IMP). These positions will form suggestions for sponsors and IRT providers on the validation requirements for systems. Specific computer system validation is not discussed in detail since this is the subject to a large number of other publications. This paper is aimed at sponsors and providers of such systems.

Read the pdf

## FAQs: How to Evaluate a CTA – CTIS Training Program Module 06

5 October 2022 — EMA published version 1.4 FAQs on how to evaluate a CTA.

This FAQ guidance provides:

- Answers to questions regarding the different types of Clinical Trials Applications (CTAs) according to the CT Regulation.
- Answers to questions regarding the different phases in the evaluation of an application and how to monitor the progress.
- Answers to questions related to the first steps in the evaluation of an initial CTA (RMS selection and validation).

Read the pdf

## Presentation – Clinical Trials Information System (CTIS) Bitesize Talk (Notifications - Part 1)

3 October 2022 — EMA published part 1 of the recent CTIS bitesize talk presentation.

This bitesize talk was presented by CTIS and provides an opportunity for sponsors to learn about the notifications related to trial and recruitment periods, e.g. start, end, restart, halt of trial, etc.

Read the pdf

## IRIS Guide for Parallel Distribution Applicants

**3 October 2022 — EMA published the updated IRIS guide for parallel distribution applicants.**

This guide has been produced to help individuals using the IRIS | Regulatory & Scientific Information Management platform understand how to use the portal to submit a notification for parallel distribution.

This document is intended for Industry users who have already been granted Industry user access roles for the IRIS portal.

Read the pdf

## ANDA Submissions – Prior Approval Supplements Under GDUFA

**14 October 2022 — FDA published final guidance on ADNA submissions for industry.**

This guidance is intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)).

Read more online

## Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA

**13 October 2022 — FDA published final guidance on comparability protocols for postapproval CMC changes.**

This final guidance is intended to assist original applicants and holders of approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) with implementing a chemistry, manufacturing, and controls (CMC) postapproval change through the use of a comparability protocol (CP).

Read more online

## Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order

**7 October 2022 — FDA published the final PAS guidance for industry and FDA staff.**

A PAS is usually a clinical or non-clinical study, as specified in the PMA approval order, and is typically intended to gather specific data to address questions about the post market performance of or experience with an approved medical device. The purpose of this guidance document is to assist stakeholders with understanding postapproval study (PAS) requirements imposed as a condition of PMA approval.

Read more online

## Post Market Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act

**6 October 2022 — FDA published the final post market surveillance guidance for industry and FDA staff.**

The purpose of this guidance document is to assist manufacturers of devices subject to section 522 post market surveillance orders (522 orders) by providing information on how to fulfill section 522 obligations.

Read more online

## Competitive Generic Therapies

**5 October 2022 — FDA published final guidance on competitive generic therapies for industry.**

This guidance provides a description of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. It also includes information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGTs. Finally, it provides information on how FDA implements the statutory provision for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs.

Read more online

## Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA

**5 October 2022 — FDA published final guidance on formal meetings between FDA and ANDA applicants of complex products under generic drug user fee amendments (GDUFA) for industry.**

This guidance describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit to FDA or an applicant that has submitted to FDA an abbreviated new drug application (ANDA) for a complex product, as defined in this guidance. Specifically, this guidance provides information on requesting and conducting product development meetings, pre-submission meetings, mid-cycle review meetings, enhanced mid-cycle review meetings, and post-complete response letter scientific meetings with FDA.

Read more online

## Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA

**5 October 2022 — FDA published the final guidance on formal meetings between FDA and ANDA applicants for industry.**

This guidance provides recommendations to industry on post-complete response letter (CRL) teleconferences (post-CRL clarification teleconferences) between FDA and abbreviated new drug application (ANDA) applicants for the purpose of clarifying deficiencies identified in a CRL to an ANDA submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). This guidance is intended to provide procedures that will promote well-managed post-CRL clarification teleconferences and help ensure that such meetings are scheduled and conducted in accordance with the time frames set forth in the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter).

Read more online

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## Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments (GDUFA)

**5 October 2022 — FDA published final guidance on IRs and discipline review letters under GDUFA.**

This guidance explains how FDA will issue and use an information request (IR) and/or a discipline review letter (DRL) during the assessment of an original abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)), as contemplated in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter).

Read more online

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## User Fees and Refunds for Premarket Approval Applications (PMAs) and Device Biologics License Applications (BLAs)

**5 October 2022 — FDA published the final guidance on user fees and refunds for PMAs and device BLAs for industry and FDA staff.**

The purpose of this guidance document is to identify: (1) the types of PMAs and BLAs subject to device user fees; (2) exceptions to user fees; and (3) the actions that may result in refunds of user fees that have been paid.

Read more online

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## Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules

**3 October 2022 — FDA published final guidance on physical attributes of generic tablets and capsules for industry.**

Tablets and capsules are widely manufactured and prescribed and may provide a number of advantages over other dosage forms, including ease of storage, portability, ease of administration, and accuracy in dosing. The recommendations in this guidance apply to abbreviated new drug applications (ANDAs) and their supplements for additional strengths that are submitted to the Office of Generic Drugs (OGD).

Read more online

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## Facility Readiness: Goal Date Decisions Under GDUFA

**3 October 2022 — FDA published industry draft guidance on facility readiness for inspection under GDUFA. Submit comments by 6 December 2022.**

This guidance provides information to applicants on how FDA intends to assign a goal date based on a facility's readiness for inspection as certified on Form FDA 356h, submitted as part of an original abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). This guidance explains how FDA incorporates a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to reauthorization of the Generic Drug User Fee Amendments (GDUFA).

Read more online

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## Review of Drug Master Files (DMF) in Advance of Certain ANDA Submissions Under GDUFA

**3 October 2022 — FDA published the draft guidance on Type II API DMFs under GDUFA for industry.**

This guidance is intended for holders of Type II active pharmaceutical ingredient (API) drug master files (DMFs) that will be referenced in an abbreviated new drug application (ANDA), or a prior approval supplement (PAS) to an ANDA.

Read more online

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## FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals

**3 October 2022 — FDA published the final PMA guidance on effect on FDA review clock and goals under MDUFA for industry and FDA staff.**

The Medical Device User Fee Amendments of 2022 (MDUFA V) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2022, including premarket approval applications (PMAs). The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the device review process to meet certain performance goals and implement improvements for the medical device review process.

Read more online

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## MORE Registrations - User Reference Guide

**14 October 2022 — MHRA published the MORE registration user guide.**

This user guide provides a step-by-step guide on using the MORE Platform for Registrations for Submissions of device related incidents.

Read more online

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## Medicines: Apply for a Parallel Import License

13 October 2022 — MHRA published the guidance on how to get a parallel import license.

The UK parallel import licensing scheme lets a medicine authorized in an EEA Member State be marketed in the UK, as long as the imported product has no therapeutic difference from the cross-referenced UK product. MR-DC product list updated on 7 October 2022.

Read more online

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## Apply for Manufacturer or Wholesaler of Medicines Licenses

On 13 October 2022 — MHRA published guidance on how to apply for manufacturer and wholesale of medicines licenses.

This guidance provides information on how to apply for, update and cancel licenses for the manufacture, import and wholesale of human and veterinary medicines. New information posted under “Change of Ownership”.

Read more online

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## Exporting Active Substances Manufactured in Great Britain for Use in EEA and Northern Ireland

11 October 2022 — MHRA published guidance on how the ‘Written Confirmation’ process operates for active substances manufactured in Great Britain.

This guidance explains how to obtain a Written Confirmation for each shipment of Active Substances manufactured in Great Britain (England, Wales and Scotland) that is exported to the EEA or Northern Ireland. Updated Register of Written Confirmations for UK active substance manufacturers.

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## Export Drugs and Medicines: Special Rules

5 October 2022 — MHRA published guidance on how to get permission to export certain drugs and medicines.

You need permission to export certain drugs and medicines.

- controlled drugs like opioids, certain stimulants or psychotropic substances
- certain drugs that can be used in lethal injections outside the EU
- medicines for humans or animals

The certificates of certain application forms and guidance notes were updated.

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## ICH Q5A(R2) Draft Guideline Reaches Step 2

11 October 2022 — ICH announced the ICH Q5A(R2) draft guideline reached Step 2 of the ICH process.

The ICH Q5A(R2) draft Guideline on Viral Safety Evaluation of Biotechnology Products reached Step 2 of the ICH process on 29 September 2022. The R2 revision retains key principles of the original Guideline and provides additional recommendations on the established and complementary approaches to control the potential viral contamination of biotechnology products. A Step 2 Informational Presentation has been developed by the Q5A(R2) EWG to summarize the content of the draft Guideline.

Read more online

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## ICH E19 Guideline Reaches Step 4

4 October 2022 — ICH announced that the ICH E19 guideline reached Step 4 of the ICH process.

The ICH E19 Guideline on A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials reached Step 4 of the ICH Process on 27 September 2022.

This Guideline is intended to provide internationally harmonized guidance on the use of selective safety data collection - by tailoring the method of safety data collection, it may be possible to carry out clinical trials with greater efficiency by streamlining the approach to data collection. This may facilitate the conduct of large-scale efficacy and safety clinical trials with large numbers of participants and long-term follow-up.

Read more online

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## Swissmedic Inspects Swiss Authorized Representatives (CH-REP)

3 October 2022 — Swissmedic published the report of Swiss authorized representatives (CH-REP) inspections in the first half of 2022 to check implementation of the provisions in the market.

Swissmedic carried out systematic, focused inspections of Swiss authorized representatives (CH-REP) in the first half of 2022 to check their implementation of the provisions in the market.

In most cases, the authorized representatives demonstrated a good understanding of the new regulations and satisfactory implementation of the legal requirements.

No deviations were found for six of the 20 authorized representatives inspected. The non-conformities found for 14 authorized representatives included:

- the scope and content of the contracts with the foreign manufacturers, and
- the responsibility for reporting serious incidents to Swissmedic.

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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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