
WSQMS Homepage Jun 2, 2022

## Updated Frequently Asked Questions about Parallel Distribution

On 31 May 2022 the EMA published updated FAQs about parallel distribution.

The updated questions include the following questions:

- 1.16. Does the 'specific mechanism' apply to parallel distribution? Rev. May 2022
- 2.9 What are some examples of grounds for invalidation, negative outcome and common mistakes often made?
- 3.20. Do parallel distributors have to adhere to particular packaging design or/and colour code when repackaging the products? NEW May 2022

Read the pdf

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## Questions and Answers Document – Regulation (EU) 536/2014

On 30 May 2022 the European Commission published Q&A guidance on the Clinical Trials Regulation, version 6.1.

The aim of this document is to provide general guidance on the implementation of the CTR, and should be read in combination with the CTIS online training modules.

Read more online

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## Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues

On 27 May 2022 the FDA published the final guidance for industry.

This guidance describes the FDA's current recommendations regarding the overall development program to establish the effectiveness and safety of gonadotropin-releasing hormone (GnRH) analogues for treating advanced prostate cancer.

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## New Regulations Applicable to In Vitro Diagnostic Medical Devices

**On 26 May 2022 the Swissmedic announced the entry into force of the new regulations on in vitro diagnostic medical devices.**

On 4 May 2022, the Federal Council adopted the new Ordinance on In vitro Diagnostic Medical Devices (IvDO) and the amendment to the Ordinance on Clinical Trials with Medical Devices (CTO-MedD). The aim of the new regulations is to improve patient safety by means of stricter requirements for conformity assessment and post-market surveillance. The new legal requirements enter into force on 26 May 2022, at the same time as the application of the IVDR in the EU. From 26 May 2022, clinical trials with in vitro diagnostic medical devices will be regulated in the Ordinance on Clinical Trials with Medical Devices (CTO-MedD) and no longer in the Ordinance on Clinical Trials (ClinO).

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## Importation of Prescription Drugs Final Rule Questions and Answers; Small Entity Compliance Guide

**On 25 May 2022 the FDA published the final Q&A guidance for industry.**

This guidance is intended to help small entities better understand the final rule, "Importation of Prescription Drugs," published October 1, 2020 (85 FR 62094). The Secretary of Health and Human Services issued the final rule to implement section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs from Canada. The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety.

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## Antibacterial Therapies for Patients with an Unmet Medical Need for the Treatment of Serious Bacterial Diseases – Questions and Answers (Revision 1)

**On 25 May 2022 the FDA published the draft Q&A guidance, revision 1. Comments may be submitted until 24 July 2022.**

The purpose of this draft guidance is to assist sponsors in the clinical development of new antibacterial drugs and provide updates based on the availability of new therapeutic options for development programs.

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## Q&A on the Interface between Regulation (EU) 536/2014 on Clinical Trials for Medicinal Products for Human Use (CTR) and Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices (IVDR)

**On 25 May 2022 the European Commission published Q&A guidance on the interface between the EU CTR and IVDR.**

This Q&A intends to clarify certain interfaces between the Regulation (EU) No 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). It was developed by clinical trials experts from Clinical Trials Facilitation and Coordination Group (CTFG) and in vitro diagnostics experts from the IVD sub-group of the Medical Device Coordination Group (MDCG).

This Q&A specifically addresses the use of assays in the framework of clinical trials conducted under the CTR, in line with requirements of the IVDR and should not be understood to apply beyond it.

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## Supervise a Clinical Trial: Inspection Records – CTIS Training Programme – Module 16

**On 25 May 2022 the EMA published FAQs on clinical trial inspection records.**

This document provides answers to common questions regarding general information of inspection records, the creation and submission of an inspection record, the upload of inspection outcomes and reports, the search, update, and cancel of inspection records, and questions regarding the roles and permissions.

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## Clinical Trials Highlights – May 2022

**On 25 May 2022 the EMA published Clinical Trials Highlights - Issue 9.**

As of 30 April 2022, 56 clinical trial applications were submitted for evaluation by Member States via CTIS. In addition, four clinical trials have been authorised and are viewable by patients, healthcare professionals and the general public through the CTIS public search. The public availability of an unprecedented amount of data on individual trials through CTIS empowers patients to find recruiting trials in their country ensures the highest levels of transparency for clinical trials in Europe.

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## Guideline on the Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections

**On 24 May 2022 the EMA published the revised guideline on the evaluation of human medicines for the treatment of bacterial infections, revision 3.**

This guideline merges, revises and adds to the guidance previously included in the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 Rev 2) and the Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (EMA/CHMP/351889/2013).

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## Addendum to the Guideline on the Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections to Address Paediatric-specific Clinical Data Requirements

**On 24 May 2022 the EMA published the addendum to the guideline on evaluation of medicinal products indicated for treatment of bacterial infections.**

This addendum to the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 rev 3) has been developed to provide guidance on clinical development programmes that are required to support the authorisation of antibacterial agents for treatment of infectious diseases in paediatric patients.

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## Medicines Shortages: Regulatory Processes to Manage Supply Disruptions

**On 23 May 2022 the UK MHRA published the guidance on regulatory processes to manage supply disruptions.**

New applications for Marketing Authorisations and product variations can be fast tracked if there is compelling evidence of benefit in a public health emergency or if there is a shortage of supply of an essential medicine that has been verified by the Department of Health and Social Care.

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## Risk Management Plans to Mitigate the Potential for Drug Shortages

**On 20 May 2022 the FDA published the draft guidance on risk management plans for drug shortages. Comments may be submitted until 19 July 2022.**

This guidance is intended to help stakeholders develop, maintain, and implement risk management plans (RMPs) to proactively assist in the prevention of human drug product and biological product shortages. RMPs can provide stakeholders with a framework to proactively identify, prioritize, and implement strategies to mitigate hazards that can cause a supply disruption. Such a supply disruption may lead to a drug shortage. Effective quality risk management can facilitate better, more informed decisions; can provide FDA with greater assurance that stakeholders understand and can manage the associated risks; and can potentially affect the extent and level of direct regulatory oversight.

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## Annual Report of the Good Clinical Practice Inspectors' Working Group 2020

**On 20 May 2022 the EMA published the annual report of the GCP IWG, which was adopted by the GCP IWG on 30 April 2022.**

This Annual Report is set out in line with the format and objectives of the 2020 GCP IWG Work Plan. However, due to the COVID-19 pandemic and imposed restrictions as well as the business continuity plans of the Agency and the Member States, the majority of activities under training and development outlined in the Work Plan for 2020, had to be postponed.

A total of 363 deficiencies, comprising 16 critical (4.4%), 200 major (55.1%) and 147 minor (40.5%) findings were recorded for the 34 CHMP requested inspections conducted in 2020. The main findings cover the following categories: Sponsor Trial Management; General; IMPs; Investigational Site; Computer System; Laboratory/Technical Facilities; Subject Protection; Informed Consent and IEC/IRB.

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

**On 19 May 2022 the UK MHRA updated the guidance on notifying the MHRA of the intention to conduct a clinical investigation for medical devices.**

A notification to the MHRA will not be required for medical devices that are UKCA / CE / CE UKNI marked for the purpose that is under investigation. If possible, please provide the MHRA with advanced notice of the intention to submit a clinical investigation by emailing info@mhra.gov.uk with some basic details about the investigational device, the intended population, the type of study, and estimated application date.

This guidance includes an updated Excel template, (MHRA Protocol Deviation Tracker) to use for tracking Study Deviations.

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## Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

**On 18 May 2022 the FDA published the final guidance on safety considerations for labeling.**

The purpose of this guidance is to help human prescription drug and biological product sponsors, application holders, and applicants minimize medication errors associated with their products. This guidance focuses on safety aspects of the application holder's container label and carton labeling design. It provides a set of principles and recommendations for ensuring that critical elements of a product's container label and carton labeling are designed to promote safe dispensing, administration, and use of the product.

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## Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production

**On 16 May 2022 the FDA published Final Level 2 revised guidance.**

This guidance for industry provides the Agency's current thinking on how to evaluate out-of-specification (OOS) test results. For purposes of this document, the term OOS results includes all test results that fall outside the specifications or acceptance criteria established

in drug applications, drug master files (DMFs), official compendia, or by the manufacturer. The term also applies to all in-process laboratory tests that are outside of established specifications.

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## IRIS Guide for Applicants

**On 16 May 2022 the EMA published IRIS guide on how to create and submit scientific applications, for industry and individual applicants, version 2.10.**

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.

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### 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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