# WSQMS Newsletter June 2023

## Regulatory Agency Updates

WS QMS



### Procedural Advice on Publication of Information on Withdrawals of Applications for Marketing Authorization and Variations/Extensions to Marketing Authorizations

27 June 2023 – the EMA published revision 2 of the guidance on publication of information on withdrawals of marketing authorization applications et al.

This paper describes the publication of information on the withdrawals of marketing authorization applications for human medicinal products and withdrawals of applications for variations/extensions to marketing authorization. This paper should be read in conjunction with EMA's general guide to information published on human medicines.

Read more online

### Guideline on Clinical Investigation of Medicinal Products in the Treatment or Prevention of Diabetes Mellitus

23 June 2023 – the EMA published revision 2 of the guideline on clinical development of new medicinal products in the treatment or prevention of diabetes.

This guideline intends to address the current EU regulatory position on the main topics of the clinical development of new medicinal products in the treatment or prevention of diabetes type 1 and type 2. The latest revision refers mainly to an update of the safety section with respect to cardiovascular (CV) safety (referring to the Reflection Paper on assessment of cardiovascular safety profile of medicinal products), but also updated guidance concerning estimands, requirements for monotherapy indications, studies in children, high strength insulin preparations, definitions of hypoglycemia and development of oral treatments for patients with type 1 diabetes.

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### Real-World Evidence Framework to Support EU Regulatory Decision-Making

23 June 2023 – the EMA published the report on the experience gained with regulator-led studies from September 2021 to February 2023.

This report aims to consolidate the acquired experience with the conduct of regulator-led RWD studies and to evaluate the opportunities and challenges of providing RWE to support regulatory decision making.

**Specific objectives are:**

- To understand the needs for RWE of EMA's Scientific Committees and Working Parties, the ability and capacity of the current RWD study framework to respond to these needs as well as the usefulness of the RWE provided;
- To understand the suitability of available RWD sources and pathways as well as the methodological challenges of data collection, study design and reporting and how they can be improved/expanded;
- To review the process for receiving study requests, proactively offering and conducting regulator-led RWD studies and to identify opportunities for improvements.

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### Updated Q&A: Good clinical practice (GCP)

23 June 2023 – the EMA updated Sections B & D of the Q&A guidance on GCP.

Section B – Question 18: "What are the expectations for productivity applications used in clinical trials?"

Section D – Question 3: "What are the considerations when direct remote access of identifiable personal and health data is required in a clinical trial?"

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### Concept Paper on the Development of a Guideline on the Quality Aspects of mRNA Vaccines

23 June 2023 – the EMA published the concept paper on establishing guidelines on the development of quality aspects of mRNA vaccines.

This concept paper addresses the need to establish a Guideline on the quality aspects of mRNA vaccines. The number of clinical trial applications for human products and marketing authorization applications for mRNA containing products significantly increased over the last few years and is expected to increase further in the future. Furthermore, a lot of experience with mRNA vaccines was gained during the COVID-19 pandemic. From an analytical and regulatory perspective, mRNA vaccines 19 are interesting since their classification depends on the target and/or whether they are obtained chemically or biologically.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

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June 2023 Part II

### ACT EU: Creating a Better Environment for Clinical Trials through Collaboration

22 June 2023 – the Accelerating Clinical Trials in the EU (ACT EU) initiative organized a kick-off workshop for a new multi-stakeholder platform to improve clinical trials in the EU.

ACT EU is a collaboration between EMA, the Heads of Medicines Agencies (HMA) and the European Commission (EC) that seeks to transform how clinical trials are initiated, designed, and run.

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to develop the European Union further as a competitive centre for innovative clinical research. ACT EU seeks to deliver on the clinical trial innovation recommendations of the European medicines agencies network strategy and the European Commission's Pharmaceutical strategy for Europe.

Read more online

### Report on Pharmacovigilance Tasks

22 June 2023 – the EMA published the report on pharmacovigilance tasks covering 2019 and 2022.

This report summarizes the work carried out by the EU pharmacovigilance Network between January 2019 and December 2022 to ensure the safety of all medicines authorized in the EU, including COVID 19 vaccines and therapeutics. The report also describes the main enhancements to the EU pharmacovigilance system introduced during this period and reflects critically on the main areas that will need further strengthening in the forthcoming period.

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### Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment

28 June 2023 – the FDA published the final guidance on developing treatment for chronic rhinosinusitis with nasal polyps.

The purpose of this guidance is to assist sponsors in the development of drugs or biological products for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). Specifically, this guidance addresses FDA's current thinking regarding trial population and design, effectiveness, statistical analysis, and safety for drugs being developed for the treatment of CRSwNP.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates



### Patient-Matched Guides to Orthopedic Implants

28 June 2023 – the FDA published the draft guidance on premarket submissions for patient-matched guides to orthopedic implants. Submit comments by 28 August 2023.

This draft guidance document provides the FDA's recommendations on information to support premarket submissions for patient-matched guides to orthopedic implants. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of submissions for patient-matched guides to orthopedic implants. This document also provides recommendations that manufacturers should consider when developing their design process for these device types.

Read more online

### Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements

27 June 2023 – the FDA published the final guidance on presenting quantitative efficacy and risk information in DTC promotional labeling and advertisements.

This guidance provides recommendations for presenting quantitative efficacy and risk information in direct-to-consumer (DTC) promotional labeling and advertisements for prescription human drug and biological products and prescription animal drugs and in DTC promotional labeling for over-the-counter animal drugs (collectively, promotional communications). For the purposes of this guidance, quantitative efficacy and risk information refers to information that numerically addresses the likelihood or magnitude of a drug's efficacy or risks.

Read more online

### Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

27 June 2023 – the FDA published draft guidance on the prohibition on wholesaling. Submit comments by 28 August 2023.

Under section 503B of the Federal FD&C Act (21 U.S.C. 353b), a drug compounded by an outsourcing facility qualifies for exemptions from certain statutory requirements if, among other conditions, the drug "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug." However, this provision "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)." This guidance describes FDA's interpretation of, and policies concerning, the prohibition on wholesaling in section 503B of the FD&C Act. This guidance also describes examples of how FDA intends to apply section 503B's wholesaling provision.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates



### Study Data Technical Conformance Guide — Technical Specifications Document

26 June 2023 – the FDA published the final guidance on study data technical conformance guide.

This Study Data Technical Conformance Guide (Guide) provides specifications, recommendations, and general considerations on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog. The Guide supplements the guidance for industry *Providing Regulatory Submissions in Electronic Format — Standardized Study Data (eStudy Data).*

This Guide provides technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format in INDs, NDAs, ANDAs, and BLAs.. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions.

Read more online

### Psychedelic Drugs: Considerations for Clinical Investigations

23 June 2023 – the FDA published draft guidance on developing psychedelic drugs for treatment of medical conditions. Submit comments by 25 August 2023.

The FDA is issuing this guidance to provide general considerations to sponsors developing psychedelic drugs for treatment of medical conditions (e.g., psychiatric disorders, substance use disorders). For the purposes of this guidance, the term psychedelic is used as shorthand to include classic psychedelics, typically understood to be 5-HT2 agonists such as psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as methylenedioxymethamphetamine (MDMA).

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### Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical

23 June 2023 – the FDA published the final guidance on manufacturing requirements of platelets.

FDA is issuing this guidance to provide a notice of exceptions and alternatives to certain requirements in Title 21 of the Code of Federal Regulations (CFR) regarding blood and blood components. This notice is being issued under 21 CFR 640.120(b) to respond to a public health need and address the urgent and immediate need for platelets for the treatment of active bleeding when conventional platelets are not available, or their use is not practical. Maintaining platelet availability in the face of logistical challenges (e.g., in military, prehospital, or austere settings) or other threats to blood availability (e.g., mass casualty events or public health emergencies) is critical to assure that platelets are available to patients with active bleeding.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

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June 2023 Part II

### Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program

20 June 2023 – the FDA published the final guidance on the pilot program for oncology drug products used with certain in vitro diagnostic tests.

FDA is issuing this guidance to announce and describe FDA's voluntary pilot program for certain Center for Drug Evaluation and Research (CDER)-regulated oncology drug products used with certain in vitro diagnostic tests.

Given the public health importance of such in vitro diagnostic tests for determining a patient's cancer treatment, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

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MHRA

Regulating Medicines and Medical Devices

### Clinical Trials for Medicines: Apply for Authorization in the UK

26 June 2023 – the MHRA published the updated guidance on clinical trial applications for authorization.

This guidance describes how to apply for a clinical trial including eligibility, phases, model IMPDs, costs and how to make changes to your application and includes a new section on In Vitro Diagnostic Medical Devices (IVDs).

Read more online

### Dialysis Guidance

21 June 2023 – the MHRA published the updated dialysis guidance.

This guidance has been produced in collaboration with the UK Kidney Patient Safety Committee (KPSC), to summarize known safety issues with dialysis and continuous renal replacement therapy (CRRT) and describe what to do to minimize or prevent serious injury.

This guidance updates the dialysis guidance following engagement with HSIB relating to their investigation: "Safety risks associated with central venous catheters (CVCs) used for hemodialysis treatment."

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates



### Changes to the Guidance Document on Biosimilars

22 June 2023 –Swissmedic published updated guidance on biosimilars.

Swissmedic has revised the section 5.10 on the interchangeability of biosimilars. Regarding content, it continues to be the case that minor differences as a result of manufacturing processes do not affect the safety and efficacy of the biosimilar compared to the reference product.

The revised guidance document went into effect on 22 June 2023.

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### Request to Check Mandates Relating to ECM Certifications

22 June 2023 – Swissmedic published guidance on the request to check mandates relating to ECM certifications.

Swissmedic requests Swiss authorized representatives (CH-REP) to check their mandates with regard to ECM certifications. This request was sent to all Swiss authorized representatives registered with Swissmedic.

Read more online

### Medicinal Products with a Medical Device Component (Combination Products)

21 June 2023 –Swissmedic published guidance on the implementation of transitional provisions for medical devices.

For combination products ("integral" and "co-packaged") currently authorized in Switzerland whose medical device component documentation also includes EU conformity certificates (CE certificates) for medical devices, the regulations on the validity of certificates set out in the changes to the EU-MDR will also apply.

However, if the variation or new issuance of a certificate is the result of a significant change to the medical device component which affects/may affect the design or intended purpose or the quality, efficacy or safety of the combination product under medicinal product legislation, a separate application for variation must be submitted.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

WS QMS

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June 2023 Part II

### Reflection Paper on Harmonization of RWE Terminology Available for Public Consultation

30 June 2023 – the ICH announced that the ICH reflection paper is now available for public consultation until 30 September 2023 on the ICH website.

ICH Reflection Papers are intended to articulate ideas for potential future harmonization work, lay out an area where harmonization work is needed, or make proposals for a series of future topics for harmonization.

Upon ICH Assembly endorsement of a Reflection Paper, its objectives are included into the ICH Association Multi-Annual Strategic Plan and the ICH Members work towards the achievement of these objectives accordingly.

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### Press Release: New collaboration between WHO International Classification of Diseases (ICD) and MedDRA Launched

27 June 2023 – the ICH announced the new collaboration between WHO ICD and MedDRA.

The WHO and the ICH are announcing a new collaboration to enhance registry and sharing of regulatory information on medical products worldwide. The collaboration aims to establish a unified language that streamlines global regulatory decision-making concerning the safety and efficacy of medical products, while offering vital insights into the scope, causes, and consequences of diseases, and mortality worldwide.

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# WSQMS Newsletter June 2023
## Regulatory Agency Updates



## Clinical Trials Information System (CTIS): Information Day

15 June 2023 – the EMA announced its CTIS Information Day webinar will take place on 17 October 2023.

This virtual event aims to support sponsors of clinical trials in preparing and proceeding with the transition to meet the deadline of 30 January 2025. Commercial and non-commercial sponsors with experience in transitioning trials as well as representatives from EMA and EU/EEA member states will share insights and best practices.

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## European Medicines Agency Practical Guidance on the Application Form for Centralized Type IA and IB Variations

15 June 2023 – the EMA published guidance on completing the application forms for centralized type IA and IB variations.

This document is intended as guidance to facilitate the completion of the application form for type IA and IB variations to be submitted in the Centralised Procedure and should be read in conjunction with the EMA/CMDh Explanatory Notes on Variation Application Form (CMDh/EMA/133/2010).

Read more online

## Joint HMA-EMA Big Data Steering Group

9 June 2023 – the EMA published guidance on the joint HMA-EMA big data steering group.

The HMA-EMA joint Big Data Steering Group (BDSG) is a strategic group established to steer better analysis and use of big data in medicines regulation for the benefit of public and animal health in the European Union (EU).

This document provides the first BDSG mandate revision. The purpose of this mandate revision is to ensure that proportionate network data governance is in place to propose and manage EMAN data analysis strategy, guidance and related pilots and EMRN experimentation to maximise the analysis and use of big data and strengthen the EU decision-making.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates



## Guidance on Pediatric Submissions: Via Syncplicity Web Client

9 June 2023 – the EMA published guidance on pediatric submissions via the syncplicity web client.

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

Read more online

## Paediatric Investigation Plans: Templates, Forms and Submission Dates

9 June 2023 – the EMA published updated guidance on pediatric investigation plans.

Update: An improved key elements form, which applicants must use beginning 12 September 2023, is available below.

EMA published the document in June 2023 to help applicants familiarize themselves with the form's new Word format and the newly added step-by-step guidance within the form.

Applicants should continue using the current PDF form for submissions until 11 September 2023.

Read more online

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

8 June 2023 – the EMA published updated Q&A guidance on GCP.

**Updates:**

**Section B. GCP matters:**

11. According to the applicable EU laws and ICH E6, is it allowed that the sponsor could contract service providers to conduct trial-related tasks, procedures, duties and functions that are under the responsibility of the investigator?

**Section D. Records of study subject data relating to clinical trials:**

3. What are the considerations when direct remote access of identifiable personal and health data is required in a clinical trial? NEW June 2023

For the purposes of this Q&A, direct remote access is any access from an access point (location and/or hardware) that is not under the control and supervision of the investigator/institution. Direct remote access involves additional data processing.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

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June 2023

## Content of Premarket Submissions for Device Software Functions

14 June 2023 – the FDA published guidance on premarket submissions for device software functions.

This guidance document is intended to provide information regarding the recommended documentation for premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, which are software functions that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Read more online

## Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma

14 June 2023 – the FDA published the final guidance on donor history questionnaires and materials for screening donors of source plasma.

This guidance recognizes, as acceptable, the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 3.0 dated June 2023, prepared by the Plasma Protein Therapeutics Association (PPTA). This guidance also advises Source Plasma manufacturers on how to report implementation of the acceptable PPTA Source Plasma donor history questionnaires and accompanying materials (SPDHQ documents) under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12).

Read more online

## Clinical Drug Interaction Studies with Combined Oral Contraceptives

8 June 2023 – the FDA published guidance on clinical drug interaction studies with combined oral contraceptives.

This guidance is intended to help sponsors of investigational new drug applications (INDs) and new drug applications (NDAs) evaluate the drug-drug interaction (DDI) effects of their investigational drugs on combined oral contraceptives (COCs), design DDI studies, and determine how to communicate DDI study results and risk mitigation strategies in labeling to address potential risks associated with increased or decreased exposure of COCs.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

WS QMS

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June 2023

## E6(R3) Good Clinical Practice (GCP)

6 June 2023 – the FDA published draft guidance on E6 (R3) GCP. Submit comments by 5 September 2023.

The objective of this Guideline is to provide a unified standard to facilitate the mutual acceptance of clinical trial data for ICH member countries and regions by applicable regulatory authorities.

This guideline builds on key concepts outlined in ICH E8(R1) General Considerations for Clinical Studies. This includes fostering a quality culture and proactively designing quality into clinical trials and drug development planning, identifying factors critical to trial quality, and engaging stakeholders, as appropriate, using a proportionate risk-based approach.

Read more online

## Nonclinical Evaluation of the Immunotoxic Potential of Pharmaceuticals

5 June 2023 – the FDA published the final guidance on nonclinical evaluation of the immunotoxic potential of pharmaceuticals.

The purpose of this guidance is to assist sponsors in the nonclinical evaluation of the immunotoxic potential of pharmaceuticals. Immunotoxicity is, for the purposes of this guidance, defined as unintended immunosuppression or stimulation (including hypersensitivity), which can include adverse effects of exaggerated pharmacology of pharmaceuticals that are intended to act as immunomodulators. This guidance applies to drug products, including small molecule drugs and oligonucleotides, as well as certain biological products such as biotechnology-derived therapeutic proteins (referred to herein as biopharmaceuticals).

Read more online

## Cover Letter Attachments for Controlled Correspondence and ANDA Submissions

5 June 2023 – the FDA published the final guidance on cover letter attachments for controlled correspondence and ANDA submissions.

This guidance is intended to assist prospective applicants, applicants, and holders of abbreviated new drug applications (ANDAs) with optional attachments that can be used when preparing cover letters that accompany controlled correspondence to the Office of Generic Drugs (OGD), as well as original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA. These attachments do not replace the recommendations for the content of cover letters provided in other FDA guidance.

Read more online

## Interstitial Cystitis / Bladder Pain Syndrome (IC/BPS): Establishing Drug Development Programs for Treatment

2 June 2023 – the FDA published draft guidance on establishing drug development programs for treatment of IC/BPS. Submit comments by 4 August 2023.

This draft guidance provides recommendations for drug development programs for drugs intended to treat patients with interstitial cystitis/bladder pain syndrome (IC/BPS). This guidance incorporates advice FDA received at a December 2017 advisory committee

meeting on appropriate patient selection criteria and trial design features, including enrollment criteria and acceptable efficacy endpoints for drugs intended to treat IC/BPS.

Read more online

## Drug-Drug Interaction Assessment for Therapeutic Proteins

2 June 2023 – the FDA published the final guidance on drug-drug interaction assessment for therapeutic proteins for industry.

The purpose of this guidance is to help sponsors of investigational new drug (IND) applications and applicants of biologic license applications (BLAs) determine the need for drug-drug interaction (DDI) studies for a therapeutic protein by providing recommendations for a systematic, risk-based approach.

For this guidance, a therapeutic protein refers to a protein that is being developed for licensure, or is licensed, as a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262). Therapeutic proteins include purified monoclonal antibodies, cytokines, enzymes, and other novel proteins for in vivo use.

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## Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

2 June 2023 – the FDA published the final guidance on how to request for feedback and meetings for medical device submissions with the FDA.

The purpose of this guidance document is to provide an overview of the mechanisms available to submitters through which they can request feedback in writing or during a meeting with the Food and Drug Administration (FDA) regarding potential or planned medical device Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, Evaluation of Automatic Class III Designations (De Novo requests), Premarket Notification (510(k)) Submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications (CW), Dual 510(k) and CLIA Waiver by Application Submissions (Duals), Accessory Classification Requests, and certain Investigational New Drug Applications (INDs) and Biologics License Applications (BLAs) submitted to the Center for Biologics Evaluation and Research (CBER)) (specifically, INDs and BLAs for devices that are regulated as biological products under section 351 of the Public Health Service (PHS) Act).

Read more online

## Migraine: Developing Drugs for Preventive Treatment

1 June 2023 – the FDA published draft guidance on developing drugs for preventive treatment of migraine. Submit comments by 1 August 2023.

The purpose of this guidance is to assist sponsors in the clinical development of drugs for the preventive treatment of migraine. Pharmacological approaches to the treatment of migraine include drugs to abort migraine attacks as they arise (acute treatment of migraine) and drugs to reduce the frequency of migraine attacks (preventive treatment).

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates

WS QMS

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June 2023

MHRA

Regulating Medicines and Medical Devices

## 150-day Assessment for National Applications for Medicines

15 June 2023 – the MHRA published updated guidance on the 150-day assessment timeline for national applications for medicines.

The MHRA offers a 150-day assessment timeline for all high-quality marketing authorisation applications (MAAs), aiming at accelerating the availability of medicines for patients in the UK.

*15 June:* New active substances and biosimilar products applications section was updated.

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## Access New Active Substance and Biosimilar Work Sharing Initiatives (BSWSI)

15 June 2023 – the MHRA published updated guidance on access to the new active substance and BSWSI.

The New Active Substance Work Sharing Initiative (NASWSI) has successfully approved several medicines through this international collaboration and continues to foster cooperation and strong relationships between its Access partners. The Biosimilar Work Sharing Initiative (BSWSI) builds on this success.

*15 June:* Overview of MHRA NASWSI approvals section was added.

Read more online

## Software and AI as a Medical Device Change Programme

14 June 2023 – the MHRA published updated guidance on software and AI as a medical device change programme.

The online AI and Digital Regulations Service helps digital health innovators and adopters of these technologies to navigate the regulatory system.

*14 June:* Partnerships section was updated.

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## Advertise Your Medicines

12 June 2023 – the MHRA published updated guidance on how to comply with the requirements on promoting medicines.

**Overview**

You can advertise any over-the-counter medicine, general sales list and pharmacy medicines, to the general public.

You can't advertise prescription-only medicines (POMs) to the general public but you can promote them to healthcare professionals and others who can prescribe or supply the product.

# WSQMS Newsletter June 2023
## Regulatory Agency Updates



You can't advertise any medicine that is not licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) or, for products in Northern Ireland, the European Commission.

*12 June:* Updated "guidance for vetting of promotional material" document.

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## Centrally Authorized Products (CAPs) Bridging Mechanism

9 June 2023 – the MHRA published guidance on measures in place until the Windsor Framework takes effect on 1 January 2025.

This guidance applies until the Windsor Framework takes effect on 1 January 2025. Under the Windsor Framework, rather than novel medicines for use in Northern Ireland requiring an application to the European Medicines Agency (EMA), the Medicines and Healthcare products Regulatory Agency (MHRA) will assess applications and license all products in the scope of the EU's Centralised Procedure on a UK-wide basis.

Read more online

## MHRA / HRA Coordinated Pathway

9 June 2023 – the MHRA published the coordinated pathway process.

The MHRA in partnership with the HRA can offer a new coordinated assessment pathway which will streamline the review of clinical investigations involving medical devices. This assessment pathway will benefit applicants by ensuring the MHRA review, and the Research Ethics Committee (REC) review are undertaken in parallel, and information will be shared.

The MHRA / HRA Coordinated pathway process resumed on 22 May 2023.

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

7 June 2023 – the MHRA published updated guidance on how to notify the MHRA of a clinical investigation for a medical device.

You may need to carry out a clinical investigation as part of the process to obtain a UKCA / CE / CE UKNI marking for your medical device. You must inform the MHRA if you are planning to do this at least 60 days before starting your investigation.

The MHRA / HRA Coordinated pathway process resumed on 22 May 2023.

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# WSQMS Newsletter June 2023
## Regulatory Agency Updates

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June 2023

## Public Consultation on ICH Guideline E6(R3) "Good Clinical Practice (GCP)" Launched in Switzerland

12 June 2023 – the Swissmedic announced the launch of the public consultation on ICH Guideline E6(R3) GCP. Deadline is 26 September 2023 for comments.

Stakeholders in Switzerland have until September 26th, 2023 to comment on the draft of Guideline E6(R3) "Good Clinical Practice (GCP)".

Comments can be provided using the feedback form specified by ICH to networking@swissmedic.ch. Stakeholders will receive confirmation of receipt of their comments but no feedback on the individual comments.

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## Delayed Implementation Time Limits for Replacement Changes

1 June 2023 – the Swissmedic published revised guidance on authorized variations and extensions.

Swissmedic now allows delayed implementation time limits for authorised variations to human and veterinary medicinal products in specially requested and duly justified exceptional cases.

This concerns technical changes (primarily quality variations) that must be implemented simultaneously worldwide (replacement changes).

The marketing authorisation holder requests the desired delay and justifies this in full in the application for variation.

The revised guidance documents are valid as of 1 June 2023.

Read more online

## Changes to Guidance Document Fast-Track Authorization Procedure and Guidance Document Temporary Authorization for Human Medicinal Products

1 June 2023 – the Swissmedic published updated specification documents for the AAA.

Submission of the decision minutes and presentation slides for the AAA is now possible via the eGov portal. The applicant now has a deadline of 3 working days after the AAA to finalise the decision minutes. As submission is via the eGov portal, the decision minutes do not require signatures.

Swissmedic has updated the specification documents accordingly. The revised documents are valid as of 1 June 2023.

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# WSQMS Newsletter June 2023

## Regulatory Agency Updates



### The ICH E6(R3) Draft Guideline Presentation Now Available on the ICH Website

13 June 2023 – the ICH announced the availability of the ICH E6(R3) draft guideline presentation.

The ICH E6(R3) draft Guideline on "Good Clinical Practice" reached Step 2b of the ICH Process in May 2023 and subsequently entered the consultation period. A Step 2 Informational Presentation has been developed by the Expert Working Group and is now available for download on the Efficacy Guidelines page.

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