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Welcome to our regular newsletter, which provides a digest of some of the latest EU/UK and some of the worldwide regulatory news. As ever, Q4 2024 has been another very busy time for new emerging guidelines from the regulatory agencies of the world.

Feel free to contact us on: smt@espl-regulatory.com if you have any questions on the information provided.

EUROPEAN-WIDE NEWS

EUROPEAN MEDICINES AGENCY (EMA)

Joint HMA/EMA multi-stakeholder Report on the workshop on submission predictability

This multi-stakeholder workshop (national competent authorities (NCAs), industry, and EMA) was organised to discuss ways to enhance submission predictability and to raise awareness of the implication and challenges that frequent and multiple delays to the submission dates pose on the Network's resources and planning.

NEW Implementation of the amended Variations Regulation applicable as of 1 January 2025

The following guidances have all been issued in anticipation of release of the new main variation guideline, which is expected in early 2025:

- EMA/CMDh explanatory notes on variation application form (Human medicinal products only) – November 2024
- Examples for acceptable and not acceptable groupings for MRP/DCP products – October 2024
- Position paper common grounds seen for invalidation/delaying day O for variations – October 2024
- Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended – October 2024
- Updated template cover letter for variations – October 2024
- New template for a Type IA "supergrouped" variation procedure (Article 7a) - October 2024
- Urgent Safety Restriction Member State Standard Operating Procedure – October 2024

Investigation of bioequivalence - Scientific guideline

On 25 January 2025, the date of coming into effect, ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms will supersede applicable parts of this EMA guideline related to bioequivalence study considerations and data analysis for a non-replicate study design

EMA NEWSLETTERS

Human Medicines Highlights

Key information on human medicines and changes to regulatory processes each month:

- October
- November
- December

Veterinary Medicines Highlights

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP)

- Q4 2024

HEADS OF MEDICINES AGENCY (HMA)

NEW **Guidance on the application of the amended Variations Regulation**

NEW **Recommendations on submission dates in 2025 for Applications of the DCP**

NEW **Recommendations on submission dates in 2025 for Applications of the MRP**

EUROPEAN COMMISSION (EC)

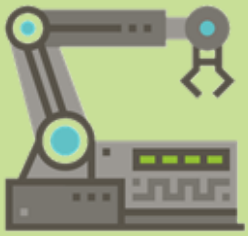
NEW **EU General Product Safety Requirements regulation - implemented 13.12.2024**

This regulation mandates that for all products sent to the EEA, there should be a Responsible Person (RP) assigned as a contact point within EU to oversee this. This includes product sent from the UK. This person or organisation takes responsibility for compliance with the product safety requirements and acts as a contact for market surveillance authorities and consumers.

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

NEW **Implementation of the European Pharmacopoeia Supplement 11.7 – Notification for CEP holders**

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

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INDIVIDUAL AGENCY NEWS

FDA - USA

NEW Draft guidance issued on the 'Accelerated Approval Pathway'

In 2023 congress gave FDA the authority to require that companies pursuing this process initiate their confirmatory trial before the accelerated approval is granted or require that the confirmatory trial is completed within a specified timeframe. This is in response to a number of companies obtaining accelerated approval and then failing to complete post-approval confirmatory trials in a timely manner. As a result, one notable addition to this guidance is that 'no later than the date of accelerated approval, FDA will set forth conditions for the progress of confirmatory trial(s).' So, requirements for successfully pursuing accelerated approval will likely become more rigorously enforced by FDA.

NEW FDA Issues Final Guidance on 510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review

This guidance clarifies the FDA's expectations for third-party review organizations, including eligibility, processes, and conflict prevention. It also highlights the FDA's focus on ensuring consistent quality in reviews and outlines compensation details for third-party organizations. The guidance supersedes the previous version and adds clarification on third-party reviews for EUA requests during public health emergencies.

MDA - MALAYSIA

Malaysia MDA Releases Update on Medical Device Registration and Reregistration

Device registration in Malaysia is aided by prior approval in the EU/US. An EC Certificate (EU CE Marking) or EC Declaration of Conformity is recognized by the Malaysia Medical Device Authority (MDA) as an approved type for the conformity assessment process for medical device registration in Malaysia. The MDA has revised the registration and re-registration process of medical devices using EC Certificates that have expired.

NMPA - CHINA

China Implements Pilot Program for Fast-track Approval of Innovative Drug Trials

China's National Medical Products Administration has issued a Pilot Work Program to fast-track innovative drug clinical trial approvals. According to the notice, the normal review period has been cut from 60 to 30 working days, and this change will be applied to Class I innovative drugs defined as new-to-the-world drugs. Cell and gene therapies as well as vaccine products are excluded.

China Issues Final Conditions for Overseas Drug MAH's and their Domestic Responsible Persons (DRP)

On November 14, China's NMPA announced the document titled "Interim Provisions on the Administration of the Designation of Domestic Responsible Persons by Overseas Drug Marketing Authorization Holders." These provisions outline the requirements for domestic responsible persons. Imported pharmaceuticals' quality and safety are secured by the DRP system.

UNION HEALTH MINISTRY - INDIA

India Updates PV Rules for Faster Reporting Times

The Drug Controller General of India (DCGI) has already issued a regulation outlining the need for makers, importers, and sellers of drugs, to report adverse events. However, on November 11, to enhance overall supervision, India issued a new pharmacovigilance document to major stakeholders. This new document requires serious adverse events (death, etc.) to be reported within fifteen days of learning of such an event and ninety days for other bad reactions to a drug.

India Announces a Uniform Code for Marketing Medical Devices

The new regulation is titled – Uniform Code for Marketing Practices in Medical Devices (UCMPMD). Prior to this new announcement, under the previous regulations including the Drugs and Cosmetics Act of 1940, the Drugs and Cosmetics Rules of 1945, and the 2017 Medical Device Rules, there were no documents that were related to the Advertising and Promotion of devices in India.

MHRA - UK

NEW New Advertising and Promotion Guidance following agreement of the Windsor Framework

MFDS - KOREA

Korea Implements Expedited Market Entry Pathway for Very Innovative Devices

On November 21, Korea introduced the "Immediate Market Entry Medical Technology System," a ground-breaking policy aimed at accelerating market entry for cutting-edge medical technologies. Before this system was initiated innovative devices could take up to 490 days to be approved. Under this new system, innovative devices such as medical robots, digital therapeutics, and AI-based diagnostic tools can enter the market within 80 to 140 days after receiving clinical evaluation.