ESPL REGULATORY CONSULTING

SMT@ESPL-REGULATORY.COM

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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, Q3 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

EMA - MEDICINES

Reflection Paper on Proof-of-Concept Pilot on Using Data from Clinical Studies

The EMA explores utilising clinical study data for improving medicines evaluation, emphasising real-world data integration to optimise drug approval processes.

Update to Nitrosamines Q&A for Marketing Authorization Holders

Further additions and refinement of the common questions and answers around the guidelines on managing nitrosamine impurities in human medicinal products.

Reflection Paper on Single-Arm Trials in Marketing Authorization

Guidance on using single-arm trials for demonstrating the efficacy of medicines, particularly for conditions where placebo-controlled trials are not feasible.

EUROPEAN COMMISSION - MEDICAL DEVICES

AI in Medical Devices

EU regulation governing the use of artificial intelligence in medical devices, setting out the compliance framework, risk management, and transparency requirements.

TEAM NB (NOTIFIED BODIES)

Code of Conduct Press Release

A release from Team NB emphasising the importance of harmonised standards and transparency in medical device regulation across Europe, especially regarding certification.

IVD Transfer Agreement Position Paper

Position paper discussing the challenges and frameworks around transferring in-vitro diagnostic devices between notified bodies, which is critical for maintaining compliance during regulatory transitions.

EMA NEWSLETTERS

The EMA publishes monthly newsletters to provide updates on various topics to patients, healthcare professionals and the pharmaceutical industry. The latest newsletters are:

Human Medicines Highlights

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

- July
- August
- September

Veterinary Medicines Highlights

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

- July
- September

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH)

Update to ICH M14 Guideline

The guideline focuses on designing and analysing pharmacoepidemiological studies using real-world data for the safety assessment of medicines. This is part of the broader push toward utilising real-world evidence in regulatory decision-making.

HEADS OF MEDICINES AGENCY (HMA)

Decisions on Market Protection for New Therapeutic Indications

CMDh outlines decisions regarding additional years of market protection and data exclusivity for new therapeutic indications.

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ESPL Regulatory Consulting
Lunna House
Lunna
Vidlin
Shetland ZE2 9QF
UK
(+44) 1806 242 852
smt@espl-regulatory.com

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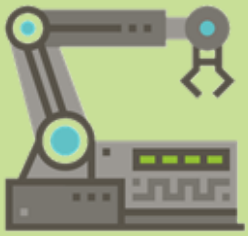

Medical Device Submissions

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www.espl-regulatory.com

https://www.linkedin.com/company/espl-regulatory-consulting/

+44 1806 242 852

smt@espl-regulatory.com

Update to CMDh Contact Points

An updated list of contact points for CMDh, ensuring communication lines between regulatory authorities and stakeholders remain open and accessible.

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

NEW **Pharmeuropa 36.4**

New proposals for the development and revision of monographs and general texts are published to ensure pharmaceutical standards evolve with scientific advancements.

NEW **European Pharmacopoeia Supplement 11.7**

The latest updates to the European Pharmacopoeia, featuring new standards and monographs for pharmaceutical ingredients to improve medicine quality across Europe.

UPDATES FROM THE 2024 TOPRA SYMPOSIUM

ESPL were present at the 2024 TOPRA Symposium in Rotterdam and attended all of the very educational and useful lectures. Some of our favourite talks and key take home messages were:

- **HM3 - EMA/FDA Fireside Chat:** Stepwise PIP Approach: EMA is piloting a more flexible approach to Pediatric Investigation Plans (PIPs) that may influence legislation. Joint scientific advice from EMA and FDA is encouraged, and the introduction of 'centres of excellence' is being considered to enhance talent attraction and expertise.
- **HM4 - Electronic Product Information (EPI):** Pilot phase using 23 products has concluded, and a report is expected soon. The implementation of EPI will depend on member states, creating potential for a fragmented system.
- **HM8 - HTA Regulation:** Joint Clinical Assessment (JCA) will be a significant change starting in January 2025, where MAA and JCA will occur simultaneously. This will initially apply to oncology and ATMP, with HTA regulations covering all products by 2030.

INDIVIDUAL AGENCY NEWS

FDA - USA

Update to Premarket Notification (510k) guidance
Updated guidance on preparing abbreviated 510(k) submissions for medical devices, streamlining the premarket approval process.

NEW **Drug Interaction Information Draft Guidance**
New guidance on including drug interaction data in the labelling of prescription drugs to ensure safe administration and awareness among healthcare professionals.

Accelerating Rare disease Cures (ARC) Program Year 2 Report
The FDA's 2024 Annual Report on the Accelerating Rare Disease Cures (ARC) Program highlights its efforts to advance rare disease drug development. Key initiatives include the Support for Clinical Trials Advancing Rare Disease Therapeutics (START) Pilot Program, patient-focused drug development meetings, and the establishment of a Rare Disease Innovation Hub. The ARC Program emphasises collaboration with patients, drug developers, and regulatory agencies, aiming to overcome challenges in clinical trial design and patient recruitment. The program's outreach efforts have expanded significantly, supporting 29 new rare disease drug approvals.

Update to Guidance for Control of Nitrosamine Impurities in Human Drugs
FDA's guidance now aligns with EMA on controlling nitrosamine impurities in human drugs, outlining expectations for manufacturers to manage these potential carcinogens.

NEW **Changes to Glass Vials and Stoppers Guidance**
New guidance on container closure systems, including modifications to glass vials and stoppers, to ensure product stability and patient safety.

MHRA - UK

MHRA Corporate Plan 2023-2026
A strategic plan outlining MHRA's goals for improving regulatory processes, fostering innovation, and enhancing patient safety in the UK post-Brexit.

Update to the Medical Device Registration Guide
A comprehensive reference guide on how to register medical devices in the UK, which includes video tutorials and step-by-step processes for manufacturers.

Updates to the Windsor Framework Guidance
The Windsor Framework guidances provide details on the cooperation between the UK and EU on regulatory standards in the post-Brexit landscape for medical products. Contains detailed specifics and requirements to stay compliant post 1st January 2025

NMPA - CHINA

NEW **Program to Reduce IND Review Time**
China is initiating programs to reduce the review time for Investigational New Drug (IND) applications, aimed at accelerating drug development and patient access to innovative treatments.

NEW **Rare Diseases Program**
New initiatives for rare diseases, including enhanced regulatory pathways and support for the development of orphan drugs in China.

NEW **Local Device Clinical Study Guidelines**
New guidelines for conducting local clinical studies for medical devices in China, focusing on improving the quality and efficiency of trials to meet global standards.

HSA - SINGAPORE

Updated Drug Registration Regulations
Singapore has updated its drug registration regulations to streamline processes and improve the efficiency of getting new medicines to market.

NEW **Guidelines for Next-Generation Medical Devices**
New guidelines have been published to support the approval of next-generation medical devices in Singapore, with a focus on innovation and patient safety.

PMDA - JAPAN

Modifications to Drug Regulations
Japan continues to update its drug regulations to simplify the approval process and improve access to new medicines, ensuring alignment with international standards.