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, Q2 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 COMMISSION - MEDICINES

Hydroxyprogesterone caproate medicines to be suspended from the EU market

https://www.ema.europa.eu/en/news/hydroxyprogesterone-caproate-medicines-be-suspended-eu-market

EMA announces two new advice pilots to improve clinical trials in Europe

https://www.ema.europa.eu/en/news/two-new-advice-pilots-improve-clinical-trials-europe

EUROPEAN COMMISSION - MEDICAL DEVICES

The European Medical Device Regulation (MDR) replaced the MDD and the AIMDD and entered into force on 25 May 2017 with 26 May 2021 as date of application.

To access legacy devices' extended timelines, by May 2024 manufacturers must have implemented an MDR compliant QMS and have applied to a Notified Body for a Conformity Assessment.

By September 2024, the Notified Body and the manufacturer must have signed a formal written agreement. Depending on legacy devices classification, MDR transition deadline is May 2026 for Class III custom-made implantable devices, December 2027 for Class III and Class IIb implantable devices (non-WET) and December 2028 for other Class IIb, Class IIa, Class Is and class Im devices. On the same date, up-classified legacy devices (whose Declaration of Conformity was signed by 26 May 2021) now requiring Notified Body involvement must be MDR certified.

Medical devices: new guidance for industry and notified bodies
https://www.ema.europa.eu/en/news/medical-devices-new-guidance-industry-notified-bodies

Update to Q&A Guidance for Applicants and MAHs
EMA/37991/2019: Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746) Rev.4

MDCG 2024-5 - Updated Guidance on the Investigator's Brochure content
https://health.ec.europa.eu/document/download/ee7ee8eb-841a-4085-a8dc-af6d55ebf1bd_en?

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:

- April: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-april-2024_en.pdf
- May: https://ec.europa.eu/newsroom/ema/newsletter-archives/53124
- June: https://ec.europa.eu/newsroom/ema/newsletter-archives/53976

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

- April: https://www.ema.europa.eu/en/news/meeting-highlights-committee-veterinary-medicinal-products-cvmp-16-18-april-2024
- May: https://www.ema.europa.eu/en/news/meeting-highlights-committee-veterinary-medicinal-products-cvmp-21-22-may-2024
- June: https://www.ema.europa.eu/en/news/meeting-highlights-committee-veterinary-medicinal-products-cvmp-18-19-june-2024

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH)

NEW ICH M14 guideline on general principles on plan, design and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines Step 2b

https://www.ema.europa.eu/en/ich-m14-guideline-general-principles-plan-design-analysis-pharmacoepidemiological-studies-utilize-real-world-data-safety-assessment-medicines-scientific-guideline

HEADS OF MEDICINES AGENCY (HMA)

NEW Procedural advice on Zero Day MR Procedures

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/MRP_RUP/CMDh_451_2024_Rev.0_2024_03_clean_-_Procedural_Advice_on_Zero_day_MR_procedure.pdf

ESPL REGULATORY CONSULTING

Guiding Global Medicine for 20+Years

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

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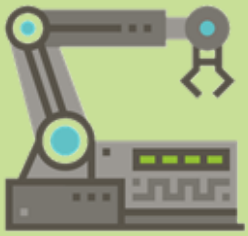

Medical Device Submissions

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www.espl-regulatory.com

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

+44 1806 242 852

smt@espl-regulatory.com

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

Revised CEP guidelines for better handling of dossiers

The revised version of the European Directorate for the Quality of Medicines & HealthCare (EDQM) guideline "Content of the dossier for chemical purity and microbiological quality of substances for pharmaceutical use" is now available and has been in force since 1 May 2024. This guideline presents clear information essential to ensuring that your CEP dossier is handled smoothly and without delay due to requests for additional information. https://www.edqm.eu/documents/52006/157201/Content+of+the+dossier+for+chemical+purity+and+microbiological+quality%2C+PA_PH_CEP+(04)+1%2C+7R%2C+March+2024.pdf/62d7afe3-0224-3820-5c7b-af19706c2b5c?

JP and Ph. Eur. launch a bilateral prospective harmonisation project for active substance and medicinal product monographs

https://www.edqm.eu/en/-/jp-and-ph.-eur.-launch-a-bilateral-prospective-harmonisation-project-for-active-substance-and-medicinal-product-monographs

Pharmeuropa 36.2 released

https://www.edqm.eu/en/-/pharmeuropa-36.2-just-released

INDIVIDUAL AGENCY NEWS

FDA - USA

NEW Draft Guidance: Data Integrity for In Vivo Bioavailability and Bioequivalence Studies

On 2nd April 2024, FDA published the draft guidance for industry, "Data Integrity for In Vivo Bioavailability and Bioequivalence Studies." This draft guidance provides recommendations to applicants and testing site management on achieving and maintaining data integrity for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drug applications, new drug applications, and abbreviated new drug applications, and the bioanalytical portion of clinical pharmacologic studies supporting CDER-regulated biologic license applications, as well as amendments and supplements to these applications https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-in-vivo-bioavailability-and-bioequivalence-studies

FDA Establishes CDER Center for Clinical Trial Innovation (C3TI)

FDA's Center for Drug Evaluation and Research (CDER) has recently launched the CDER Center for Clinical Trial Innovation (C3TI). C3TI is a central hub that supports innovative approaches to clinical trials that are designed to improve the efficiency of drug development. C3TI aims to promote existing CDER programs and spur future innovation activities through enhanced communication and collaboration. C3TI will enable internal and external parties to access information more easily, engage in collaborations, identify resources that can further support the use of innovative modalities, and find development programs where a concerted approach to the use of clinical trial innovations would be impactful. https://www.fda.gov/drugs/drug-safety-and-availability/fda-establishes-cder-center-clinical-trial-innovation-c3ti

US FDA finalises rule incorporating ISO 13485 into new Quality Management System Regulation (QMSR)

On 2 February 2024, the Food and Drug Administration (FDA) published a final rule to implement the most significant revisions in the FDA's quality system requirements for medical devices in decades. Specifically, the final rule – known as the Quality Management System Regulation (QMSR) – will largely replace the FDA's existing Quality System Regulation (QSR) with ISO 13485. The final rule also makes conforming edits to clarify the device Quality Management System requirements for combination products.

IND Safety Reports Can Now Be Electronically Submitted

FDA is reminding drug sponsors and researchers the agency recently published a guidance with instructions for electronic submission of investigational new drug application (IND) safety reports to the FDA Adverse Event Reporting System (FAERS). FDA is now accepting IND individual case safety reports (ICSRs) submitted electronically via the Electronic Submission Gateway in ICH E2B (R3) format or via the Safety Reporting Portal. Starting in April 2026 IND safety reports must be submitted via these two methods.. https://www.fda.gov/media/132079/download

FDA Selects START Pilot Program Participants to Help Accelerate Development of Rare Disease Therapies

On May 29, 2024, FDA notified selected participants of their acceptance into the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program. The pilot is being conducted by FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). Selected participants will be able to interact with FDA through rapid, ad-hoc communication mechanisms to provide a mechanism for addressing program-specific development issues, including but not limited to clinical study design, choice of control group, fine-tuning the choice of patient population, leveraging nonclinical information, or product characterization.

PMDA - JAPAN

Japan Wants to Streamline its Drug Clinical Trial Processes

In an effort to improve the Japan drug lag problem, the Japanese government plans to initiate several programs to simplify and optimize its drug clinical trial program. First, there are too many systems for clinical trials in Japan including the PMD Act, Clinical Trials Act, Safety of Regenerative Medicine Act, and requirements for gene therapies. The PMDA plans to make these clinical trial programs more consistent. In an effort to do this, one Japanese health ministry group has promoted the idea of centralized Institutional Review Boards (IRBs) as an alternative to individual IRBs. https://www.pacificbridgemedical.com/news-brief/japan-wants-to-streamline-its-drug-clinical-trial-processes/

Japan's regulatory requirements for Software as a Medical Device (SaMD)

Whether software constitutes a medical device under Japanese law requires careful consideration due to the substantially different regulatory regimes applicable to regulated and unregulated software products. The regulations applicable to software that constitutes a medical device (i.e. Software as a Medical Device, SaMD) under Japanese law must consider the legal framework for SaMD in Japan, the treatment of SaMD under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the scope of SaMD, Ministry guidelines, and disease risk indicating software.

HPRA - IRELAND

Update to the Guide to Clinical Investigations Carried Out in Ireland

https://topra.informz.ca/TOPRA/data/images/1Catrin/EditedRRpics/2024/aut-g0095-guide-to-clinical-investigations-carried-out-in-ireland-v7.pdf

MHRA - UK

NEW UK Parallel Import Licences Following Agreement of the Windsor Framework

https://www.gov.uk/government/publications/uk-parallel-import-licences-following-agreement-of-the-windsor-framework

Guidance (Draft): Statement of policy intent: international recognition of medical devices

https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations

IDP - INDIA

Indian Government Announces a New Ethical Program for Marketing of Drugs

On March 12, the Indian Department of Pharmaceuticals issued a new regulation for drug marketing called the – Uniform Code for Pharmaceutical Marketing Practices (UCPMP). Accordingly, all pharmaceutical associations in India are required to set up Ethics committees for Pharmaceutical Marketing Practices. Each ethics committee will include 4-6 members to supervise drug marketing practices, identify complaints and the related companies causing these issues, and outline appropriate remedies. https://www.pacificbridgemedical.com/news-brief/indian-government-announces-a-new-ethical-program-for-marketing-of-drugs/

CDSCO - INDIA

India Again Extends Class C and D Medical Device Registrations and Increases Post Market Surveillance

Last Fall, the Indian CDSCO said that high risk Class C and D medical devices could not be sold without an import/manufacturing license after September 30. Risky Class C and D products included – surgical robotic devices, linear accelerators, imaging equipment, etc. Then, in an effort to facilitate this required transition, the CDSCO also stated that importers and manufacturers' registrations could be extended by 6 months or until the CDSCO made a decision on their applications if they submitted their applications prior to September 30, 2023. https://www.pacificbridgemedical.com/news-brief/india-again-extends-class-c-and-d-medical-device-registrations-and-increases-post-market-surveillance/

FAMHP - BELGIUM

FAMHP announces new application Dossier Tracking Management System (DTS) for the management of a.o. variations and renewal applications

Together with the start of DTS, the FAMHP no longer asks advance payments, but moved to payment via invoice with structured messages.
In order to send an invoice to the MAH (who is responsible for paying the fees according to annex VII of the financing law) with correct data, kindly send the VAT number of the MAH to: peggy.briers@fagg-afmps.be
https://www.famhp.be/en/news/data_tracking_system_new_application_for_the_effective_management_of_marketing_authorisation