ESPL REGULATORY CONSULTING

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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 2023 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)

COMP - New Public List of Opinions on Orphan Medicinal Product Designation

A new Public - List of Opinions on Orphan Medicinal Product Designation has been released on the IRIS portal which replaces the way the Agency used to provide sponsors of orphan medicinal products with a Public Summary of Opinion following the granting of the orphan designation by the EC.
https://iris.ema.europa.eu/odpublicregister/

European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (updated)

Pre-authorisation procedural advice for centralised procedure users has been updated.
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure_en.pdf

Guidance on paediatric submissions (updated)

Guidance on the paediatric submission process has been updated.
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-paediatric-submissions_en-0.pdf

Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable) - human (updated)

Checklist for the submission of Type IA and Type IB product information annexes have been updated.
https://www.ema.europa.eu/en/documents/template-form/checklist-submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if_en.pdf

EMA NEWSLETTERS

The EMA publishes monthly newsletters to provide updates on various topics to patients, healthcare professionals and the pharmaceutical industry.
https://www.ema.europa.eu/en/news-events/publications/newsletters

The latest newsletters are:

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

- August: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-august-2023_.pdf
- September: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-september-2023_en.pdf

NOTE: there is no Newsletter issued in July due to holiday absences

Veterinary Medicines Highlights
Quarterly news, activities and interviews from EMA Veterinary Medicines Division
https://ec.europa.eu/newsroom/ema/newsletter-archives/47420

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

CEP 2.0: Changes from September 2023 to information published in Certification Online and Knowledge databases

The launch of CEP 2.0 brings changes to the information on CEPs published on the Certification Online and Knowledge databases.
https://www.edqm.eu/en/-/cep-2.0-changes-from-september-2023-to-information-published-in-certification-online-and-knowledge-databases

CEP 2.0 – Certificates of suitability: electronic signature features

On 1 September 2023, the European Directorate for the Quality of Medicines & HealthCare (EDQM) implemented electronic signatures for CEPs and some other documents as part of the CEP 2.0 project. A document explaining the features of electronic signatures is now available.
https://www.edqm.eu/en/-/cep-2.0-certificates-of-suitability-electronic-signature-features

HEADS OF MEDICINES AGENCY (HMA)

Applicant's response document in Mutual Recognition and Decentralised Procedures for Marketing Authorisation Applications updated

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Applicant_Response/CMDh_091_2003_Rev.11_2023_09_clean_-_Applicants_response_document_in_MRP-DCP_for_MAAs.pdf

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Medical Device Submissions

Publishing

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INDIVIDUAL AGENCY NEWS

MHRA - UK

UK-wide licensing for human medicines

This guidance is designed to provide information on the implementation of changes to the licensing of medicines for human use in the UK following the agreement of the Windsor Framework. The Windsor Framework will be implemented from 1 January 2025.
https://www.gov.uk/government/publications/uk-wide-licensing-for-human-medicines/uk-wide-licensing-for-human-medicines

Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework

This guidance is designed to provide information on the implementation of labelling and packaging requirements for medicinal products for human use following agreement of the Windsor Framework.
https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework

Clarifications on parallel import licences and arrangements

This updated web-page provides clarity on how to get a parallel import licence for your medicine in the UK, including pharmacovigilance requirements and submitting your application.
https://www.gov.uk/guidance/medicines-apply-for-a-parallel-import-licence#full-publication-update-history

FDA - USA

FDA Issues Final Guidance on Human Factors Engineering Principles for Combination Products

The U.S. Food and Drug Administration (FDA) issued this final guidance, to help facilitate the development of combination products. This guidance contains questions and answers for industry on applying human factors engineering (HFE) principles to the development of combination products. The guidance clarifies how the unique aspects of a combination product influence the considerations within the HFE process. This guidance finalizes the February 2016 draft version entitled Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development. Changes from the draft to the final guidance include deleting human factors information that is redundant with other FDA guidance documents, clarifying the combination product critical task definition, and further explaining considerations to help identify combination product critical tasks.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/application-human-factors-engineering-principles-combination-products-questions-and-answers?utm_medium=email&utm_source=govdelivery

FDA Issues Guidance for Industry on ehanced drug distribution security at the package level (under the drug supply chain security act)

The U.S. Food and Drug Administration (FDA) issued this guidance, to assist supply chain stakeholders, particularly trading partners, with requirements for enhanced drug distribution security at the package level which goes into effect on November 27, 2023.
https://www.fda.gov/media/171666/download

NMPA - CHINA

China's NMPA Adjusts Medical Device Classification Catalog

On August 17, the NMPA announced that its classification catalog would be adjusted given the influx of new innovative devices. Fifty-eight product categories have been updated. However, only 4 product categories have been changed from Class 1 to Class 2 or from Class 2 to Class 3 due to increased risks according to clinical experts. 8 product categories have been changed to lower classification from Class 3 to Class 2 or from Class 2 to Class 1 .
https://www.pacificbridgemedical.com/news-brief/chinas-nmpa-adjusts-medical-device-classification-catalog/?utm_source=Medical+Main+List&utm_campaign=8a34d4f086-mailchimp_email_2019-07_newsletter_english_COPY_01&utm_medium=email&utm_term=0_b8b603ce3c-8a34d4f086-58462561

PMDA - JAPAN

Japan Reveals More Information on Expediting SaMD Registration

Japan is planning to implement a two-step registration process for SaMD products in early 2024. If a SaMD product shows strong safety and efficacy, it will get initial approval. Later, if the SaMD shows safety and efficacy in clinical use or during a post-market study, a second approval will be granted. To facilitate this process, the PMDA will enlarge its existing SaMD review staff. In addition, a brand-new subscription-type service will be established to allow SaMD manufacturers access to multiple consultation sessions in a fixed time frame with the SaMD review staff.
https://www.pacificbridgemedical.com/news-brief/japan-reveals-more-information-on-expediting-samd-registration/

MPA - MALAYSIA

Malaysia Now Offers New Medical Device Consultation Services

In the past, it was not possible to meet Malay MDA officers face-to-face. They were always resource-constrained and did not have time. However, on August 2, Malaysia's MDA announced new consulting services for device manufacturers seeking registration approval in Malaysia. Two types of regulatory consulting services are now available – 1. Consulting package services and 2. Non-package consulting services.
https://www.pacificbridgemedical.com/news-brief/malaysia-now-offers-new-medical-device-consultation-services/?utm_source=Medical+Main+List&utm_campaign=8a34d4f086-mailchimp_email_2019-07_newsletter_english_COPY_01&utm_medium=email&utm_term=0_b8b603ce3c-8a34d4f086-58462561

FDD - LAOS

Laos Announces First Ever Medical Device Registration Requirements

On September 9, Laos will implement its first-ever medical device regulations. While in 2011, a registration policy was discussed, medical device registration was not implemented. Laos' Ministry of Health Food and Drug Department (FDD) has outlined the required registration documents and specific registration procedures. Laos' policies basically follow the 2015 Medical Device Directive for ASEAN.
https://www.pacificbridgemedical.com/news-brief/laos-announces-first-ever-medial-device-registration-requirements/#:~:text=Laos%20Announces%20First%20Ever%20Medial%20Device%20Registration%20Requirements,-September%205%2C%202023&text=On%20September%209%2C%20Laos%20will,device%20registration%20was%20not%20implemented.