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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 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)

Update to regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches - Scientific guideline

https://www.ema.europa.eu/en/regulatory-acceptance-3r-replacement-reduction-refinement-testing-approaches-scientific-guideline

Update to guidance Appendix 1: Acceptable intakes established for N-nitrosamines

https://www.ema.europa.eu/documents/other/appendix-1-acceptable-intakes-established-n-nitrosamines_en.xlsx

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:

- October: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-october-2023_en.pdf

November and December not yet available.

Veterinary Medicines Highlights
Quarterly news, activities and interviews from EMA Veterinary Medicines Division:
https://ec.europa.eu/newsroom/ema/newsletter-archives/49064

HEADS OF MEDICINES AGENCY (HMA)

Update to data requested for New Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/Recommendation papers

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_197_2010_Rev_9_2023_11_TC_-_Data_requested_for_Variations_and_Renewals.pd

EUROPEAN COMMISSION (EC)

Member State members of the Borderline and Classification Working Group issue a manual on borderline medical device classification

Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. https://health.ec.europa.eu/system/files/2023-09/md_borderline_manual_en.pdf

EC issue updated Guidelines on Data Exchange with EUDAMED (Production v 2.13)

https://webgate.ec.europa.eu/eudamed-help/en/files/Guidelines%20on%20data%20exchange.pdf

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

Ph. Eur. allows the use of recombinant factor C for control of bacterial endotoxins in water monographs

https://www.edqm.eu/en/-/ph.-eur.-allows-the-use-of-recombinant-factor-c-for-control-of-bacterial-endotoxins-in-water-monographs

Ph. Eur. pre-publishes Cannabis flower monograph on the EDQM website

https://www.edqm.eu/en/-/ph.-eur.-pre-publishes-cannabis-flower-monograph-on-the-edqm-website

EDQM implements CEP 2.0 – Certificates of suitability: electronic signature features

https://www.edqm.eu/en/-/cep-2.0-certificates-of-suitability-electronic-signature-features

EDQM makes changes to the acceptability of CEP applications for sterile grade materials

https://www.edqm.eu/en/-/changes-to-the-acceptability-of-cep-applications-for-sterile-grade-materials

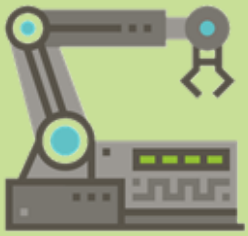
European Paediatric Formulary publish Chloral hydrate oral solution monograph

https://www.edqm.eu/en/-/european-paediatric-formulary-chloral-hydrate-oral-solution-monograph-published

Safe cosmetics for young children – Second edition provides state-of-the-art guidance on cosmetic products for infants and young children

https://www.edqm.eu/en/-/safe-cosmetics-for-young-children-second-edition-provides-state-of-the-art-guidance-on-cosmetic-products-for-infants-and-young-children

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

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INDIVIDUAL AGENCY NEWS

FDA - USA

FDA Publishes Draft Guidance on Quality Considerations for Topical Ophthalmic Drug Products

The U.S. Food and Drug Administration (FDA) has announced a new draft guidance for industry, Quality Considerations for Topical Ophthalmic Drug Products. Ophthalmic drug products refer to any FDA-regulated drug products that are used for topical delivery around the eye such as solutions, suspensions, emulsions, gels, ointments or creams. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-considerations-topical-ophthalmic-drug-products

FDA Issues Final Guidance on Dose Banding for Drug and Biological Products

On October 2nd, 2023, the FDA announced the availability of a final guidance for industry entitled Human Prescription Drug and Biological Products – Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers – "Dose Banding." This final guidance provides recommendations to assist applicants in incorporating information into human prescription drug labeling on how to dose patients with drugs that have weight- or body surface area-based doses when using ready-to-use containers offering a range of strengths (for example, as provided in pre-mixed infusion bags). The recommendations outlined in the final guidance are intended for applicants seeking to include information in labeling under a supplement to an existing new drug application (NDA) or 351(a) biologics license application (BLA) or for an original NDA or 351(a) BLA. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-prescription-drug-and-biological-products-labeling-dosing-based-weight-or-body-surface-area

FDA Issues Advice on Direct-to-Consumer Prescription Drug Advertisements

Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format – A Rule by the Food and Drug Administration on 11/21/2023.
https://www.federalregister.gov/documents/2023/11/21/2023-25428/direct-to-consumer-prescription-drug-advertisements-presentation-of-the-major-statement-in-a-clear

PMDA - JAPAN

Japan Reveals More Information on Expediting Software as a Medical Device (SaMD) Registration

Japan is planning to implement a two-step registration process for SaMD products in early 2024. If an SaMD product shows strong safety and efficacy, it will get an 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.
https://www.pacificbridgemedical.com/news-brief/japan-reveals-more-information-on-expediting-samd-registration/

Japan Phase 1 Drug Clinical Trials No Longer Needed for Global Clinical Trials

In an effort to reduce the drug lag in Japan, in mid-September, the MHLW said, in general, Phase 1 drug clinical studies are not required before late-stage global studies. This notification will amend the prior notification in 2007 and render invalid a 2014 notification on the same topic. This future notification will emphasize that Phase 1 studies are not needed especially for drugs where there is a high demand like orphan and pediatric drugs. https://www.pacificbridgemedical.com/news-brief/japan-phase-1-drug-clinical-trials-no-longer-needed-for-global-clinical-trials/

UNION HEALTH MINISTRY - INDIA

Indian Government Cracking Down on its Drug Manufacturers

India provides the world with many drug products and drug substances. To ensure high quality, the Union Health Ministry now requires that all state drug authorities gather data on all Indian pharmaceutical companies. The Indian central government wants to collect information on drug formulations and imported and exported drugs, so there is more transparency in their oversight.
https://www.pacificbridgemedical.com/news-brief/indian-government-cracking-down-on-its-drug-manufacturers/

MHRA - UK

NEW **International Recognition Procedure guidance**

The MHRA has launched the process which replaces the Reliance Procedures ECDRP and MRDCRP
https://www.gov.uk/government/news/mhra-launches-online-eligibility-checker-tool-for-applications-via-the-new-international-recognition-procedure-irp

Medicines marketing authorisation: change of ownership guidance updated
https://www.gov.uk/guidance/medicines-marketing-authorisation-transfer-ownership

Guidance on qualified person responsible for pharmacovigilance (QPPV) including pharmacovigilance system master files (PSMF) updated

https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf

HSA - SINGAPORE

Singapore's HSA Makes Public a New Draft Guidance for Device Clinical Evaluation

In late October, the Singapore HSA requested that relevant players provide feedback on their draft Guidance for Device Clinical Evaluation. Before devices are registered in Singapore, they must show clinical evidence aligning with the appropriate – Essential Principles of Safety and Performance of Medical Devices. This Draft Guidance, which improves the current GN-20 regulation, specifically addresses the use of real-world data for device clinical evaluation. https://www.pacificbridgemedical.com/news-brief/singapores-hsa-makes-public-a-new-draft-guidance-for-device-clinical-evaluation/

DEPARTMENT OF HEALTH - HONG KONG

Hong Kong Joins ICH as an Observer

On October 31, Hong Kong's Pharmacy and Poisons Board was allocated "observer status" with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Observer status will help Hong Kong become more knowledgeable about ongoing global drug registrations and help strengthen its relationship with the WHO.
https://www.pacificbridgemedical.com/news-brief/hong-kong-joins-ich-as-an-observer/