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, Q1 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)

Update to the guideline on the acceptability of names for human medicinal products processed through the centralised procedure

https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure-scientific-guideline

NEW Guideline covering information for the package leaflet regarding proline used as an excipient in medicinal products for human use

https://www.ema.europa.eu/en/proline-scientific-guideline

NEW Document: Request a change of the applicant for an ongoing marketing authorisation application

https://www.ema.europa.eu/en/documents/template-form/request-change-applicant-ongoing-marketing-authorisation-application_en.pdf

Updated QRD product-information template, version 10.4

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-templates-human

Updated QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics

https://www.ema.europa.eu/en/documents/template-form/qrd-appendix-ii-medical-dictionary-regulatory-activities-terminology-be-used-section-48-undesirable-effects-summary-product-characteristics_en.docx

Updated QRD Appendix V - Adverse-drug-reaction reporting details

https://www.ema.europa.eu/en/documents/template-form/qrd-appendix-v-adverse-drug-reaction-reporting-details_en.docx

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:

- January: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-january-2024_en.pdf
- February: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-february-2024_en.pdf
- March: https://www.ema.europa.eu/en/documents/newsletter/human-medicines-highlights-march-2024_en.pdf

Veterinary Medicines Highlights
2023 highlights from the EMA Veterinary Medicines Division:
https://www.ema.europa.eu/en/news/veterinary-medicines-highlights-2023#related-content-65169

HEADS OF MEDICINES AGENCY (HMA)

Update to CMDh Best Practice Guide on Multilingual Packaging
Available in tracked format

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_413_2019_Rev._4_2024_02_CMDh_BPG_on_multilingual_packaging_TC.pdf

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH)

Update to ICH Q2(R1) "Guideline on Validation of Analytical Procedures"
The scope of the revision of ICH Q2(R1) includes validation principles that cover analytical use of spectroscopic or spectrometry data (e.g., NIR, Raman, NMR or MS) some of which often require multivariate statistical analyses.

https://database.ich.org/sites/default/files/ICH_Q2%28R2%29_Guideline_2023_1130.pdf

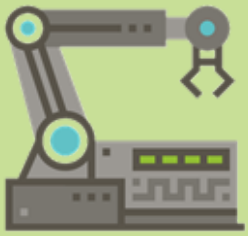
NEW **ICH Q14 "Analytical Procedure Development"**
The new guideline harmonises the scientific approaches of Analytical Procedure Development and provides the principles relating to the description of Analytical Procedure Development process.

https://database.ich.org/sites/default/files/ICH_Q14_Guideline_2023_1116.pdf

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

Updated strategy for N-nitrosamine impurities in Ph. Eur. Monographs
https://www.edqm.eu/en/-/new-strategy-for-n-nitrosamine-impurities-in-ph.-eur.-monographs

Scientific Advice, Strategy & Specialist Applications



Medical Device Submissions

Publishing

www.espl-regulatory.com

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

+44 1806 242 852

smt@espl-regulatory.com

INDIVIDUAL AGENCY NEWS

FDA - USA

FDA expands in-person face-to-face meetings

Beginning January 22, 2024, CDER and CBER will expand in-person face-to-face (FTF) industry meetings (with a hybrid component), to include all Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BsUFA), and Over-The-Counter Monograph Drug User Fee Program (OMUFA) meeting types.

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

NEW FDA Launches New Webpage for Searching Pharmaceutical Quality Documents

FDA launched a new search function on FDA's Office of Pharmaceutical Quality webpage to improve access to drug quality resources and web content. The new search webpage scans existing FDA guidance documents, manuals of policies and procedures (MAPPs), and compliance programs to provide users with relevant and up-to-date resources and information.

https://www.fda.gov/drugs/pharmaceutical-quality-resources/search-pharmaceutical-quality-documents

FDA issue Draft Guidance on Potency Assurance for Cellular and Gene Therapy Products

On December 28, 2023, FDA announced the availability of the draft guidance, Potency Assurance for Cellular and Gene Therapy Products

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/potency-assurance-cellular-and-gene-therapy-products

FDA issues Clinical Trials Transformation Initiative (CTTI) report

The report contains the findings of a collaborative project with FDA to understand the barriers to timely, accurate and complete registration and reporting of summary results information for applicable clinical trials on ClinicalTrials.gov. Through the project, CTTI documented the experiences and perspectives of interested parties from academia, the medical product industry and others on registering and submitting summary results information for applicable clinical trials into ClinicalTrials.gov.

https://ctti-clinicaltrials.org/our-work/quality/challenges-meeting-u-s-clinicaltrials-gov-reporting-requirements/

DEPARTMENT OF HEALTH - HONG KONG

NEW Hong Kong Announces New Drug Registration Process – "1+" Mechanism

The Hong Kong Department of Health announced the "1+" mechanism which now allows drug approval if the drug has been approved in only 1 reference country (not 2), and the drug is also bolstered with some local clinical data. This new program is geared towards innovative lifesaving drugs, drugs for severe illnesses, and drugs for unfulfilled medical needs.

https://www.pacificbridgemedical.com/news-brief/hong-kong-announces-new-drug-registration-process-1-mechanism/

PMDA - JAPAN

Japan Continues to Update its Drug Regulations with a New Report on RX-to-OTC Switches

Japan is initiating a number of regulations to improve its drug market including increasing novel drug reimbursement, expediting its fast-track approval system further (Sakigake), etc. In late December, the Japanese government issued a report that will decrease the time for RX drugs to become OTC products and also relax some of the burdensome requirements. If a certain foreign drug had changed its status to OTC in at least 2 foreign countries by the end of 2023, it will be eligible to switch status in Japan within 3 years (2026).

https://www.pacificbridgemedical.com/news-brief/japan-continues-to-update-its-drug-regulations-with-a-new-report-on-rx-to-otc-switches/

Japan Expands its Orphan Drug Designation System

Japan has always been a good orphan drug market with high reimbursement and oftentimes government financial support for development. However, in the past, it was not flexible on designation unless 3 criteria were met – 1. the drug had to treat fewer than 50,000 patients for a specific disease or a government-chosen disease, 2. there was a strong healthcare demand, and 3. there was good development potential. If a drug applicant reduced the patient numbers by claiming that their product addressed a subset of a disease, an orphan drug designation was still not available.

https://www.pacificbridgemedical.com/news-brief/japan-expands-its-orphan-drug-designation-system/

MOH - VIETNAM

NEW **Vietnam Introduces New Labelling Requirements for Drugs**

Vietnam's MoH announced Circular 23/2023/TT-BYT which updated the 2018 drug labeling requirements. The new drug labelling law will take effect on January 15, 2024. However, there will be a transition period until January 1, 2025. Therefore, drugs imported or made domestically this year can still use package inserts and labels before the specific batch expires.

https://www.pacificbridgemedical.com/news-brief/vietnam-introduces-new-labeling-requirements-for-drugs/

FDD - LAOS

Laos Further Clarifies Medical Device Registration

Laos' Food and Drug Department (FDD) put into practice its Registration and Notification of Medical Devices (Decision 1470) in October 2023. Laos follows the ASEAN harmonized risk classification list for medical devices. According to their new device registration scheme, all class C and D medical devices will need to begin product registration on January 1, 2024. All Class A and B devices will need to notify the FDD (Class A) and register class B products by January 1, 2025.

https://www.pacificbridgemedical.com/news-brief/laos-further-clarifies-medical-device-registration/

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

OUR SERVICES

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MHRA - UK

NEW MHRA's new International Recognition Procedure (IRP) goes live from 1 January 2024

From 1 January 2024, the EC Decision Reliance Procedure (ECDRP) has been replaced by the new International Recognition procedure (IRP). The Mutual Recognition/Decentralised Reliance Procedure (MRDCRP) has been incorporated under the umbrella of IRP. The IRP allows MHRA to reference an existing authorisation from another chosen regulatory agency to support review.

https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure

NEW Guidance: Established Medicines marketing authorisation application process implemented

From 1 March 2024, new process changes are being introduced for applications for marketing authorisations for "Established Medicines". The scope of "Established Medicines" includes products that are not new active substances and line extensions to new active substances. These process changes apply specifically to 'chemical' products (i.e. 'biosimilars' are excluded). The key changes to the process are: a. incomplete applications will not be processed; b. only one Request for Further Information (RFI) will be sent; c. following approval, applicants will be asked to submit a template pre-populated with the Lay Summary for the UK Public Assessment Report (UKPAR)

https://www.gov.uk/guidance/established-medicines-marketing-authorisation-application-process-changes

The MHRA's new RegulatoryConnect portal and its first services are now available for customers to log in and use.

RegulatoryConnect is a new IT system being developed by the Medicines and Healthcare products Regulatory Agency (MHRA) to modernise its existing regulatory IT systems and make our regulatory services more streamlined. From 25th March 2024, log-in using your existing MHRA Submissions credentials to track the status of applications and view live authorisation details, including the status of, and key data held against your existing licences.

https://regulatoryconnect.mhra.gov.uk/

TFDA - TAIWAN

NEW Taiwan's TFDA Announces New Device Regulations

On November 27, 2023, Taiwan issued an amendment to the – Regulations Governing Issuance of Medical Device License, Listing, and Annual Declaration. Medical device registration in Taiwan includes two separate applications – 1. a dossier on the product and 2. a Quality System Documentation (QSD) submission for the manufacturing facility. Now, going forward all Taiwanese medical device product licenses must also include the QSD number too – except for 125 non-sterile Class I products.

https://www.pacificbridgemedical.com/news-brief/taiwans-tfda-announces-new-device-regulations/