ISSUE. 16 NEWSLETTER 2Q 2023

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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 2023 has been a 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 NEWS

EXPERTS: POTENTIAL EU BAN ON TITANIUM DIOXIDE WOULD THREATEN ACCESS TO DRUGS

The EU proposal for manufacturers to replace titanium dioxide in medicines, if enacted, is expected to affect more than 90,0000 authorised medicines. Panelists at the recent Excipient World conference asserted that EU patients will lose access to many lifesaving medicines, as the replacement of TiO_2 would almost certainly cause significant medicines shortages and discontinuations. They also agreed that finding an alternative material would be difficult and the regulatory burden involved with the variations required to substitute TiO_2 would be significant.
See: https://www.raps.org/news-and-articles/news-articles/2023/5/experts-proposed-eu-ban-on-titanium-dioxide-would?mkt_tok=MjU5LVdMVS04MDkAAAGLoYDG_dL9qD0TSPPqVnJovDuyIY32CwL2TJy2uVXcNJ158jJwx73_vmqCn4I-qqibDJY_L8jIecCc36z0qlKm2UTI6rZcYwZj9hgZA2Vm

EUROPEAN MEDICINES AGENCY

UPDATE TO QRD TEMPLATE APPENDIX 1- PREGNANCY AND LACTATION STATEMENTS

This recent update to the QRD template has provided wording for manufacturing authorisation holders to include within section 4.6 of their SmPCs on pregnancy and lactation.
See: https://www.ema.europa.eu/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-lactation-summary-product-characteristics_en.docx

PAVING THE WAY TOWARDS COORDINATED CLINICAL TRIALS IN PUBLIC HEALTH EMERGENCIES IN THE EU

A report is now available which outlines the lessons learned on Clinical Trials in Public Health Emergencies, (EMA/ETF workshop). In particular this considers, the need to coordinate clinical trials at speed / scale to avoid fragmentation of research; the need to unite forces multinationally to make Europe more attractive to research; and to reassure on the support of the EU bodies and the member states in these endeavours.
See: https://www.ema.europa.eu/documents/report/report-ema/etf-workshop-lessons-learned-clinical-trials-public-health-emergencies_en.pdf

REFLECTION PAPER ON THE USE OF ARTIFICIAL INTELLIGENCE IN THE LIFECYCLE OF MEDICINES

The EMA has published a draft reflection paper outlining the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines. This paper, is open for public consultation, and reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting.
See: https://www.ema.europa.eu/en/news/reflection-paper-use-artificial-intelligence-lifecycle-medicines

EMA ABBREVIATIONS

This recently updated document provides abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities.
See: https://www.ema.europa.eu/documents/other/abbreviations-used-ema-human-medicines-scientific-committees-cmdh-documents-relation-emas-regulatory_en.pdf

NITROSAMINES:

a) QUESTIONS AND ANSWERS FOR MARKETING AUTHORISATION HOLDERS / APPLICANTS

The EMA has recently amended the Q&A on their approach to control the presence of N-nitrosamines
See: https://www.ema.europa.eu/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-marketing-authorisation-holders/applicants-chmp-opinion-article-53-regulation-ec-no-726/2004-referral-nitrosamine-impurities-human-medicinal-products_en.pdf

b) APPENDIX 1: ACCEPTABLE INTAKES ESTABLISHED FOR N-NITROSAMINES

A table has also been published outlining the acceptable intakes established for N-nitrosamines.
See: https://www.ema.europa.eu/documents/other/appendix-1-acceptable-intakes-established-n-nitrosamines_en.pdf

EMA NEWSLETTERS

The EMA publishes monthly newsletters to provide updates on various topics to patients, healthcare professionals and the pharmaceutical industry.
See: 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 in the past month. See:
https://www.ema.europa.eu/documents/newsletter/human-medicines-highlights-june-2023_en.pdf

SME newsletter

The latest SME newsletter is available at:
https://www.ema.europa.eu/documents/newsletter/news-bulletin-small-medium-sized-enterprises-issue-59_en-0.pdf

Veterinary medicines highlights

An update on progress towards implementing the new veterinary medicinal products regulation which took effect in January 2022. See:
https://www.ema.europa.eu/documents/newsletter/veterinary-medicines-highlights-issue-12_en.pdf

eAF (DADI) newsletter

The latest EMA newsletter containing news, views and interviews relating to the web-based Human Variations electronic application form (eAF) for Centrally Authorised Products, (sometimes known as DADI) is available at:
https://www.ema.europa.eu/documents/newsletter/electronic-application-form-eaf-product-management-service-pms-newsletter-issue-3_en.pdf

"PUBLIC HEALTH EMERGENCY CRITICAL MEDICAL DEVICES LIST"

The Medical Device Shortages Steering Group is establishing a list of categories of critical medical devices which it considers to be critical during a public health emergency. The latest document outlines the inclusion criteria and methods for selection of devices for the list.
See: https://www.ema.europa.eu/documents/other/methodology-establishment-public-health-emergency-critical-medical-devices-list_en.pdf

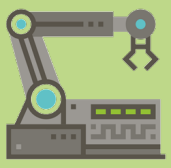
EMA GUIDANCE ON THE PRIME SCHEME (UPDATED)

The latest update provides guidance to prospective applicants to the PRIME (Priority Medicines) scheme, including relevant templates.
See: https://www.ema.europa.eu/documents/other/european-medicines-agency-guidance-applicants-seeking-access-prime-scheme_en-0.pdf

PHASING OUT OF EXTRAORDINARY COVID-19 REGULATORY FLEXIBILITIES

EMA, the European Commission (EC) and the Heads of Medicines Agencies (HMA) are phasing out the extraordinary regulatory flexibilities for medicines put in place during the COVID-19 pandemic. This follows the end of the COVID-19 public health emergency declared by WHO in May 2023.
See: https://www.ema.europa.eu/en/news/phasing-out-extraordinary-covid-19-regulatory-flexibilities

SCIENTIFIC ADVICE, STRATEGY & SPECIALIST APPLICATION



MEDICAL DEVICE SUBMISSIONS

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PRAC RECOMMENDATIONS ON SIGNALS

The latest overview of recommendations adopted by the Pharmacovigilance Risk Assessment Committee (PRAC) on safety signals discussed during the mtg of 5-8 June 2023 is available at: https://www.ema.europa.eu/documents/prac-recommendation/prac-recommendations-signals-adopted-5-8-june-2023-prac-meeting_en-0.pdf

NEW VARIATIONS GUIDANCE: UNFORESEEN VARIATIONS

New guidance is available for products authorised by the centralised procedure and describes how to request a recommendation for classification of a variation.

See: https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-recommendations-unforeseen-variations-according-article/2008_en.pdf

EDQM

PHARMEUROPA 35.3 JUST RELEASED

The latest Pharmeuropa, which includes all new European Pharmacopoeia (Ph. Eur.) texts and texts is open for public consultation. The deadline for comments is 30.09.23.

See: https://www.edqm.eu/en/-/pharmeuropa-35.3-just-released

COMMISSIONE UE

PUBLICATION OF HARMONISED STANDARDS UNDER THE MDR

The publications in the Official Journal of references of harmonised standards under the MDRs are available at: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

MHRA (UNITED KINGDOM)

SUNSET CLAUSE: REQUEST FOR PUBLIC HEALTH EXEMPTION

Under the sunset clause Marketing authorisation (MA) owners must notify MHRA when they intend to market a medicinal product or if it has been temporarily or permanently taken off the market. The MA will no longer be valid for a product that hasn't been placed on the market for 3 consecutive years unless an exemption is granted on the basis of public health – such an exemption can be applied for online at: https://www.gov.uk/government/publications/sunset-clause-request-for-public-health-exemption

BORDERLINE DETERMINATIONS

An additional section to the guideline on borderline products has been recently added to assist manufacturers in arriving at the appropriate classification for their product. See: https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medical-device#annex-a--mhra-borderline-determinations

UPDATED GUIDANCE / INCREASE IN FEES FOR MEDICAL DEVICES PLACED ON THE MARKET

Updated guidance on registering medical devices with the MHRA is available at: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#full-publication-update-history

TIMEFRAME EXTENDED FOR ACCEPTING CE MARKED MEDICAL DEVICES IN GREAT BRITAIN

CE marked medical devices will continue to be accepted on the Great Britain market beyond 30 June 2023 to support the ongoing and safe supply of medical devices and facilitate a smooth transition towards a future strengthened regulatory framework for

See: https://www.gov.uk/government/news/timeframe-for-accepting-ce-marked-medical-devices-in-great-britain-extended

HPRA (IRELAND)

DEVELOPMENTS ON THE IMPLEMENTATION OF THE NEW VETERINARY REGULATION (NVR)

The HPRA are sharing updates on key legislative, regulatory, ICT, and procedural changes relating to veterinary medicinal products

See: http://www.hpra.ie/homepage/veterinary/regulatory-information/implementation-of-the-new-veterinary-regulation-(regulation-2019-6)/monthly-update/july-2023

AIFA (ITALY)

MODIFICATION OF THE MA RENEWAL PROCEDURE FOR MEDICINAL PRODUCTS AUTHORISED UNDER THE NATIONAL PROCEDURE

AIFA has recently issued guidance for all medicinal MAs with a national procedure, regardless of their legal basis. The renewal application will follow the so-called 'standard' procedure which requires only a cover letter, application form, proof of payment and stamp duty and additional national requirements. A full renewal can be requested under exceptional circumstances.
See: https://www.aifa.gov.it/en/-/modifica-della-procedura-di-rinnovo-aic-per-medicinali-

INDIA

INDIA LAUNCHES ITS NATIONAL MEDICAL DEVICE POLICY

India has published a roadmap for accelerating growth of the medical devices sector which addresses: regulatory streamlining, enabling infrastructure, facilitating R&D and innovation, attracting investment in the sector, human resources development and brand positioning and awareness creation.
See: https://pharmaceuticals.gov.in/policy/national-medical-device-policy-2023

TGA (AUSTRALIA)

PROPOSED APPLICATION AUDIT FRAMEWORK FOR MEDICAL DEVICES

The TGA is seeking feedback on how medical device applications are selected for audit and how the audits are conducted.
See: https://www.tga.gov.au/resources/consultation/proposed-application-audit-framework-medical-devices