REGULATORY NEWSLETTER

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Global Complexity, Simplified Locally

Whats New?

The MHRA has Published a Statement on International Recognition of Medical Devices

The comparable regulator countries (CRCs) for the proposed framework will be:

- Australia (TGA)
- Canada (Health Canada)
- European Union (National competent authorities)
- United States of America (USA) (FDA)

The proposed framework would provide a certificate of international recognition that will grant devices access to the Great Britain market but would not provide a UKCA marking or UKCA certification.

EU Announces EUDAMED & IVDR Extension

The European Union has adopted new rules updating the law on medical devices in order to help prevent shortages and ease the transition to greater transparency and access to information.

The regulation adopted today amends the legislation on medical devices, including IVDs, by:

- Further extending the transition period for certain IVDs
- Enabling a gradual roll-out of EUDAMED, the new electronic database
- Requiring manufacturers to flag up potential shortages of critical medical devices and IVDs.

Top News

MHRA Announce International Recognition

EU MDR / IVDR Eudamed and IVDR Extension

MHRA Consultation on High Risk IVDs

MHRA Opens Public Consultation on Common Specifications for High-Risk IVDs

The MHRA have announced a 4 week consultation which would require manufacturers to comply with additional measures for certain high risk IVDs under the UK MDR 2002. The public consultation seeking the views of various stakeholders to improve safety measures for high-risk IVDs by including Common Specification (CS) requirements in the UK MDR 2002. In addition, they also seek views on the removal of the Coronavirus (SARS-CoV-2) Test Device Approval (CTDA) process (desktop review) to avoid duplication with the CS requirements.

https://www.gov.uk/government/consultations/common-specification-requirements-for-in-vitro-diagnostic-devices

New guideline from the EMA on the Environmental Risk Assessment of Medicinal Products for Human Use

New guideline from the European Medicines Agency (EMA) on the Environmental Risk Assessment of medicinal products for human use, accepted on February 15 and set to come into effect on September 1, 2024, stipulates that an ERA report will be required for all new applications for marketing authorization of medicinal products for human use.

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-environmental-risk-assessment-medicinal-products-human-use-revision-1_en.pdf

US FDA Published: Remanufacturing of Medical Devices

The FDA has published the final guidance "Remanufacturing of Medical Devices Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff"

This final guidance is intended to help clarify whether activities performed on devices are likely "remanufacturing." This final guidance also clarifies existing regulatory requirements for remanufacturers and includes recommendations that should be included in labelling to help assure the continued quality, safety, and effectiveness of devices.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

EU Commission Released a Survey on Notified Bodies!

The EU Commission has published the 8th Notified Bodies Survey on certifications and applications with survey results and data status.

The aim of the study is to support monitoring and analyzing the availability of medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations from the perspectives of key stakeholders. See the full survey:

https://health.ec.europa.eu/document/download/59b9d90e-be42-4895-9f6f-bec35138bb0a_en

Team-NB has published a press release 'Team-NB sector survey 2023'

Since 2010, all Team-NB members contribute to the annual Team-NB survey. This allows Team-NB to provide data on the sector over the past year and to identify trends by comparison with data from previous years.

This year the questionnaire has been enriched to provide data to shed light on the effects of Regulation 2023/607 for the extension of the transitional period for certain systems. In addition, other questions aim to shed light on specific transitions for certain articles (16, 17, 22), for artificial intelligence aspects or for Annex XVI of Regulations 2017/745and 2017/746, where applicable. In addition, 1 question focused on certificates issued under MDSAP.

www.team-nb.org/wp-content/uploads/2024/05/Team-NB-MD-Sector-Survey-PressRelease-20240515.pdf

New Notified Bodies

The European Commission has announced new Notified Bodies under Regulation (EU) 2017/745 on medical devices:

MTIC InterCert Italy
Kiwa Istanbul
QMS Services GmbH Austria

Global Regulatory Updates

South Korea has released the English version of the "Regulations on Unique Device Identification Management.

Mexico COFEPRIS announces revised labelling standard.

Ireland release guide for health institutions that manufacture and use in-house IVDs.

Australia release guide to following regulatory requirements for in-house IVDs

Upcoming Conferences

Med-Tech Conference
15 October - 17 October 2024 Toronto, Canada

American Medical Device (AMD) Summit
30 September - 1st October 2024 Chicago, USA

MedTechLIVE
18 June - 20 June 2024 Stuttgart, Germany

Medica 2024
11 November - 14 November 2024 Düsseldorf, Germany

Please reach out to us at contact@apotechconsulting.com to learn more about the impact of these updates!