RA news round-up

Last edition of 2020

Europe

The long-awaited first module of EUDAMED is online. MDR EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. The actor registration was made available on 1 December 2020. A MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States was published in MDCG 2020-15.

https://webgate.ec.europa.eu/eudamed/landing-page#/

COVID-19 related

Canada

Health Canada announced to leave COVID-19 Interim Orders in place Until fall 2021. Health Canada has put in place 5 interim orders (IO) to respond to the urgent need for access to health products as a result of the COVID-19 pandemic, e.g. for the importation, sale of and clinical trials for medical devices.

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/ensuring-predictability-interim-orders-notice.html

Health Canada's interim order regarding drug importation, sale and advertising during the COVID-19 pandemic was used to authorize the COVID-19 vaccine co-developed by Pfizer and the German firm BioNTech for use in individuals 16 years of age and up.

https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00730

Europe

The importance of cybersecurity not only for medical devices was drastically shown by the recent cyberattack that hit the European Medicines Agency (EMA). The goal of that attack was to access documents related to the regulatory submission of the COVID-19 vaccine developed in partnership of BioNTech and Pfizer. But the

EMA has assured that the cyberattack will have no impact on the timeline for its review.

https://investors.biontech.de/news-releases/news-release-details/statement-regarding-cyber-attack-european-medicines-agency

U.S. FDA

Progress Tracker for Premarket Submissions

The FDA is building a secure, web-based tracker that displays the progress on medical device submissions focused on premarket review. The progress tracker is the first feature of a larger platform to help the FDA collaborate with the medical device industry regarding the status of pending premarket device submissions.

https://www.fda.gov/medical-devices/industry-medical-devices/progress-tracker-premarket-submissions?utm_medium=email&utm_source=govdelivery

New Guidances on Safety and Performance Based Pathway

FDA issues new final guidances on Safety and Performance Based Pathway criteria for certain device types. Under the Safety and Performance Based Pathway, a medical device manufacturer has the option to use FDA-identified performance criteria to demonstrate that a device is as safe and effective as a predicate device. The Safety and Performance Based Pathway is an expansion of the concept of the Abbreviated 510(k) pathway for certain, well understood device types. The new guidance affects the following device types:

- Spinal Plating Systems
- Orthopedic Non-Spinal Metallic Bone Screws and Washers
- Magnetic Resonance Receive-Only Coils
- Cutaneous Electrodes for Recording Purposes
- Conventional Foley Catheters

https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway?utm_medium=email&utm_source=govdelivery

International news

Australia

The TGA released a new guidance for applicants (sponsors, manufacturers and agents) preparing for pre-submission meetings with the TGA related to applications. The objective of these applications are to enter therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). This includes all medicines, biologicals (cell and tissue-based products), medical devices and other listed and registered therapeutic goods.

https://www.tga.gov.au/resource/pre-submission-meetings-tga

China

THE NMPA publishes a policy interpretation of the technical guidelines for clinical evaluation of medical devices using real-world data (for trial implementation). These technical guidelines came into force on November 24, 2020 and the main contain includes

- real-world data and evidence
- the advantages and limitations of real-world research, and common Real-world data sources
- quality evaluations
- common types of real-world research designs and statistical analysis methods, and
- common situations where real-world evidence can be considered for clinical evaluation of medical devices.

https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdylqx/20201130144911110.html

South Korea

The Korean Ministry of Food and Drug safety published several news guidelines for medical devices:

- Guideline on the Review and Approval of In Vitro Diagnostic Devices for COVID-19
- Guideline on Review and Approval of Digital Therapeutics (For Industry)
- Guideline on Review and Approval of Artificial Intelligence (AI) and big data-based Medical Devices (For Industry)
- Guideline on Review and Approval for Cybersecurity of Medical Devices (For industry)

https://www.mfds.go.kr/eng/brd/m_40/list.do