



RA news round-up **CW24**

MDR – MDCG updates

New guidance document (MDCG 2020-12) was released concerning the transitional provisions from MDD and AIMDD to MDR for consultations of authorities on devices incorporating a medicinal substance as well as on devices manufactured using animal tissues.

https://ec.europa.eu/docsroom/documents?documentsIds=41622_native&iframe=true&locale=de&languagesExpanded=true&autoHeight=true

Corona related news (excerpt):

Australia:

The TGA published a regulation of thermometers and other temperature measuring medical devices for COVID-19 in response to a significant number of applications for those devices. The guidance is suppose to support manufacturer

and sponsors with meeting all the regulatory requirements and with submitting applications.

<https://www.tga.gov.au/behind-news/regulation-thermometers-and-other-temperature-measuring-medical-devices-covid-19>

A webinar concerning the supply and advertisement of certain therapeutic goods for COVID-19 was published by the TGA. <https://www.tga.gov.au/tga-webinar-supplying-and-advertising-certain-therapeutic-goods-covid-19>

EU:

The European Commission created a guidance document to help verifying that medical devices and personal protective equipment can be lawfully placed on the EU market. This document is addressed to interested parties who are not familiar with these regulated sectors.

<https://ec.europa.eu/docsroom/documents/41385?locale=de>



International news:

Canada:

The pilot project *Regulatory Enrolment Process (REP)* that digitalize regulatory activities by using web-based templates in XML format has been expanded. Medical device companies can take advantage of the fast and secure transmission via the Common Electronic Submissions Gateway (CESG). Regulatory transactions e.g. licence or Privat Label applications and amendments need to be filed in the IMDRF ToC format.

<https://www.canada.ca/enC/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/regulatory-enrolment-process/notice-expansion-medical-device-rep-via-common-electronic-submissions-gateway.html>

Malaysia:

The MDA is granting a transition period of 18 month starting in July 2020 to implement the Medical Device (advertising)

Regulation 2019 due to some implementation issues. The new regulation will now come into force in January 2022.

<https://portal.mda.gov.my/announcement/556-circular-letter-of-the-medical-device-authority-1-year-2020-transition-period-for-medical-device-advertisement.html>

UK:

New guidance on effective field safety notices (FSNs) was published to advice manufacturer of medical devices on writing clear notices and maximising replies to their FSNs.

https://www.gov.uk/guidance/effective-field-safety-notices-fsns-guidance-for-manufacturers-of-medical-devices?utm_source=f213bece-65bf-4697-8cd4-62844ac9bf93&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

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