RA news round-up
CW17

MDR – Breaking News (update)

It is done! - As per our last RA news update, the proposal for the MDR postponement was accepted by the parliament and the amending regulation (EU) 2020/561 was even published already in the Official Journal of the European Union today!

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0561

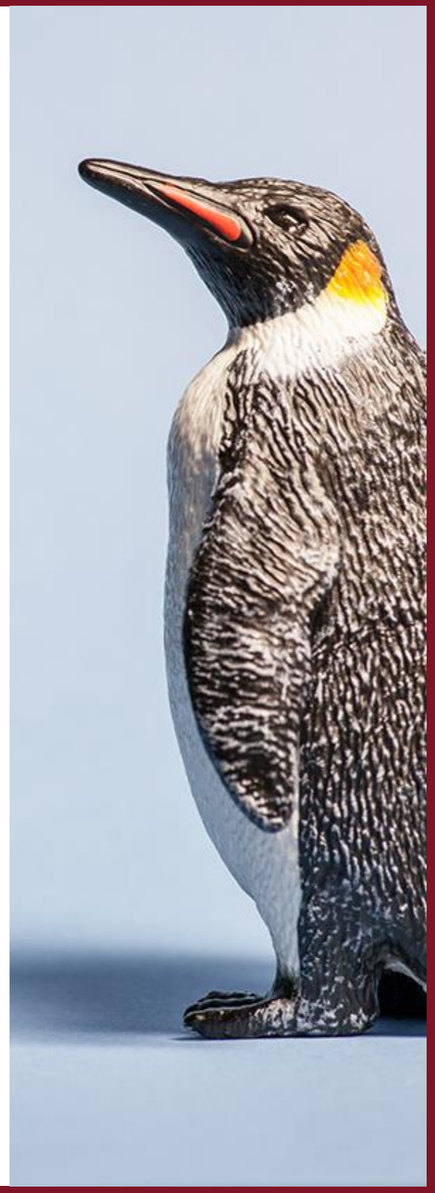
MDR – MDCG update

The European commission has published four additional MDCG Guidance documents on 24th of April 2020.

Even if the EU MDR might be postponed these Guidance shall be considered by the legal manufacturers immediately.

- **MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies**
  https://ec.europa.eu/docsroom/documents/40906?locale=de
- **MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies**
  https://ec.europa.eu/docsroom/documents/40905?locale=de
- **MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies**
  https://ec.europa.eu/docsroom/documents/40904?locale=de
- **MDCG 2020-5 Clinical Evaluation - Equivalence. A guide for manufacturers and notified bodies**
  https://ec.europa.eu/docsroom/documents/40903?locale=de

*also look out for a more detailed analysis of the new guidance in the upcoming week…



Corona related news (excerpt):

EU: The EU commission service has published a working document for Current performance of COVID-19 test methods and devices and proposed performance criteria –

Current performance of COVID-19 test methods and devices and proposed performance criteria - Working document of Commission services

Additionally, the annex I Commercial devices: provides an overview of approved test Kits as well an overview of the regulatory status.

- ID
- Source
- Status
- Speed
- Type
- Immuno-subtype
- Manufacturer
- Commercial Name
- Regulatory Status

https://ec.europa.eu/docsroom/documents/40805?locale=de

APAC Region EUA Information: Several Countries in the APAC Region are still working on an Emergency Use Authorization (EUA) for Products during the COVID-19 pandemic.

Chinese Taipei:

List of COVID-19 related EUA on Manufacturing/Import of Medical Device

http://www.fda.gov.tw/ENG/site.aspx?sid=11194

Kingdom of Saudi Arabia:

Saudi FDA Regulatory requirements for Emergency Use Authorization (EUA) for IVDD and Personal Protective Equipment (PPE) during the outbreak of COVID-19

https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-Efforts-COVID19.pdf

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Corona related news (excerpt) - continued:

China:

1. NMPA gives emergency approvals to COVID-19 test kits

http://english.nmpa.gov.cn/2020-03/27/c_465663.htm?from=singlemessage&isappinstalled=0

2. Regulatory Requirements and Standards for Coronavirus Reagent Test Kits and Protective

Equipment in China

http://english.nmpa.gov.cn/2020-03/30/c_467202.htm

Republic of Korea:

List of COVID-19 Diagnostic Kits Authorized for Use under Emergency Use Authorizations

https://www.mfds.go.kr/eng/brd/m_52/view.do?seq=74424&srchFr=&srchTo=&srchWord=&srch

IMDRF Updates:

The International Medical Devices Regulatory Forum (IMDRF) has published 4 new documents on 20th of April 2020.

- IMDRF/CYBER WG/N60FINAL:2020 Principles and Practices for Medical Device Cybersecurity

This document provides concrete recommendations to all responsible stakeholders on the general principles and best practices for medical device cybersecurity (including in vitro diagnostic (IVD) medical devices) and Employ a risk-based approach to the design and development of medical devices with appropriate cybersecurity protections.

It shall Ensure the safety, performance, and security of medical devices and the connected healthcare infrastructure during the total Product life Cycle (TPLC) and differentiate between Pre-Market Considerations for Medical Device Cybersecurity and Post-Market Considerations for Medical Device Cybersecurity in respect to

- Design Principle,
- Secure Communications,
- Data Protection, Device Integrity,
- User Authentication, Software Maintenance,
- Physical Access as well as Reliability and Availability

Principles and Practices for Medical Device Cybersecurity - PDF (951kb)Principles and Practices for Medical Device Cybersecurity - DOCX (407kb)

- IMDRF/GRRP WG/N59FINAL:2020 Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

  Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews - PDF (730kb)

- IMDRF/PMD WG/N58FINAL:2020 Personalized Medical Devices - Regulatory Pathways

  Personalized Medical Devices - Regulatory Pathways - PDF (612kb)

- IMDRF/AE WG/N43FINAL:2020 (Edition 4) Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes

Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes - PDF (1.21Mb)

Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes - XLSX (42kb)

Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER): Type of investigation - XLSX (13kb)

Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER): Investigation Findings ('what were the findings?') - XLSX (22kb)

Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER): Investigation Conclusion - XLSX (14kb)

Annex E IMDRF terminologies for categorized Adverse Event Reporting (AER) Health Effect - Clinical Signs, Symptoms and Conditions - XLSX (75kb)

Annex F IMDRF terminologies for categorized Adverse Event Reporting (AER) Health Effect - Health Impact - XLSX (14kb)

Annex G IMDRF terminologies for categorized Adverse Event Reporting (AER): Medical Device Parts and Component Terms and Codes - XLSX (29kb)