Newsletter | May 2023

For more information and regular updates please consult our website HERE.

As we continue our efforts to support the implementation of the **Medical Devices Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)**, we aim to keep you informed about the latest developments, and all relevant news and events.

In this edition of our newsletter, we bring you updates on the adoption and publication of amendments to the Regulations with respect to transitional provisions and re-assessment of notified bodies, the EU Chair of the IMDRF and the events in Brussels, along with new guidance documents, and much more!

In this issue:

Adoption of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, and publication of a Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607

On 15 March 2023, the European Parliament and the Council adopted Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro medical devices (IVDR) as regards the transitional provisions for certain devices. The amendment introduces a staggered extension of the transition period provided for in the MDR, subject to certain conditions. It also deletes from both the MDR and the IVDR the 'sell-off' deadline after which devices placed on the market before or during the transition periods that are still in the supply chain would have had to be withdrawn.

The amending Regulation (EU) 2023/607 was published in the *Official Journal of the European Union* (OJEU) on 20 March 2023 and entered into force on the same day.

Shortly afterwards, the Commission published a Q&A document on practical aspects related to the

- MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
- Commission Guidance on the content and structure of the summary of the clinical investigation report
- Updated list of ongoing guidance development and deliverables of MDCG Subgroups
- Updated information on coverage of designation codes by MDR/IVDR notified bodies
- Updated information on the applications for designation as a notified body
- New EU UDI Helpdesk
- Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)
- Annual overview of devices subject to the clinical evaluation consultation procedure (CECP) - April 2021-June 2022
- SCHEER - Call for information for updating the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices
- EU 2023 Chair of the Management Committee of the International Medical Device Regulators Forum (IMDRF) – Events in Brussels

implementation of Regulation (EU) 2023/607.

For more, see here and here, from the Commission's webpage on Extension of the transition periods provided for in the regulations.

Publication of Delegated Regulations 2023/502 and (EU) 2023/503 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the frequency of complete re-assessments of notified bodies

After scrutiny by the European Parliament and the Council, two Commission Delegated Regulations (EU) 2023/502 and (EU) 2023/503 amending Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* medical devices as regards the frequency of complete re-assessments of notified bodies, adopted in December 2022, were published in the Official Journal of the European Union (OJEU) on 8 March 2023 and entered into force on 11 March 2023.

For more, see here and here, from the Commission's webpage on Delegated acts adopted under the regulations.

Amendment to the MDR/IVDR standardisation request

On 31 January 2023, the European Commission adopted Implementing Decision C(2023) 694 (M/575 Amd 1) amending Implementing Decision C(2021) 2406 (M/575) on a standardisation request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) as regards medical devices in support of Regulation (EU) 2017/745 (MDR) and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 (IVDR). It makes some changes to the list of items in Annexes I and II.

The amending act was notified to CEN and CENELEC and they accepted it on 28 February 2023, to make the amended MDR/IVDR standardisation request fully applicable.

For more, see here from the Commission's eNorm Platform, and the Commission's webpage on Harmonised Standards.

Meetings of the Medical Device Coordination Group (MDCG)

On 17-18 April 2023, new meetings of the Medical Device Coordination Group (MDCG) took place, with the participation of national competent authorities and stakeholders. On the agendas, the ongoing transition to the MDR and IVDR, EU4Health actions in support of the implementation, and other issues for information and discussion.

For more, see here and here, from the Register of Commission Expert Groups and Other Similar Entities.

The 2023 planning of the MDCG and MDCG Subgroups is available here, from the Commission's webpage on Medical Device Coordination Group Working Groups.

Revision of MDCG 2020-16 Guidance on Classification Rules for *in vitro* Diagnostic Medical Devices under Regulation (EU) 2017/746

The Medical Device Coordination Group (MDCG) endorsed MDCG 2020-16 rev.2 as guidance on classification rules for *in vitro* diagnostic medical devices under Regulation (EU) 2017/746. This revision concerns in particular modifications to Rules 3(f) and (m), the addition of Annex 2, and some editorial changes.

For more, see here from the Commission's webpage on Guidance.

MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

The Medical Device Coordination Group (MDCG) endorsed MDCG 2023-1 as guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

For more, see here from the Commission's webpage on Guidance.

MDCG 2023-2 List of standard fees

The Medical Device Coordination Group (MDCG) endorsed MDCG 2023-2 with the list of standard fees for notified bodies, with specific forms for the Medical Devices Regulation (EU) 2017/745 (MDR form) and for the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR form).

For more, see here, here and herefrom the Commission's webpage on Guidance.

MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices

The Medical Device Coordination Group (MDCG) endorsed MDCG 2023-3 with questions and answers on vigilance terms and concepts as outlined in Regulation (EU) 2017/745 on medical devices.

For more, see here from the Commission's webpage on Guidance.

Commission Guidance on the content and structure of the summary of the clinical investigation report

The Commission Guidance on the content and structure of the summary of the clinical investigation report was published in accordance with Article 77(6) of Regulation (EU) 2017/745 on medical devices. It aims to ensure that the summary of the clinical investigation report presents information about the design, conduct, analysis and results of the clinical investigation in terms and in a format that are easily understandable to the intended user of the medical device.

For more, see herefrom the Commission's webpage on Guidance.

Updated list of ongoing guidance development and deliverables of MDCG Subgroups

The European Commission published updated information on the ongoing guidance, development and deliverables of the Subgroups of the Medical Device Coordination Group (MDCG).

For more, see here from the Commission's webpage on Guidance.

Updated information on coverage of designation codes by MDR/IVDR notified bodies

The European Commission published updated information on coverage of designation codes by notified bodies under Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR).

For more, see here from the Commission's webpage on Notified Bodies.

Updated information on the applications for designation as a notified body

The European Commission published updated information on the applications for designation as a notified body for Regulations (EU) 2017/745 and (EU) 2017/746 via an overview at each stage of the process.

For more, see here from the Commission's webpage on Notified Bodies.

New EU UDI Helpdesk

On 14 March 2023, the Commission's new EU UDI Helpdesk went live. It will help economic operators to implement the requirements introduced by the unique device identification system.

For more, see here from the Commission's webpage on Unique Device Identifier - UDI.

Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)

On 2 March 2023, the European Commission published an expert decision and opinion from expert panels on medical devices and *in vitro* diagnostic devices (Expamed) in the context of the clinical evaluation consultation procedure (CECP).

For more, see here from the Commission's webpage on Expert Panels.

Annual overview of devices subject to the clinical evaluation consultation procedure (CECP) - April 2021-June 2022

On 16 January 2023, the European Commission released a Staff Working Document with the annual overview of devices subject to the clinical evaluation consultation procedure (CECP) pursuant to Article 54(4) of Regulation (EU) 2017/745 on medical devices (April 2021-June 2022).

For more, see here from the Commission's webpage on Expert Panels.

SCHEER - Call for information for updating the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices

The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has received a request for updating the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting properties. Interested parties are invited to submit any relevant information that could assist the scientific committee with their assessment and update of the existing guidelines document.

For more, see here.

EU 2023 Chair of the Management Committee of the International Medical Device Regulators Forum (IMDRF) – Events in Brussels

During the EU 2023 Chair of the Management Committee of the International Medical Device Regulators Forum (IMDRF), two public events took place in Brussels on 27 and 28 March 2023. All the information, the presentations given, and the audios are available:

- Day 1 - 27 March 2023 - Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop – Meeting audio
- Day 2 - 28 March 2023 - IMDRF Stakeholder Forum – Meeting audio

The next session of the IMDRF will take place in Berlin, Germany on 25-26 September 2023.

For more, see here from the Commission's webpage on International Cooperation, and the specific webpage on the IMDRF 2023 EU Chair.

Stay tuned for future updates!

To stay up to date on all information related to medical devices and *in vitro* medical devices, please visit the Medical Devices section on the Commission's Public Health website regularly.

For more information and regular updates please consult our webpages

- **Public health - Medical Devices:** https://health.ec.europa.eu/medical-devices-sector_en
- **Overview on the new Regulations including factsheets and communication material:** https://health.ec.europa.eu/medical-devices-new-regulations/overview_en
- **Publications and factsheets:** https://health.ec.europa.eu/medical-devices-sector/publications_en
- **Getting ready for the new Regulations:** https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en
- **New Regulations including legal texts, implementing measures and delegated acts:** https://health.ec.europa.eu/medical-devices-sector/new-regulations_en
- **Guidance documents:** https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- ***In Vitro* Diagnostics:** https://health.ec.europa.eu/vitro-diagnostics_en
- **Topics of interest including counterfeiting, custom-made devices, financing, in-house medical devices, software and apps:** https://health.ec.europa.eu/medical-devices-topics-interest/overview_en
- **Harmonised standards:** https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
- **Notified bodies:** https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en
- **Unique device identifier (UDI):** https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en
- **EU UDI Helpdesk:** https://webgate.ec.europa.eu/udi-helpdesk
- **Reprocessing:** https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices_en

- **Dialogue between interested parties:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties_en
- **Medical Device Coordination Group (MDCG) and subgroups/working groups:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en, https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en
- **Medical Device Coordination Group (MDCG) in the Register of Commission Expert Groups and Other Similar Entities:** https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=3565
- **International Cooperation:** https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_en
- **Expert panels:** https://health.ec.europa.eu/medical-devices-expert-panels_en
- **Eudamed:** https://health.ec.europa.eu/medical-devices-eudamed_en
- **Eudamed database:** https://ec.europa.eu/tools/eudamed/
- **Eudamed Information Centre:** https://webgate.ec.europa.eu/eudamed-help/
- **EuropeanMedical Device Nomenclature (EMDN):** https://webgate.ec.europa.eu/dyna2/emdn/A