EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical products and innovation
Medical devices

Brussels, 18 October 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) with stakeholders 24/08/2022

1. Opening, adoption of the agenda

The Chair welcomed the MDCG members and stakeholders to this extraordinary meeting dedicated to notified body capacity and availability of medical devices and IVDs, and introduced the draft agenda, which was adopted.

The minutes of the MDCG meeting with stakeholders on 19 May 2022 had been endorsed prior to the meeting through written procedure and published on the Commission's Registry for expert groups.

2. Draft MDCG position paper "Transition to the MDR and IVDR: Notified body capacity and availability of medical devices and IVDs" – *for discussion*

The draft MDCG position paper was supported by all stakeholders that took the floor. They considered that the actions listed in the draft paper would facilitate the transfer to the Regulations. Many of them called for urgent follow up of the actions and a more detailed implementation plan, including timelines. While supporting the identified actions in the position paper, most stakeholders indicated that, as regards the MDR, those actions would not be sufficient and that additional legislative measures to give more time for the mitigating actions to take effect would be needed.

In particular:

Representatives of **notified bodies** supported especially actions 1 to 8 related to notified body capacity. With regard to action no. 8, the omission of mentioning hybrid joint assessments was considered a missed opportunity. As regards actions no. 12 and 13, notified bodies stressed that the majority of manufacturers applying for conformity assessment are actually SMEs. In respect to action no. 14, notified bodies informed that they had capacities available for conformity assessments both under the MDR and IVDR; however, the situation was particularly challenging for some codes, such as soft tissues, orthopaedics, infectious diseases. With regard to action no. 16, notified bodies informed that they were in the process of preparing guidance for manufacturers.

Representatives of all **industry associations** also supported all actions, considered however that more measures were needed to provide more clarity and timelines for the individual non-legislative actions as well as legislative actions. Among the non-legislative actions listed in the draft position paper, provisional/conditional certification, leveraging of evidence from Directives for MDR/IVDR certification, structured dialogue between manufacturers and

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

notified bodies, pragmatic approach to clinical evidence and hybrid audits were considered as the most effective ones. Another industry association stressed the focus on assessment of compliance with MDR requirements rather than surveillance of MDD requirements, changed frequency of complete re-assessments of notified bodies and additional guidance on clinical evidence.

As regards legislative changes to the MDR, some preliminary ideas were suggested such as postponement of May 2024 deadline, extension of the validity of Directives certificates and gradual risk-based roll-out, removal of sell-off date. It was stressed that expiring certificates put manufacturers in front of immediate challenges in 2022 and 2023 for which harmonised solutions were needed. Diverging national approaches to Article 59 MDR (derogations) and/or Article 97 MDR (other non-conformity) were considered very resource-intensive, contrary to the single market and have an impact on market access to 3rd countries traditionally relying on CE marking (some 3rd countries were switching to relying on FDA approvals instead). Article 59 was not considered as a suitable solution, while application of Article 97 should be based on clear and uniform criteria and only be used as bridging solution to allow transition to the MDR. The urgency of the need for solutions was underlined (by end 2022 at the latest).

One industry association confirmed that all its members have access to a notified body, but limited notified body capacity and reinforced requirements had a negative impact on the length of ongoing conformity assessments. Another association highlighted that solutions were needed for manufacturers (mainly SME) that do not have access to a notified body yet. A survey conducted by one association among SMEs and first-time applicants revealed that 30% had been turned down by a notified body, 50% considered exchanges with notified bodies as complicated, 50% experienced more uncertainty and 50% expected device shortages due to MDR. One industry association reminded that the adoption of the common specifications for Annex XVI products was urgently needed. It also called on Member States to refrain from national registration initiatives.

In respect of the IVDR, industry representatives stressed the need for predictable and timely certification of innovative or significantly changed IVDs. In particular for class D IVDs solutions were needed having regard to the very low number of notified bodies designated under the IVDR. It would also be necessary to put in place other infrastructure for the regulatory system not mentioned in the MDCG position paper. One industry association asked notified bodies under the IVDR to communicate on where they have free capacity to take up applications.

The association of **medical societies** also expressed full support for actions and highlighted the need for solutions for orphan/niche devices, innovative devices and clarification of clinical evidence requirements. Surveys are being conducted by some medical societies to identify risk of device shortages.

The association of **authorised representatives** called for the removal of the sell-off date and asked for clarification of the concept placing on the market in respect of imported products.

The association of **clinical laboratories** expressed concerns that problems related to IVDR implementation were shifted to the laboratories. There were first signs that certain reagents were not any more available. The sector was double hit by the IVDR and REACH restrictions.

In the subsequent discussion, a MDCG member asked that additional measures should be considered and that Article 59/Article 97 were not suitable as a general solution to the current challenges.

3. Preliminary draft for Commission delegated acts amending Article 44(10) of Regulation 2017/745 of the European Parliament and of the Council on medical devices and Article 40(10) of Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as regards the frequency of complete re-assessments of notified bodies - *for discussion*

Industry representatives welcomed the planned acts, but suggested that also the scope and depth of the complete re-assessment should be considered in order to make it quicker and less resource intensive.

Notified body representatives also welcomed the planned acts, but considered that the timing of complete re-assessments should be more flexible also with the possibility to further postpone them. The situation of ongoing re-assessment should be further clarified and the interests of those notified bodies already re-assessed duly taken into account.

Stakeholders were given until 2 September 2022 to provide comments in writing.

4. AOB

NA

List of participants

MDCG members: AT, BE, BG, HR, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HU, IE, IT, LU, LT, MT, NL, PL, PT, RO, SI, SK, SE.

Observers: LI, NO, TR.

Commission: SANTE B6, SANTE F5, JRC F2.

Stakeholders' organisations / associations participating in MDCG Subgroups