EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

Minutes of the expert groups

Brussels, 30 November 2021

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) with stakeholders 18/10/2021

1) Opening, adoption of the agenda

The agenda was approved and minutes of last meeting held on 28 May 2021 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

2) Implementation MDR / IVDR – Medical Devices Regulation / *In vitro* Diagnostic Medical Devices Regulation

Commission welcomed participants to another meeting between MDCG members and main relevant EU-based stakeholders' associations that have been nominated as observers in various MDCG sub-groups. The main objective of the meeting was to facilitate exchange of information on the implementation status of the two Regulations. The Commission provided information and general state of play on a variety of topics, mainly:

- IVDR amendment proposal for a progressive roll out published on 14 October 2021; date of application remains the same with an extension of transitional provisions; text must be adopted by the European Parliament and Council to come into force;
- Ongoing work, priorities and planning of next deliverables in MDCG sub-groups;
- MDCG Task Force on legacy devices;
- Joint Assessments for notified bodies;
- Notified bodies survey on certifications and applications (MDR/IVDR);
- EUDAMED development;
- Update on the work of expert panels.

Representatives of the associations AESGP, COCIR, MedTech Europe, Team-NB and Biomed Alliance shared their perspectives on the implementation of the legal framework, appreciated the opportunity to intervene and highlighted from their point of view the most relevant aspects, main achievements and remaining challenges. Dedicated discussions with a number of stakeholders are organised in parallel and consultations on specific technical issues are ongoing

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

and will continue either in the various MDCG sub-groups or in writing based on priorities and available resources.

3) AOB

The Commission briefly informed on the following:

Use of octylphenol ethoxylate (Triton-X-100) in medical devices and in vitro diagnostic medical devices for diagnosis, treatment or prevention of COVID-19: there is a sunset date (22 December 2023) concerning the use of octylphenol ethoxylate (e.g. Triton X 100) that is currently still allowed in medical devices/IVDs for COVID-19 related uses. If manufacturers intend to use OPE/Triton-X-100 beyond the sunset date, they need to submit an application for authorisation under REACH before 22 June 2022 (18 months before sunset cate). In order to help industry in preparing the application file and allow for ECHA's own planning, ECHA requests companies to notify their intention to submit an application at least 6 months before the application deadline, **i.e. by 22 December 2021**.

Revision of the EU general pharmaceuticals legislation (europa.eu) The consultation is open **until 21 December 2021**. It aims to collect views of stakeholders and the general public in order to support the evaluation of the existing general pharmaceutical legislation on medicines for human use, and the impact assessment of its revision to ensure a future-proof and crisis-resistant medicines regulatory system. Especially relevant from the perspective of the MDR/IVDR are the topics related to borderline & classification, combination products (i.e. drug device combinations), companion diagnostics, digital products/therapeutics (i.e. MDSW), AI utilised in clinical trials and many other issues will be open to evaluation under the pharma strategy.

Ongoing public consultation on the revision of the classification, labelling and packaging (the so-called CLP) regulation. The consultation will end on **15 November 2021** and might result in modifying existing CLP exemptions and potentially extend some labelling obligations to the medical device sectors. In particular questions number 10 and 45 are especially relevant for the medical device sector.

EU Declaration of Conformity and parallel trade: Commission informed that they received complaints from a "parallel trader" that some (big) manufacturers add in their DoC that it is 'for internal use' or for use only by a specific distributor and that the DoC may not be disclosed to any 3rd party with prior authorisation. The preliminary assessment by Commission services with market surveillance competent authorities was that the DoC should not bear a statement that would restrict its use and would make disclosure subject to the manufacturer's prior approval. The stakeholder representatives, especially those representing manufacturers, were invited to inform whether they are aware of those practices and what could be the rationale at sante-med-dev@ec.europa.eu not later than **10th November, 2021.**

Next meeting

The next MDCG meeting with stakeholders will take place in 2022 and exact dates will be communicated as soon as possible.

List of participants

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

Observers: IC, LI, NO, TR.

Commission: SANTE B6, SANTE F5, JRC F2, SANTE A4

Stakeholders' Organisations / associations participating in MDCG Subgroups.