EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical Devices

Minutes of the expert groups

Brussels, 20 October 2020

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) – 14/09/2020

MDCG meetings are not public and they are intended only for MDCG members. Due to challenges caused by COVID-19, the meeting was organised with video-audio connection.

This was an extraordinary meeting organised by the Commission to discuss with MDCG members the issue of **Joint assessments of notified bodies during Covid-19 quarantine orders and travel restrictions.**

The Commission (Chair) noted that Joint Assessments (JAs) and subsequent designations of notified bodies is a key element to ensure effective implementation of the Regulations as well as availability of devices and a high level of patient safety thereof. Under the Regulations, JAs are a joint responsibility for the Commission and Member States. So far, on-site assessments have not been greatly delayed by the pandemic (only in one case). However, the pandemic is already having a detrimental effect on the availability of national experts. Some experts have expressed concerns in participating in on-site assessments, due to the uncertain epidemiological situation. As a consequence, it has not yet been possible to assemble some joint assessment teams for the assessments planned for the rest of the year. It was reminded that the role of national experts to be nominated by MS is pivotal for the conduct of the joint assessment process. Taking into consideration the unprecedented circumstances caused by COVID-19, and the resulting travel and quarantine restrictions, the Commission called for this meeting in order to discuss the issue with MDCG members and call on increased solidarity and commitment from Member States.

Main conclusions:

- There was a general agreement that joint assessments are key in ensuring effective implementation of the MDR and IVDR and based on the list of planned on-site assessments. Every effort should be made not to postpone any on-site assessment, even if changes in the joint assessment team may occur with very short notice. Commitment for the participation of national experts has not been obtained for all planned JAs and a dedicated call for availability will be launched.

- The possible need to use, in specific circumstances and on a case-by-case basis, a different (i.e. reduced) number of experts in the joint assessment team was recognised and reference was made to Article 39(3) MDR and Article 35(3) IVDR. It was clarified that those situations may arise with no material time to ask for the endorsement of the MDCG (e.g. if experts are suddenly

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

prevented from travelling the day before they are meant to do so, or if they are denied entry in the country); however MDCG will nevertheless be informed.

- Plan for back up teams and/or alternate dates for planned on-site JAs was suggested by one delegate.

- Some called for a broader discussion on the ability to conduct the on-site element of the joint assessment process during the pandemic. Flexibility to consider the possibility of conducting at least part of the on-site assessment remotely (hybrid solution) was suggested by some delegations, including the possibility to review some documentation off site.

- The need to ensure that social distancing requirements can be maintained at all times was emphasised as key in protecting the members of the JATs'.

- MDCG also called on the EU Commission to look at other sectors, including to see what is typically happening as regards audit processes for designations of notified bodies during COVID-19.

MDCG concluded that there was a common understanding in search for pragmatic solutions during these exceptional circumstances. Every effort will be made in order to proceed with the on-site assessments, even in a continuously evolving situation around COVID-19. The possibility to accept some flexibility as regards the number of National experts in the joint assessment team and/or to perform parts of the JA from distance will be explored on an ad hoc basis in close collaboration between the Commission and MDCG.

The Commission will follow up the discussion and work to identify the best possible solutions on a case-by-case basis as regards the on-site assessments planned for the rest of the year.

At the margin of the meeting, one MS raised the question of remote audits of manufacturers by Notified Bodies under the MDR. Concerns were expressed that at this time of travel restrictions in a global pandemic, Notified Bodies designated to the MDR will not be able to issue certificates to the MDR unless they can complete quality system assessments and thereby limiting the possibility of having MDR certified devices on the market in May 2021. COM informed that consultation of NBO (Notified Bodies Oversight MDCG WG) and stakeholders on the draft Q&A on alternative temporary measures to notified body audits was concluded and comments will be processed soon. Discussion will continue at the level of NBO.