EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical devices

Brussels, 27 May 2020

Minutes

Call of the MDCG Subgroup In Vitro Diagnostics (IVD WG)
Competent Authorities with stakeholders
Brussels, 25 May 2020, 14:00-15:15

1) Welcome and agenda

The Chair noted that the objective of the call was to exchange an overview of COVID-19 related activities and the impact of COVID-19 on the IVD sector.

2) Commission and competent authority activities related to COVID-19

The Commission explained different levels of ongoing IVD-related COVID-19 work. The following examples were given. COVID-19 discussion on testing is taking place at the Integrated Political Crisis Response forum in the Council, the Health Security Committee (Member State group) in the Commission. In the Commission, a special inter-DG structure has been created, the COVID-19 Clearing House (CCH, a hub to facilitate matching supply and demand of medical equipment at EU level and support MS and stakeholders with bottlenecks in the supply chain, organized into 5 thematic multi-DG clusters, one of the clusters is test materials). The medical device units continue to fulfil their usual duties. The European Centre for Disease Prevention and Control (ECDC) monitors the epidemiological situation and issues advice. Weekly calls take place between Commissioners Kyriakides and Breton and pharmaceutical and medical device industry. Calls with Member States and industry also take place in the framework of the CCH on supply and demand issues.

Publication of the following documents was highlighted:

- 3 Apr - Informal Commission guidance: Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context
- 8 Apr - MDCG guidance: Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions
- 15 Apr - Communication from the Commission: Guidelines on in vitro diagnostic tests and their performance – adopted by COM, OJ text here
  Linked to Joint European Roadmap to lifting of containment measures
- 16 Apr - Working document of Commission services: Current performance of COVID-19 test methods and devices and proposed performance criteria
- 16 May – database of devices and publicly available performance data COVID-19 In Vitro Diagnostic Devices and Test Methods

In the IVD WG, the regulators have had numerous exchanges on COVID-19 device market surveillance. Exchanges on other topics have included COVID-19 device performance and need for guidance, possible amendment of Annex II of Directive 98/79/EC (IVDD) to add COVID-19 devices, “professional use” and “health professionals”.

3) Interventions from stakeholders

Stakeholders were invited to take the floor to explain how they have been impacted by COVID-19 and what actions they have taken. They highlighted delays and difficulties for their members due to the crisis, notably also with work towards implementation of the Regulation (EU) 2017/746 (IVDR), such as auditing constraints for notified bodies and challenges with obtaining clinical data. It was underlined that a postponement of the IVDR should be considered. The key role of in-house devices was noted in response to the pandemic. Other issues included limited knowledge of new market players about the EU legislation and the role of different market operators such as authorised representatives. It was noted that the EU framework offers quick market entry via self-declaration. While this does not include any third-party verification, it has allowed placing devices on the market faster compared to more thorough but lengthy assessment by notified bodies, which is currently not applicable to COVID-19 tests. The stakeholders raised the need for stronger enforcement of the IVDD and more transparency on regulatory actions against non-compliant devices. Devices may also currently be used even without CE-marking if permitted in exceptional circumstances by national derogations. The stakeholders called for bringing forward the application of EU-wide derogations foreseen by Article 54 of the IVDR.

4) Discussion

Regarding EU reference laboratories (EURLs) foreseen by the IVDR, the Chair clarified that according to Article 113 (d) of the IVDR, Article 100 on EURLs applies from 25 November 2020. Therefore EURLs cannot be designated earlier and the relevant implementing acts may also apply from this date at the earliest. Designation is likely in 2021.

Regarding expert panels, selection of experts has been completed and the Commission is working on setting up the secretariat.

The stakeholders enquired whether class D devices were the priority for the work on implementing the IVDR. This was confirmed.

Regarding COVID-19 tests and possible amendment of IVDD Annex II to include them, the stakeholders highlighted that given the time needed (several months) for the procedure and transition period to allow market operators to adjust, the duration of the application of such an amendment would be rather short before the IVDR comes into application on 26 May 2022. This concern brings the added value of the amendment into question. They also raised the need to consider timing as by the time the Annex is amended, the epidemic may be at a different stage. The Commission noted that this could be a medium-term measure, while needs in the short term may be served by guidance on COVID-19 device performance. The next steps will be considered by the competent authorities.

The stakeholders enquired why national competent authorities did not consider it necessary to bring forward the application of IVDR Article 54 on EU-wide derogations to earlier than 26 May 2022. The Chairs noted that the situation in each Member State is different with respect to e.g. delivery of tests, availability of distributors, extent of use of in-house tests, and therefore they may have different needs. It is also the responsibility of each national competent authority to assess applications for derogation.

The stakeholders raised the need to coordinate between laboratories. The Chairs clarified that such coordination is taking place with the assistance of the ECDC and JRC. While the outputs are relevant to the work of the IVD WG, coordination of laboratories is not directly in the remit of the IVD WG.

The Chairs informed the participants that the Commission will publish an overview of follow-up actions to the Communication Guidelines on in vitro diagnostic tests and their performance.

5) AOB – none

Next meeting: To be confirmed

List of participants

Competent authorities:

HR, CY, DK, EE, FI, FR, DE, HU, SE, IE, SK, LV, FI, CZ, NL, NO, PT, IT, ES, AT, CH

Stakeholders: BioMed Alliance, EAAR, EFLM, EFPIA, MedTech Europe, NB-MED, TEAM NB

Commission: SANTE / B6, SANTE / F5, SANTE / F4