

MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time: **05 February 2021 (10:30 – 12:00)**

Venue: **Audio meeting**

1. Opening, adoption of the agenda

COM welcomed participants in the NBO extraordinary meeting on temporary extraordinary measures during Covid-19 exceptional circumstances and Commission Notice 2021/C 8/01.

The agenda was adopted.

2. Temporary extraordinary measures during Covid-19 exceptional circumstances and Commission Notice 2021/C 8/01 – Presentation from the Commission

COM summarised the actions taken jointly with the Member States to address the issue of inability of notified bodies to carry out on-site audits since the beginning of the COVID-19 pandemic.

COM described the main contents of Commission Notice 2021/C 8/01 adopted on 8 January 2021¹, highlighting in particular:

- the role of Member States in monitoring and enforcing application of the Regulations, also in the exceptional and unforeseen circumstances caused by the COVID-19 crisis;
- the need for notified bodies to perform a case-by-case assessment of individual circumstances, and to duly justify the individual derogations, not going beyond what is required to ensure continuous availability of safe and performant devices;
- the need for notified bodies to apply a risk-based approach, with the results duly documented and substantiated;
- the need to take decisions on certification limited to the time strictly necessary to allow for a proper on-site audit to be performed as soon as possible.

COM also referred to the initiative of notified bodies to draft a position paper on the issue. The draft needs further alignment and COM invited participants to approach notified bodies

¹ Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (2021/C 8/01) (OJ C 8, 11.1.2021, p. 1).

designated in their Member States helping to ensure that contents of the Notice are properly understood.

For the sake of continuous monitoring of the situation, COM proposed to set out a specific CIRCABC workspace and invited Member States to share information about extraordinary measures taken by notified bodies designated under the Regulations.

3. Exchange of views with Member States

Member States generally appreciated the initiative taken by COM with Notice 2021/C 8/01 and asked for some clarification on contents and practical implementation. A number of clarifications was provided, including:

- the meaning and the impact of the Notice: COM recalled that the possibility of carrying out remote audits is based on application of notion of *force majeure* and each such derogation from the requirements of the Regulations needs to be duly justified on the basis of a case-by-case assessment and monitored by Member States;
- the need for notified bodies to implement a specific procedure: COM agreed that, as a first step, notified bodies should establish internal procedures in case they need to apply extraordinary measures;
- the scope of devices covered by the Notice: COM clarified that the Notice is not limited to clinically necessary devices for Covid-19, but in principle concerns all devices, when in duly justified circumstances the placing on the market of devices concerned cannot take place otherwise and continuous availability is at risk;
- the monitoring activities to be performed by the Member States and the information to be collected and shared with COM and the other Member States: COM will set up a CIRCABC workspace and give access to all NBO Members. Some Member States expressed their willingness to establish a set of data to be reported in a standardised template. COM underlined the key role of Member States on defining their needs and encouraged them to put forward concrete proposals on the information they would consider convenient and useful to share. COM confirmed its availability to receive concrete proposals and to facilitate exchanges among the Member States. Information required by COM would be limited to those mentioned in the Notice.

4. AOB

No other business was discussed.

List of participants

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

Observers: CH, IC, NO, TR.

Commission: SANTE B6, SANTE F5.