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INFORMATION NOTE

JOINT ASSESSMENTS UNDER THE NEW REGULATIONS ON MEDICAL DEVICES

Regulation (EU) 2017/745 on medical devices (the MDR)¹ and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR)² were published on 5 May 2017 and entered into force on 25 May 2017. As of 26 November 2017, under one or both Regulations, any conformity assessment body already designated under the Medical Devices Directives³ or any new conformity assessment body may submit an application for designation as a notified body to the responsible authority in a Member State (the ‘designating authority’).

The Commission services are aware of the challenges posed by the new regulatory regime. For instance, it can be expected that, in the early stages, a high number of bodies already designated under the Medical Devices Directives will apply for designation under one or both Regulations. These challenges have raised questions as to whether the Commission and the Member States will have sufficient capacity to deal with the new Regulations. This note, jointly prepared by DG GROW and DG SANTE, seeks to address some of the concerns raised in this regard.

The Commission services and the authorities in the Member States are fully committed to facilitating the smooth implementation of the MDR and the IVDR. This commitment is reflected in the ongoing intensive preparations for future joint assessments, including providing the guidance and training needed to secure a sufficient number of qualified national experts. The involvement of all actors in this field, including the industry, will be crucial to the success of the new regulatory regime.

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

² Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

³ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1), and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

1. Criteria for the order in which joint assessments will be performed

In accordance with Articles 39(3) and 40 of the MDR and Articles 35(3) and 36 of the IVDR, experts qualified to participate in joint assessments are to be nominated by Member States and the Commission and included on the list. Then, for each particular joint assessment, the members of the joint assessment team (JAT) are to be chosen from that list. Unless the specific circumstances require otherwise, the JAT is to be composed of three experts: one from the Commission and two from Member States other than the one in which the applicant conformity assessment body is established. The Commission services, together with the Member States, are in the process of preparing the list of nominated experts.

A tentative schedule of prospective on-site assessment dates will be put in place to check the availability of both national and Commission experts. Future on-site assessments will then take place on those pre-established dates.

The designation procedures laid down in Chapter IV of each Regulation set out the steps to be taken by those involved in the designation process, in particular, the designating authority and the JAT.

Among other things, in accordance with Article 39(3) of the MDR and Article 35(3) of the IVDR, the appointment of the JAT and subsequent planning of a joint assessment is dependent on the Commission receiving the preliminary assessment report from the designating authority. The date of receipt functions as the main criterion in deciding on the order of joint assessments and their allocation to any next available on-site assessment date. Submissions must be sent to a single functional mailbox. Therefore, if several preliminary assessment reports are submitted on the same day, their exact time of receipt will make it possible to establish a precise order.

At the same time, other criteria — such as the availability of the JAT experts, the designating authority or the applicant conformity assessment body — will play an important role in arranging the order of joint assessments. For instance, an application may come from a body established in a given Member State, but one of the only two national experts available on the next available on-site assessment date comes from the same Member State. In that case, the on-site assessment will need to be scheduled on a subsequent available date, when two national experts from other Member States will be available. Another example may be that the next available on-site assessment date is not suitable for the designating authority or the applicant body itself, in which case the joint assessment may also need to be postponed.

In addition, other concurrent factors could be taken into account, such as the quality of the conformity assessment body's application dossier or of the designating authority's preliminary assessment report. A delay in scheduling the on-site joint assessment may be necessary if any of these documents do not meet the requirements. For instance, if the preliminary assessment report identifies the need for additional substantial clarifications or significant supplementary information, postponing the scheduling of a joint assessment may be justified to allow sufficient time for the conformity assessment body to provide all the necessary clarifications/information. It is therefore of the utmost importance that both the applicant body's application dossier and the designating authority's preliminary assessment report are complete and properly address all the relevant legal requirements.

It follows from the above that, while the order of joint assessments will in principle be established according to the sequence of preliminary assessment reports, other specific circumstances may necessitate adjustments.

2. Combined designation procedures under the Medical Devices Directives and the new Regulations

A question about the possibility of combined assessments under the Medical Devices Directives and the new Regulations has been raised. On the face of it, organising an on-site assessment under the Medical Devices Directives and the new Regulations on the same dates could contribute to an efficient use of the resources available to those involved in the designation process. However, it should be emphasised that the respective designations have a different legal basis and, accordingly, are subject to different legal requirements. For that very reason, the joint assessment processes and the corresponding outputs are also different in terms of deadlines, reporting, consultation, etc. Therefore, it is not possible to conduct a ‘combined designation procedure’ which includes a ‘combined joint assessment’. While on-site assessments for each respective procedure could theoretically take place at the same time and include a review of the similar supporting documentation, the respective requirements and steps of each designation procedure under the relevant legal framework will need to be followed.

Finally, it should be noted that joint assessments under the MDR and IVDR will require different qualifications from the JAT experts. Therefore, where a conformity assessment body applies for designation under both Regulations, two different on-site assessments will be scheduled, taking into account the above-mentioned criteria. That said, for the sake of efficiency, every effort will be made to ensure that both on-site assessments are organised at a reasonable interval so that the information collected during the first assessment can be used for the second one.
