High-level Analysis of the Second IVDR/MDR Corrigenda

9 January 2020

The second Corrigenda to the EU Regulations were published in the EU Official Journal on 27 December 2019 (IVDR here and MDR here) and take immediate legal effect.

The below analysis by MedTech Europe's Secretariat provides a high-level overview of the corrections perceived to have a substantive impact on members.

(1) MDR Articles 120(3) and 120(4)

Enlargement of the MDR "grace period" to include devices which were Class I self-certified under the Medical Devices Directive (MDD) and which need to undergo conformity assessment with a Notified Body in order to comply with the MDR, e.g.,

- Class I reusable surgical instruments referred to in MDR Article 52(7)(c), e.g., scalpels, scissors, forceps and drill bits,
- Medical device software up-classified by virtue of Rule 11, e.g., for dental imaging,
- Medical devices incorporating nanomaterials up-classified by virtue of Rule 19, e.g., dental impression materials, and
- Substance-based medical devices up-classified by virtue of Rule 21, e.g., saline solutions for nasal cleaning.

Impact

This change allows the devices in question to be placed on the market after 26 May 2020, and up until 26 May 2024, in accordance with the MDD, i.e., without the need to undergo conformity assessment to the MDR, provided that:

a) By 26 May 2020, a valid MDD declaration of conformity has been drawn up for the device, and that
b) After 26 May 2020, there are no significant changes in the design or intended purpose, and that the MDR requirements regarding post-market surveillance, market surveillance, vigilance, and regarding registration of economic operators and of devices, are complied with in place of the corresponding MDD requirements.

Note

The Corrigenda do not bring the following into the scope of the Grace Period:

- *in vitro* diagnostic medical devices (IVDs),
- Products which were not medical devices under the MDD but which are brought into the scope of the MDR, e.g., those without an intended medical purpose, nor
- Medical devices that were Class I self-certified under the MDD and do not depend on the availability of MDR-designated Notified Bodies in order to comply with the MDR.

These devices must comply with the applicable Regulation by the date of application, i.e., 26 May 2020 for MDs, and 26 May 2022 for IVDs, unless the Regulations say otherwise.

(2) **MDR and IVDR Annex III, Section 1**

Change of term from "event" to "incident" in the context of trend reporting.

Impact

This change remedies a wording which might have been interpreted as to include, in trend reporting, *all* events recorded with the use of a device, even though the scope of trend reporting only includes non-serious (i.e., not individually-reportable) incidents.

(3) **MDR Article 120(8) and 122 first paragraph, second and fourth indent / IVDR Article 110(8), Article 112 first paragraph and Article 113(3):**

Exemption of certain provisions in the former Directives from repeal, in order to facilitate transition to the IVDR/MDR as regards the requirements to register information about Notified Body certificates in Eudamed. Also included in these sections are editorial corrections to the IVDR text that align the references with what the MDR says.

Impact

While these changes have no direct impact for manufacturers, they may be noteworthy because they take into account the delay of Eudamed's deployment, by clarifying that the provisions' entry into application are linked to the full functionality of the new database.

(4) **IVDR Annex VIII, Rule 2**

Extension of the scope of risk classification Rule 2 to IVDs intended to determine foeto-maternal blood group incompatibility.

Impact

IVDs for determining Rhesus system markers, regardless of intended purpose (i.e., including those intended to determine foeto-maternal blood group incompatibility and other purposes), are in Annex II list A of the IVD Directive, and thus correspond to IVDR risk Class D. The lack of a clear reference to such IVDs in IVDR Rule 2 was seen as leading to potentially-incorrect classification of such tests as being in a lower risk class.

(5) **MDR Article 88(1)/IVDR Article 83(1), first subparagraph**

Clarification in the article on trend reporting, that the benefit-risk analysis is in relation to Annex I Sections 1 and 8 instead of Sections 1 and 5. Instead of referring to risks related exclusively to user error, reference is now made to all known and foreseeable risks and any undesirable side effects.

Impact

This change appears to be helpful by keeping trending focused of non reportable incidents.

All other changes in the Corrigenda are editorial in nature.