August 24, 2017

Therapeutic Goods Administration
Business Improvement and Support Section
Medical Devices and Product Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Consultation: Alignment with European medical device regulatory framework - Up-classification of surgical mesh & Patient implant cards

Dear Sir or Madam,

On behalf of MED-EL Elektromedizinische Geräte GmbH please see the following comments to the aforementioned consultation, specifically the section pertaining to the "*Introduction of formal requirements for medical device manufacturers to provide patient implant cards and product information for all implantable medical devices*."

We concur that the proposed change to the Therapeutic Goods Regulations, which would make the requirement for patient cards and information explicit in the regulations, will assist in improving the information flow to patients and doctors. We are also supportive of measures to ensure the provision of sufficient information to the patient and are confident that effective implementation of these requirements will contribute to ensuring safe use of the device by the patient, and ultimately to increased patient safety.

Nevertheless, we wish to provide comments to the proposed implementation of the medical devices patient implant card and patient information leaflet, in particular with reference to the transition period stated on page nine (9) of the consultation document.

> **Transition**
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> The European transition period for this change is also three years, and by early-mid 2020 the manufacturers of all relevant medical devices will have been re-certified under the new regulatory arrangements, including this requirement. At that stage, it is proposed that Australian sponsors relying on European certification for their relevant ARTG entries will be required to submit a manufacturers' evidence update to demonstrate compliance with this change.
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> From the time the regulatory amendments come into force, all relevant conformity assessment applications will be explicitly required to comply with this requirement.

The consultation document proposes that transitional arrangements will be aligned with those of the EU Medical Device Regulation (MDR), with a period of three years, and that "*by early-mid 2020 the manufacturers of all relevant medical devices will have been re-certified under the new regulatory arrangements, including this requirement.*"

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Firstly, we wish to clarify that there are two stages to 'certification' under the new MDR:

1. The manufacturers' quality management system shall be certified.
2. All medical devices shall be certified to the MDR through conformity assessment.

The provision of a patient implant card and leaflet is a requirement to be fulfilled for device certification under the MDR, and not to the 're-certification' of a manufacturer. As will be discussed below, these may not occur concurrently during the transition period, therefore the timeline for implementation of this requirement from TGA should be clarified.

Further, this proposal does not consider the designation process of notified bodies nor the mechanism provided in Article 120(2) of the EU MDR regarding "Transitional Provisions", which provides for the extended validity of EC certificates beyond the date of entry into force of the regulation (26 May 2020).

Finally, MED-EL would recommend that the proposed timeline for implementation of this requirement in the Therapeutic Goods Regulations be adjusted to reflect the provisions detailed in Article 120.

1. During the period of Transition (from 25 May 2017 to the date of application on 26 May 2020) notified bodies may continue to perform conformity assessment procedures in accordance with the Directives 90/385/EEC and 93/42/EEC.

In order for notified bodies to be able to certify manufacturers' quality systems and to perform conformity assessment activities under the new regulation, they must first be designated. The application process for designation of notified bodies is defined in Articles 38 and 39 of the regulation, and it is stressed that by the date of application,

> *"a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of medical devices on the market*".

However, a "sufficient number" does not implicitly mean "all" and, as it is unclear how long the initial process of designation of notified bodies will take, the subsequent tasks to "re-certify" all manufacturers and to perform conformity assessment of all medical devices to the MDR will likely extend beyond the date of application.

Therefore, it may not be the case that all manufacturers are re-certified under the new regulatory arrangements by the end of the transition period, and it will not be the case that all medical devices will have been through the new conformity assessment process by this date as this is not a mandatory requirement. Provisions have been made in the MDR in light of this as follows:

> *(95) "... Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directives 90/385/EEC and 93/42/EEC and to their capacity to continue issuing valid certificates under those two Directives until the date of application of this Regulation."*

It should therefore be considered that even during the transition period medical devices may continue to be approved via conformity assessment to the existing directives. The validity of certificates issued in accordance with these directives is discussed below.

2. Certificates issued under Directives 90/385/EEC and 93/42/EEC will continue to be valid after the date of application of the regulation (26 May 2020).

Article 120
Transitional Provisions

> *2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.*
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> *Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.*

The cited article provides for the continued validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC until after the date of application of the new regulation (26 May 2020), the latest validity period of these certificates expiring on 27 May 2024.

As discussed previously, notified bodies may continue to issue such certificates until the end of the transition period, therefore it is highly likely that a great many devices will continue to be placed on the market after mid-2020 which do not (have to) comply with the MDR requirements for provision of an implant card or patient information leaflet. Article 120 provides the mechanism to allow manufacturers up to seven years of transition (until 2024) rather than three to 'finalise' their EU MDR certification, and they are under no expectation to have their entire product portfolios MDR-compliant by May 2020.

The intention that "*From the time the regulatory amendments come into force, all relevant conformity assessment applications will be explicitly required to comply with this requirement"* is therefore not aligned with the provisions of Article 120 and the proposed change to the Therapeutic Goods Regulations would not "*parallel the new European requirements*" as is foreseen in the consultation document. Devices may be submitted for conformity assessment to the TGA using a valid EC certificate issued in accordance with Directives 90/385/EEC and 93/42/EEC, even after mid-2020.

MED-EL would recommend that in order to effectively align Australia's medical device regulatory framework with European Union medical device regulations, the mechanism in Article 120 for the extension of validity of EC certificates beyond the date of application should be noted and the TGA transition period for implementation of the requirements for medical device manufacturers to provide patient implant cards and product information for all implantable medical devices, updated accordingly.