TGA Consultation – Alignment with European medical device regulatory framework

MedTech Europe Submission - August 2017

The Therapeutic Goods Administration (TGA) has opened a consultation on the *Alignment with European medical device regulatory framework – Up-classification of surgical mesh, Patient implant cards.* As the European trade association representing the medical technologies industries MedTech Europe welcomes the initiative to seek alignment with the European medical device regulatory framework.

In this context MedTech Europe welcomes the opportunity to comment on the proposal by TGA in particular with regards to how it relates to the new regulatory framework in Europe concerning surgical meshes as laid out by Regulation 2017/745 on medical devices (MDR).

Specifically the TGA consultation document states:

> *Transition (page 9 of 11)*
> *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.*

However the transition period for most devices including surgical meshes in particular with regard to the delivering of notified body certificates, can be significantly longer than three years under the MDR.

During the development of the MDR it was recognised that the time needed to update the notified body system – which includes setting up mechanisms for joint assessments of notified bodies, re-evaluation of the all existing notified bodies, which only then can start to perform audits and design examinations for all the relevant CE marked devices – was likely to take longer than the overall 3 year timeframe before the entry into application of the MDR.

As such Article 120 [Transitional provisions] of the MDR states:

> *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.***
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> *3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.*
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> *Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.*

This indicates that in some situations, certificates issued under the Medical Devices Directive (MDD) will continue to be valid as a path for devices such as surgical meshes to continue to be placed on the EU market through till 2024.

There are a number of practical implications to this which have an impact on the proposed alignment with the European medical devices framework, in particular:

- Surgical meshes which have been placed on the market under the MDD are not required to have a design examination certificate by May 2020 (MDR date of application) in fact this only becomes a requirement by May 2024.
- In practice it is unlikely that notified bodies will be able to perform all of the design examinations for surgical meshes which are already on the market by May 2020 – the current system is set up to give priority to novel devices which have not been placed on the market under the MDD and which would otherwise not have a route to market.

Given the details of how the European system is set up, it will not be possible for most manufacturers to provide the certificates required in the provisions proposed in the consultation by May 2020.

Some flexibility in the Australian system to reflect the realities of the MDR implementation and its transition will be needed for an effective alignment with the European regulatory framework.

Regarding the other sections of the consultation MedTech Europe is fully supportive of the comments sent in by the Medical Technology Association of Australia (MTAA).

MedTech Europe and its members would like to thank the TGA for the opportunity to submit these comments and are open to further discussions on alignment with the European medical device regulatory framework.