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

Implementation and Recommendation

Version 1.0, September 2017

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

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From: AusBiotech Ltd
ABN 87 006 509 726
Level 4, 627 Chapel St
South Yarra VIC 3141
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

AusBiotech is pleased to provide comments on the 'Alignment with European medical device regulatory framework – Up-classification of surgical mesh & Patient implant cards, Version 1.0, September 2017'.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 400 – 900 medical technology companies) and employs in excess of 45,000 Australians.

AusBiotech's membership have reviewed the consultation document and their comments have formed the basis of this submission, including feedback from AusBiotech's AusMedtech Regulatory Affairs Expert Panel, an expert group from amongst AusBiotech's member organisations, who provide advice on matters including the regulation of medical devices.

Background of the consultation paper 'Alignment with European medical device regulatory framework – Up-classification of surgical mesh & Patient implant cards'

The Australian Government outlined its program for regulatory reform in its response to the recommendations detailed in the Review of Medicines and Medical Devices Regulation (MMDR). This consultation paper addresses the Government's '…decision in September 2016 to accept Recommendation Twenty of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR)...'

The Panel recommended that:

1. The regulation of medical devices by the TGA is, wherever possible, aligned with the European Union framework including in respect of the:

    A. Classification of medical devices;

    B. Essential principles/requirements;

    C. Adoption of a risk-based approach to variations to medical devices.

2. Should the TGA seek to apply specific requirements, there must be a clear rationale to do so.

AusBiotech's response

AusBiotech commends the TGA's continued efforts to improve the safety and efficacy of products supplied to the market and their impact on the population.

We are in full support of the MMDR review Recommendation 20 to up-classify surgical mesh products to align with the revised European regulations from Class IIb to Class III. The transition arrangements in the EU will end in May 2024. The Australian transition should therefore be scheduled to end on 30 November 2024, around 6 months after the end of the EU transition.

AusBiotech is also in support of patient safety, specifically through the provision of information supplied to patients and caregivers. However, the introduction of a patient card has been attempted through other

regulatory agencies and proven to be of no value, and in some instances, unsuccessful. The requirement for the Manufacturer to provide such information for a patient with the assumption they have it on their person at all times, is not realistic or beneficial in many instances. The importance of the availability of such information is in some cases not understood by the patient and more importantly not available at the critical time it may be needed by the healthcare provider. We recommend that the Australian Government introduce a voluntary option for providing the patient card as part of meeting Essential Principle 13. Detailed below are some recommended alternative approaches.

The Government may also consider using existing platforms of Medical Records for the supply of specific device information, including websites which would allow the manufacturers content to remain up to date, through to other systems such as the Medicare system etc. This would not require additional steps by the manufacturer nor health practitioners, but would allow the availability of such information to both the patient and the healthcare provider when and if required. It would also allow the responsibility to be removed from the patients directly who will have to ensure the patient implant cards are always readily available.

There also appears to be, through our communication with members, misunderstandings with the proposed time lines and plans for implementation of the cards that may potentially impact the continued supply of existing product to the market, and cause possible delays in the introduction of innovative technology.

As raised by specific members, no EU Notified Bodies are expected to be designated to assess devices or issue certificates under the new MDR until late 2018. It therefore remains to be seen how they will interpret/enforce the requirements around the Unique Device Identifiers (UDI). Without this information being formalised, we would suggest that the TGA hold off on introducing new regulatory requirements to align with Europe, considering the road ahead with implementation of the MDR yet to be determined, and more importantly still understand the fallout.

It was also flagged by members that the transition period itself appears unclear. Clarity around these specific timings need to be fully understood by both industry and the regulators prior to any decisions being made.

Finally with respect to the publication of specific information on the TGA website, members are in disagreement with this approach considering the information being requested is already made available by the Manufacturer's website. This would be an additional requirement put to Manufacturers, and add to any of the introduced MDR regulations.

Questions

- Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?

As suggested above, AusBiotech considers the Patient Implant Card as an additional requirement of Manufacturers, which is yet to be proven as adding safety or value. With this, we'd recommend this information (if required) be managed electronically only, with no physical card being provided.

- Do you have any comments or suggestions on alternative or additional strategies to promote the provision of the implant card to the patient?

AusBiotech members suggest that the media used for the provision of a Patient Implant Card be determined by the Manufacturer and allow alternative means other than a printed physical card.

- Are there any issues or unintended consequences that may arise out of this change?

The regulator and industry need a clear understanding of the existing requirements in the EU, and their associated timelines before any specific change to the Australian requirements can be implemented. We recommend that there be clearer understanding before any further change or implementation.

- If there are issues, provide suggestions for mitigating them?

As outlined in the previous points, AusBiotech recommends that further clarity be reached and fully understood by all stakeholders prior further consultations, recommendations or changes to our existing regulatory framework.

In summary, AusBiotech supports the criteria and implementation of comparable overseas regulators – medical devices as described in the consultation paper. However, AusBiotech recommends greater clarity with regard to the TGA's requirements around specific the provision of patient implant cards or time-lines.