AusBiotech's response to the TGA's proposal: 'Potential reclassification of active medical devices for diagnosis and patient therapy'

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Context

AusBiotech is pleased to provide comment as requested by the Therapeutic Goods Administration (TGA) in relation to proposed potential reclassification of active medical devices for diagnosis and patient therapy.

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. Within AusBiotech, the medical device and diagnostic industries are represented by AusMedtech, an industry group dedicated to the development, growth and prosperity of the Australian medical technology industry.

The AusMedtech Regulatory Affairs Expert Panel is a subcommittee of AusMedtech, providing expert advice on operational and policy-related regulatory matters. This response has been led by the panel and its Chair, Grant Bennett.

Overview

AusBiotech welcomes the opportunity to comment on the *Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy* discussion paper.

In general, AusBiotech agrees with the recommendations on aligning with the European Medical Device Regulation for the intention of streamlining the application process in Australia, and reducing the burden on the Australian regulator. However, considerations need to be given as to the rationale supporting the alignment, and the potential implications for Australian Manufacturers and Sponsors.

In this case, it appears that the TGA is not completely aligning with the new regulations, therefore potentially causing possible unforeseen barriers in gaining market access to Australia. It is recommended that further consultation be circulated with a clear justification for the variation between the two regulatory agencies.

Response to proposal

AusBiotech is of the opinion that as defined in the updated EU Medical Device Regulation (EU) 2017/745, where only 'Active therapeutic devices are reclassified as Class III', the proposed wording to be included in the Australian regulations would capture additional active devices, not just the subset of active devices which meets the definition of 'Active medical devices for therapy'.

This means the proposed TGA classification rule and definition could capture a broader group of active devices than the EU MDR classification rule intends. It should also be noted that at this stage, no guidance has been published from the EU suggesting that devices like CPAP machines will become Class III under the new rule.

We suggest that the TGA provide further clarification as to how the updated recommendations have been considered and determine the potential impact if implemented in Australia.

As defined in the updated EU Medical Device Regulations, rule 22 states:

EU MDR 7.9. Rule 22

Active therapeutic devices *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.*

As is being proposed by the TGA:

TGA Proposed action

It is proposed that a new classification rule be included in the Therapeutic Goods (Medical Devices) Regulations 2002:

Active medical devices *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (such as closed loop systems or automated external defibrillators) are classified as Class III.*

This is not equivalent to the types of devices covered by EU MDR Rule 22 as it only applies to 'Active therapeutic devices' NOT all 'Active medical devices'.

In Appendix A of the TGA paper it also states that they do not need/intend to change the Australian definition of 'Active medical device for therapy' because it is considered equivalent to the EU MDR definition of 'Active therapeutic device'.

Therefore, if TGA wish the new Australian classification rule to be aligned with EU MDR Rule 22, then the proposed Australian classification rule should say:

'Active medical devices for therapy *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (such as closed loop systems or automated external defibrillators) are classified as Class III.'*