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18 February 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

RE: Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy

Dear Medical Devices Branch,

In review of the consultation on the potential reclassification of active medical devices for diagnosis and patient therapy I have the below comments:

Variant distinction for active medical devices

Currently the definition of variant in the Therapeutic Goods (Medical Devices) Regulations 2002 states:

Variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other variation approved by the Secretary for the purposes of this definition, if the variation does not change the intended purpose of the device.

Many active medical devices have differing 'configurations' under the same UPI.
For example, a defibrillator may have Wifi or Cellular capability. Each of these features could constitute a different product listing under the same UPI.

The current capabilities under the variant definition will not allow for these different configurations to be distinguished for multiple products under the one UPI.

Will the TGA be updating this definition and subsequent Class III application to ensure these details will be captured?

Level 2 Mandatory Audit Data

As part of an industry wide review, the TGA has recently requested Post Market Review and Clinical data for a range of Defibrillators that are currently on the ARTG.

Will the data provided as part of the Post Market Review be able to be used to expedite the Class III applications for the Defibrillators so as to not duplicate the TGA's efforts?

Transition Period

The TGA has stated on several occasions that they wish to align with the EU Medical Device

Regulations where possible to avoid an unnecessary burden on Australian sponsors. For this reason, it is recommended that the transition period be extended a few months beyond the European timeline to ensure the European documentation is available at the time the TGA assesses the reclassification application. It is not uncommon for the Notified Body to take additional time to release a physical copy of either the EC Certificate or the EC Design Examination Certificate or both. A small extension of a few months beyond the EUMDR deadline should allow for the additional time it takes the Manufacturer to make this certificate available to the sponsor to then support the TGA application.

If you have any questions or comments on my response, please do not hesitate to contact me.

Yours Sincerely,

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