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Assistive Technology
Suppliers Australia

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Therapeutic Goods Administration
Department of Health
PO Box 100
Wooden ACT 2606

Reference:
Consultation - Scope of regulated software-based products

Thank you for the opportunity to provide feedback.

ATSA supports the proposed new classification rules for software–based medical devices as set out in the consultation paper.

The approach for Australian classification rules for software-based medical devices that broadly aligned with the EU classification supports, ATSA's policy for international alignment of all Australian regulation for AT.

Below ATSA has responded to the series of questions posed by the consultation paper.

Questions

What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

The listed circumstances below is conditional, that the exemption is only supported if there is no injury risk to the user or operator of the AT in the event there was a software failure.

- Software that is not intrinsic to the function of the AT device and that its functions as part of the AT will not cause injury if there was a malfunction.
- When the AT device, software function or application cannot cause injury if there is a failure, e.g. Battery charging controls, location devices, docking controls for when the device is "unmanned" and been sent automatically to a charging station.
- Software that has no safety impact on the AT user
- AT eye gazing controls – uses eye movement via reflecting a light that is reflected off the retina, allowing the person without hands, to control

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instructions on a tablet. (the software only, as the device should still be considered as a Class 1 Medical device and listed under the ARTG)

What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

Please provide details:

Of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

- Mainstream devices that may host AT software, e.g. a tablet
- AT Communication software for person – these are generally apps on a tablet device.
- AT Location devices – e.g. used to track location of dementia patient
- AT computer aids – e.g. voice controls such as Dragon to manage computer functions

Which approaches from international jurisdictions, if any, should

be used to inform the Australian approach to this issue?

Alignment with European standards

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