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Consultation: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia

Dear Madam / Sir,

As a sponsor and manufacturer of devices in the Australian healthcare market Diversey Australia Pty Ltd. broadly supports the initiatives of the TGA in introducing a number of new and amended definitions, and a revised scope of the products regulated as medical devices in Australia. Diversey wishes to thank the TGA for the opportunity to respond to this proposal, and supports the efforts of the TGA to consider the EU requirements as an input to determine the extent to which a similar approach may be appropriate in Australia, while also maintaining high standards of quality, safety and performance.

Diversey notes that the specific focus of this consultation is on identifying where the Therapeutic Goods Act 1989 (the Act) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the Australian MD Regulations) could be aligned with the EU MD Regulation, specifically:

- the definitions that underpin the medical device regulatory frameworks of both jurisdictions
- the products that fall within the scope of the regulatory framework.

This is designed to achieve better clarity and consistency in understanding of the requirements and the products that are regulated as medical devices.

In alignment with these goals we wish to comment on and propose the following:

1. Diversey agrees with the TGA to support the adoption of the EU MD Regulation for "medical device". We note, however, that currently in Australia cleaners as classified as Class 1 Devices and all device disinfectants as Class IIb. There is a different classification in the EU MD Regulation for device disinfectants as follows:

7.3. Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

2. We therefore also recommend adopting the EU MD Regulation (Regulation (EU) 2017/745) classification and definition of a non-invasive device (Chapter 3, Classification Rules, Section 4 on non-invasive devices).

We believe it is beneficial for both sponsors and the regulator to align with the EU in providing clarity of definitions according to the intended purpose of the disinfectant, that is:

- Cleaning products for devices are class 1
- Disinfectants as being suitable for use on non-invasive devices are class IIa
- Other disinfectants (sterilants and those to be used on invasive devices) are class IIb

It is our belief that this will achieve better clarity and consistency in the following ways:

- Clarity will be added to the intended purpose of disinfectants and will be in line with the EU regulatory framework
- There will be reduced regulatory burden for sponsors and the regulator as low-risk, non-critical devices disinfectants will demonstrate compliance to the specified Order
- The assessment of product compliance and fitness for purpose will be commensurate with their risk

The required level of Conformity Assessment for the above hierarchy of intended purposes and risks will align well with both the current Medical Devices Regulations and the proposed new Order for Disinfectants (Therapeutic Goods (Standard for Disinfectants) Order 2018 (Therapeutic Goods Order X)) as follows:

Category of device	Proposed Conformity Assessment requirements
Device cleaner (Class I)	nil
Device disinfectant – non-invasive (Class IIa)	Compliance with new Order for disinfectants
Device disinfectant – invasive / sterilant (Class IIb)	Compliance with Medical Devices Essential Principles

Yours faithfully,

[redacted]

15th February, 2019