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18th February 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
devicereforms@health.gov.au

Dear Sir/Madam,

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

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

While ASMI primarily represents medicines, the increasingly complex regulatory environment produces areas of overlap and has potential impacts on ASMI members, and hence we are providing some brief comments in response to this consultation.

ASMI appreciates the opportunity to provide input into this consultation.

Definitions and Scope of Medical Devices Framework

ASMI members have provided the following comments in response to this consultation:

- The expansion of the definition of medical devices to include products for the cleaning, disinfection or sterilisation, has potential to capture cleaning goods not explicitly excluded as therapeutic goods unless this is appropriately qualified e.g. denture cleaners.
- Insufficient transparency has been provided regarding the future intention of the TGA regarding adoption of the EU Regulation on medical devices (2017/745) (EU MD Regulations), specifically whether this is a standalone project or part of a broader project aimed at harmonisation with EU MD Regulations.
- The proposed changes to the definitions do not express what part of the Australian legislation these will be captured in, however understanding which will be in the Medical Devices Regulations and which will be in the Therapeutic Goods Act 1989 (the Act) is important for interpreting the suitability of each of the proposals. If they are to be included in the Act this presents additional challenges for ensuring the scope of the definition is not taken to be broader than intended i.e. does it specifically identify that it relates to devices, or are some definitions intended to apply to all therapeutic goods. Similarly, regarding the pending consultation on the definitions in Table A4, this

additional information regarding where in legislation the definition will be captured will assist in ensuring an efficient consultation process.

- Even if the scope of a definition is clearly expressed as pertaining to medical devices, if there is no other legislated definition there becomes a risk of industry and the regulator attempting to extrapolate the legislated definition to products beyond its expressed scope.

We remain available to provide further comment or meet with you to discuss any of the above should you require any further clarification relating to this submission.