Australian Self-Medication Industry Ltd.
ACN 607 233 116 ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Direct Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

18th February 2019

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

Dear Sir/Madam,

Re: Proposal to introduce a Unique Device Identification (UDI) system for medical devices 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.

Scope of Unique Device Identification (UDI)

The primary concern raised amongst ASMI members regarding the introduction of a UDI system in Australia is the extra and unnecessary burden this system would carry for low risk Class I devices (non-sterile and non-measuring) that are already included on the Australian Register of Therapeutic Goods (ARTG), and therefore have sufficient traceability to reflect the very low risk of these devices. Consideration of a risk-benefit framework would indicate that these devices are already very low risk and do not warrant additional regulatory burden. ASMI therefore requests that low risk Class I devices (but not Class Is and Im) are excluded from the mandatory requirement to carry a UDI, however that a UDI can be optionally applied to maintain harmonisation where this is appropriate.

Further to this, consideration should be given to applying this flexibility to all retail devices e.g condoms, personal lubricants, and toothpastes for sensitive teeth. Many of these devices are classified as Class IIa, however these are already regulated by the TGA, and have low risk and limited label space. The EU MD Regulations already have provision for lower obligations for these devices as Annex VI part 4.4 states “For devices exclusively intended for retail point of sale the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.” In this regard, should a UDI system be introduced due consideration needs to

be given to medical devices supplied directly to consumers and an appropriate degree of flexibility provided.

Additionally, there is a lack of justification of the proposed transition times, aside from apparently being presented to align with European adoption timeframes. If the development of an Australian system is to be conducted and implemented, consideration should be given to the most appropriate transition arrangements for the Australian industry rather than simply aligning transition dates with other jurisdictions.

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.