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18th February 2019

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

Submitted as an attachment to the online Consultation submission form

Dear Sir/Madam,

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

GlaxoSmithKline Consumer Healthcare (GSK) welcomes the opportunity to comment on the above Consultation.

GlaxoSmithKline is a global research-based healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

In Australia, GlaxoSmithKline is represented by two businesses: GlaxoSmithKline Australia Pty Ltd which represents our prescription pharmaceuticals business and GlaxoSmithKline Consumer Healthcare Australia Pty Ltd which represents our consumer healthcare business.

This submission represents the views of the consumer healthcare business.

The consumer healthcare business markets device products in a retail setting. These device products are subject to various other pieces of regulation or industry practices that mimic the intended efforts of a UDI.

All devices supplied for sale in a retail setting must have a trade description, and for practical purposes a product name and variant if applicable, unit measure marking, sponsors name and address, legal manufacturers name and address, directions for use including any contraindications, lot number/batch code and expiry if applicable, an indication of the sterility of the product and most importantly, a bar code for trade and supply data gathering.

Retail devices already have the information the UDI appears to be requiring on the finished product.

GSK's position is that devices supplied through retail channels be exempt from the requirements of UDI.

This is supported in the EU Medical Device regulation on UDI as stated in article 4.4;

4.4. 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.

We understand that the USFDA is also of the position that UDI's are not required for devices sold to the consumer.

Therefore, it is reasonable for the TGA to harmonise practices with these overseas regulators.

Should you require further information please do not hesitate to contact me.

We request that any contact details be treated as confidential information and not be published on the TGA internet site (i.e. not be made publicly available).

Yours sincerely,

GlaxoSmithKline Consumer
Healthcare Australia Pty Ltd
ACN. 603 310 292