Therapeutic Goods Administration,
Symonston,
ACT 2609.
Submitted via the TGA consultation portal

18 February 2019

Dear Sir/Madam,

Consultation on implementation of Unique Device Identifier (UDI) in Australia

Please find Novo Nordisk Pharmaceuticals P/L's comments to the UDI consultation following.

Yours sincerely,
Novo Nordisk Pharmaceuticals Pty. Ltd.

Rowan O'Brien
Regulatory Affairs and Pharmacovigilance Manager

Novo Nordisk Pharmaceuticals Pty. Ltd.
Level 3
21 Solent Circuit
Baulkham Hills NSW 2153
Australia

Telephone:
+61 2 8858 3600
Direct dial:
+61 2 8858 3796
Telefax:
+61 2 8858 3799

E-mail:
rowo@novonordisk.com
Internet:
www.novonordisk.com.au

Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?

Yes, Novo Nordisk is generally supportive of the proposal.

The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?

Whilst SaMD (software as a medical device) is a device category that will obviously need consideration for exemption from some requirements, Novo Nordisk would need to see the exemptions proposed for Australia before we could comment if they are or are not appropriate. In general we recommend following IMDRF or a lower requirement.

Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the AusUDID - what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?

The UDI core data elements need to be maintained by the manufacturer and shared with the sponsor.

How should we link the ARTG and the UDI database? What information should they share?

The linking of information in the ARTG to the new AusUDID will require a concept similar to Basic UDI-DI. This is new for EU/ Eudamed and not proven. It is not clear what information should be shared and how the links will be represented and if this is also the responsibility of the sponsor to ensure correct linkage. If a grouping like Basic UDI-DI is used it is desirable if the same grouping can be used world-wide (and same Basic UDI-DI), as it will be easier to maintain and ensure data are up to date.

Consultation paper question: Is the alignment with EU transitional times appropriate?

p. 15 reads that "There will be staged implementation to enter UDI_DI and other specified core data elements into AusUDID." However the table on the same page only refers to proposed timeframes for placing the UDI carrier on labels and direct marking in Australia. We therefore conclude that the intended timeframe for assigning UDI-DI and reporting of data is unclear. In order to collect experience from implementation in EU it is desired that

the AusUDID reporting deadline is no earlier than the deadline for placing the UDI carrier on the labelling/packaging for the respective classes of medical devices.