Submission to TGA consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

February 2019

Johnson & Johnson
MEDICAL COMPANIES

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens–support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Submission Information

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Comments

On behalf of the Johnson & Johnson Medical Devices (herein referred to as Johnson & Johnson), we appreciate the opportunity to provide comments on the Therapeutic Goods Administration (TGA) proposal to introduce an Unique Device Identification (UDI) system for medical devices in Australia.

It should be noted that we have contributed to and broadly support the submission made by the Medical Technology Association of Australia (MTAA). Our additional commentary is summarised below.

Overall, we agree with the proposal to establish a UDI System in Australia, based on the principles in the IMDRF UDI Guidance and implemented consistently with the proposed IMDRF Application Guide. The research conducted by the TGA to develop a solid understanding of global thinking for UDI systems is commendable, unfortunately, it is not always clear in the proposal what elements TGA is proposing for the Australia UDI system and what elements simply reflect the current state in other jurisdictions. For example, the list of UDI database elements appears to be a duplication of the EU requirements and includes data elements, like EU Authorised Representative, that are not relevant to an Australian UDI database.

We fully support the proposal for staggered timeline implementation. The implementation dates should allow for a sufficient period after the AusUDID database requirements have been established. We recommend a 24-month time to first implementation deadline, based on our experience with implementation in the US. Alignment of the Australian time lines to US FDA and EU Eudamed databases is not appropriate as the FDA system has been implemented since 2012 and the EU system is still evolving.

We also urge TGA to consider provisions for sufficient time to deplete inventory of non-UDI-compliant medical devices in distribution channels and allowances for continued use of reusable medical devices (not direct marked) currently in use.

Johnson & Johnson appreciates the ongoing engagement and opportunity for input to the TGA's proposal to introduce an UDI system. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.