THERAPEUTIC GOODS ADMINISTRATION

ALIGNMENT WITH EUROPEAN MEDICAL DEVICE REGUALTORY FRAMEWORK

SUBMISSION
August 2017

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, 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 reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognise their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfil their family 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 competent management, 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 be good citizens - support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. 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 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 realise a fair return.

Submission Information & Company Overview

Organisation: Johnson & Johnson Pty Ltd
Type of Organisation: Proprietary Limited Company
Address: 1 – 5 Khartoum Road, Macquarie Park NSW 2113
Email and phone contact: [redacted]

Johnson & Johnson Pty Ltd (JJPL) is a subsidiary of Johnson & Johnson, the world's most comprehensive and broadly based healthcare company. In Australia, we provide products and services including medical devices, diagnostics, pharmaceuticals and consumer healthcare products.

The Johnson & Johnson Family of Companies in Australia consists of:

- Johnson & Johnson Pacific – consumer health brands;
- Johnson & Johnson Medical – medical devices and related technology; and
- Janssen – pharmaceuticals.

We employ approximately 1,800 Australians who bring innovative ideas, products and services to advance the health and well-being of the patients we serve. We recognise the impact of serious conditions on people's lives, and we aim to empower people through disease awareness, education and access to quality care. Our research and development focuses on identifying medical needs and harnessing the best science, whether from our own laboratories or through strategic relationships and collaborations.

Johnson & Johnson Pacific is a provider of consumer health and wellbeing products, offering families more than 650 trusted solutions for their most common health and wellbeing needs. Many of our brands have earned consumers' trust over generations.

Johnson & Johnson Medical produces a range of innovative products and solutions used primarily by healthcare professionals in the fields of orthopaedics, neurological disease, vision care, diabetes, infection prevention, diagnostics, cardiovascular disease, and aesthetics. We are the largest medical technology provider in Australia working across public and private sectors.

Janssen is dedicated to addressing unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Janssen has a long-standing history in making a meaningful difference in global public health, dating back to Dr Paul Janssen's pioneering work in mental health and pain medications, as well as the development of more than 80 medicines.

Comments on the Proposal

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.

We welcome the opportunity to comment on the TGA's proposal to implement two measures to align Australian and European regulatory requirements:

- Reclassification of all implantable surgical mesh medical devices from Class IIb (medium to high risk), to Class III (high risk); and
- Introduction of formal requirements for medical device manufacturers to provide patient implant cards and product information directed at consumers for all implantable medical devices.

Overall, we support the TGA's approach on alignment with the European Medical device regulation 2017/745 related to up-classification of surgical meshes and provision of implant cards.

We note that final interpretation of the recently published European regulations[1] is still under consideration so it is critical that any outcome of the TGA's proposal aligns accordingly.

We would like to focus our comments on three main areas of concern:

1. Proposed application times – transitional arrangements
2. Delivery of the patient implant card
3. Publication of patient information

1. Proposed application times – transitional arrangements

The TGA consultation paper states (p6):

*"It is proposed that transitional arrangements in Australia will mirror those in Europe, with a period of around three years. The transition arrangements in Europe for medical devices **will end in May 2020**. The Australian transition would be scheduled to end on 30 November 2020, around 6 months after the end of the European transition. This provides a window for applicants to **finalise** European certification prior to lodging applications to include the device in the ARTG in Australia."*

However, this proposal is not considering the mechanism of the EU Regulation 2017/745: Article 120 (2)

"……Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the

[1] Revision of Medical Device Directives http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#new_regulations

certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.'

This article provides the possibility to keep devices certified under the AIMD or MDD on the market after the date of application (May 26, 2020), they also can be recertified to the AIMDD or MDD up till 26 May 2020 and **have valid AIMDD or MDD certificates up until May 2024.** This implicates that manufacturers **have up to 7 years (not 3)** to finalise their EU MDR certification and **to comply with the (new) MDR requirements, among them, up-classifications and provision of implant cards.**

In view of the EU Regulation 2017/745 article 120, we propose to adjust the transitional arrangements:

*It is proposed that transitional arrangements in Australia will mirror those in Europe, with a period of around three years. The transition arrangements in Europe for medical devices **will end in May ~~2020~~ 2024.** The Australian transition would be scheduled to end on 30 November ~~2020,~~ **2024** around 6 months after the end of the European **transition arrangements.** This provides a window for applicants to finalise European certification prior to lodging applications to include the device in the ARTG in Australia.*"

2. Delivery of the implant card

We recommend the acceptance of generic implant cards that can be provided to the Health Care Practitioner (HCP) in bulk. The specific implant information required could be printed on suitable stickers and provided by the manufacturer with the individual device for the HCP to affix to the card. This would accommodate scenarios where multiple implant components are implanted during a surgery and where it is unknown which specific components will be used until the time of surgery.

Alternatively, the manufacturer could make available to the health institution or HCP, the ability to access the same information that would otherwise be required on an implant card, and make this information available to the patient at the point of care (i.e., following surgery but before patient discharge). This could, for example, take the form of an electronic print out or report that would be customised to the individual patient and contain a listing of all the devices that were implanted in the patient at the time of surgery.

3. Publication of patient information

The TGA consultation paper states (p9) that patient information for implants will be published online on the TGA's website, in addition to the manufacturer's website which is indicated on the implant card.

Further consideration is required as to

- how the HCP/patient will be able to identify the correct device/IFU/patient information from the TGA's website considering the EU requirement will incorporate the Unique Device Identifier (UDI) that is currently not implemented in Australia.
- the process for maintaining the patient information on the TGA's website, which should be simple for the sponsor to update and should not require pre-approval from the TGA.

Therefore, like the European Medical devices regulation, we recommend the patient information related to implants to be available on the manufacturer's website only, to ensure consistency and patient access.