THERAPEUTIC GOODS ADMINISTRATION

PROPOSED REGULATORY CHANGES RELATED TO PERSONALISED AND 3D PRINTED MEDICAL DEVICES

SUBMISSION
December 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
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Johnson & Johnson Medical Pty Ltd
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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

We appreciate the opportunity to submit comments in response to the proposed regulatory changes related to personalised and 3D printed medical devices and we look forward to further collaboration to develop a mutually agreeable program of regulatory reform.

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 on the questions is summarised below.

Proposals 1 and 2

We agree the definition of custom made medical device aligns with the definition in the US and EU. We don't believe a limitation on the number of custom made devices a manufacturer can supply in one year is necessary, as the definition provided has clear criteria and it is the responsibility of the manufacturer to document that all requirements are satisfied when declaring a device as custom made.

We do not recommend an application and approval process for the use of a custom made device and encourage the TGA to look at both the EU (MDR Annex XIII – Procedure for Custom Made Devices) and US (Custom Device Exemption) processes and develop a manufacturer declaration process, rather than an application and approval process. The EU procedure for a manufacturer declaration is comprehensive and covers the elements of concern outlined in the consultation paper. We believe that reduced regulatory burden for custom made devices, that are unique and are used in very limited circumstances, is in the best interest of patients.

Proposal 3

The proposal to create a new category of medical device called "medical device production system" aims to address what other global regulators have termed "point of care manufacturing". This proposal creates a global regulatory precedent, blurring (or potentially eliminating) the line between manufacturing and marketed product. While we believe this concept may have merit in addressing "point of care manufacturing", further elaboration on the concept is warranted. Some of our concerns around how this concept might work in practice include:

- How will this new category of medical device fit in the legal definition of medical device (*any instrument, apparatus, appliance, material or other article…*)? Will there be legal impediments to implementation of this new category, specifically with distinction between the terms "medical device" and "manufacture"?
- How would requirements/expectations for elements that are typically covered under manufacturing quality system controls be addressed? For example, under the ISO 13485 standard, elements such as human resources, infrastructure, work environment and contamination control, validation processes, requirements for validation of sterilisation processes are applicable to both the manufacturer of the "medical device production system" as well as the user.

- How would significant "post-processing" operations like annealing and heat-treating operations, cleaning, sterilisation and labelling of devices from a "medical device production system" be treated? 3D printing systems have not yet developed to a point where these post-printing operations can be eliminated.
- Currently, manufacturers of 3D printing systems rely on original device manufacturers to provide the device design and design control. How would ARTG inclusion work if the 3D printing system were to reference multiple original device manufacturer designs?
- What are the practical implications/limitations of "dual use" technology, specifically is there enough differentiation between a 3D printer intended for medical purposes compared to what could essentially be the same 3D printer intended for general or non-medical usage?

Illustrative examples of device types that would be considered under this concept would be extremely helpful to explain and clarify how this concept could work in practice

Proposal 4

This proposal expands the definition of devices intended to record diagnostic images to include "software and anatomical models intended for the diagnosis or investigation of the anatomy". This definition is overly broad and would encompass all physical anatomical models into the definition of medical device, including those currently considered educational tools, like simulated bone models used by surgeons to explain the surgical procedure to a patient. We understand that medical devices are defined by the manufacturer's "intended purpose", but are concerned that the broad definition proposed may cause in market interpretation concerns. Limiting the definition to "software and anatomical models intended for diagnosis" achieves the objectives described by the TGA in the consultation paper without encompassing anatomical models that are educational tools.

Proposal 5

We agree and support the proposed change to the pathway for medical devices that incorporate materials of human origin, recognising this effort to harmonise with other global regulators.