Submission to TGA consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

March 2019

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.

Comments

On behalf of the Johnson & Johnson Family of Companies (herein referred to as Johnson & Johnson), we appreciate the opportunity to provide comments on the Therapeutic Goods Administration's (TGA) *Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices, February 2019.*

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.

Proposal 1: Introduce new definitions for personalised medical devices

Johnson & Johnson supports the adoption of IMDRF definitions for custom-made, patient-matched and adaptable medical devices. We also commend the TGA's efforts in leading the IMDRF working group for Personalised Medical Devices and driving harmonisation with respect to these definitions and subsequent regulatory pathways.

We support the introduction of the new patient-matched category of devices which will not be eligible for the custom- made exemption but will require third party conformity assessment according to the device risk classification. This proposal provides the necessary regulatory control to protect patient safety as the industry continues to innovate with personalised, particularly 3D-printed devices.

Proposal 2: Change the requirements for supplying custom-made medical devices

Johnson & Johnson agrees there is a need for greater transparency for patients receiving custom-made devices and that the informed consent process could be improved. We also support in principle the provision of a written statement about the device to the patient, but **we require additional clarity regarding the TGA's expectations for the content and request that the form in which the statement is provided remain flexible.**

The TGA is proposing additional requirements for devices that meet the definition of custom-made, including submission of annual reports of the custom-made devices the company has supplied. **We believe this proposed requirement should be limited to moderate and high-risk medical devices, e.g., implants.** This would provide the needed transparency into the highest risk devices and be consistent with current annual reporting requirements for devices included on the ARTG.

Proposal 3: Introduce a framework for regulating medical device production systems

We support the concept of a Medical Device Production System (MDPS) as a novel way to address "point of care manufacturing" for lower risk devices (Class I and IIa). However, as noted in our response to the TGA's 2017 consultation paper, we have concerns on how the conformity assessment, review and control process would work in practice.

Many aspects of an MDPS are a shared responsibility of the "device manufacturer" and the hospital or facility where the MDPS is installed, specifically:

- Environmental and contamination controls. In the manufacturing environment, these controls are addressed through Good Manufacturing Practices and the ISO 13485 standard for Quality Systems. How does the TGA envision the conformity assessment procedure to work for ongoing environmental controls that are necessary to ensure the appropriate cleanliness and biological/biocompatibility requirements?
- How would significant "post-processing" operations that would typically require manufacturing validation (annealing and heat-treating operations, cleaning, sterilisation and labeling) many of which are dependent on the facility, not the MDPS itself be addressed through the conformity assessment procedure?
- How would the conformity assessment procedure address connectivity and cybersecurity controls to ensure that networks are maintained in accordance with the manufacturer's prescribed specifications and to reduce cybersecurity risk?

We are concerned that creating the framework for a new category of medical device, an MDPS, that potentially could never meet conformity assessment expectations is contrary to enabling a system for point of care manufacturing. **We recommend that the TGA consider adding controls for health care facilities to address the above areas and suggest more targeted consultation on this concept is undertaken.**

Proposal 4: Update the classification rule for medical devices that record diagnostic images

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 may potentially be misinterpreted due to inclusion of the term "anatomical models" which are not considered devices in their own right, but rather the output of a medical device. **We recommend that the TGA revise this proposal to include "software and systems that produce anatomical models intended for diagnosis or investigation of the anatomy."** This recommendation is consistent with current regulation of X-ray systems: X-ray systems are regulated as medical devices, but the individual images generated by these systems are not separately regulated as devices.

Furthermore, we appreciate the TGA's clarification that models intended purely for training or education purposes would not be captured by this rule, as they are not considered to be medical devices. **We recommend providing additional clarity that such training/educational purposes would include use for informed consent, i.e., presentation to patients by a specialist to inform the patient about the procedure.**

Proposal 5: Regulate medical devices with a human origin component as medical devices with a biological component rather than as pure biologicals

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.

Proposal 6: Clarify conditions for modifications and adaptions to personalise a medical device

We support this proposal to clarify the circumstances in which an entity holds responsibilities as a medical device manufacturer and to reinforce the provision of validated instructions by the original manufacturer.

Transitional arrangements

The TGA have proposed that devices meeting the patient-matched definition, would no longer be eligible for the custom-made exemption and would require conformity assessment according to their risk classification. The proposed transition provisions for patient-matched devices currently on the market is unclear in the consultation paper but the length of transition timing should consider the risk classification of the device and the level of documentation required. The TGA should allow an adequate transition period for manufacturers and sponsors to prepare the necessary documentation and apply for conformity assessment under the new rules. It is also critical that implementation and transition timelines are aligned internationally, as other regulators work in parallel to adopt the IMDRF framework for personalised medical devices.

Johnson & Johnson appreciates the ongoing engagement and opportunity for input to the TGA's proposed regulatory scheme for personalised medical devices. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.