THERAPEUTIC GOODS ADMINISTRATION

DESIGNATION OF AUSTRALIAN CONFORMITY ASSESSMENT BODIES FOR MEDICAL DEVICES

SUBMISSION
January 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
[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 on the questions is summarised below.

Scope

Question #1: Should designated Australian conformity assessment bodies (subject to capability etc.) be able to provide conformity assessment certification for all medical device applications? Should some device types or classes continue to be required to hold TGA conformity assessment certification?
If the Australian Conformity Assessment Body (CAB) can demonstrate they have the appropriate level of technical expertise and meet all requirements set as part of the designation process, it should be able to provide conformity assessment certification for all medical device applications. The TGA should fully accept evidence of the Australian CAB certification for those high risk devices specified under both Regulation 5.3[1] and Regulation 4.1[2] which currently require a mandatory application audit or TGA conformity assessment certification respectively. Outsourcing of medical device assessments could be competently managed through the designation process in the same manner as the European regulatory system. The same approach should also be applied to Pathway Two[3] which could allow all devices to be Conformity Assessed by a body that has been designated by a comparable overseas Designating Authority without the need for a either mandatory application audit or TGA conformity assessment.

Question #2: Does your organisation market devices to countries relying on 'home market' regulatory approval? How would this proposal impact on this?
No, we are currently only required to seek TGA conformity assessment for those devices under Regulation 4.1.

Context

Question #3: Are there other key issues which should be considered in developing this proposal?
No comments.

[1] Therapeutic Goods (Medical Devices) Regulations 2002, Part 4, Regulation 5.3 specifies that certain kinds of medical devices including Class IIIs will be selected for a mandatory application audit.

[2] Therapeutic Goods (Medical Devices) Regulations 2002, Part 4, Regulation 4.1 specifies that medical devices containing medicines, tissues of animal, biological or microbial origin and Class 4 IVDs must hold TGA conformity assessment certification.

[3] Australian Government Response to the Review of Medicines and Medical Devices Regulation, 15 September 2016, Recommendation Fifteen, Pathway Two - Conformity Assessed by a body that has been designated to undertake Conformity Assessments by a comparable overseas Designating Authority.

Cost Recovery

Question #4: Should the costs of designation be recovered directly as fees from conformity assessment bodies, or is it appropriate that some or all costs be recovered through other mechanisms such as charge on all medical device sponsors?
The designation costs should be fully recovered from the CABs as the main beneficiaries of the designation activity. These private sector competitors can then recover assessment and evaluation costs from applicants at a potentially higher rate than the TGA but with the possible benefit to applicants of guaranteed faster review times.

Question #5: Are there other competitive neutrality concerns for the Designating Authority function that you can identify?
No comments.

TGA conformity assessment function

Question #6: TGA would continue to offer a full suite of conformity assessment functions. Is this important to you or your organisation?
It is important that the TGA continue to offer a full suite of conformity assessment functions in order to maintain the necessary competence and capacity within a government regulator. However we recommend that the TGA should reduce its level of involvement in direct assessment and concentrate resources on post-market regulatory supervision which could be possible with the introduction of other Australian CABs.

Possible interested bodies

Question #7: Do you or your organisation have an interest in seeking designation as a conformity assessment body? What are the issues which would affect your decision to apply for designation?
We do not have an interest in seeking designation as a CAB.

Designation framework

Question #8: Should the designation framework be aligned to MDSAP requirements, European requirements or a hybrid?
We support the comments in the paper that the designation framework is likely to be a hybrid given the Medical Device Single Audit Program (MDSAP) process is still in pilot and the European designation framework is already established. However, the designation framework should move towards a globally harmonised model aligned with the framework being established by the International Medical Device Regulators Forum (IMDRF).

Question #9: Should particular aspects of each system be adopted for a hybrid approach?
The current status of both the MDSAP and European framework will determine which aspects of each system will be adopted i.e. MDSAP for the Quality Management System (QMS) requirements while the European designation framework would likely cover the assessment of medical device compliance with the essential principles.

Question #10: How might alignment to the MDSAP and/or European framework be managed as international regulatory convergence develops?
Adoption of the designation framework being established by the International Medical Device Regulators Forum (IMDRF) should occur as soon as practical.

Designation criteria

Question #11: Are the listed criteria appropriate and comprehensive?
The listed criteria are deemed to be appropriate and comprehensive as they have been taken from the Notified Body Operations Group (NBOG) Best Practice Guides and MDSAP documents.

Question #12: Are there particular issues which should be considered in developing these criteria for the regulatory framework?
No comments.

Overall

Question #13: In addition to any feedback on specific aspects of the proposed approach to designation of Australian conformity assessment bodies, we are also interested in broader comments on the proposal. Comments might take into consideration the context for change and issues to consider outlined in the introduction, and consider the risks and benefits of this proposal and how these might be managed.
We support the overall proposal and believe that the TGA should adopt the role of a designating authority for domestic CABs which can demonstrate competence to evaluate all medical devices requiring premarket assessment for supply in Australia. We believe this approach may address the concerns raised by the TGA and others throughout the Review of Medicines and Medical Device Regulations, and will improve both public health outcomes and public confidence in the TGA and the Australian regulatory framework. We do however share the concerns raised in the paper around the viability of a private sector CAB industry in Australia and the considerable time and resource required to establish this pathway. Overall it is difficult to comment on the full impact of this proposal without considering the details of recommendation 15, Pathway Two which seeks to have greater utilisation of overseas approvals. In particular, if greater confidence in the EU system removes the mandatory application audit requirement for Class IIIs, than assessment by a TGA-designated commercial body in Australia may be a less attractive pathway.