THERAPEUTIC GOODS ADMINISTRATION

ACCELERATED ASSESSMENT OF MEDICAL DEVICES – PRIORITY REVIEW PATHWAY

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 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.

General Comments

We support the introduction of a Priority Review Pathway which enables expedited access to innovative medical technology that meets critical patient needs without compromising safety.

However we have concerns that the current proposal does not actually allow for accelerated assessment but rather "front of queue" processing with a designation process that may limit the overall reduction in review times. We are also concerned that only those technologies having substantial clinical data would be considered for priority review. This would seem to exclude promising new technologies that may have limited clinical data at the earliest stages of development, but would benefit from expedited review. For example, in the US, the Expedited Access Pathway (EAP) established by the FDA allows manufacturers whose device meets the specified eligibility criteria for EAP designation to work with the FDA to reduce the time and cost from development to marketing decision without changing the standard of reasonable assurance of safety and effectiveness. This is done through priority review, submission of a data development plan, interactive review, senior management involvement and assignment of a case manager to oversee the process.

Current environment

Question #1: Are there any other environmental issues that would inform or benefit the development of this proposal?

The paper references the TGA's acceptance of conformity assessment certification issued by a Notified Body in the European Union (EU) which reduces duplication in assessments. There is still a large degree of duplication 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. The details of recommendation 15, Pathway Two[3] which seeks to have greater utilisation of overseas approvals must also be considered as another mechanism to expedite assessment with the TGA to understand the full impact of the Priority Review Pathway proposal.

[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.

Question #2: Are there other issues to be considered in developing this proposal?
We are concerned about the TGA's ability to assign additional review resources to this pathway without adversely impacting applications being evaluated under standard mechanisms. We note the TGA's recent delay in Level 2 Application Audits due to clinical assessor resource constraints as an example of this risk and that there may be further limitations as to the availability of appropriately qualified subject matter experts to evaluate such novel technologies.

Principles and criteria

Question #3: Are the criteria appropriate to restrict acceptance for Priority Review to the truly new and novel devices for patients in immediate need? Noting that acceptance of a large number of applications would undermine the viability of Priority Review.
Further definition or clarification on key terms such as life-threatening, seriously debilitating and major clinical advantage is required to evaluate the full extent of this proposal. We also have concerns regarding the eligibility criteria which appear to rely heavily on pre-market clinical evidence to demonstrate "major clinical advantage." As pre-market clinical data may be limited for novel devices, we recommend an evaluation of the benefit/risk profile for the device to support the argument for greater reliance on post-market clinical data where patients will benefit from expedited access to the technology. In these cases, we recommend an option for the TGA to grant provisional approval, as proposed for prescription medicines, which allows sponsors to collect and submit post-market clinical data before the product is granted full approval. Devices could be granted provisional approval where the benefit to a specified patient population of earlier availability outweighs the risk inherent in the fact that additional clinical data is still required.

Question #4: Do the proposed criteria cover all issues which should be considered in assessing a medical device for Priority Review designation?
Clarification is needed as the last criterion *"early availability in Australia will result in a major public health benefit"* only applies to IVDs and not all medical devices.

Question #5: What is your estimated likelihood of making an application for a medical device to have Priority Review designation?
It is unlikely but we would need to clarify device eligibility for priority review (especially as it relates to clinical data requirements) and establish whether the TGA Priority Review Pathway would be advantageous compared to standard assessment pathways.

Implementation of Priority Review

Question #6: Is the proposed sponsor alert timeframe adequate for industry?
We appreciate the TGA's need for planning and ensuring appropriate resourcing however the proposed pathway should allow for greater flexibility in the sponsor alert timeframe in cases where the TGA have been able to identify the relevant technical and clinical experts to facilitate the Priority Review in less than four (4) weeks.

Question #7: Decisions will need to be made promptly, within six (6) weeks. Large submissions will undermine this, as will applications that are incomplete in meeting the criteria. Will applicants be able to present a succinct and compelling argument for Priority Review designation, independent of the full application process?
While we trust that all applicants will aim to present a succinct and compelling argument per the guidelines, the TGA must be agreeable to accept the applicant's medical expert support submitted with the summary of clinical evidence. The TGA's current increased scrutiny of Clinical Evaluation Reports has shown that clinical assessors are reluctant to make a determination based on the clinical expert's critical evaluation and conclusions and the supporting documents such as full clinical investigation reports and full text articles from literature reviews are then also required to be submitted. We also have concerns that the six (6) week review timeframe is too lengthy and may reduce any real gain in overall review times given the device will still be required to undergo standard assessment processes. We note the current proposed designation decision time for prescription medicines is 20 working days.

Question #8: In the proposed implementation it is expected that sponsors on receipt of designation advice will promptly submit their full application for conformity assessment or inclusion. Is this a reasonable expectation?
We believe this is a reasonable expectation but recommend there be the capacity to request an extension in reasonable circumstances.

Question #9: It is proposed that priority review status will be revoked if timeframes for reply to request for information are not met. Is the existing practice of a twenty (20) working day timeframe appropriate?
The due date specified in the request for information (e.g. Section 41JA) should be dependent on the type of information required and should again include the capacity to request an extension in reasonable circumstances.

Question #10: Is the proposed approach to publication of Priority Review applications and decisions appropriate?
We understand the TGA's interests in improving the transparency and accountability in their decision making processes but we do not support the publication of Priority Review applications, requests and decisions. This information should remain commercial-in-confidence. Information that a device went through the Priority Review pathway should only be published at the time of inclusion on the ARTG.

Question #11: Is the proposal to publish medical device product information for consumers supported, and what extent of detail would consumers seek?
We do not support the proposal for the TGA to publish medical device product information for consumers as this is not a requirement for other devices assessed under standard pathways. The same assessment requirements will apply to Priority Review devices so once included on the ARTG they should not be treated differently. We do on occasions provide device and surgical procedure information to health care professionals and the surgeons sometimes use these materials in communication with their patients.

Question #12: Is the Priority Review pathway for designated applications adequately detailed? If not, which areas are unclear or require more detail?
Further guidance on the format and detail required for an application for Priority Review designation would be beneficial.

TGA operational impacts

Question #13: Are there any gaps in the proposed implementation plan?
Further information regarding TGA's plan for identifying and obtaining the relevant technical and clinical resources to manage the proposed pathway is required.

Question #14: What aspects of the proposed implementation would you suggest for inclusion in a post-implementation review?
None further than those already identified on page 16 of the paper.

Question #15: What timeframe would you suggest for the review – 1 year, 2 years or 3 years after commencement?
We support a yearly review, particularly to ensure this pathway does not affect TGA business as usual operations.