THERAPEUTIC GOODS ADMINISTRATION

CONSULTATION: WHETHER THE TGA SHOULD PUBLISH THAT A PRESCRIPTION MEDICINE IS UNDER EVALUATION

TRANSPARENCY REFORMS

SUBMISSION
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Contents

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.

Submission Information & Company Overview

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

We employ approximately 1,500 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 focus 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 creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Comments on the Consultation: Whether the TGA should publish that a prescription medicine is under evaluation

Overall Comments
The Johnson & Johnson Family of Companies welcomes the review of transparency with regards to prescription medicines under evaluation and our comments provided to the options proposed by the TGA are below. We support the TGA's proposed option 2 i.e. list all applications accepted for evaluation for prescription medicines including: • new chemical entities (including biological prescription medicines); • extensions of indications; and • all generic and biosimilar medicines We do not agree with the proposed option 1 of retaining the current limited transparency nor options 3 and 4 whereby all prescription medicines are not treated equally and there is delayed transparency or no transparency for generics and biosimilar products. The Australian public are entitled to full transparency of all medicines accepted for review by the TGA.

OPTION 2 **List all applications accepted for evaluation.** **Under this option, the TGA would publish that a prescription medicine has been accepted for evaluation for:** **• new chemical entities (including biological prescription medicines);** **• extensions of indications; and** **• all generic and biosimilar medicines**
Summary We support Option 2, providing information on all new chemical entities (including new biological prescription medicines), all generic and biosimilar applications, and extensions of indications, when applications for registration are accepted for evaluation. We strongly oppose Option 3 (list all applications at two different time points with generic/biosimilar medicines published later in the process, on approval of an application but before registration on the ARTG), and we strongly oppose Option 4 (list applications of innovator medicines but not generic or biosimilar medicines). **Discussion** We recommend the TGA adopt Option 2, which most effectively fulfils the need for full transparency and is fair in applying equally to all prescription medicines, not just to innovator products only. This approach is consistent with Comparable Overseas Regulators including Health Canada (Work Sharing with the TGA is already in place), the EMA and Swiss Medic. In the USA, the same

transparency is available from company stock exchange disclosures which is covered by separate, rigorous legislative requirements. There is full transparency in New Zealand, with Medsafe publishing details of all submissions (including product name, sponsor name and application type) on their website although we note the TGA did not include this in their consultation document. Many products in Australia have shared packs with New Zealand and often align in timings for filings in both countries.

The TGA have noted that Japan does not publish generic and biosimilar applications at the same time as innovator medicines, however, in Australia we do not align with the Japanese Health Authority or guidelines, therefore this is less relevant than the approach taken by the CORs listed above.

With the rise in availability of information online, as a sponsor, we often receive enquiries from the public regarding the availability of new medicines in Australia. There is also clearly an increased public interest in faster access to medicines and many of the MMDR reforms have been aimed at reducing the times for approval of important new products and line extensions. The TGA issued a consultation in February 2019, "Reforms to the generic medicine market authorisation process", which outlines a proposal to expedite and encourage generics and biosimilars.

We do not agree with the TGA's comments in the consultation paper that there is less public interest in whether a generic or biosimilar medicine is under evaluation by TGA in Australia. Access to medicines of all kinds and classifications is of interest, and the public should be entitled to form its own view, and place its own emphasis, on the importance of different types of medicines. In the recent TGA consultation, the proposed reduction in some regulatory requirements for generic medicines even further reinforces the need for increased transparency in these medicines.

Additionally, applying the same transparency to all products, the visibility of generic and biosimilar products entering the regulatory pathway presents an opportunity to allow innovator and generic companies to resolve potential intellectual property conflicts in a timely manner, and in some cases avoiding costly and time-consuming litigation.

QUESTION 1

Please specify your preference in terms of information that should be included in a potential published list (e.g. active ingredient, tradename, therapeutic area versus indication, sponsor name)?

We propose that the following information should be published for all prescription medicines under evaluation as described above.

- Medicine name – active ingredient and tradename
- Sponsor name
- Disease state (eg multiple myeloma) and therapeutic area (eg haematology)
- Proposed indication
- Whether it is a new medicine (new chemical or biological entity), generic, biosimilar or extension of indication.
- Date accepted for evaluation (Month Year)

The medicine name (presented as both the active ingredient and tradename) as well as the sponsor name should all be included to make it as easy as possible for the public to search by different terms. The therapeutic area alone is not specific enough to find products of relevance and hence we recommend that the disease area is also included. We recommend including the proposed indication even though this may change during the evaluation.

It would be helpful for simple background information on the regulatory process to also be published on the same website so the public can better understand that not all products/indications may be approved by the TGA, as well as some general information about evaluation timelines.

We suggest that the website should be updated every month to include the new applications accepted for evaluation during the previous month.

Conclusion
The Johnson & Johnson Family of Companies thanks the TGA for the opportunity to comment on this transparency consultation. We support Option 2 to publish the details of all prescription providing information on all new chemical entities (including new biological prescription medicines), all generic and biosimilar applications, and extensions of indications. This approach is the most fair in treating all medicines equally, is the only proposed option to fulfil complete transparency and may help to reduce the impact of potential intellectual property conflicts.