THERAPEUTIC GOODS ADMINISTRATION

Consultation – Transition to eCTD only for prescription medicines

SUBMISSION
November 2018

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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: [redacted]
Email and phone contact: [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 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 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 Consultation – Transition to eCTD only for prescription medicines

OVERALL COMMENT
The Johnson & Johnson Family of Companies welcomes the review of this consultation and our comments are provided to the questions posed by TGA. We support the TGA's proposed change to the allowable formats being a part of a broader electronic dossier reforms agenda to provide an updated electronic submissions platform that is appropriate for Australian stakeholders and observes and adopts some of the best-practice initiatives that are operating in the international environment.

Applications included in future eCTD requirements

Question for Consideration 1: Do you agree with the included and not included lists?
Johnson & Johnson Family of Companies comments: Yes, we agree to the list as recommended by TGA.

Proposed Implementation Strategy

Questions for Consideration 1: Do you support the staged approach?
Johnson & Johnson Family of Companies comments: Yes, we agree to the staged approach as it allows the building of capacity and experience.

Questions for Consideration 2: Do you support the timing of the stages?
Johnson & Johnson Family of Companies comments: We agree with the staging concept and we agree with the timing of Stages 1 and 2. However as noted by the TGA in the consultation the transition for older products is more challenging (large volume of products) and we recommend a longer transition. We recommend that Stage 3 eCTD become mandatory from 1 January 2021 (an extension of 6 months).

Implications

Questions for Consideration 1: Please outline any additional hurdles and also strategies to mitigate these hurdles.
Johnson & Johnson Family of Companies comments: We agree with the potential constraints outlined by TGA, that is, resourcing and training, cost and managing older products. We continue to support a significant number of older products which tend to be very active in updating both Safety and CMC. We support TGA provision of a flexible approach to baselining giving sponsors the option to baseline, provide a partial baseline, or no baseline.

Proposed Transitional Arrangements

Questions for Consideration 1: Are there any other tools or services the TGA could provide to assist with the transition?
Johnson & Johnson Family of Companies comments: We have no additional tools or services to recommend except that during the major transition time (stages 2 and 3) that TGA consider a "hyper-care" support for the month prior to the mandatory date which is typical for implementation of new technology systems.

Additional Reforms

Updates to regional Australian specifications; Dossier submission gateway; and implementation of ICH eCTD version 4.0
Johnson & Johnson Family of Companies comments: We recommend that TGA provide a longer transition time of a minimum of 12 months for the implementation of updated eCTD specifications and guidance. Our recent experience with the transition from AU specification v3.0 to v3.1 where industry was given 8 months to implement the change (released October 2017 with mandatory use by 1 July 2018), was a very tight timeline. Based on our experience in the EU, any change to the eCTD technical specification can and usually do involve the following activities: • Development and testing of the new specification and technical files (DTD, XSL, MOD, Schema) • Vendors develop and release updated eCTD solutions for the updated specifications • Health Authorities and industry then verify, test and implement new or updated solutions into production environments

- Transition into full production and withdrawal of previous guidance

We recommend that updates to eCTD specifications are managed carefully to minimise the number and frequency of changes, and that upon issue of new and revised eCTD Guidance a transition period where clear optional and mandatory timelines are provided, with a minimum of 12 months between availability of the new standard and mandatory use. This approach would be consistent with the European regulatory agencies.

We agree and support TGA's intent to develop a dossier submission gateway.

We also recommend to TGA a technical enhancement to the current system. We recommend TGA that consider having all expected envelope information in Module 1 detailed for Sponsors to fill in or select, in addition to the "included/Not included" lists.

General Comments:

Johnson & Johnson Family of Companies thanks the TGA for the opportunity to comment on the eCTD Consultation. We support the transition to the internationally accepted and standardized eCTD format and to TGA moving towards an updated electronic submission platform as this will enable medicines to reach Australian patients faster without compromising the quality of the regulatory review.