THERAPEUTIC GOODS ADMINISTRATION

2017 CONSULTATION: NOMENCLATURE OF BIOLOGICAL MEDICINES

SUBMISSION
September 2017

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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
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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 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 2017 Nomenclature of Biological Medicines Consultation

Overall Comments
Biological medicines are complex, and biosimilars are similar but not identical to their reference biological reference products. Under the current TGA requirements, all biosimilar medicines are registered with the same non-proprietary name as the reference product. Identical names suggest the safety and efficacy, and approved indications are identical and this is not the case. Non-proprietary names that are similar but not identical will reflect the reality that the products are similar but not identical. Changes are needed to improve the current pharmacovigilance systems to better detect safety signals for individual biological products, with many adverse events reported using only the non-propriety name. By conveying similarity and difference, distinguishable names will be an essential tool for effective pharmacovigilance and for reducing risk of inadvertent switching between products (ie switching without or contrary to the intent of the prescriber). We support proposal 4 from the TGA consultation, to introduce a suffix to the non-proprietary name.

INTRODUCTION
Biological medicines are very different from chemically synthesised medicines. They can range from small molecules to large protein-containing agents, often produced by complex biotechnology techniques. Biosimilars are similar to, but not identical to their reference biological products, both scientifically and legally. As noted on the TGA website (https://www.tga.gov.au/publication/evaluation-biosimilars - accessed 31 August 2017), the biosimilar and its reference medicine will have ***similar*** characteristics, specifically physicochemical, biological, immunological, efficacy and safety. Biosimilars may differ structurally, manufacturing processes are not identical and often there is less established clinical and safety data available for a biosimilar medicine. After registration, products can change further as manufacturing changes (intentional or inadvertent) are made, meaning that even products that are initially highly similar at the time of registration can become more divergent and less similar over time. This has the potential to impact both safety and efficacy. Since the biosimilar products are not identical, the safety and efficacy profile can differ between reference and biosimilar products. Not all biosimilars are approved for the same indications as the reference products. The safety profile of a biosimilar could be significantly different to the reference product, and in some instances, rare adverse events may only be detected after prolonged periods of use. An identical name suggests the products are identical, with the same safety profile and same indications, but this may not be the case. Not all products may be appropriate for switching. The

decision for switching is dependent on the approved label, indications, supporting clinical data and a clinician's decision on a case by case basis. An identical name suggests to the HCP and patients that the products are the same, are able to be switched and are approved for all the same indications, have the same safety profile whereas this is not always the case.

Reliable and accurate pharmacovigilance mechanisms are essential for the detection and investigation of post market safety signals for all biological products. Currently there are few biological therapeutics, marketed in a given class. However the Australian biologics market is already growing and will continue to change significantly in the coming years with more biosimilars expected to be introduced and increased number of biological products in the same product class (some of which will share reference products). There is expected to be more multi-source biologics coming through and a wider variety of companies as manufacturers, potentially bringing new challenges, and making post market surveillance more complex.

Reliable pharmacovigilance mechanisms are essential for detection and investigation of postmarket safety signals. Given the limited premarket clinical testing of biosimilars, postmarket surveillance is essential to effectively detect product differences that may not have been apparent prior to registration. As noted above, biosimilars may not have the same safety profile, and manufacturing changes (intentional or inadvertent) throughout the lifecycle of a product could result in further differences in safety. The pharmacovigilance systems need to be robust and sensitive enough to detect safety signals for individual products.

Effective pharmacovigilance systems must be able to distinguish between products. As noted in the TGA consultation, it is not mandatory to include the tradename in reporting of adverse events to the TGA. Currently, in the absence of a tradename or AUST R for an adverse event, it is likely the event may be misreported or attributed to the reference product by default. It is essential that AE reports include distinguishing non-proprietary names, to ensure accuracy in reporting and effective signal detection for individual products.

There is strong support for differentiating non-proprietary names from various stakeholders throughout the healthcare system in Australia and there is concern for traceability of biological products under the current adverse event reporting system.

Option 1: Status Quo

QUESTION 1

Do you support maintaining the current system with no change? Please provide reasons to support this view, or not.

We do not support this option to maintain the current system with no change.

As outlined in the Introduction above, we have concerns that the current naming of biological reference products and biosimilars suggests the products are identical and this is not the case.

Inaccurate reporting or misreporting of adverse events due to lack of differentiation between products can significantly hinder effective signal detection.

Currently it is not mandatory to include the tradename in reporting of adverse events to TGA.
If no tradename is included, reports are often attributed to the reference biologic by default. This can lead to inaccurate reporting and underreporting of AEs for biosimilars.

Option 2: Status Quo with activities to increase public reporting of adverse events with inclusion of tradename, AUST R and batch number.

QUESTION 2

Do you support this option? Please provide reasons to support this view, or not.

We do not support this option to maintain the current system but attempt to better educate the public.

We encourage additional education on adverse event reporting, however, it is unlikely that this alone would have a significant impact on better adverse event reporting of biologics and biosimilars. We are aware that many hospitals use dispensing software that does not include the tradename. Furthermore, even if a clinician was trying to report by tradename, if the product has been switched at pharmacy level without their knowledge the correct product is still not going to be reported.

We do not consider that education alone without further action to differentiate product names, would be sufficient in improving the accuracy of adverse event reporting and better ensuring safety and efficacy of medicines for patients.

Option 3: Move towards adopting a barcode system similar to the EU.

QUESTION 3

Do you support use of a similar barcode system in Australia? Please provide reasons to support this view, or not.

We do not support this as a sole measure to address the issues described above. This could be effective as a supply chain management tool, and better tracking of batch-specific issues, however, this would be expected to have limited or no impact on accuracy of adverse event reporting alone.

A very large shift in approach to AE reporting would be required, along with the infrastructure and software for bar code scanning. It is very unlikely that all HCPs, hospitals, clinics, pharmacies would have barcode scanning software integrated for use and also compatible with a very wide range of systems. It is even less likely that a consumer would scan a barcode in reporting an adverse event. As well as the tools to make this effective, the significant behavioural change in adverse event reporting would make this a less impactful option.

This barcode approach could potentially improve supply chain management and tracking of issues with particular batches. However, alone this would not be sufficient to address the concerns raised in AE reporting. Other measures to differentiate names of products are required for an effective solution.

Option 3: Move towards adopting a barcode system similar to the EU. **QUESTION 4** **What system and level of serialisation should a barcode use?**
If utilised for tracking of batches and supply chain management, we support the adoption of the QR bar code used in EU.

Option 3: Move towards adopting a barcode system similar to the EU. **QUESTION 5** **What is the impact (including financial impact) of this option on you?**
No comments on financial impact .

Option 4: Introduce the use of suffixes to the naming of biological medicines **QUESTION 6** **Do you support this option? Please provide reasons to support this view, or not.**
We support this option of introducing suffixes to the naming of biological medicines. The use of suffixes will create non-proprietary names that are similar but not the same. This would be the most effective option to help improve more accurate reporting of adverse events, more accurate signal detection and improve the safe and efficacious use of medicines for patients. This naming approach would be the most effective approach to address the concerns raised in the Introduction (see above) and summarised below: - Biosimilar medicines are similar but not the same. They may not have the same safety profile and may not be approved for the same indications. Switching might be approved but not in all cases. Identical names indicate the products are identical and can be used for the same indications and have the same safety profile and this is not the case. - Reliable and accurate pharmacovigilance mechanisms are essential for the detection and investigation of post market safety signals for all biological products. Effective pharmacovigilance systems must be able to distinguish between products. Distinguishable non-proprietary names would improve accuracy of adverse event reporting, particularly when the reports do not include the tradename or AUST R.

Distinguishable names are critical to effective identification and traceability of biologics/biosimilars at all stages of patient care.

It will be important to ensure that all systems and software programs (including prescribing and dispensing software) all accommodate the addition of the suffix, to ensure maximum impact.

Option 4: Introduce the use of suffixes to the naming of biological medicines
QUESTION 7
What is the impact (including financial impact) of this option on you?

No comment.

Option 4: Introduce the use of suffixes to the naming of biological medicines
QUESTION 8
If this option was to be implemented should Australia adopt the outcomes of the FDA scheme or develop its own scheme for adding a suffix? Please provide reasons to support your view.

We would support the FDA scheme if this was the only option available in Australia. However, we consider a different scheme would be more effective.

We have concerns that randomly generated, or non-meaningful suffixes, will be less effective. In the US, the sponsor can propose some combinations of letters for consideration, but they cannot be related to the sponsor name. In some cases, the codes will be generated by the FDA. These random combinations are harder to remember, and therefore less likely to be used by the public, and more subject to errors.

One suggested approach would be to include a unique identifier for each sponsor and that is included on each of their biological products. For example, "JNSN" could be used for Janssen products. Occasionally products are transferred between sponsors, however, the frequency of this would be very low.

If TGA took a different approach to the US FDA this would mean different suffixes would be used in Australia compared to the US, however other countries are already adopting different systems with Japan utilising a numbering suffix and the EU with no suffix at all. We consider the inconvenience of having different naming to the US would be minimal and vastly outweighed by the benefits of a more meaningful naming convention in Australia.

Option 4: Introduce the use of suffixes to the naming of biological medicines **QUESTION 9** **If this option was to be implemented should it apply retrospectively? Please provide reasons to support this view, or not.**
We support the implementation of suffixes for new biological medicines and biosimilars however, we are concerned that this may be less effective retrospectively. We consider the changing of names once they are already well known and established for many years would have less impact. It will be challenging to encourage health care practitioners as well as the public to start adding suffixes to product names that they are familiar with and have been using for a long time. In addition there would be significant challenges logistically to change the product names for established products, considering not just packaging components but also the wide variety of materials that also include the product name. This would range from dispensing and prescribing software, through to patient level materials. Implementation would be difficult to roll out, particularly managing stock during a transition period of old and new names, with the potential for confusion by patients and HCPs. We recommend the suffixes apply to new products moving forward.

OTHER **QUESTION 10** **Are there other options which should be considered? Please provide reasons to support this view, or not.**
Not at this time.

Comment – Page 10 of TGA consultation document
The TGA have included the following text on page 10 of the consultation document regarding the option to adopt a suffix naming system: *"This option would make the biosimilar and reference biological brands appear as different drugs for prescribing purposes because they would be presented as distinct entries in prescribing lists and would therefore be displayed separately for the prescriber to choose from. This may undermine the scientific findings concerning their level of similarity, which could be contrary to whole of government messaging around uptake of biosimilars*." We consider that any initiative around biological naming should be patient-focused, aimed at improving safe and efficacious use of medicines by the public. The addition of a suffix would help in improving accuracy of adverse event reporting and safety signal detection in biological and

biosimilar medicines. Patient safety should be the primary aim of the biological naming approach, and not the government policies around encouraging update of biosimilars.