NPS MEDICINEWISE

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Biological Science Section
Therapeutic Goods Administration
PO Box 100
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To whom it may concern

Re: Consultation: Nomenclature of Biological Medicines

NPS MedicineWise would like to thank the Therapeutic Goods Administration (TGA) for providing the opportunity to offer feedback on the proposed options for the nomenclature of biological medicines.

NPS MedicineWise is an independent, not-for-profit and evidence-based organisation that works to improve the way health technologies, medicines and medical tests are prescribed and used. We do this through clinical improvement interventions, evidence-based information to support decision making, educational programs and targeted health communications campaigns.

We work in partnership with peak health organisations and government, connecting health consumers and health professionals with evidence-based resources and tools to improve the health of all Australians.

After reviewing the consultation document, we are of the opinion that option #3—moving towards adopting a barcode system similar to the EU—combined with the educational component of option #2 would constitute the most pragmatic approach to this issue.

In our view, maintaining the status quo, as described in option #1, is not sufficient to support public confidence in interchangeability and switching between reference medicines and biosimilars. It does not provide enough information for health professionals and consumers to ensure accurate data collection of adverse events, and is therefore insufficient to support effective pharmacovigilance.

Option #4 raises the concern that using suffixes would effectively identify the products as different drugs, which could suggest biosimilar medicines are not equivalent to their reference medicines. This won't help with the government's messaging around the safety of biological and biosimilar medicines and could further impede progress in the uptake of biosimilar medicines.

This leaves options #2 and #3. Adopting a barcode system, as outlined in option #3, would ultimately help with the uptake of biosimilar medicines by:

- reducing the risk of incorrect or incomplete data being collected, thus improving accuracy of pharmacovigilance data to allow traceability of batches and monitor any adverse events associated with these medicines.
- reducing ambiguity about which medicines people are taking. This will provide clarity for prescribers, treating health professionals and consumers, and build confidence in the use of biosimilars.

As some manufacturers already use barcodes, implementation of this option may not be overly challenging.

Option #3 should also be supported by an education campaign in order to increase knowledge, for both health professionals and consumers, around biosimilar medicines and pharmacovigilance. Option #2 could

be integrated with option #3, with NPS MedicineWise information updated to reflect the new requirements for reporting adverse events.

NPS MedicineWise is willing to support the TGA with education and information dissemination regarding biological medicines going forward. We are very happy to provide further clarification or guidance as needed and look forward to our continued collaboration with the TGA in the future.

Yours sincerely

Kerren Hosking
Executive Manager, Corporate Affairs & Governance