8 September 2017

Biological Science Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN, ACT 2606

Consultation: Nomenclature of Biological Medicines.

Dear Sir/Madam

Roche thanks the TGA for the opportunity to provide comments on the important topic of the Nomenclature of Biological Medicines.

As a research-based healthcare company, Roche believes strongly that sustainable healthcare systems are those that can deliver continuous advances in treatment through innovative products. It is also our strong belief that regulations relating to biosimilars should promote, rather than impede, innovative research towards new medicines.

Roche recognises the important role of biosimilars and acknowledges that they may help improve access to medicines for patients and ensure the continued sustainability of the Pharmaceutical Benefits Scheme (PBS). Roche supports the use of competition in the off-patent market to drive savings that can be reinvested in innovative medicines. To ensure the continued value of medicines and the viability of the Australian pharmaceutical industry, it is critical that these savings are not lost to non-medicine-related activities. Patient safety, however, must always be the highest priority.

Pharmacovigilance and risk management planning are essential for any biological product, including biosimilars. Robust pharmacovigilance measures are essential for any new biological product.

Despite the fact that a biosimilar and a reference drug can show similar efficacy, the biosimilar may exhibit a different safety profile in terms of the nature, seriousness, or incidence of adverse reactions. The data from pre-authorization clinical studies normally are insufficient to identify all potential differences between a biosimilar and the reference drug. In addition, all biotechnology products, including biosimilars, have the potential to cause immunogenic events that may sometimes take years to develop and that may occur only infrequently and yet have profound clinical consequences.

Therefore, the clinical safety of similar biological medicinal products must be monitored closely on an ongoing basis during the post-approval phase and include continued risk–benefit assessment.

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A key element to the pharmacovigilance measures for biosimilars and biologics is the need for unique identification It is essential to identify and trace the product used if an adverse reaction (particularly immunogenicity) occurs. Biosimilars therefore must be branded in order to allow identification of the actual biological product used in clinical practice.

For safe prescription and dispensing, and effective pharmacovigilance monitoring, it is necessary that different products (even if similar) can be uniquely identified.

Prescription by non-distinguishable International Nonproprietary Name (INN) only would result in different products being considered identical. For example, if two biologicals had the same INN, they could be switched when there may be no scientific evidence to support that switch. The interchangeability could have negative clinical consequences for the patient, as the two products are similar but not identical, and the differences between them may have a therapeutic impact.

For routine pharmacovigilance, it has been recognized that it is essential that, as a minimum, brand name, active substance, and batch number are reported and captured on the safety database. This will allow the case report to be used for signal detection and data quality analyses.

As members of Medicines Australia, Roche has provided input into the Medicines Australia submission.

Yours sincerely,
Roche Products Pty Limited

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