14 September 2017

TGA Nomenclature of Biological Medicines Consultation
Biological Science Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email to: bloodandtissues@health.gov.au

To Whom It May Concern

Submission on Nomenclature of Biological Medicines

Thank you for the opportunity to comment on this proposal.

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines and vaccines in New Zealand. A central objective of Medicines New Zealand is to promote the benefits of a strong research based industry in New Zealand.

Although this consultation has been initiated by the Therapeutic Goods Administration (TGA) and relates to the regulatory system in Australia, we wish to provide comment on aspects of the consultation paper with special consideration of the potential impact on companies supplying share packs to Australia and New Zealand.

Like Medicines Australia, the members of Medicines New Zealand comprises both originator biological medicines companies as well as companies manufacturing biosimilars. We recognise biological medicines are highly complex structures, in contrast to chemically synthesised medicines. Generic versions of chemically synthesised medicines have identical active ingredients to the originator. Whereas, the active ingredients of biosimilars are similar, but not identical, versions of the originator biological medicine.

Biosimilars are approved based on the assessment of comparative data to the originator biological reference product. Medicines New Zealand is supportive of the entry of biosimilars into the market, provided that regulatory approval has determined they have a robust safety profile and satisfactory effectiveness when compared to an innovator biological reference product.

However, Medicines New Zealand wishes to highlight that the proposal has potential to impact on companies supplying share packs to Australia and New Zealand and this must be acknowledged by the TGA. New Zealand receives batches of medicines produced or packaged for larger regional or international markets, including the Australasian market.

Therefore, Medicines New Zealand believes adoption of an existing system for labelling or naming requirements is more advantageous than development of an Australian-specific approach. Adopting an Australian-specific approach for labelling or naming will likely create additional regulatory barriers for companies supplying share packs to Australia and New Zealand. Harmonising with an existing system and having a sufficiently long transition period is recommended to help mitigate the potential impact on New Zealand.

Thank you again for providing the opportunity to comment on the proposal. As noted, Medicines New Zealand supports a robust pharmacovigilance reporting and tracking but recommends that the impact of the proposal on New Zealand and companies supplying share packs to Australia and New Zealand be given serious consideration by the TGA.

Please do not hesitate to contact me if you have further queries with regards to our submission.

Yours Sincerely

Medicines New Zealand