

Biological Science Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via email: bloodandtissues@health.gov.au

15 September 2017

Dear Sir/Madam

Thank you for the opportunity to respond to the Therapeutic Goods Administration's *Nomenclature of Biological Medicines Consultation Paper* (July 2017).

Medicines Australia ('MA') members research, develop, manufacture and supply, medicines and vaccines to the Australian community. They represent over 80 per cent of the Australian prescription medicines market by value.

MA, which represents the originator biologic manufacturers and the vast majority of biosimilar manufacturers, considers that biosimilars assessed by the TGA as safe, and effective, have an important and legitimate role to play in the Australian health care system. In our submission (attached), we note that MA has previously and consistently indicated in regard to biological medicines nomenclature, that all biologics and biosimilars need to be distinguishable from each other. We highlight that the MA Board-endorsed position with regard to biosimilars and biologics states clearly that "an effective system of pharmacovigilance relies upon the ability to distinguish every biologic medicine, including every biosimilar, through unique identification mechanisms". This is consistent with Option 4 in the TGA paper and therefore the preferred option.

Additionally, whilst Options 2 and 3 would improve the tracking of products through widespread use of proprietary trade name, AUST R, and batch number as well as bar-code upgrades, they are inconsistent with other current Australian Government policies and therefore would fail to achieve the TGA's 'Outcomes Sought'.

We are keen to work with the Australian Government, as well as other stakeholders, to ensure appropriate uptake and use of biosimilars in Australia. We have a strong record of working constructively with the Australian Government on biosimilars policy, for example, through the most recent Strategic Agreement (2017), which will deliver savings to the Federal Budget and create headroom for innovative medicines. We also provided a position statement on biosimilars to the Department of Health, Biosimilars Education and Awareness Initiative Reference Panel in 2016.

Finally, we appreciate the one week extension and look forward to the next steps.

Yours faithfully



Elizabeth de Somer
Director, Research & Policy