Bristol-Myers Squibb Australia Pty Ltd
ABN 33 004 333 322

Bristol-Myers Squibb

[redacted]

7 September 2017

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

Consultation on Nomenclature of Biological Medicines

Dear Sir/Madam,

Bristol-Myers Squibb Company ("BMS") would like to provide the following comments regarding the proposed options on whether there is a need in Australia for additional naming requirements for biological medicines.

In summary, BMS supports distinguishable non-proprietary names for all biological products (both biosimilars and originators). Of the options set out by the Therapeutic Goods Administration in the consultation paper titled Nomenclature of Biological Medicines, BMS supports proposed Option 4, which recommends the introduction of suffixes in the naming of biological medicines.

BMS believes that this option, which should be applied across originator and biosimilar products, provides a consistent and recognisable mechanism to correctly identify products.

Using the non-proprietary name and a unique suffix would be the most robust mechanism to ensure correct adverse event attribution, especially in cases where there may be substitution of the prescription with a biosimilar.

Relying on the public to increase reporting of trade names and AUST Rs would be insufficient to support effective pharmacovigilance. When adverse events are reported, the patient/healthcare professional generally refers to the product by the INN name and drops the trade name, or reports the prescribed product by trade name but is unaware that there was substitution at the time of dispensing of the prescription. Furthermore, collection of this additional information will put additional burden on both reporters and sponsors and it is unlikely that reporters will provide this additional information. The worldwide format for reporting of adverse drug reactions from sponsors to Health Authorities is via CIOMS format – this does not include any of these fields. It is therefore not clear how this information would be provided to the TGA, particularly when the transition to automated (E2B) reporting occurs.

Accordingly, if a doctor issues a prescription using the non-proprietary name, including a unique suffix that appears on the label, this will allow the patient to unequivocally identify what product

(or biosimilar) was actually dispensed, which would help with proper adverse event reporting/tracking.

In implementing an INN suffix scheme, BMS is advocating for a harmonised approach internationally. Although WHO does not yet have a final framework, BMS would still primarily refer to WHO as a framework for harmonisation.

BMS does not recommend the retrospective implementation of an INN suffix scheme. BMS is aligned with the IFPMA team's advice to the WHO INN Committee that changes to INNs retrospectively would have global impact to artwork, packaging, licenses, pharmacovigilance systems, etc. In Australia, retrospective implementation would also have consequential effects in countries for which the product is authorised with Australia as the reference country.

In conclusion, BMS overall supports Option 4, but BMS does not support its retroactive application.

If you require further information, please contact me either by phone: [redacted] and [redacted]

Yours sincerely

Bristol-Myers Squibb Australia Pty Ltd

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