[redacted]

8 September 2017

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

Dear Sir/Madam,

Re: TGA Consultation – Nomenclature of Biological Medicines

We refer to the July 2017 TGA consultation on Nomenclature of Biological Medicines. Please find below MSD's response to the proposals outlined in the Consultation document.

MSD Position

Overall MSD welcomes the introduction of a nomenclature system for biological medicines in Australia that enables robust pharmacovigilance reporting and is harmonized as far as possible with international best practice (in particular that of the European Union (EU)).

MSD acknowledges the submission made by Medicines Australia, and supports their recommendations. These should be implemented in a way that is aligned to the aims of the Strategic Agreement between the Commonwealth and Medicines Australia, with regards to promoting greater use of biosimilars. This will help to create a viable, sustainable market for biosimilars in Australia, which will in turn deliver savings and create further headroom for innovative medicines.

Our specific comments on the options outlined in the consultation paper are as follows:

Option 1 – Status quo

MSD does not agree with the proposal to maintain current biological medicines nomenclature without any activity to enhance adverse event (AE) reporting as new biosimilar products enter the market.

Option 2 – Status quo with activities to enhance AE reporting [MSD Preference Short-Term]

MSD supports maintenance of the current system of using the agreed Approved Biological Name to identify the active ingredient in both the reference product and all subsequent biosimilars, with unique identification of individual products being reliant on the allocated Australian registration number (AUST R) and proprietary trade name. We support this in conjunction with the introduction of educational activities to enhance the quality of AE reporting, in particular to include product and batch specific information in these reports.

MSD agrees with the proposals outlined in the consultation paper to educate healthcare professionals and members of the public on the importance of reporting adverse events. We also recognise the benefits that will be generated through the introduction of systems to facilitate or mandate inclusion of product and batch specific details in AE reports. We note that this proposal is consistent with similar initiatives in the EU, where activities to enhance pharmacovigilance reporting for biological medicines are currently being explored. In the Netherlands, a recent study was conducted which analysed information-recording systems and practices in the Dutch hospital setting to identify determinants for brand name and batch number recording [Klein *et al*. Drug Saf (2016) 39: 185]. This study also looked at success factors and impediments to product traceability following AE reports, resulting in the recommendation that improvements in information-recording systems should be considered as a first step towards improving the traceability of specific biologics in AE reports.

Option 3 – Move towards adopting a barcode system similar to the EU [MSD Preference Long-Term]

MSD also supports the adoption of a barcode system similar to that being mandated in the EU. We see this as an ideal long term solution for post-market monitoring of biological medicines in Australia. However, we believe that the feasibility of such an initiative (i.e., the potential for 2D barcoding to be integrated it into current systems and infrastructure in Australia) requires extensive discussion prior to implementation. Such discussions should include consideration of the resources required to implement a new and potentially complex system. Consideration would also need to be given to in-practice use of a barcode system for patients and healthcare practitioners to maximise its utility and effectiveness.

Option 4 – Introduce use of suffixes to the naming of biological medicines

MSD is supportive of efforts to harmonise non-proprietary names internationally. MSD believes that non-proprietary naming conventions for biological products should allow for the ability to distinguish between each biological product, while conveying relationship to the reference product. MSD supports the need to rapidly identify biological products by manufacturer for the purposes of pharmacovigilance and patient safety. Therefore, whilst MSD would accept the use of suffixes, we believe that the suffix should be meaningful, and should apply to all biological medicines (i.e. it should not single out biosimilars to require suffixes). However, as the introduction of a suffix is likely to create confusion for patients and prescribers it is not MSD's preferred nomenclature option.

We trust that MSDs response to this consultation will be of assistance to the TGA in developing and implementing a nomenclature system for biological medicines in Australia that is harmonized as much as possible with international best practice and supports robust post-market monitoring of individual products. Should you require any additional information regarding this response, please do not hesitate to contact the undersigned.

Yours sincerely,