1st September 2017

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

Dear Sir/madam,

Juno Pharmaceuticals thanks the TGA for providing us with the opportunity to provide comment on the consultation paper, Nomenclature of Biological Medicines. We feel this is a very important topic in the evolution of biosimilar medicines.

Please find our input to each of the options included in the consultation paper on the following pages. Should you require clarification of any of the points raised or wish to discuss anything, please feel free to contact me on [redacted] or at [redacted].

Yours sincerely,

[redacted]

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1. Status quo. Use the agreed Approved Biological Name to identify the active ingredient in both the reference product and all subsequent biosimilars. Unique identification of individual products would rely on its allocated Australian registration number (AUST R) and proprietary trade name.

   Do you support maintaining the current system with no change? Please provide reasons to support this view, or not.

   Juno does support maintaining the current system with no change.

   Pharmaceutical products available on the Australian market already contain sufficient unique identifiers such as trade name and ARTG number to enable the products to be readily identified. It is important that these unique identifiers are included when recording and reporting adverse drug events.

   Maintaining the status quo also maintains the alignment Australia shares with Europe which is currently where the significant proportion of biosimilar uptake and experience has occurred.

   This does not create any additional regulatory burden either for companies/sponsors nor for the TGA. However, in line with Option 2 below, it does highlight the need to ensure that the relevant identifiers are reported and hence there should be consideration to appropriate messaging to medical practitioners and consumers with regards to adverse event reporting.

   Biological, and importantly, biosimilar medicines, have undergone an extensive review process by the TGA before they are approved for use. In the case of biosimilar medicines this includes assessment of a significant number of complex in-vitro and in-vivo studies, including immunogenicity studies, to demonstrate that such products are sufficiently similar to the reference product in terms of comparable quality, safety and efficacy. As a result of this extensive data collection process and review it is important that the naming convention applied to the reference product and biosimilar product remains the same in order to reflect the conclusion that these products are in fact comparable.

   Maintaining the status quo avoids unnecessary confusion amongst prescribers and patients with regards to the medicines being prescribed and as a result contributes to safe prescribing and dispensing practises.

   The Australian government, European governments, and the generic/biosimilar industry have spent a great deal of time and resource to drive the uptake in biosimilar medicines to reduce government expenditure on these important, and often very expensive, products. This effort has generally been in the face of continual lobbying by major pharmaceutical companies and industry associations to thwart such initiatives and create uncertainty. We believe that maintaining the status quo with regards to naming convention supports the ongoing initiatives and government policies, whereas changing the naming conventions of biological medicines will simply create additional uncertainty and has the potential to reduce uptake of biosimilar medicines.

2. Status quo with activities that increase public reporting of adverse events with the inclusion of the product's trade name, AUST R and batch number.

Do you support this option? Please provide reasons to support this view, or not.

Juno does support maintaining the current system with activities that increase public reporting of adverse events with the inclusion of the product's trade name, AUST R and batch number.

The arguments provided above in relation to Option 1 equally apply with regards to Option 2.

Although provision of trade name, ARTG number and batch number is not mandated when reporting adverse drug events, the provision to include such information already exists and this information is already being provided in many ADE reports. Particularly those originating from health care professionals.

Mandating the inclusion of this information when reporting adverse events should only create a minor regulatory burden and would require appropriate messaging to medical practitioners and consumers with regards to adverse event reporting.

3. Move towards adopting a barcode system similar to the EU.

Do you support use of a similar barcode system in Australia? Please provide reasons to support this view, or not.

What system and level of serialisation should a barcode use?

What is the impact (including financial impact) of this option on you?

Juno supports the idea of adopting a barcode system similar to the system being adopted by the EU. However we support this with some caution and believe that it is still extremely important that at the same time we maintain the status quo when it comes to naming of biological medicines.

The introduction of barcoding provides a good method of tracking and identifying products however there are many factors that need to be considered and agreed before such an initiative will be successful;

- all stakeholders within the supply chain need to agree on what the 2D barcodes would be used for
- agreement is needed on what information is contained within these barcodes
- stakeholders need to have the necessary equipment to read the 2D barcodes and potentially store the information contained within the barcode.

The impact on the pharmaceutical industry will differ depending upon the type of information contained with the bar code. If only the tradename and ARTG number for example are required then this can be included on a product label as part of the product artwork and will therefore have minimal impact other than a re-design of the artwork. As soon as variable information such as batch numbers and expiry dates are to be included then the impact increases dramatically as this

information needs to be printed at the time of manufacture and manufacturers will need to invest in appropriate equipment and systems to enable this variable information to be printed.

An obvious concern regarding the use of bar codes relates to the quantity of information required. The more information included in the 2D bar code the larger the bar code may need to become in order to allow for it to be printed in a readable manner. This can have a major impact on the labelling and packaging of products. In particular for biological products which are routinely presented in small vials or syringes with little room for large amounts of text on the labelling.

Although bar codes can clearly be of assistance when it comes to tracking products through the supply chain and reducing dosing errors at the point of dispensing we feel this initiative may not contribute significantly to improved reporting of adverse events since many adverse events are reported by patients who will unlikely be in a position to read and record the information contained within the bar code.

4. Introduce the use of suffixes to the naming of biological medicines.

Do you support this option? Please provide reasons to support this view, or not.

What is the impact (including financial impact) of this option on you?

If this option was to be implemented should Australia adopt the outcomes of the FDA scheme or develop its own scheme for adding a suffix? Please provide reasons to support your view.

If this option was to be implemented should it apply retrospectively? Please provide reasons to support this view, or not.

Juno strongly does not support the introduction of suffixes to the naming of biological medicines.

We do not believe there are sufficient concerns associated with capturing information required to identify a medicine in relation to adverse drug events that would warrant the need to include such a suffix.

As identified above, Pharmaceutical products available on the Australian market already contain sufficient unique identifiers such as trade name and ARTG number to enable the products to be readily identified. It is important that these unique identifiers are included when recording and reporting adverse drug events.

In the EU, where there has been extensive experience in the prescribing of biosimilar products, there is ample evidence to demonstrate that the existing naming convention of INN and tradename adequately guarantees the identification of medicines in relation to adverse event reporting.

European regulators have reported that product identification of biosimilars is well ensured at 96.2% across 3 product classes (filgrastim, epoetin and somatropin). This is especially the case for epoetin (98.9% of suspected epoetins) where information is included in the SmPC to improve the traceability of erythropoiesis-stimulating agents (ESAs), the trade name of the administered ESA should be clearly recorded (or stated) in the patient file[1].

Data retrieved from the Italian Adverse Event Database, and published in November 2014, demonstrated that that 94.8% of biological-related reports included an identifiable product name and this increased to 98.7% for biosimilar products.

The above indicates that traceability of biological medicines associated with adverse event reporting is only a minor issue and could be readily resolved by improved recording of the unique identifiers such as tradename and ARTG number.

The biosimilar industry has spent many years engineering biosimilar products, conducting huge batteries of characterisation tests and clinical studies to demonstrate that these are clinically comparable to their biological reference products. There has also been an enormous amount of resource expended on education and promotion of such products by both industry and governments on a global basis to convince health care professionals and patients that these products are in fact the same. This effort has generally been in the face of continual lobbying by major pharmaceutical companies and industry associations to thwart such initiatives and create uncertainty due to their own self interests.

Any deviation of the currently accepted naming standards for biosimilar medicines would result in a significant step backwards in these efforts by the biosimilar industry and government. It would create confusion and uncertainty within the healthcare profession and patients and could be used to mislead healthcare professionals that these products may in fact not be therapeutic equivalents to their references products. We feel that the confusion and misinterpretation created as a result of adding a suffix to the INN for biosimilar products may in fact have a negative influence in the uptake of these products and hence undo the extensive efforts to date to actually increase uptake.

An illustration of how a change in naming convention of a biosimilar product can have a major impact on product uptake is the example of epoetin in Australia. Sandoz's epoetin was given a lambda designation instead of beta as it was given in Europe. While the uptake of this product has been considerable in Europe, there is still very little uptake of the Sandoz product in Australia after many years of marketing and an aggressive pricing strategy.

References

1. www.ema.europa.eu/docs/en_GB/document_library/Presentation/2012/05/WC500127934.pdf

2. www.ncbi.nlm.nih.gov/pubmed/25255847,'Safety profile of biological medicines as compared with non-biologicals: an analysis of the italian spontaneous reporting system database', Cutroneo PM, Nov 2014.