GBMA
Generic and Biosimilar Medicines Association

# Submission

## Consultation: Nomenclature of Biological Medicines

September 2017

## INTRODUCTION

The Generic and Biosimilar Medicines Association (GBMA) represents the manufacturers and suppliers of generic and biosimilar medicines in Australia. As a representative body, GBMA is making this submission on behalf of members and it is our intention to provide a balanced assessment of the reform proposals with specific comments on the commercial and operation implications for Australian sponsors.

GBMA appreciates the opportunity to make this submission to the Therapeutic Goods Administration (TGA).

## COMMENTS ON THE CONSULTATION

GBMA is committed to supporting a viable and competitive market for biosimilar medicines, the Biosimilar Awareness Initiative and the biosimilar uptake drivers announced in the 2017-18 Budget.

GBMA is also committed to pharmacovigilance and the need to collect accurate information regarding a suspected adverse event.

GBMA acknowledges that consultation paper provides an excellent context and outline of the issues regarding nomenclature of biological medicines and the TGA's goal to enhance pharmacovigilance.

GBMA notes that the current TGA approach to nomenclature of biological medicines complies with international naming conventions and standards, where the non-proprietary name reflects the active ingredient as established by conventions of the World Health Organisation (WHO).

For all medicines, the international non-proprietary name provides information on the active ingredient, but it is the brand name that most readily enables identification of the product. Once identity is established, other product characteristics, such as the batch number, then enable traceability of the product to support pharmacovigilance activities.

GBMA takes the opinion that changing how biological medicines are named will not enhance pharmacovigilance, but would:

- Increase regulatory burden;
- Be inconsistent with the current evidence based approach to regulate based on risk rather than category of medicine;
- Act as a barrier to market entry;
- Undermine healthcare professional and consumer confidence in biosimilar medicines;
- Create confusion in prescribing and dispensing software; and
- Undermine the government's policy to increase the uptake of biosimilar medicines.

**GBMA therefore strongly supports Option 2 outlined in the consultation paper.**

If all stakeholders are genuine about pharmacovigilance for biologic and biosimilar medicines in the real world, encouraging the proper and consistent reporting of adverse events for all medicines is a much better solution than applying different names or adding another meaningless, unique identifier.

Traceability is an issue for all drugs, not just for biosimilars. The current system already has a number of unique identifiers to discriminate between products with the same active ingredient (e.g. brand name, AUST-R or AUST-L). However, in terms of pharmacovigilance, the most important identifier required to trace potential problems to their source is the batch number.

The current process for reporting adverse events is well established and highlights all necessary fields to effectively identify the individual medicine, down to brand and batch level, associated with the event. GBMA implores TGA to remind stakeholders that the current online system for reporting an adverse event encourages the completion of a number of fields for data entry, including the brand name, active ingredient name, batch number, AUST-R or AUST-L number, and expiry date. In parallel, education and encouragement for healthcare professionals and consumers on how to report an adverse event, and why it's so important, is also needed.

## OPTION 1

GBMA **supports in principle** the status quo where the Approved Biological Name (ABN) is used to identify the active ingredient in both the reference product and all subsequent biosimilars. Identification is enabled through other existing unique characteristics including the product's Australian Registration (AUST R) number and proprietary trade name.

However, maintaining the current system with no improvements to the adverse event reporting system would be an unsatisfactory outcome and is not supported.

## OPTION 2

GBMA **strongly supports** the status quo when it is coupled with activities to increase public reporting of adverse events. This will enhance what is already in place without increasing regulatory burden or adversely impacting the government's policy to support the increased uptake of biosimilar medicines. This option also recognises the TGA evidence based approach to regulate according to the risk rather than medicine category.

Increasing education activities for healthcare professionals and the public to report suspected adverse events for all medicines will support the quality use of all medicines.

As there is no rationale for treating the post-market surveillance of biological and biosimilar medicines any differently to other medicines, these awareness activities must not be specific to biological medicines.

In addition to increasing awareness, GBMA supports improvements to the adverse event reporting process to make certain reporting fields mandatory – specifically the trade name, batch number and expiry. It would be impossible not to identify a medicine suspected of causing an adverse event of all four of these identifies are reported.

## OPTION 3

GBMA **could consider** the move towards a barcode system similar to the EU **in future**, pending further consultation.

GBMA agrees with the benefits of introducing a barcode as a future packaging requirement for all medicines, not just biological medicines. A bar code on all medicines could support the Government's broader e-prescribing and dispensing initiatives, linking with the My Health record to improve pharmacovigilance and quality use of medicines.

GBMA supports aligning with requirements in the EU as this is consistent with the TGA's current practice of adopting EMA guidelines with respect to biosimilar medicine evaluation. As biosimilar medicines are generally being developed for the global market, it may be possible for Australian packaging to mirror that of the EU, including the 2-dimentional bar code.

However, as medicine packaging requirements have only recently been updated in Australia, the regulatory burden and cost of introducing another requirement cannot be ignored. Careful consideration must be given to the consequences of introducing additional packaging requirements for all medicines, such as increased sponsor overhead costs, loss of operational efficiency, increased wastage, increased potential for supply delays, and risk to commercial viability of low cost medicines.

GBMA proposes that a separate consultation on alignment of packaging requirements with EU for all medicines be conducted to inform any future consideration of this option.

## OPTION 4

GBMA **strongly opposes** the option to introduce suffixes to the naming of biological medicines. A suffix is unlikely to enhance pharmacovigilance, but would cause confusion and undermine government policy.

GBMA has opposed the WHO Biological Qualifier in the past on the grounds that it may act as a barrier to market entry and we are pleased this proposal has not been adopted. It is not evidenced based, but rather assumes all biosimilar medicines are high risk, regardless of pre-marketing assessment for the risk/benefit profile of these products. Furthermore, it does not address the issue of traceability.

GBMA has already stated that there are already a number of unique characteristics that will enable the identification of a medicine for the purpose of pharmacovigilance, so adding another unique characteristic is unnecessary.

As changes to prescribing software are introduced to enable active ingredient prescribing, applying a suffix to a biosimilar would make the reference product and any subsequent biosimilar appear as different drugs. This has the potential to undermine the Government's policy objective to increase uptake and may act as a market entry barrier, particularly if not applied retrospectively.

GBMA understands those in favour of introducing a suffix are concerned that currently unknown adverse events may in theory, arise from switching between a reference biological and a biosimilar medicine. Such concerns must also apply as a result of variability between batches of the same biological medicine, especially post any significant changes to the production methods.

It would logically follow therefore that if a suffix is to be applied to a biosimilar, a unique suffix must also be applied to the reference product post every significant manufacturing change.

Finally, while the desire for TGA to harmonise nomenclature with international practices is understood, the adoption of an FDA naming approach would be inconsistent with the TGA's current practice of harmonising with the EMA and adopting EMA guidelines with respect to biosimilar evaluation.

GBMA
Generic and Biosimilar Medicines Association

Making medicines affordable

Generic Medicines Industry Association Pty Ltd
ABN 19 096 009 540 trading as
Generic and Biosimilar Medicines Association
PO Box 87 Deakin West ACT 2600

gbma.com.au