NSW TAG submission to TGA Consultation: Nomenclature of Biological Medicines, September 2017

Submission is provided according to the Sections in the Consultation document

Section	NSW TAG Response
6.1 Status quo	***NSW TAG does not support maintaining the current system with no change.*** Such an approach would not solve the identified issue in the paper i.e. the need to capture accurate, sufficiently detailed information about a medicine that is associated with an adverse event, including information about a batch or batches if this is implicated in an adverse event, as detailed in *Section 2.The issue* of the consultation paper. Pharmacovigilance is particularly important with the use of these new medicines as clinical trials may not adequately identify rare adverse events or provide comprehensive evidence for long term safety and efficacy.[i] In order to optimise pharmacovigilance strategies in Australia, information regarding the batch and expiry of the specific medicine is required. In addition, given the complex nature of biological medicines and the extrapolation of indications that may occur with the use of biosimilars, monitoring for loss of effectiveness if, for example, immunogenicity occurs, should be undertaken by the TGA. This latter is a relatively new area for pharmacovigilance and will require linkages with prescribing and outcome data. Australia has been following the European Medicines Agency (EMA)'s lead in the regulation of biological medicines including biosimilars. We support this approach given the EMA's long-standing expertise in biological medicine evaluation and regulation. Where possible, a continued consistency of approach is recommended.

6.2 Status quo with activities that increase public reporting	***NSW TAG does not support maintaining the status quo with activities that increase public reporting of adverse events with inclusion of the product's name, AUST R and batch number.*** Education (to increase reporting of adverse events by healthcare professionals [HPs] and the public) used as the sole intervention is well known to be relatively ineffective in changing behaviors. The evidence demonstrates that, while education may be part of a successful multi-faceted strategy for behavior change, indeed a necessary part, as a lone strategy however, it is ineffective, costly for its limited impact and is placed on the lowest rung in the hierarchy of intervention effectiveness.[ii] Instead system-focused technological interventions are viewed as more reliable. Passively providing information (whether specific or non-specific) through websites is not appropriate nor a sufficient mechanism for improving adverse drug event reporting by either consumers or HPs. Although the information on the NPS MedicineWise website is valuable, anecdotally, there are a gaps in consumers' awareness of the NPS MedicineWise website as well as competition for consumers' attention. Furthermore, although HPs may become familiar with NPS MedicineWise resources during undergraduate and early career training, time constraints and competing priorities limit HPs' further engagement with new and/or changed information. In addition, while NPS MedicineWise conducts regular education visits with general practitioners (GPs) and is thus recognized as providing high quality information on medicines to these HPs, NPS MedicineWise historically has had much less interactions with medical specialists and thus is less well known to this group who are likely to be the key prescribers of many biological medicines. As identified in the consultation paper, the trade name is currently not a mandated field on TGA reporting forms. During the changes that will be made as a result of this TGA Consultation, NSW TAG recommends that the trade name becomes a mandated field for biological medicines on the reporting form with enhancement mechanisms put in place as outlined in the Consultation paper. Furthermore, having undertaken the effort of developing the the TGA/NPS MedicineWise education module for ADR reporting, this (or an accredited alternative) should be mandated as part of undergraduate and early career training. In addition, uptake and effectiveness of the module should be evaluated. Thought should be given to implementing other incentives to increase uptake e.g. could ADR reporting training be mandated for relevant healthcare professional registration in a similar way to that of cardiopulmonary resuscitation (CPR) training for doctors in each triennium?

6.3 Move towards a barcode system similar to the EU	***NSW TAG supports the implementation of a barcoding system similar to the EU.*** This simple 'clean' approach is system-focused and as such has a greater chance of achieving the goal of optimized of adverse event and effectiveness reporting, tracking and monitoring. It is simple, able to be incorporated into prescribing, dispensing and administration software, can provide standardized information and, if its use is mandated, can provide a forcing function to ensure strategy effectiveness. *What system and level of serialization should a barcode use* NSW TAG's preference would be for a 2-dimensional (2D) barcoding system which includes batch and expiry information. NSW TAG also hopes that this approach will facilitate the application of 2D barcoding on all medicinal products in the futures. Given that the 2D barcoding approach is being undertaken by the Australian National Blood Authority for similar safety reasons, it is reasonable to adopt a similar approach for biological medicines in the first instance, and then other medicines. 2D barcoding would also be useful for monitoring other medicines such as vaccines that are associated with significant adverse event reporting and are commonly administered by general practitioners and nurses in community settings. Smartphone technology could be used for scanning and transmission of data obtained in the ambulatory setting such as the patient's home to medical record software. Indeed, to take full advantage of the purchase of the scanners and the changes to software, 2D barcoding should be phased in for all medicinal products, with biological medicines and vaccines to be the first products to use this technology. All new medicines entering the Australian market should be required to have 2D barcoding. 2D barcoding is able to provide a lot of information in a very small area. NSW TAG recommends that 2D bar coding should be placed on unit dose packaging. This is particularly important in a hospital setting where whole packages or sleeves of medicines are broken up when supplying medicines to patients and ward areas. The barcode system and level of serialization that is able to provide 2D bar coding to unit dose packaging must be the system used. (If there is choice

	between systems, priority should be given to systems that have an evidence base in effective and efficient medicine management and are shown to be most cost-effective). The 2D bar codes will need to be replicable such that unit doses obtained from splitting of packs containing more than one dose, can be repackaged with the 2D bar code. The use of internationally standardized barcodes will allow for the exchange of medication data, if appropriate. Given that biological medicines have variation between batches of the same branded biological medicine, it is important that pharmacovigilance monitoring and reporting is able to identify specific batches. It will also enable a greater real-time response (rather than a late reactive approach) to pharmacovigilance given the greater efficiency that can be achieved when adopting a model that records when and where specific batches are supplied and uses standardized computerized information. Targeted patient and HP advice will be enabled by the use of computerized recording and reporting systems. *Impact (including financial impact) of this option* The introduction of 2D bar codes for biological medicines should not be an additional regulatory or financial burden for pharmaceutical companies as they will be implementing 2D barcoding for the European market. Utilising barcoding technology during dispensing is a widespread and recommended practice in Australian hospital and community pharmacies. It assists in reducing medication error from incorrect product selection. Hence the work practice will not be a burden on pharmacists. The main barrier for the use of 2D bar code scanning is the purchase of the appropriate scanners and ensuring that software is able to recognise the bar code's alignment patterns, decode, store and transmit the data. Given that i) everyday devices such as smartphones have this technology, ii) numerous companies (e.g. retail, shipping) already use this technology, iii) the intervention targets human safety, iv) data will be standardised (rather than reliant on variable human input), v) monitoring processes will be streamlined to identify safety and loss of effectiveness signals, and vi) medicine recalls will be more efficient, the advantages of 2D barcoding far outweigh any cost barrier related to software update and implementation and purchase of barcode scanners.

	Using barcoding technology during nurse (or other) administration of medicines in hospitals enabling bedside verification of patient, medicine and potentially dose is not as yet standard practice in Australia. Nevertheless it is acknowledged that it would significantly reduce medication error. Many international hospitals have introduced such a practice. The introduction of 2D barcoding for biological medicines would facilitate the uptake and of barcoding systems for medicines administration. The use of 2D barcoding means that the relevant information is inherently captured and can be tracked across care and consumer settings, and also medical record sources including My Health Record. This would assist with achieving five of the seven Australian Digital Health Agency's strategic priorities: • digitally-enabled models of care that improve accessibility, quality, safety and efficiency • better availability and access to prescriptions and medicines information • high quality data with a commonly understood meaning that can be used with confidence • a workforce confidently using digital health technologies to deliver health and care • health information that is available whenever and wherever it is needed.[iii]
6.4 Introduce suffixes to the naming of biological medicines	***NSW TAG does not support the use of suffixes to the naming of biological medicines.*** *Impact (including financial impact) of this option* NSW TAG agrees that improved pharmacovigilance for biological medicines is required in Australia but does not believe the addition of a four letter suffix is the best way to achieve optimal pharmacovigilance. Using a four letter suffix to distinguish the reference product and biosimilar products increases complexity and will lead to patient, carer and healthcare professional confusion, particularly when products have been classified by the Pharmaceutical Benefits Scheme as interchangeable. Given that it is recommended that patients should know both the active ingredient name and their usual brand, the addition of a four-letter suffix, which is inherently meaningless from a patient and healthcare professional perspective, could increase risk of medication misadventure. When distinguishing products is appropriate, patients and health care providers will still be able to rely on the use of trade names, as they do now.

	The burden to patients and healthcare professionals if additional naming requirements are mandated is not justified as it does not make possible the recording of batch and expiry and has potential negative consequences. *Should Australia adopt the FDA scheme or develop an Australian scheme for adding a suffix? Should this option be applied retsrospectively?* Generally the best practice recommendation for hospital prescribing is that it should be done using the active ingredient name. Exceptions are all types of insulin and medicines that come in various formulations (e.g. immediate release and modified release formulations of a number of opioid medicines). In the latter case, it is recommended that both the active ingredient and the brand name is written so that healthcare professionals can recognize that i) by providing the trade name, there is greater certainty that the correct product will be selected and ii) a class of high risk medicines is being prescribed that require further vigilance. Given the concerns regarding switching between biological products, CATAG's *Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals* recommend that these medicines be prescribed by both the active ingredient name and the trade name and that the active ingredient and trade name of the biologic/biosimilar should be clearly communicated at all transitions of care (Guiding principles 3 and 9, respectively). [i] A suffix is contrary to the approach taken by the Australian government for prescribing of a biosimilars, particularly in respect to having active ingredient names as the default in e-prescribing software. If suffixes are required, the default biosimilar chosen by the prescribing software may not be the biosimilar kept at a pharmacy and a mismatch of the active ingredient name in records will occur with potential negative consequences arising. As stated in the Consultation paper, a suffix scheme is contrary to the interpretation of the scientific findings regarding similarity and interchangeability as well as the whole of government messaging around the uptake of biosimilars. Such messaging is a pragmatic and evidence-based approach (on a case-by-case basis) in order to ensure future long term affordability of medicines to the Australian population. Having distinct medicine names for individual biological medicines would be unworkable and confusing in the hospital setting where similarity and interchangeability was established.

	NSW TAG does not recommend Australia develop its own scheme if a suffix scheme is implemented. Duplication in effort, time and costs and having non-aligned suffixes is not sensible. Furthermore, Australia is only a population of 24 million and pharmaceutical companies could be resistant to providing a different suffix scheme for such a small population (even if Australia developed a better scheme to that of the FDA). We do not recommend the suffix scheme be applied retrospectively given the challenges identifying trade names in the current Australian ADR reporting system.
Other comments	NSW TAG thanks the TGA for the opportunity to make comment on its efforts to provide a more rigorous pharmacovigilance system for biological medicines. Not only will it make possible the identification of adverse effects between different biosimilars and the originator biological medicine, it will enable the ability to identify adverse events for the whole class or indication more readily in real world patients rather than clinical trial patients, particularly if there is linkage with other electronic medical record systems. For example, NSW TAG notes the report by the Institute for Safe Medication Practices regarding cancer risks with biological products for psoriasis. [iv] It should be noted that whatever approach is taken with regard to the naming of biological medicines, there will need to be assurance that the technology will be able to be purchased at reasonable prices; that relevant software systems are able to comply; that the infrastructure for monitoring and reporting is in place; and that a public/healthcare professional awareness and education program will be implemented. As such, a lead time of approximately 2-3 years may be needed.

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[i] Council of Australian Therapeutic Advisory groups. Overseeing biosimilars use. Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals. CATAG, 2016

[ii] Cafazzo JA and St-Cyr O. From Discovery to Design: The Evolution of human Factors in healthcare. Healthcare Quarterly 2012; 15:24-29.

[iii] Australian Digital Health Agency. Strategic Priorities. https://www.digitalhealth.gov.au/australias-national-digital-health-strategy [Accessed 5th September 2017]

[iv] Institute for Safe Medication Practices. Acute Care ISMP Safety Alert April7, 2016. Cancer Risks with Biological Products for Psoriasis. https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=1134 [Accessed 5th September 2017]