



Response to the Therapeutic Goods Administration

“Nomenclature of Biological Medicines”

Consultation Paper July 2017

15 September 2017

Summary recommendation

Medicines Australia has reviewed the consultation paper on the nomenclature for biologics and biosimilars medicines.

Medicines Australia's Board-endorsed position with regard to biosimilars and biologics clearly states that "an effective system of pharmacovigilance relies upon the ability to distinguish every biologic medicine, including every biosimilar, through unique identification mechanisms".¹

This is consistent with the proposal articulated in Option 4 of the consultation paper and is therefore the preferred option.

Additionally, whilst Options 2 and 3 suggest commendable improvements to the tracking of products through widespread use of proprietary trade name, AUST R, and batch number as well as bar-code upgrades, they are inconsistent with other current Australian Government policy and would therefore fail to achieve the desired objectives.²

Introduction

Medicines Australia welcomes the opportunity to respond to the Therapeutic Goods Administration's July 2017 Consultation Paper "*Nomenclature of Biological Medicines*".

Medicines Australia is the peak industry body representing the research-based innovative pharmaceutical industry in Australia. Our members research and develop, manufacture and supply medicines and vaccines to the Australian community. Our members represent over 80 per cent of the Australian prescription medicines market by value. Medicines Australia represents the originator biologic manufacturers and also the vast majority of biosimilar manufacturers. Medicines Australia provided a position statement on biosimilars to the Department of Health, Biosimilars Education and Awareness Initiative Reference Panel in 2016.

Medicines Australia believes that biosimilars assessed by the TGA as safe and effective, have an important and legitimate role to play in the Australian health care system and that they can contribute to the financial sustainability of the Pharmaceutical Benefits Scheme ('PBS'). We have a strong record of working constructively with the Australian Government on biosimilars policy, for example, through the most recent Strategic Agreement (2017)³, which will deliver savings to the Federal Budget and create headroom for innovative medicines. As such, we are keen to work with the Australian Government, as well as other stakeholders, to ensure appropriate uptake and use of biosimilars in Australia.

In relation to nomenclature of biological medicines as discussed in the TGA Consultation Paper, Medicines Australia has previously and consistently indicated that all biologics and biosimilars need to be distinguishable from each other.

The Medicines Australia position on biologic and biosimilar medicines is informed by the following principles:

¹ Medicines Australia's Biosimilars position was provided to the Australian Government Department of Health Biosimilars Education and Awareness Initiative Reference Panel in 2016.

² Strategic Agreement between MA and Commonwealth section 7.2.1 "support consistent approaches across prescribing and dispensing software packages that produce default prescriptions by applying international non-proprietary names² (or a similar medicines naming methodology determined by the Minister), while still preserving prescriber choice; and 7.2.4 "recognise the importance of pharmacovigilance principles and reporting, including the adoption of naming conventions and where needed, notifications to prescribers; [https://www.health.gov.au/internet/main/publishing.nsf/Content/CC4088EE246D44BFCA25811B002759EE/\\$File/Medicines%20Australia%20-%20Strategic%20Agreement.pdf](https://www.health.gov.au/internet/main/publishing.nsf/Content/CC4088EE246D44BFCA25811B002759EE/$File/Medicines%20Australia%20-%20Strategic%20Agreement.pdf)

³ [Strategic Agreement](#)

1. Decisions regarding all medicines should be based on appropriate and well understood standards of scientific and clinical evidence;
2. Prescribing physicians (clinicians) should retain the right to choose what brand of medicine to prescribe for their patient, in consultation with their patient, and what brand of medicine is dispensed; and
3. Post-market quality safety and efficacy should be assured through robust pharmacovigilance and traceability mechanisms.⁴

In applying these principles to the TGA Consultation Paper, Medicines Australia:

1. Agrees the need for improved naming requirements for biologics and biosimilars that are prescribed and dispensed in Australia,
2. Asserts that biologic and biosimilar naming conventions should:
 - a. enhance pharmacovigilance and post market surveillance;
 - b. facilitate accurate attribution of adverse events to the correct product;
 - c. acknowledge that biosimilars are highly similar but not identical to the reference biologic;
 - d. improve identification at a product level to facilitate physician and patient understanding and choice,
3. Supports distinguishable non-proprietary names for all biological products (i.e. biosimilars and originator biologics) to meet the TGA objectives, namely to:
 - a. improve the identification of biological medicines in the reporting of adverse events;
 - b. align, as far as possible, with international best practice;
 - c. harmonise with international jurisdictions and thus minimise regulatory burden;
 - d. support safe prescribing and dispensing practice;
 - e. not adversely impact the government's policy of increased uptake of biosimilars,
4. Recommends that a distinguishable non-proprietary name should comprise:
 - a. a common "core name" (typically, the International Non-proprietary Name (INN) or Australian Approved Name (AAN)); and
 - b. a suffix identifier connected by a hyphen;
5. Contends that key stakeholders⁵ would support these naming conventions as they would build greater confidence in the evolving biologics and biosimilars market,
6. Supports, in principle, consideration of retrospective application of the described suffix convention to existing biologic non-proprietary names through an orderly process, and acknowledges the benefits of a harmonised approach which aligns with either the WHO or FDA approaches,

Our detailed response to each of the four Options presented in the TGA Consultation Paper follows at [Attachment 1](#).

⁴ Medicines Australia is on the record, in the context of the current regulatory reforms being implemented pursuant to the Australian Government's response to the Medicines and Medical Devices Review, as supporting the TGA's proposals to both enhance post-market monitoring, and implement its Pharmacovigilance Inspection Programs from 1 September 2017.

⁵ *Biologic and Biosimilar Medicines: 2020 Making the most of the opportunity*: Outcome 3: Pharmacovigilance and naming conventions
 Developing more comprehensive up-to date pharmacovigilance systems and reporting processes for biologic and biosimilar medicines was a consistent theme throughout the Forum discussions. It was noted that this relies, in large part, upon clarifying naming conventions and ensuring they are appropriate... as how this is addressed will improve traceability and confidence in switching". Stakeholders: AusBiotech; Consumers Health Forum of Australia; Council of Australian Therapeutic Goods Advisory Group; Medicines Australia; NPS MedicineWise; The Pharmacy Guild of Australia; The Royal Australasian College of Physicians; and The Society of Hospital Pharmacists of Australia.

ATTACHMENT 1

Medicines Australia's detailed responses to TGA Consultation Paper Options for biological medicine nomenclature

Option 1: Status quo.

Unique identification of individual products would rely on its allocated Australian registration number (AUST R) and *proprietary trade name*.

Medicines Australia believes that the status quo is untenable and therefore does not support Option 1.

Existing shortfalls in adverse event reporting, product misattribution and unreliable provision of either AUST R or proprietary names demonstrates the widely accepted need to adopt measures that will enhance patient safety and pharmacovigilance systems, viz. that a medicine provided to a patient should be able to be identified clearly and without ambiguity.

The complexity of biologics compared to small molecules, including the fact of biosimilarity rather than bioequivalence, and that all medicines and especially biologics, have the potential for unwanted immune reactions, creates the need to ensure systems enable robust identification, attribution and traceability to a specific biologic product, whether that product be an originator biologic or one of many biosimilars.

Biosimilars have been available on the Australian market (through ARTG registration and PBS listing) since the late 2000s. For most of this time, PBS-listed biosimilars have been relatively simple biologics and have been limited to only a small number of products. By contrast, since 2015, the Australian market has begun to see the launch of far more complex biologics (e.g. monoclonal antibodies) combined with a significant acceleration in launches.

Medicines Australia understands that the pace of launches is only going to increase, and that Australia will soon see many multiple biosimilars of originator biologics, combined with further growth in launches of even more highly complex new biologics. The TGA Consultation Paper therefore provides an excellent opportunity to consider how best to ensure the most reliable and enduring framework is in place to accommodate this evolving, rapidly expanding market.

In relation to pharmacovigilance, Medicines Australia emphasises that reporting of adverse events should be strengthened to ensure that they can be easily and quickly attributed to the correct medicine for ongoing patient safety and reliable accuracy and quality of post market safety data monitoring. Adverse event reporting data for biological medicines, using the AAN or Approved Biological Name (ABN) does not enable sufficient clarity regarding the precise medicine provided to a patient and therefore limits the ability to accurately ascribe an adverse event to a particular product.

For example, data obtained from both Amgen (a member company of Medicines Australia) and data analysed from the TGA Database of Adverse Event Notifications (DAEN) system between 2010 and 20 April 2017, show that over 36 per cent of all adverse event reports for filgrastims were not able to be attributed to a specific product. They were reported as "filgrastim" only.

Conversely, data for epoetins, which possess *unique names* (e.g. epoetin alfa, epoetin beta, etc.), demonstrate that only three per cent (3%) of adverse event reports were classified as ambiguous (e.g. reported as "epoetin only"). In this case, the use of distinct names allowed events to be traced back to specific products, thereby very significantly reducing the incidence of ambiguous reporting.

In addition, misattribution of adverse events when reporting primarily by non-proprietary name has also been identified and highlighted by the WHO:

“Spontaneous reporting still remains the cornerstone of pharmacovigilance but has several weaknesses. Often, only the international non-proprietary name (INN) is used as the sole product identifier and in the case of several products with the same INN (originator, plus generics or biosimilars) it may be difficult to trace the exact manufacturer of the product.”⁶

Moreover, new Australian Government policy settings will adjust prescribing software to default to AAN (or INN) prescribing. Therefore, it will be critical to ensure that TGA systems are in place to improve product level traceability to avoid any exacerbation of inaccurate reporting and misattribution of adverse events due to the absence of the proprietary trade name or AUST R number in prescribing data.

Pharmacy level substitution of a-flagged biologics and biosimilars, and the introduction of systems that default to AAN/INN prescribing, may inadvertently obscure patient level traceability. As has already been identified, the absence of a unique identifier, (including such things as proprietary trade name, batch number, AUST R and suffix) frequently leads to misattribution.

A reliable and multi-layered adverse event (AE) recording system can be used to further build patient and clinician confidence and further support Government policy for encouraging uptake and use of biosimilars. In comparison, the inability to attribute an observed safety issue to a particular product (i.e. a lack of accuracy in safety data monitoring) could undermine confidence in the biologic medicine environment in Australia.

It is widely agreed, and international experience clearly demonstrates, that confidence amongst prescribers is a critical factor in strengthening biosimilar uptake. Therefore, implementing measures which serve to boost confidence that the pharmacovigilance system will accurately assign adverse events, would help promote the Australian Government’s policy objectives regarding the uptake and use of biosimilars and a functioning competitive biologics market. Disregarding these concerns and maintaining status quo would be counterproductive to these objectives.

This view is substantiated in a recent Australian prescriber survey conducted by the Alliance of Safe Biologic Medicines (ASBM) which showed that 76 per cent of surveyed doctors stated that the TGA should insist on distinct non-proprietary scientific names for all biosimilars and originator biologics⁷.

The ASBM survey also highlighted how the application of identical nomenclature may be misleading. Eighty percent (80%) of respondents indicated that identical nomenclature implied identical approval status including across indications. In the event that TGA approvals differ between the reference biologic and the biosimilar (i.e. with regard to indications) this cannot be identified through the product name and apart from being misleading, could lead to inappropriate prescribing and misattribution of AEs.

Furthermore, during a 2016 forum on biosimilars policy, a broad range of Australian Stakeholders identified:

⁶ Biosimilar medicines and safety: New challenges for pharmacovigilance, 23(2) WHO DRUG INFORMATION 87, 91 (2009) (Attachment B), available at <http://apps.who.int/medicinedocs/documents/s16240e/s16240e.pdf>

⁷ Alliance for Safe Biologic Medicines (ASBM) 2016.

“Developing more comprehensive up-to date pharmacovigilance systems and reporting processes for biologic and biosimilar medicines was a consistent theme throughout the Forum discussions. It was noted that this relies, in large part, upon clarifying naming conventions and ensuring they are appropriate.”⁸

In conclusion; retaining the status quo as per Option 1 will not meet stakeholder, clinician, patient or industry expectations. Indeed, given the importance of accurate adverse event reporting, as well as upholding robust data, promoting physician confidence and ensuring naming reflects the TGA’s assessment, we consider this an opportunity to improve the current system beyond the status quo.

Option 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.
This option would focus on increasing education to healthcare professionals and the public to report all medicines, particularly biosimilars, associated with adverse events by their trade name, AUST R and with the associated batch number.

Maintaining the status quo is inadequate and therefore Option 2 with the status quo on naming is not supported by Medicines Australia. However, Medicines Australia supports, in principle all efforts, including prescriber education and consumer health literacy initiatives, that are designed to enhance both public reporting of adverse events and the quality of adverse event reports, such that the subject medicine can be clearly and unambiguously identified.

Utilisation of the proprietary trade name accompanied by the batch number, would help foster the objectives in the TGA Consultation Paper. However, strengthening these components should be introduced as adjuncts to Option 4 and are insufficient as an adjunct to the status quo.

Whilst MA supports measures that will improve the quality of information provided in AE reports to encourage proprietary names, it is clear that a number of factors require further consideration. For example, Amgen has provided data which shows that over 90 per cent of the filgrastim adverse event reports were attributed to the proprietary name Neupogen®, while the Australian market share of that product was only 39 per cent over that time period. Unless there had been a significant increase in the frequency of adverse events for Neupogen® upon the introduction of biosimilar filgrastim (and Amgen advises that this is not its understanding), it is reasonable to conclude that a significant percentage of these adverse events specifically attributed to Neupogen® were misattributed. This example highlights that familiarity with originator brand names may lead to inadvertent misattribution to the originator product and undermine the desired objective to improve the quality of the captured data.

Medicines Australia also contends that if certain fields for online reporting are mandated, those fields should be very carefully designed, so as encourage adverse event reporting whilst avoiding unintended consequences. For example, it is conceivable that consumer and healthcare practitioners may not report (or not be able to report) the adverse event at all, if some of the mandatory information is not available to them at the time they would seek to report the adverse event. We recognise that information such as AUST R or batch number is not always available at the time of reporting, or upon follow-up by the regulatory authority. The 2016 ASBM survey showed that 41 per cent of respondents did not report batch number,

⁸ Biologic and Biosimilar Medicines 2020: Making the most of the opportunities. Available from: <https://www.ausbiotech.org/documents/item/48>

because they did not have it available upon reporting. All information fields should therefore be made available, together with education initiatives aimed at improving these statistics.

Similarly, in a study of the FAERS database by Lietzan et al, it was shown that National Drug Code (NDC) numbers were included in less than 0.01 per cent of all adverse event records, while less than a quarter (23 per cent) of adverse event reports had a marketing application field (i.e. NDA or BLA number) and that only 10 per cent of adverse event reports had the lot number field populated. In its draft guidance on naming, the FDA clearly stated that “the use of distinct proprietary names or national drug code NDC numbers is insufficient to address concerns regarding pharmacovigilance.”⁹

This data reflects what we know from experience, viz. that patients, physicians, and others reporting adverse events, often do not have product brand names, batch numbers, or drug codes available to them at the time of the reporting. Whilst Option 2 in its current form may not immediately address patient safety concerns and provide the quality of data to the pharmacovigilance system that would support physician and patient confidence, it could operate alongside Option 4. We would therefore suggest an ‘enhanced Option 2’ be considered.

The TGA may also like to consider the worldwide format for reporting of Adverse Drug Reactions from sponsors to Health Authorities via CIOMS format, and how sponsors would provide the information to the TGA, particularly when we move to automated (E2B) reporting. An ‘enhanced Option 2’ would mean reporting requirements above and beyond CIOMS format. We would encourage the TGA to consider developments like CIOMS.

In conclusion, elements of Option 2 have considerable merit but by itself will not achieve the objectives identified in the TGA Consultation Paper. We strongly recommend that the TGA consider combining Option 2 with Option 4, to help ensure that AEs can be reported in a timely way and be correctly attributed.

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

This bar code contains information including the product code, national identification number, batch number and expiry date.

As stated throughout this response, Medicines Australia members support reliable and accurate identification of products. Therefore, in principle, Medicines Australia supports the policy objectives of a data matrix barcode similar to the system being implemented under European Union (EU) Directive 2011/62/EU, and Delegated Regulation (EU) 2016/161.

As the TGA Consultation Paper notes, the EU’s Unique Identifier (UI) and Anti-tampering Device is more accurately described as a system for medicines supply chain management, and as a highly organised scheme to limit the opportunity for counterfeit medicines to enter the legal supply chain. However, this may not adequately address the adverse event pooling risks, clinical perception considerations, and other issues involved with shared non-proprietary names for biologics and biosimilars. However, improved scanning technologies in medication management processes can reduce errors and potential harm to patients, and reduce costs to the health system¹⁰.

⁹ FDA, Draft Guidance for Industry: Non-proprietary Naming of Biological Products (Aug. 2015).

¹⁰ Australian Commission on Safety and Quality. Barcoding and other scanning technologies to improve medication safety in hospitals. June 2017.

The data issues discussed in the Consultation Paper could be addressed *in part* through Option 3, but we recognise they cannot all be resolved simply by introduction of a data-matrix barcode system. A number of additional elements are necessary to enable appropriate pharmacovigilance protections through end-to-end track and trace capability.¹¹

An additional important element relevant to Option 3 is the TGA's Therapeutic Goods Order 91 - *Standard for labels of prescription and related medicines*. TGO91 commenced on 31 August 2016, and is currently in a four year transition period that will expire on 1 September 2020. TGO91 contains the requirement that a machine-readable code be included on the label, except for starter packs. The machine-readable code must be formatted as one of the GS1 Bar Codes specified within the GS1 General Specification, and will not preclude future international convergence for serialisation of prescription medicines¹².

Machine-readable codes will facilitate electronic tracking throughout the supply chain and act as a means of double-checking that the correct medicine is dispensed. However, ensuring the system is integrated with patient level dispensing information at the pharmacy will further help ensure that both patient and physician can always determine which precise medicine was dispensed.

Importantly, linking the existing barcode systems with patient information as might potentially be envisaged under Option 3, would not negate the need for a unique identifier suffix to be added to the INN of a biologic medicine, nor the inclusion of information like trade name, AUST R and batch number, as the existing barcode systems are not sufficiently advanced to ensure capture of all relevant information for accurate pharmacovigilance.

In relation to what system and what level of serialisation a barcode should use, Medicines Australia recommends that the TGA continue to align with the GS1 General Specification for serialisation as per TGO91 in the short term, whilst considering how best to implement Option 3 in the medium to longer term. We would note that adding extra data elements beyond what is common in the healthcare industry might add complexity and cost for manufacturers and the supply chain.

Critically, the capability for a human-readable suffix that provides clarity and transparency amongst biologic medicines remains important to drive clinical confidence, as discussed above.

Medicines Australia notes that there would be significant regulatory impact and costs placed on all elements of the supply chain if it is decided to implement an EU style data-matrix with associated scanning, database and software systems, which does not meet the stated objective to minimise regulatory burden in the consultation paper. We would recommend industry be consulted further, to ensure any enhanced system is implemented with sufficient transition periods and the benefits are clearly understood by stakeholders to outweigh additional burdens.

In conclusion, Option 3 will not adequately manage the key issues sought to be addressed by the Consultation Paper, but may be an important adjunct to optimising Options 2 and 4.

¹¹ For example, the current EU system does not currently link a specific data-matrix contained on a medicine's packaging with a patient's electronic record, and therefore, there is no single database containing records of all medicines that a patient may be taking.

¹² Therapeutic Goods Administration, Regulation Impact Statement General Requirements for Labels for Medicines, Version 3.0, July 2016.

Option 4: Introduce the use of suffixes to the naming of biological medicines.
Use of suffixes to uniquely identify all biological medicines consistent with the approach taken by the US FDA.

Medicines Australia's Board-endorsed position with regard to biosimilars clearly states that "an effective system of pharmacovigilance relies upon the ability to distinguish every biologic medicine, including every biosimilar, through unique identification mechanisms".¹³ This is underpinned by principles that state:

1. Decisions regarding all medicines should be based on appropriate and well understood standards of scientific and clinical evidence;
2. Prescribing physicians (clinicians) should retain the right to choose what brand of medicine to prescribe for their patient, in consultation with their patient, and what brand of medicine is dispensed; and
3. Post-market quality safety and efficacy should be assured through robust pharmacovigilance and traceability mechanisms.¹⁴

Medicines Australia notes that unique identifiers exist for biological products through existing proprietary trade names. However, as highlighted above, reliance on the use of trade names to uniquely identify products for attribution of adverse events is insufficient to achieve the objectives of the consultation and cannot be considered in isolation from Option 4.

Therefore, for the reasons outlined in this paper (including in the context of the analysis of Option 1), Medicines Australia recommends implementation of Option 4 for the adoption of suffixes to non-proprietary names of all approved biological products, whether for an originator biologic or biosimilar product, and whether or not the products are a-flagged.

Most Medicines Australia members support assignment of distinguishable non-proprietary names for all biological products comprising:

- a common "core name"; and
- a suffix identifier connected by a hyphen.

A system that includes the use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices for biological products would provide a consistent, readily available and recognisable mechanism for patients and healthcare professionals, including clinicians and pharmacists, to correctly identify these products and also avoid errors in ordering, dispensing, and recordkeeping.

Option 4 would achieve the objectives of the TGA consultation paper to:

1. improve the identification of biological medicines in the reporting of adverse events;
2. align, as far as possible, with international best practice, noting specific alignment with the USA
3. harmonise with international jurisdictions and thus minimise regulatory burden
4. support safe prescribing and dispensing practice
5. not adversely impact the government's policy of increased uptake of biosimilars¹⁵

¹³ Medicines Australia Biosimilars position was provided to the Department of Health Biosimilars Education and Awareness Initiative Reference Panel in 2016

¹⁴ Medicines Australia is on the record, in the context of the current regulatory reforms being implemented pursuant to the Australian Government's response to the Medicines and Medical Devices Review, as supporting the TGA's proposals to both enhance post-market monitoring, and implement its Pharmacovigilance Inspection Programs from 1 September 2017.

¹⁵ Strategic Agreement between Medicines Australia and the Commonwealth; 2017: PBS Medicines Package 2017: The Package is a comprehensive set of interlinked initiatives, comprising both savings and investments, designed to support ongoing, timely and reliable

At the same time, the use of proprietary trade name will also support patient and physician choice of a particular treatment for an individual patient. Particularly in the treatment of complex, debilitating, or life-threatening diseases, a physician must be able to communicate clearly with a patient about his or her treatment. The system must be optimised to support both this communication and also clearly identify the physician's prescribed medication to the dispensing pharmacist in a reliable and efficient manner. Distinguishable non-proprietary names for all biologic products offer an effective means to enhance these objectives.

Misattribution or confusion over the identity of the specific biologic product(s) associated with an adverse event could impede or delay the effective analysis and correction of a potential safety or quality issue, and reduce confidence in biologic medicines. Distinguishable non-proprietary names would assist the accurate attribution of adverse events to a specific product, especially in cases where proprietary name, AUST R, or batch number are harder to determine/unavailable or where bar-coding is limited.

In terms of the unique suffix, Medicines Australia acknowledges the benefits of harmonising with either the WHO or the FDA approach, rather than developing an Australian-specific framework.¹⁶ This harmonisation should consider opportunities to align processes for submissions being considered prior to, or in parallel with, other jurisdictions such as the USA, to ensure consistent naming conventions.

It will be vital to have careful implementation and phase-in of any new naming or labelling convention to existing non-proprietary names, which should be in a manner that:

- Minimises confusion and regulatory burdens on the industry and regulatory agency
- Avoids disruption in the healthcare delivery system
- Complements any aspects of Options 2 and 3 that are adopted in the medium to longer term,
- Affords licence holders sufficient flexibility to make labelling changes to meet the needs of patients as well as licence holders' operational requirements, and
- Enables alignment with other jurisdictions such as New Zealand Share-Pack requirements where possible.

In addition, we note that the Australian Government has indicated systems are in development to increase accuracy of information about which medicine a patient may be taking, via the My-Health Record.¹⁷ We further note the support from the Pharmacy Guild which is "working with the Australian Digital Health Agency (ADHA) to ensure that community pharmacy dispensing and medicine-related services are fully integrated into the My-Health Record."¹⁸ We encourage the Australian Government to ensure uptake of the system as quickly as possible so that trust in the pharmacovigilance system is maintained. However, we note that there will likely be significant lag time before this system can be relied upon to achieve the post market monitoring and AE attribution sought.

consumer access to medicines and the financial sustainability of the PBS; including changes to electronic prescribing and introducing, on a case by case basis, biosimilar uptake drivers.

¹⁶ It is noted that the WHO framework now appears to be stalled, and is unlikely to proceed in the short- to medium term. Although it would be beneficial to be as harmonised as possible with as many jurisdictions, depending on the status of the WHO framework, for the reasons outlined above, it may be better to adopt an existing framework like the FDA rather than await the (uncertain) finalisation of the WHO framework.

¹⁷ Australian Digital Health Agency. Benefits of the My Health Record system for pharmacists. <https://www.digitalhealth.gov.au/using-the-my-health-record-system/for-pharmacists/benefits>

¹⁸ Australian Digital Health Agency. Benefits of the My Health Record system for pharmacists. <https://www.digitalhealth.gov.au/news-and-events/news/health-ministers-approve-australia-s-national-digital-health-strategy>

In a similar light, we emphasise the terms of the recent Strategic Agreement that Medicines Australia has struck with the Commonwealth, which specifically recognises the importance of pharmacovigilance principles and reporting, including the adoption of naming conventions, and where needed, notification back to prescribers of the precise product that has been dispensed to their patient.

Conclusion

Medicines Australia considers that the TGA's Consultation Paper on nomenclature of biological medicines provides a timely opportunity to consider how best to support the appropriate uptake and use of biosimilars in Australia, based on our view that improved naming requirements for originator biologics and biosimilars are necessary in Australia.

Medicines Australia considers that to best achieve the TGA's objectives and in line with Medicines Australia's position, Option 4 should be pursued in the near term whilst enhanced Options 2 and Option 3 should also be undertaken.

Option 4 would achieve the objectives of the TGA consultation paper to:

- improve the identification of biological medicines in the reporting of adverse events
- align, as far as possible, with international best practice
- harmonise with international jurisdictions and thus minimise regulatory burden
- support safe prescribing and dispensing practice
- not adversely impact the government's policy of increased uptake of biosimilars¹⁹

Furthermore, Medicines Australia recommends that greater confidence in the use of biologics and biosimilars and improved accuracy in post market monitoring could be further strengthened by focussing on improving health literacy and enhancing consumer, prescriber and pharmacy education and awareness initiatives.

We look forward to the outcomes of this consultation and to working with the TGA on implementation of options that move beyond the presently unsatisfactory status quo.

¹⁹ Strategic Agreement between Medicines Australia and the Commonwealth; 2017: PBS Medicines Package 2017: The Package is a comprehensive set of interlinked initiatives, comprising both savings and investments, designed to support ongoing, timely and reliable consumer access to medicines and the financial sustainability of the PBS; including changes to electronic prescribing and introducing, on a case by case basis, biosimilar uptake drivers.