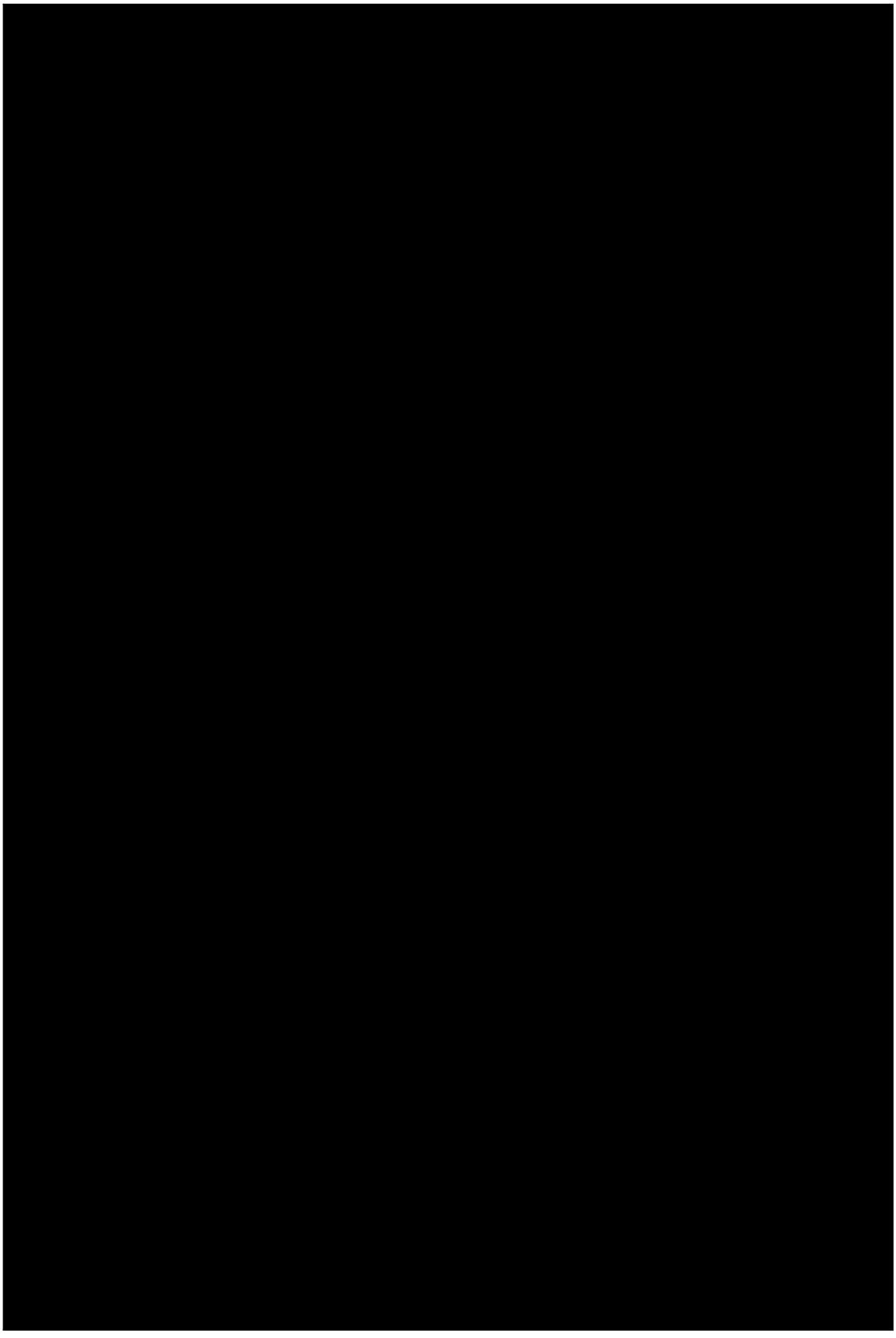

The Pharmacy Guild of Australia

TGA Consultation: Nomenclature of Biological Medicines

Introduction

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to comment on the Nomenclature of Biological Medicines prepared by the Therapeutic Goods Administration (TGA).

The Guild is the national peak organisation representing community pharmacy. It supports community pharmacy in its role delivering quality health outcomes for all Australians. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

Position

The Guild supports improving pharmacovigilance capabilities for all medicines, including biologic medicines and believes this can be achieved by ensuring that sufficient information is captured with any adverse event report.

While the inclusion of a unique biologic identifier such as a suffix or prefix may be of some assistance in achieving this, the Guild does not believe it is a critical factor and that it could be achieved by:

- Retaining the current approach to naming biological medicines with the inclusion of the product's Trade Name and active ingredients (International non-proprietary name or INN).
- Use of a two dimensional barcode on all prescription medicine packs with the inclusion of product description as well as batch number and expiry date.
- Revising the templates for reporting of adverse events to capture Trade Names, INN, batch numbers and expiry.

However, whatever biosimilar nomenclature convention is adopted by the TGA, the Guild believes it is critical that it be consistently adopted across all relevant areas, including the Pharmaceutical Benefits Scheme (PBS), the Australian Digital Health Agency as well as prescribing and dispensing systems.

Background

When a prescription is dispensed in a community pharmacy, the following details are recorded as part of the patient records:

- Trade Name
- International non-proprietary name (INN)
- Form and Strength
- Quantity supply
- Repeats authorised by the prescriber and the number remaining
- Directions for use
- Prescriber details
- Date of dispensing
- Pharmacist details

In addition, for people that have a MyHealth Record, there are four sources of information about the person's medicine:

- Information from the Prescriber about what has been prescribed
- Information from the pharmacy about what has been dispensed

- Information from Medicare about PBS items that have been dispensed
- Information that the patient/carer uploads

Medicine information available from the MyHealth Record includes:

- Trade Name
- INN
- Form and Strength
- Quantity supply
- Repeats authorised by the prescriber and the number remaining
- Directions for use
- Date of dispensing
- Prior Prescription Record with Trade Name, strength and directions

Naming

While the inclusion of a suffix or prefix may assist in identifying a biologic medicine, the Guild believes that having access to the Trade Name, INN, strength, form and batch details is sufficient to uniquely identify an individual medicine a person may be using or have used.

The Guild acknowledges that patients and their carers often rely on the consistent shape and colour of a particular medicine brand and/or packaging or device to assist them in recognising their medicines. To avoid patient confusion, healthcare professionals should reinforce the name of the active ingredient in the medicine (the INN), when prescribing, dispensing, labelling and administering medicines to patients. It would be a concern if the use of prefixes or suffixes attached to a biosmilar's INN caused confusion for consumers and the Guild would support further investigation into whether this may be a problem.

The Guild has always maintained that the active ingredient should have prominence on all medicine packaging and labelling to avoid confusion especially when multiple brands may be available, including for biologic medicines. Patients should be encouraged to recognise the active ingredient of their regular medicines and be encouraged to have a MyHealth Record which provides a useful source of information for patient care and pharmacovigilance.

Barcodes

The Guild would expect that every Section 90 approved community pharmacy in Australia would be using a bar code scanner in the dispensary for the following reasons:

- The Pharmacy Board of Australia requires the use of barcode scanners as part of the dispensing process to scan dispensed medicines where barcodes exist and dispensing labels as a quality assurance aid to minimise dispensing errors.[1]
- Complementing the Pharmacy Board's Guidelines is Pharmacy's Professional Practice Standards requiring as a minimum that dispensing has processes such as barcode scanning to ensure optimised and safe dispensing practices and coordinated team effort.[2]
- Community pharmacists also use dispensary bar code scanners to scan prescriptions and repeats to expedite the data entry process associated with dispensing and minimise transcription errors.

Many community pharmacies are already set up with scanners to enable them to scan two dimensional bar codes such as a QR code and some suppliers are ensuring that new scanners being purchased by pharmacies are QR enabled. The eRx electronic prescription exchange produces both EAN and QR codes on its prescriptions. However, while we expect that many pharmacies could accommodate a

[1] Guidelines for dispensing of medicines; 2 Sep 2015; http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx
[2] Professional Practice Standards vs 5 2017 (3.7.8); Pharmaceutical Society of Australia; www.psa.org.au

change to two dimensional codes, it would be important that pharmacists are prepared and advanced. Providers of prescriber and dispense hardware and software would need to be informed well in advance to ensure that all systems are able to accommodate any proposed changes and that the supply of pharmacy orders will be compliant with any changed arrangements.

Noting that a move to two dimensional bar codes may also assist with other medicine safety functions such as product recalls, the Guild supports moving to the use of two dimensional barcodes subject to ensuring advance warning to ensure that all hardware and software providers are informed and all community pharmacies have sufficient time to ensure their systems meet any changed arrangements.

Template for Reporting Adverse Events

The most recently available report on adverse event reporting (TGA statistics for 2015)[3] indicates that of the 17,000 adverse event reports in 2015, 54% were made by sponsors, 15% by State and Territory Health Departments and 14% by hospitals and hospital pharmacies. Of the remainder, 6% were made by community pharmacists and 4% by general practitioners.

From a community pharmacy perspective, pharmacists are supported by platforms such as GuildCare which enables the pharmacist to record the details for informing the TGA and/or sponsors as appropriate.

It would be sensible for the recording templates for reporting adverse events to allow for the capture of as much information as possible to identify the medicine, including Trade Names, active ingredient or INN, strength, form and batch details. Other details relating to the patient and their use of the medicine in question as well as other medicines and possible causes of the adverse event still remain relevant.

[3] https://www.tga.gov.au/medicines-and-vaccines-post-market-vigilance-statistics-2015