GaBiJournal
Generics and Biosimilars Initiative Journal

ORIGINAL RESEARCH

Biosimilars for Healthcare Professionals

A survey of Australian prescribers' views on the naming and substitution of biologicals

Stephen P Murby, FRSA; Michael S Reilly, Esq

Introduction: As the number of biosimilar approvals in Australia increases, it is important to build on the existing regulatory framework to continue to bring high quality, safe and efficacious biosimilars to the widest number of patients most cost-effectively. As new policies regarding the regulation, reimbursement and uptake of biosimilars are being considered, the Alliance for Safe Biologic Medicines (ASBM) has asked Australian prescribers for their views on the naming, substitution and prescribing of biologicals and biosimilars. Currently, biologicals and biosimilars are approved by Australia's Therapeutic Goods Administration (TGA). The country's Pharmaceutical Benefits Advisory Committee (PBAC) has indicated it will consider pharmacy-level substitution of biosimilars for reference biological medicines on a 'case-by-case basis'.
Methods: In June 2016, the ASBM surveyed 160 prescribers in Australia to gauge their opinions on the naming of biologicals and biosimilars and how the use of these medicines is recorded. Prescribers were also asked for their views on substitution of, as well as their familiarity with, knowledge of, attitudes to, and beliefs in, biosimilars.
Results: Nearly all (97%) respondents consider the best way for TGA to differentiate a biosimilar medicine from its reference biological is either with the same non-proprietary scientific name and a differing prefix or suffix, or with a completely unique name. Those surveyed used brand name (39%) and non-proprietary scientific name (38%) in about equal frequency when recording reference biologicals and biosimilars in patient records. 53% rarely or never include batch members when reporting adverse events. 89% of respondents thought it critical or very important that they be notified in the event of a pharmacy-level substitution. 61% thought that TGA should be responsible for providing the primary advice to the Australian Government that a product is suitable for pharmacy-level substitution, while only 33% thought that PBAC should be responsible.
Conclusion: Most respondents agreed that TGA should insist on distinct non-proprietary scientific names for all biosimilars and reference products, and most agreed that robust data are needed to support substitution rather than clinically supervised switching. While the prescribers surveyed use several different information sources to learn about the medicines they prescribe, the proportion of prescribers using any one of these sources was small. Perhaps because of this, half the prescribers surveyed thought, incorrectly, that biosimilars and originators are approved through the same regulatory process.

Keywords: Australia, biologicals, labelling, naming, prescribers

Introduction

In Australia, biologicals and biosimilars are approved nationally by the Therapeutic Goods Administration (TGA). Aczicrit and Grandicrit (epoetin lambda) were the first products approved in Australia as biosimilars in 2010 [1]. To date, TGA has approved 13 biosimilars within the product classes of human growth hormone, granulocyte colony-stimulating factor (G-CSF), insulin, erythropoietin, follicle stimulating hormone (FSH) and tumour necrosis factor-inhibitor [1].

With an increasing number of biosimilars seeking entry to the Australian market, it is important to build on the existing regulatory framework established to continue to bring high quality, safe and efficacious biosimilars to the widest number of patients most cost-effectively. As new policies regarding the regulation, reimbursement and uptake of biosimilars are being considered, the Alliance for Safe Biologic Medicines (ASBM) has asked Australian prescribers for their views on the naming, substitution and prescribing of biologicals and biosimilars.

Australia's Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body appointed by the Australian Government to recommend new medicines for listing on the PBS (Pharmaceutical Benefits Scheme), has indicated that it will consider pharmacy-level substitution of biosimilars for reference biological medicines on a 'case-by-case basis'.

Some clinicians hold concerns with pharmacy-level substitution due to the current paucity of data on such practices, and also matters associated with tracking which product is dispensed. PBAC has stated that its 'default position' would be to advise that a biosimilar is suitable for substitution by a pharmacist 'where the data are supportive of this conclusion' and that a relevant consideration is 'the absence of data to suggest significant differences in clinical effectiveness or safety compared with the originator product' [2].

Biologicals are used in the prevention, diagnosis, or treatment of a range of chronic diseases. Since biologicals have large, complex, inherently diverse molecular structures made, or derived, from living organisms, they are always heterogeneous. Unlike non-biological medicines, there is a degree of natural variability in biologicals, and there are generally some differences between the reference and biosimilar products. Current methods to analyse physicochemical and structural differences are extremely sensitive. Analysis of different batches of reference products following a change in the manufacturing process has revealed differences between the pre- and post-change batches [3]. This molecular heterogenity within the originator biological is distinct from molecular differences between the originator and biosimilar.

A biosimilar is a version of the active substance of an already authorized original (or reference) biological, see Box 1.

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Submitted: 9 May 2017; Revised: 13 July 2017; Accepted: 19 July 2017; Published online first: 1 August 2017

Box 1: Biological medicines and biosimilars

Biological medicines are therapeutic proteins produced using living organisms. The active substances of biological medicines are larger and more complex than those of non-biological medicines. A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). While a biosimilar approved by a competent national regulator will be safe and effective, biosimilars nevertheless differ from generic versions of small molecule drugs in that they are not identical copies of their reference products.

Biosimilars introduce competition, which has the effect of lowering prices of both originator and biosimilar and increasing patients' access to these therapies [3].

With a growing number of reference biologicals and biosimilars, regulatory authorities across the globe are in discussion over how biosimilar medicines should be named and labelled [4, 5]. Distinct names will be crucial in order to facilitate post-market safety monitoring and help minimize the potential for medication errors.

There is a clear need for sufficiently detailed and transparent labelling and product information to enable informed decision-making by physicians and patients, ensuring appropriate safe and effective use of these medicines [6].

International Nonproprietary Names (INNs) are intended for use in drug regulation, prescribing, dispensing, pharmacopoeias, labelling, pharmacovigilance and in scientific literature [7]. However, biologicals, due to their increased molecular complexity and structural micro-heterogeneity, are not categorized by the INN alone [7]. An INN Expert Group recommended that the World Health Organization (WHO) develop and implement a system for assignment of Biological Qualifiers (BQs) to similar biotherapeutic products (SBPs) [8]. WHO has proposed the development of a global BQ for biological medicines that will provide a unique identifier for all biological active substances that are assigned an INN [6]. While the INN is a common and public non-proprietary name for a given active substance, the BQ would be applied to a particular manufacturer's active substance. The BQ would not be part of the INN and it is envisaged that it would enhance identification, prescribing, dispensing and pharmacovigilance of biological medicines.

The US Food and Drug Administration (FDA) issued its guidance for the non-proprietary naming of biological products in January 2017 [9] following the release of two draft guidance documents outlining proposed methods for biological product naming and biosimilar product labelling [10]. According to its latest guidance, FDA will assign a non-proprietary name for all reference biologicals, related biologicals and biosimilars that will include an 'FDA-designated suffix'. The 'proper name' will consist of a combination of the 'core name' and distinguishable suffix, which will be 'devoid of meaning' and be 'composed of four lower case letters'. A survey of prescribers of biologicals in the US, carried out before the release of this guidance, found that two thirds (66%) of the prescribers surveyed supported the introduction of distinct names. Of those, the majority would prefer a suffix that indicated the manufacturer [11]. The WHO and FDA emphasis stands in contrast to the EMA approach to biosimilar naming, under which an originator biological and all biosimilars to that product will share the same non-proprietary name.

In Australia, biologicals and biosimilars are approved nationally by TGA. TGA issued a biosimilars guidance in 2013 that includes a section on naming conventions for biosimilars [12-14]. This guidance required the name of a biosimilar in Australia should be made up of the reference product Australian Biological Name (ABN), thus identifying the reference product with which the biosimilar has demonstrable comparability; and a biosimilar identifier, consisting of: the prefix sim(a)– and a three-letter code issued by the WHO INN Committee, according to its draft policy. This guidance was subsequently revoked and recently approved biosimilars to etanercept and infliximab have been given the same non-proprietary name as their reference products.

The country's PBAC has indicated that it will consider pharmacy level substitution of biosimilars for reference biological medicines on a case-by-case basis, see Box 2. Since the introduction of this policy, two biosimilars to infliximab have been 'a' flagged, as has one biosimilar to etanercept.

In June 2016, 160 prescribers in Australia completed a survey sponsored by the ASBM about their knowledge of, attitudes toward and beliefs regarding biosimilars. They were asked their opinions on the naming of biologicals and biosimilars and how these medicines are identified in the patient record and in adverse event reporting. They were also asked for their views on substitution.

Methods

Sample characteristics and methodology

In June 2016, 605 prescribers in Australia were invited to complete a 15-minute web-based survey on biologicals and biosimilars. Potential respondents were identified in, and recruited from, a large, global, commercial database of healthcare professionals. A high response rate was expected because prescribers in this database had previously indicated a willingness to participate in market research.

A total of 451 prescribers responded. Respondents were screened as follows: they had to specialize in one of seven therapeutic specialties, including dermatology, endocrinology, gastrointestinal, nephrology, neurology, oncology or rheumatology; they had to have been in practice for one year or more; and they had to have prescribed biological medicines in their practice. A total of 174 respondents were screened out because they did not meet these criteria. A further 80 prescribers did not qualify because they

Box 2: The role of the Pharmaceutical Benefits Advisory Committee

The Pharmaceutical Benefits Advisory Committee (PBAC) has indicated that it will consider pharmacy-level substitution of biosimilars for reference biological medicines on a 'case-by-case basis'. Where a product is deemed suitable for pharmacy-level substitution (a process known as 'a' flagging), a patient can be switched by a pharmacist from the reference biological medicine to the biosimilar medicine and from the biosimilar medicine back to the reference biological medicine. This could potentially be done on multiple occasions. The prescriber can however prevent this substitution by selecting 'no substitution', and pharmacy guidelines reference consultation with the patient.

specialized in a therapeutic specialty for which data collection had closed. In addition, 37 started but failed to complete the survey. Any data they contributed are not included in the analysis and report.

A total of 160 prescribers completed the survey. All data collected refer only to those who completed the survey. Participants received a standard cash stipend of US$76 for their time.

Prescribers practised in public hospitals (46%); private hospital/private practice (42%); academic medical centre (11%); and other (1%). They had spent between one and 30 years in practice, see Figure 1.

A quarter (25%) of the prescribers were rheumatologists, 25% were oncologists, and 25% were gastroenterologists. The remaining 25% prescribers were divided equally among dermatologists, neurologists, nephrologists and endocrinologists, see Figure 2.

Regarding responses from participants to the question of how often they used different information sources to learn about the details of a medicine for prescribing and monitoring, 46% of prescribers said they always used published literature, whilst 43% said they never used published literature. Only 19% of prescribers said they always used information from TGA, and 27% said they always used information from PBAC. Only a fifth (19%) of those surveyed said they learnt about the details of a medicine by reading the product information label, and 13% from hospital formulary, see Figure 3.

Results

Reporting and naming of biologicals and biosimilars

Participants were asked how they identified biological medicines when they were prescribed or entered in patients' records. Similar numbers of prescribers identified medicines by brand name or non-proprietary scientific name (39% and 38%, respectively). A smaller proportion identified medicines by brand name and non-proprietary scientific name (21%), and 2% identified them by Australian Register of Therapeutic Goods (ARTG) number. When adverse events (AEs) were reported, medicines were identified by brand name by 39% of prescribers, by brand name and non-proprietary scientific name by 34% of prescribers, by non-proprietary scientific name by 25% of prescribers, and by ARTG number by just 2% of prescribers, see Table 1.

Respondents were asked how often they included batch numbers when reporting AEs. A total of 23% of prescribers said they never used batch numbers, almost a third of prescribers (30%) said they rarely included batch numbers, 20% sometimes

Figure 1: Sample characteristics of prescribers who completed the survey – practice setting and experience

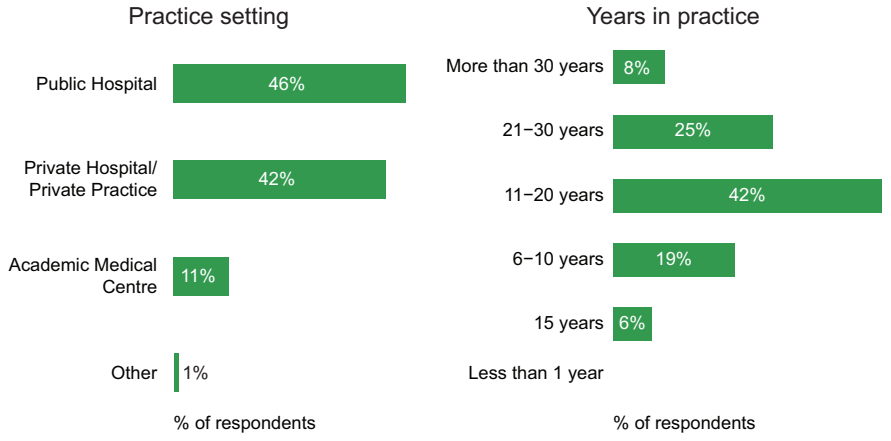


Figure 2: Sample characteristics of prescribers who completed the survey – therapeutic specialty

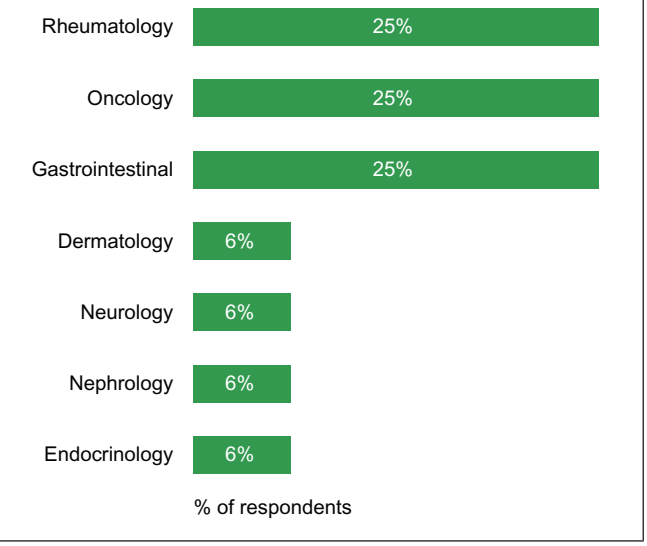
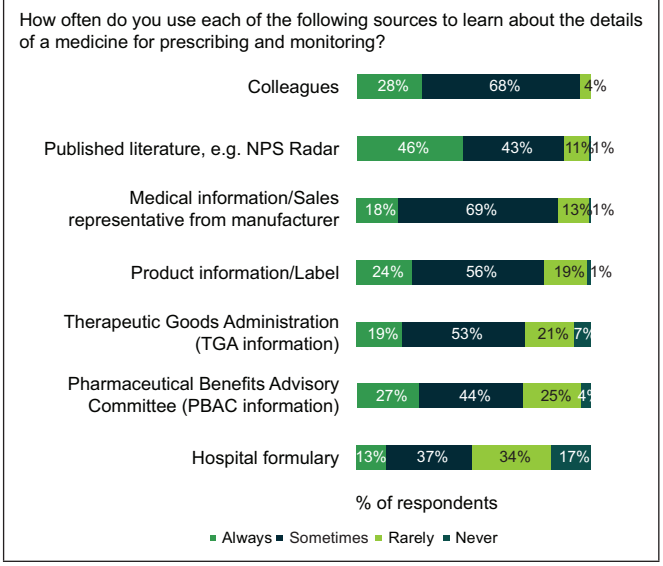


Figure 3: Use of information sources



used batch numbers and 28% said they always included batch numbers.

When prescribers were asked why a batch number was not always reported, they replied that the batch number was not available at time of reporting (41%); or they were not sure where to find the information (36%); or they had forgotten to include the information (19%).

Respondents were also asked whether a loss of efficacy should be reportable as an AE. Most prescribers (65%) said it should not, while 19% of prescribers thought it should, and 16% of prescribers had no opinion about whether a loss of efficacy should be a reportable AE.

Asked whether TGA should insist on a distinct non-proprietary scientific name for every biological or biosimilar medicine that it approves, three quarters of prescribers (76%) said yes, 18% of prescribers said no, and 7% of prescribers had no opinion.

Asked what the best way was for TGA to differentiate a biosimilar medicine from its reference product, a large proportion of physicians responded that it would be best if biosimilars had the same non-proprietary scientific name as their reference medicines but with either a differentiating prefix (38%) or suffix (29%). 30% of participants opted for entirely different non-proprietary scientific names for the biosimilar and its reference product.

Table 1: How a biological medicine is identified

	When making a prescription or in a patient's record (%)	When reporting an adverse event (%)
Brand name	39	39
Non-proprietary scientific name	38	25
Brand name and non-proprietary scientific name	21	34
Australian Register of Therapeutic Goods (ARTG) number	2	2
Other	1	–

Substitution attitudes and beliefs

Prescribers were asked what level of evidence would be supportive of pharmacy-level substitution, see Table 2. They were also asked what role they thought TGA should play in advising PBAC on the suitability of a product for pharmacy-level substitution, see Figure 4, and whether TGA or PBAC should be responsible for providing the primary advice to the Australian Government that a product is suitable for pharmacy-level substitution, see Figure 5.

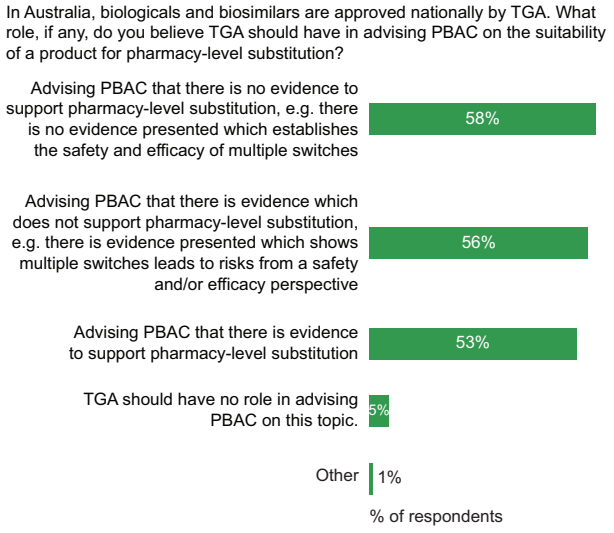
Prescribers completing the survey were asked how important it was for them to have the sole authority to decide, together with

Table 2: Evidence required for substitution

Responses	Questions	
	What evidence would you regard as sufficient to be supportive of PBAC's conclusion that a biosimilar product is suitable for pharmacy-level substitution? (Select all that apply)	Where there is more than one biosimilar medicine to a single reference biological, what evidence would you regard as sufficient to conclude that one biosimilar is appropriate for pharmacy level substitution for another biosimilar? (Select all that apply)
Statistically robust comparative clinical trial data that show no increase in risk to safety and efficacy after switching	53%	81%
Statistically robust comparative clinical trial data that show no increase in risk to safety and efficacy after multiple switches from the reference biological medicine to the biosimilar medicine and back to the reference biological medicine	53%	
Statistically robust comparative clinical trial data that show no increase in risk to safety and efficacy after a one-way switch from the reference biological medicine to the biosimilar medicine	39%	
In-market practice/experience	27%	26%
Observational or open-label data	24%	28%
No evidence would be sufficient	6%	6%
Unsure	1%	1%
Other		1%

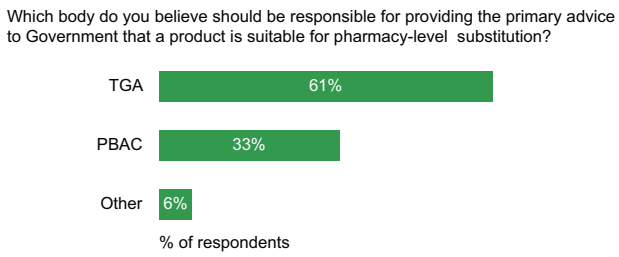
PBAC: Pharmaceutical Benefits Advisory Committee.

Figure 4: The role of TGA



PBAC: Pharmaceutical Benefits Advisory Committee; TGA: Therapeutic Goods Administration.

Figure 5: TGA or PBAC for substitution



PBAC: Pharmaceutical Benefits Advisory Committee; TGA: Therapeutic Goods Administration.

their patient, the most suitable biological medicine to be dispensed to the patient. Over half of prescribers (54%) thought it was very important and over a third (36%) thought it was critically important, see Figure 6. When the prescribing physicians were asked whether their prescription software/documentation included a box marked 'brand substitution not permitted', 61% responded that it did, 21% responded that it did not, and 18% were unsure.

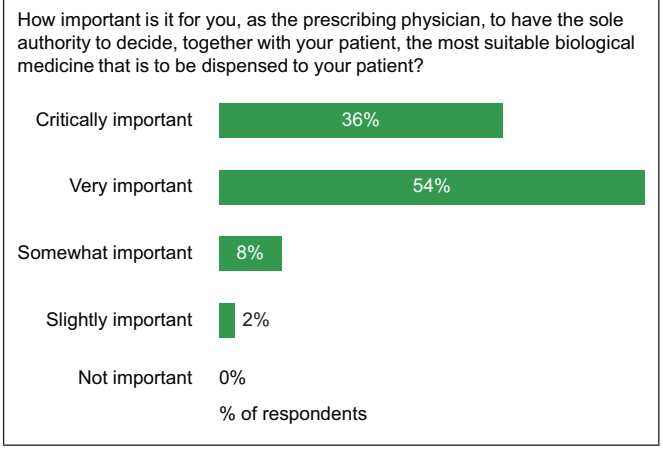
Respondents were asked about switching between biological medicines for patients with chronic disease. Over half (51%) of prescribers said that pharmacy-level substitution was not acceptable for these patients, 9% thought it was totally acceptable, while 40% thought it was acceptable providing they were notified in advance.

Biosimilars familiarity and knowledge

In response to the question of how familiar survey respondents were with biosimilar medicines, 21% said they were very familiar and had a complete understanding, 73% said they had a basic understanding, 6% said that they could not define them (although they had heard of them), and 1% said they had never heard of them.

Prescribers were asked a series of questions to gauge their understanding of biosimilars, their awareness of and comfort

Figure 6: Importance decision authority



with the biosimilars approval process, and their opinions on switching. Responses to these questions are given in Table 3.

Respondents were asked how comfortable they would be prescribing a biosimilar medicine that had been approved for several or all of the indications of its reference medicine on the basis of clinical trials in only one of those indications, or in fewer indications than for which the biosimilar is approved, 73% would have some concerns, depending on data and indications; 16% would be comfortable; and 11% would not be comfortable.

Conclusion

Of the prescribers who completed the survey, over three quarters (76%) agreed that TGA should insist on distinct non-proprietary scientific names for all biosimilars and reference products. In addition, well over half (61%) of respondents believed TGA should be responsible for recommendations on pharmacy-level substitution, while only a third (33%) thought that PBAC should be responsible.

Nearly all the prescribers in this survey (98%) use either brand name or non-proprietary scientific name for recording and prescribing biosimilars and their reference biologicals. Most prescribers (61%) want TGA to play a major role in naming biosimilars.

It was clear that the reporting of biosimilars use via brand name and batch number varied between respondents. Respondents indicated that robust data are needed to support substitution, and the vast majority of prescribers (94%) said that the final decision over which biological to prescribe should rest with the prescriber and the patient, and strongly supported clinically supervised switching over pharmacy-level substitution.

Respondents used different information sources to learn about the details of a medicine for prescribing and monitoring, but each source was used by surprisingly few prescribers. Less than half of prescribers said they always used published literature, and a similar proportion said they never used published literature. Clearly there were gaps in how the regulatory process is understood since about half of those surveyed thought, incorrectly, that biosimilars and originators are approved through the same regulatory process.

Table 3: Prescribers' understanding of biosimilars, awareness of the biosimilars approval process and views on switching

Question	Yes (%)	No (%)	Unsure or no opinion (%)	Some concerns (depends on the data and indications) (%)
Is it your understanding that all biosimilar medicines go through the same regulatory process for approval as the original reference biological medicine?	50	33	18	
Are you aware a biosimilar medicine may be approved for several or all indications of the reference biological medicine on the basis of clinical trials in only one of those indications/fewer indications than the reference biological is approved for?	70	14	16	
In Australia, all biological medicines must have a non-proprietary scientific name, e.g. infliximab, trastuzumab, and a brand name, e.g. Remicade; Herceptin, upon approval. If two biological medicines have the same non-proprietary scientific name, does this suggest to you or imply that				
• Both the originator medicine and its biosimilar medicine are approved for the same indications?	80	16	4	
• The medicines are identical	52	44	4	
• A patient could be switched from a reference biological medicine to its biosimilar medicine during a course of treatment and expect the same result in terms of safety and efficacy as with either of the medicines?	57	34	9	
• A patient could be switched on multiple occasions from a reference biological medicine to its biosimilar medicine during a course of treatment and expect the same result in terms of safety and efficacy as with either of the medicines?	48	41	12	
Would you be comfortable prescribing a biosimilar medicine where it has been approved for several or all indications of the reference biological medicine on the basis of clinical trials in only one of those indications/fewer indications than the biosimilar medicine is approved for?	16	11		73

Key points

- 76% of respondents believe TGA should insist on distinct non-proprietary scientific names for all biosimilars and reference products.
- 97% of respondents consider the best way for TGA to differentiate a biosimilar medicine from its reference biological is either with the same non-proprietary scientific name and a differing prefix or suffix, or with a completely unique name.
- 98% of respondents prescribed identified biological medicines in patient records by either brand name (39%), non-proprietary scientific name (38%), or both (21%).
- 53% of respondents rarely or did not include batch numbers when reporting adverse events.
- Respondents generally agreed that statistically significant comparative clinical data are needed before pharmacy-level substitution can be recommended, but opinion was divided over the evidence required for a PBAC recommendation for substitution.
- 61% of respondents believe TGA should be responsible for recommendations on pharmacy-level substitution compared to 33% for PBAC.
- 90% of respondents believe it is critical or very important that the prescriber and patient hold the ultimate decision for which biological is dispensed.
- 89% believe it is critical or very important that they be notified in the event of a pharmacy-level substitution.

Despite a spread of responses from the prescribers surveyed, there was general agreement that biosimilars should be distinguished from originators with either the same non-proprietary scientific name and a differing prefix or suffix, or with a completely unique name. The vast majority of prescribers thought that they and their patients should decide which biological is dispensed and that they should be notified of any substitution by the pharmacist.

Funding sources

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals – from patients to physicians, innovative medical biotechnology companies and others – who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. The activities of ASBM are funded by its member partners who contribute to ASBM's activities. Visit www.SafeBiologics.org for more information.

The Australia 2016 prescribers and biosimilars survey was sponsored by ASBM.

This paper is funded by ASBM.

Competing interests: Mr Stephen P Murby, FRSA, is a member of the International Advisory Board of Alliance for Safe Biologic Medicines (ASBM). Mr Michael S Reilly, Esq, is the Executive Director of and employed by ASBM. Mr Reilly served in the US Department of Health and Human Services from 2002–2008.

Provenance and peer review: Not commissioned; externally peer reviewed.

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DOI: 10.5639/gabij.2017.0603.022