



# Biologic medicines and biosimilars

## **Costs before Caution – Australia’s unique approach to the interchangeability of biosimilars**

Recent developments in Australia suggest that there has been a deliberate prioritisation of the cost benefits of facilitating biosimilar interchangeability over the safety and efficacy risks that can arise when biosimilars are used interchangeably.

Whether this policy stance will actually support a sustainable market for biologic medicines is questionable. The response of those trying to bring biosimilars to market in the last year, and in particular when faced with the government’s attempts to implement these policies, suggests it may not.

## The economics of interchangeability

It is often assumed that for biosimilars to have the same overall impact as generic drugs in reducing cost and improving access to biologic medicines, the policy settings should ensure that the original and follow-on products are, at each level of the market, treated as if they are the same – mere commodities. This reflects the place that generic drugs have in small molecule markets.

Where biosimilars are also interchangeable, there would be no impediment to changing the product used from one dispensing to the next – ie facilitating direct competition. In such circumstances, it is assumed that the deal making within the supply chain ought to ensure that patients can obtain the products they need at the lowest prices. This is especially the case for those medicines that are taken long term. For medicines that are taken once or for a single period, interchangeability is much less relevant.

However, from the reimbursement or payer perspective, the details of the reimbursement scheme will have a significant influence on the approach that will provide the greatest benefit. If the scheme operates on the basis that the lowest priced competitor gains the vast majority of the market, interchangeability may be a barrier to who can bid. However, the day-to-day price competition – as facilitated by allowing switching between the various biosimilar versions – is not a real factor. Examples of such schemes are the New Zealand PHARMAC scheme and some hospital formulary based purchasing systems. By way of alternative, commencing all new patients on a new cheaper biosimilar brand (or whatever is currently the cheapest of multiple biosimilars) can also provide the payer with cost savings. In such a case, it is not the substitution between brands that drives the savings, it is the price differential between the earlier brand and the new one and the rate at which new patients commence treatment.

However in Australia, where the pricing impacts of ongoing price competition is baked into the PBS scheme, there is an incentive to the payer – the government – to prioritise interchangeability.

There is an initial price cut of 16% on listing of a bioequivalent or biosimilar competitor on the PBS that occurs regardless of whether the products are interchangeable. However, at least in the history of generic small molecule entry, the more significant reductions occur for the government as a result of price disclosure based price cuts. In simple terms, these occur in the following way.

1. Once there is a bioequivalent or biosimilar competitor, each supplier is required to disclose information to the government about the actual price pharmacists pay the supplier for a product and the market share of that product. The focus is on the supplier price because it is pharmacists who are reimbursed by the government. That reimbursement is the notional cost of the product. In reality that cost is the maximum price the pharmacist will pay for the medicine. The pharmacist obtains additional profits from the difference between the reimbursed price and the actual price they pay to suppliers.
2. After a period of time (previously 18 months, now reduced to six months), the weighted average price for the group of bioequivalent or biosimilar products is determined and the

price that the government will reimburse is reduced to that new lower price.

The consequence is that it takes time for the reimbursed price to come down to the lowest price a supplier is prepared to accept. Even then it relies on pharmacists dispensing the product with the lowest cost to them, or, put another way, the product that delivers them with the greatest profit margin between the price the government will reimburse and the price they actually pay – an economically sensible assumption.

However, this only works where the pharmacist is free to dispense that lowest price product. This is why interchangeability matters so much in the Australian scheme. Further, unless the prescribed medicine has been determined to be ‘schedule equivalent’ with another brand of medicine (*a-flagged*), then any substitution by the pharmacist is not allowed.

It is not clear that interchangeability will always deliver the best outcome for those for those supplying biosimilar products. It makes brand loyalty almost irrelevant. It undermines any benefits that a supplier could gain from promoting the product because prescribing behaviours by health care professionals of particular brands can be undone by pharmacists’ dispensing behaviours. In addition, any lock in of patients to particular brands on the basis of commencing therapy with a particular supplier’s product disappears when interchangeability is permitted. This means that prioritising interchangeability will reward certain types of market behaviour – high volume, low price strategies which rely on commodity style products where low cost of goods is of prime importance.

This strategy works well for generic small molecule products that are essentially identical. However, where the products may not be identical and the costs of development of the follow-on products is high, it is doubtful that this will facilitate quality medicines and sustainable supply chains. Even in the small molecule market, continued downward price pressure appears to be taking its toll, with some brands listed on the PBS being “out of stock” or being delisted, presumably because the price at which the product can now be sold when compared with the cost of goods is no longer profitable. While this might be understood as the market operating effectively, it can also undermine medicine availability where too many suppliers exit.

## The science of interchangeability

Unlike small molecule medicines where the generic copies can be truly identical, it cannot be assumed that biosimilar products are identical to the reference product. In such circumstances the debate centres on the question of how interchangeability should be assessed.

In essence, the assessment of biosimilar products for the purpose of marketing authorisation is a assessment of whether the two products, used separately, deliver comparable safety and efficacy. This includes an assessment of the comparability of the biosimilar product and the reference biologic medicine for the purposes of deciding whether a follow-on biologic is entitled to rely on the clinical and non-clinical data of the reference biologic medicine.

The assessment of whether the two biosimilar products should be used interchangeably seeks to answer a different question: *Does the switching between products, perhaps repeatedly and between multiple different biosimilar products raise any issues?*

The reason this matters goes back to the lack of ‘identicalness’ of biosimilar products including in relation to the chemical make-up and the more complex tertiary structure of the active ingredient. In turn, these may influence the way a patient reacts to the medicine. For those products that act by provoking or mediating immunological responses, the response to the different biosimilar products may be different.

This is further complicated by the not uncommon situation where the precise chemical make up, structure and modes of action of the original product may not be fully understood. In such circumstances, the potential impact of the differences on switching between the products may present risks to safety and have impacts on efficacy impacts. This occurs because the biosimilar products may cause similar, but different, immunological responses when compared to consistently using a particular product.

It had generally been thought that the question should be: *What evidence should the sponsor be required to submit in order to allow its drug to be treated as interchangeable with the original?* This allowed for a sponsor to argue that for a particular medicine—for example where the important aspects of structure or mode of action were well understood—no further studies were required. However, now in Australia, the default appears to have shifted to a presumption of interchangeability. Based on the PBAC’s guidance, it seems that the question now is: *Is there any evidence that the biosimilar products should not be interchangeable?* Further exemplifying the shift in the Australian approach, this question appears to be answered in the negative where no evidence has been provided either way on the issue.

In the PBAC’s consideration of biosimilars so far we have:

- Basaglar (Eli Lilly’s version of Sanofi’s insulin glargine product Lantus). This was recommended by the PBAC to be ‘a-flagged’ with Lantus, something contrary to the TGA’s advice which required that this only occur “under the supervision of the prescribing medical practitioner”. It seems that Eli Lilly did not request its product be treated as interchangeable with Lantus and provided no evidence to support that approach. Eli Lilly withdrew the product from the reimbursement scheme before it was listed on the PBS. (The circumstances of this and its ongoing implications are addressed in more detail below).
- Inflectra (Pfizer’s version of Janssen’s infliximab product Remicade). This was recommended by the PBAC to be ‘a-flagged’, with Remicade.
- Bemfola (Finox Biotech’s version of Merck’s follitropin alfa product Gonal-f). This was not recommended to be ‘a-flagged’ with Gonal-f.

As this shows, there is no clear pattern. Although it might be said that the PBAC was acting consistently with the published studies for infliximab<sup>1</sup>, it appears to be making the same mistake as many

reporting on those studies in generalising from specific studies to biosimilars generally.<sup>2</sup>

## Current approaches in the US and Europe

Other regulators such as the US’s Food and Drug Administration (or FDA) and the European Medicines Agency (or EMA) take robust, clearly articulated, and above all, cautious approaches to follow-on biologics and interchangeability.

The scope of the FDA’s authority clearly encompasses both the primary assessment of safety and efficacy and whether a biosimilar remains safe and efficacious when used interchangeably with the reference product. Indeed, the first biosimilar product to demonstrate interchangeability is rewarded with a period of market exclusivity of up to 42 months. Relevantly, the FDA is required to consider whether:

the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.<sup>3</sup>

The FDA guidance makes clear that this requires evidence from the sponsor either in the application or in a supplement to the application “sufficient to show” this standard is met.

When the FDA approved Inflectra it was reported that the FDA had approved a single switch from Remicade to Inflectra without medical intervention – a more limited concept than interchangeability. This is likely to be a misunderstanding based on what was being sought by the sponsor. The FDA’s actual position is that Inflectra is approved as a biosimilar but not approved as interchangeable.<sup>4</sup>

The Canadian Agency for Drugs and Technologies in Health has also concluded that there is insufficient data to support interchangeability of the biosimilar infliximab products that have received marketing authorisation in Canada.<sup>5</sup>

The EMA’s authority is more limited. The EMA’s role is confined to assessing safety and efficacy of follow-on biologicals, while the question of interchangeability is left to member states. The current situation is fluid, however, as most member states do not allow interchangeability or provide for it only in quite limited circumstances. In no member state is interchangeability the default position.<sup>6</sup>

<sup>2</sup> See for example, Steve Mitchell Biosimilars Are as Good as Brand-Name Drugs, New Study Finds, 8 August 2016, [www.consumerreports.org/drugs/biosimilars-are-as-good-as-brand-name-medications-biologics/](http://www.consumerreports.org/drugs/biosimilars-are-as-good-as-brand-name-medications-biologics/) accessed 16 August 2016.

<sup>3</sup> 42 USC 262(k)(4)(B)

<sup>3</sup> 42 USC 262(k)(4)(B)

<sup>4</sup> FDA news release, 5 April 2016 “FDA approves Inflectra, a biosimilar to Remicade”

<sup>5</sup> Switching from Innovator to Biosimilar (Subsequent Entry) Infliximab: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines, 26 February 2015.

<sup>6</sup> Legislations on biosimilar interchangeability in the US and EU – developments far from visibility, Generics and Biosimilars Initiative (GaBI), [www.gabionline.net/Sponsored-Articles/Legislations-on-biosimilar-interchangeability-in-the-US-and-EU-developments-far-from-visibility](http://www.gabionline.net/Sponsored-Articles/Legislations-on-biosimilar-interchangeability-in-the-US-and-EU-developments-far-from-visibility), Posted 01/06/2015, accessed on 18/02/2016.

<sup>1</sup> See for example, Chingcuanco F, Segal JB, Kim SC, Alexander GC. *Bioequivalence of Biosimilar Tumor Necrosis Factor- $\alpha$  Inhibitors Compared With Their Reference Biologics: A Systematic Review*. Ann Intern Med. [Epub ahead of print 2 August 2016] doi:10.7326/M16-0428

# The Australian approach

## The Australian regulators

The regulation of pharmaceutical products is administered by two separate but complementary arms of the Department of Health – the Therapeutic Goods Administration (**TGA**) and the Pharmaceutical Benefits Advisory Committee (**PBAC**) – both of which advise decision makers (being either the Minister for Health or the Secretary for Health).

The TGA – Australia’s equivalent to the FDA and EMA – has responsibility for marketing authorisation (or ‘registration’ in Australian parlance). The test is whether the medicine is safe, efficacious and of an acceptable quality. The TGA’s analysis focusses on safety, efficacy and quality—conducting a holistic assessment of new medicines, enquiring into ingredients, manufacturing process, quality control, laboratory tests and clinical trials.

The PBAC’s primary role is advising the Minister for Health as to whether drugs should be provided as subsidised pharmaceutical benefits to Australians considering the medical condition targeted by the medicine, and the medicine’s efficacy, safety and cost-effectiveness when compared to other treatments. The aim is to ensure that the Australian government only subsidises medicines that are cost effective.

Hence, cost-benefit analysis is the primary focus of the PBAC’s assessment. Questions of safety and efficacy have in the past only been relevant to that cost-benefit enquiry.

## Australia’s controversial position – reimbursement issues the primary concern

Until early 2015, the division of responsibility between the TGA and the PBAC in relation to interchangeability was thought to be clear. Interchangeability occurred within the PBS scheme using the ‘a-flagging’ of interchangeable brands. The inclusion of an ‘a-flag’ against a group of brands in the PBS indicates to pharmacists that they are entitled to dispense any of those brands on the prescription of any one of those brands.

While this process of ‘a-flagging’ was within the remit of the PBAC, it was understood that this required the sponsor to obtain a certificate from the TGA that the products proposed to be interchangeable were bioequivalent. At that time, there was no statutory mechanism for this. Rather, it was a matter of long established administrative practice. This state of affairs had continued for many years, during an era where chemical drugs dominated the market. After all, since follow-on chemical drugs were identical to the originators, interchangeability could be assumed. However, there was little history of addressing biosimilars.

In April 2015, the PBAC recommended that Basaglar be ‘a-flagged’ with Sanofi’s Lantus. This was a surprise.

At the same meeting, the PBAC published a policy that shocked the pharmaceutical industry in Australia and beyond. It appeared to suggest that it intended to treat biosimilars, by default, as interchangeable.

The minutes of a special meeting of the PBAC in April 2015 recorded the following.

The PBAC advised that biosimilar products would be “a” flagged, and therefore suitable for substitution at the pharmacy level, where the data are supportive of this conclusion. The PBAC considered that this would be the Committee’s default position.

The PBAC advised that the following would be relevant considerations in establishing that a biosimilar product could be “a” flagged with the originator product:

- Absence of data to suggest significant differences in clinical effectiveness or safety compared with the originator product;
- Absence of identified populations where the risks of using the biosimilar product are disproportionately high;
- Availability of data to support switching between the originator product and the biosimilar product;
- Availability of data for treatment-naïve patients initiating on the biosimilar product;
- Whether the Therapeutic Goods Administration has deemed a product to be biosimilar with the originator product.

This statement was widely taken to mean that the PBAC would consider that, unless there is evidence that the biosimilar produces different effects in patients than the reference product, the PBAC will consider biosimilars to be substitutable for originator medicines. In other words, it appears to reverse the usual burden of proof for interchangeability. Instead of drug sponsors having to prove their products may be safely interchangeable with the reference drug, the PBAC will assume interchangeability is safe unless it is shown otherwise.

If correct, and the PBAC intends to treat biosimilars as substitutable unless there is evidence that they should not be substitutable, the PBAC’s policy would represent a substantial departure from international norms. Further, it is contrary to the generally accepted wisdom that, without evidence, follow-on biologic medicines should be considered to be different to the original biologic medicine.

Plainly, the PBAC’s policy announcement had the potential to shape the face of Australian medicine over the next decade as the first wave of biosimilars come off patent protection and are opened up to competition. It would appear to be an attempt at providing policy settings which provide biosimilar manufacturers with more beneficial market access and which has the potential to drive down the price of subsidised for biologic medicines once biosimilars enter the market more quickly with clear consequential savings to the government.

## Empowering the PBAC with safety and efficacy responsibility

The PBAC attempted to justify its position in its 18 June 2015 statement on “Safety of biosimilar medicines”. It stated that the assessment of safety and efficacy is outside its remit. That is, the PBAC will only recommend medicines for reimbursement where the TGA has decided that the medicine is safe and efficacious. The PBAC’s attempt to clarify the controversy stated:

According to PBAC guidelines, if the biosimilar is approved by the Therapeutic Goods Administration as a safe and equally effective treatment compared to another drug, the PBAC will then consider listing the biosimilar drug on the PBS.<sup>7</sup>

This was undermined by the government fast tracking (albeit for unrelated reasons) amendments to the PBS scheme which granted the Minister an express power to determine interchangeability with the PBAC given sole responsibility to advise the Minister. The government expressed surprise that giving the PBAC these responsibilities was controversial, suggesting instead that it was “codifying existing practice”.

The PBAC’s stated position that it will only list a biosimilar on the PBS where the TGA approves that biosimilar misses the point entirely. The question is not whether the biosimilar is safe and efficacious on its own—the question is whether it continues to be safe and efficacious after a patient switches between all the biosimilar products that become available (including the original reference product) without limitations. The PBAC, by making decisions about interchangeability, is making decisions about safety and efficacy.

## Universal concern

The apparent prioritisation of cost benefits above patient safety did not go unnoticed by pharmaceutical sector stakeholders.

On 16 June 2015, the Senate Economics Legislation Committee held a public hearing on the amendments. At that hearing pharmaceutical companies, clinicians and consumer advocacy organizations aligned to express great concern over what they all saw as a threat to patient health and welfare. This informal alliance of strange bedfellows impressed on the Senate Committee that what the PBAC proposed was out of step with the rest of the world and did not ensure patient safety as a first priority.

The Australian Rheumatology Association (**ARA**) submitted to the Senate Committee that it was critical that “decisions regarding safety and efficacy of all medicines, including biologics and biosimilars, should rest with the TGA”. There was a clear indication that the amendments should reflect that this should be the TGA’s role. In particular, the ARA raised the lack of research into the effects of multi-brand substitution, where a patient experiences multiple brand substitutions of biosimilars in a short space of time—something possible where biosimilars are ‘a-flagged’.

Likewise, Medicines Australia urged the Senate Committee to recommend that there be public consultations with a view to produce “informed guidance on how and under what circumstances

‘a-flagging’ of biosimilar medicines can occur”. In particular, Medicines Australia submitted that any decision to a-flag should be ‘supported by appropriate evidence rather than an absence of evidence to the contrary’. The industry group advocated for a rebalancing of power away from the PBAC to the TGA in making the substitutability assessment.

The Consumers Health Forum of Australia, a consumer peak body group, also raised consumer uncertainty with the prospect of substitution by pharmacies.

At the Senate hearing, Andrew Stuart, Deputy Secretary for the Department of Health submitted that the concerns raised by the ARA, Medicines Australia and the Consumers Health Forum did not account for the distinction between what the legislation allowed and administrative practice.

The legislation makes something possible but certainly does not mandate it, so I would say that, if you are contemplating amendments to the legislation, be very careful about making something impossible which most of the stakeholders wish to be possible under the right and controlled conditions. The debate is about what the right and controlled conditions are, and I would say that is an administrative matter, not a legislative matter.<sup>8</sup>

On 18 June 2015, the PBAC stated in a press release that it would not recommend the substitution of originator biologicals with biosimilars unless the PBAC was sure of their equal safety and effectiveness and that such consideration would be on a case-by-case basis. However, the PBAC stopped short of indicating it would require evidence that substitution would be safe as a prerequisite to allowing substitution. It also included contradictory statements that safety and efficacy are the remit of the TGA while claiming that the PBAC separately and independently considers interchangeability.

In the same statement, the PBAC’s primary concern was made sufficiently clear:

The Australian Government and the PBAC are concerned that the introduction of biosimilars may lead to the spread of misinformation, as has happened in other countries, which will slow the progress of the development of these medicines.<sup>9</sup>

In a show of solidarity, the Minister for Health, Susan Ley, issued a press release the next day celebrating the PBAC’s “world-first” recommendation to allow clinicians and pharmacists to give patients the option of substituting biologic medicines with biosimilars. Like the PBAC press release a day earlier, the Minister highlighted the prerequisite that biosimilars be determined to be safe and equally effective to the originator biologic, but did not elaborate on whether the Minister would expect to see evidence that substitution itself was safe.

The Senate Committee released its report on 23 June 2015. The Committee recommended that:

<sup>7</sup> Statement by the PBAC, 18 June 2015 “Safety of biosimilar medicines”.

<sup>8</sup> Statement by the PBAC, 18 June 2015 “Safety of biosimilar medicines”.

<sup>9</sup> Statement by the PBAC, 18 June 2015 “Safety of biosimilar medicines”.

the government give close and careful consideration to the role of the TGA with a view to ensuring that its role offered reassurance to the industry, clinicians and patient organisations that the safety of patients would not be compromised by the process for determining whether a biosimilar is suitable for substitution at the pharmacy level.<sup>10</sup>

In the face of this, the TGA sought to clarify its role but that clarification offered no real reassurance. At the October 2015 “eyeforpharma” conference, a member of the TGA’s scientific evaluation branch, Mr Bill Turner, suggested that interchangeability was not a matter for the TGA stating that the TGA’s role was to evaluate the quality, safety and efficacy of biosimilars, not price, substitutability or interchangeability. He suggested that these are the role of the PBAC. There was an acknowledgment that if the “TGA sees data that suggests that a product could not be substituted or interchanged we would draw that to PBAC’s attention so that a decision could be made.”<sup>11</sup>

Relevantly, the revised PBAC guidelines released in February 2016 include no guidance in relation to how the PBAC will assess interchangeability (or, in the language of the PBS, ‘schedule equivalence’ or ‘a-flagging’).

## A very unsatisfactory situation

The particular difficulties associated with the interchangeability of biosimilar drugs have apparently been ignored, or at best down played, by adapting a process designed for generic chemical drugs which fundamentally differ from follow-on biologics with respect to interchangeability. This seems to be driven by a desire to reduce reimbursement costs for biologic pharmaceuticals. If that is the case, it is not soundly based.

- First, it is not sufficient to say, as the PBAC seems to be, that an originator biological should be interchangeable with a biosimilar merely because the biosimilar is effective or not shown to be significantly more toxic. Due to the lack of identity, there should be evidence supporting interchangeability, not merely the absence of evidence to the contrary. The relevant evidence in particular cases may be as simple as evidence that for all relevant purposes the two products are identical.
- Second, the higher risk profile should necessitate that the Minister always be required to seek advice from the TGA, or perhaps both the TGA and the PBAC, before making a decision regarding interchangeability. Considering the risks represented by biosimilars, it is not appropriate for the Minister to assume that biosimilars may be a-flagged simply because the biosimilar is demonstrated to exhibit equal safety and efficacy as the Minister currently does for generic chemical drugs.

- Third, given the safety and efficacy issues raised by the lack of identity between biologics and their biosimilars, charging the PBAC with sole responsibility for advising the Minister is a mystifying choice due to the PBAC’s focus on cost effectiveness.

In addition, there is no evidence that presuming interchangeability will achieve any policy objective. The PBAC’s initial policy announcement in April 2015 was in the context of the consideration of the application for the PBS listing of Eli Lilly’s insulin glargine biosimilar, Basaglar. Eli Lilly did not request interchangeability from the PBAC and presumably provided no data to support it.

Relevantly, the TGA had approved the Eli Lilly product as biosimilar to Sanofi’s Lantus product using the EMA guidelines as adopted in Australia at that time (and which have since been amended). The approval noted that ‘substitution by the pharmacist without consulting the treating medical practitioner is not addressed in the relevant adopted EMA Guidelines’.

The approved Product Information included the following text (as recommended in the TGA’s guideline):

The level of comparability that has been shown [between a biosimilar and a reference product] is not sufficient to designate this product as a generic version of [Reference product name]. Replacement of [Reference product name] with [biosimilar product name], or vice versa, should take place only under the supervision of the prescribing medical practitioner.

The resultant conflicting advice between the TGA and the PBAC, and presumably concerns about whether there was a basis for interchangeability, resulted in the Eli Lilly’s application being withdrawn in December 2016 in the face of the government’s insistence that the products be interchangeable.

The Minister’s bold claim that the PBAC had:

made a world-first recommendation to allow clinicians and pharmacists to give patients the option of substituting expensive biologic medicines at the chemist if there is a cheaper replacement or ‘biosimilar’ available,<sup>12</sup>

and her commitment to implementing that decision now rings a little hollow.

Presumably in an attempt to explain away the different advice between the two arms of the Department of Health and the reason why the biosimilar evaluation guidelines were under review, Mr Bill Turner stated at the “eyeforpharma” conference that the TGA:

hadn’t seen any data – it was just the default words and which may or may not be applicable to any given product. And cut across the decisions that were going to be made by our colleagues in [the PBAC].<sup>13</sup>

All this made clear was that neither the TGA or the PBAC is in fact assessing the safety and efficacy issues that can arise from treating biosimilar medicines as interchangeable.

10 Report by the Senate Economics Legislation Committee into the National Health Amendment (Pharmaceutical Benefits) Bill 2015 [Provisions], 23 June 2015.

11 Confusion sparked biosim review, Pharma in Focus, 14 October 2015 (accessed at [www.pharmainfocus.com.au/NewsPrint.asp?newsid=9814](http://www.pharmainfocus.com.au/NewsPrint.asp?newsid=9814) on 23/10/2015).

12 PBAC world-first biosimilar drug decision, Media Release, 19 June 2015, the Hon Sussan Ley MP, Minister for Health, Minister for Sport

13 Confusion sparked biosim review, Pharma in Focus, 14 October 2015 (accessed at [www.pharmainfocus.com.au/NewsPrint.asp?newsid=9814](http://www.pharmainfocus.com.au/NewsPrint.asp?newsid=9814) on 23/10/2015).

Since that time, the TGA has issued new guidelines. These removed the recommendation that interchanging between biologic drugs only occur under “the supervision of the prescribing medical practitioner”. There is also a change to the naming of biosimilar products, removing the previously mandated ‘biosimilar identifier’. This mirrors the EU position where the use of biosimilar identifiers was considered to undermine public and professional confidence in the biosimilar products. However, it is contrary to the practice in the US and current recommendations from the World Health Organization.

Again these changes appear to be driven by reimbursement considerations. The PBS scheme uses the drug name as part of the statutory criteria for interchangeability.

Whether these policies will actually support a sustainable market for biologic medicines is questionable. Eli Lilly’s withdrawal of Basaglar following the PBAC’s decision to treat it as interchangeable suggests they will not. In addition, the implementation of a model of brand competition developed for generics may not actually deliver the greatest cost savings, especially where there is significant hospital use, use for a limited course of treatment, or where clinicians are not confident in the assessment of interchangeability. The sustained entry of biosimilars and the cost benefits to payers is likely to require a more nuanced approach – one that examines how any particular biosimilar will be used in the market and how the greatest long-term cost benefits can be achieved for that biologic medicine.

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## YOUR FEEDBACK

Please contact us if you would like to discuss the challenges and opportunities presented by biologics and biosimilars.

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