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Ms Lisa La Rance
Assistant Secretary
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GPO Box 9848
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Dear Ms La Rance

I refer to your letter of 29 September 2017 in which you seek comments on the proposed implementation of two measures which aim to increase the prescribing of biosimilars under the PBS.

The AMA upholds that medical practitioners must maintain clinical independence in order to make the best treatment recommendations for patients, based on current evidence. It is vital that the medical profession remains independent to make their own clinical judgements regarding treatment options.

The AMA encourages medical practitioners to offer generic medicine choices when it is safe and appropriate to do so, and to discuss these options with patients.

The AMA opposes any compulsion on medical practitioners to prescribe a generic or biosimilar medicine. This is especially important in the case of a biosimilar brand which by its nature cannot be identical to the reference biological or to other biosimilar brands. Furthermore, while similar in action, these agents come in different syringes / injection systems so that there is a real risk that switching between brands will interfere with established successful treatment regimes.

The AMA also accepts the need for measures to ensure high cost and/or high risk pharmaceuticals are used appropriately in the interest of effective PBS expenditure.

However prescribing regulations and measures, such as the PBS Authority policy, should not pose a barrier to medical practitioners treating their patients or impose an administrative burden without evidence that they are effective and necessary. A blunt regulatory tool like the PBS Authority system is not the way to increase prescribing of biosimilars.

The AMA's comments on the two measures are provided in this context and are detailed below.

Insertion of Note in the Schedule of Pharmaceutical Benefits

The AMA understands the insertion of a 'Note' in the Schedule is an interim measure until changes to prescribing software are made so that it defaults to the international non-proprietary name.

The AMA has already publicly stated that it supports the future software prescribing changes, on the basis that prescribers are still able to specify a particular brand name and mark the prescription as 'do not substitute'.

However it is important that medical practitioners are consulted early in the software development process to ensure that changes do not add unnecessary or inappropriate complexity to prescribing processes.

In relation to the interim measure described in Attachment B, the AMA has two concerns.

The first is that the proposed Note will appear as a 'restriction' for initial prescribing. The Government has stated that it is NOT restricting the choice of brand that can be prescribed. It is therefore misleading to place the Note in this context.

The second is the intended wording for the Note: *Prescribing of the biosimilar brand xxx is preferred for treatment naïve patients.*

The AMA objects to the term 'preferred'. There is no clinically-based preference and the term in this context risks (again) misleading prescribers to believe that they must prescribe biosimilar brands.

The wording should reflect that used in Government statements and the further explanatory text proposed below the Note. The reason – cost – should also be clear. The AMA supports the following wording:

> *Prescribing of the biosimilar brand xxx is encouraged for naïve patients in order to deliver the most cost-effective treatment.*

Lower Authority for prescribing a biosimilar brand compared to the reference biological

On the basis of what is described in Attachment C, the AMA cannot support the proposal to apply a lower Authority level for biosimilar brands while requiring a higher level Authority for a reference biological brand.

On 30 November 2013, the then Coalition Government announced that it was committed to "improv[ing] patient safety and care by removing unnecessary red tape for clinicians prescribing, processing and claiming for PBS medicines". To give effect to this announcement, the Government announced funding in the 2014-15 Budget to "cut red tape for health professionals" by conducting a review of all PBS Authority Required medicines.

During 2014 and 2015, a PBS Authority Review Reference Group systematically and methodically assessed every PBS medicine requiring an Authority to advise PBAC whether it was justified and should continue. PBAC subsequently agreed to most of the recommendations

and many medicines were moved to Authority streamlined arrangements, to Restricted benefits, or removed from restrictions altogether.

The AMA does not want to see this significant progress rolled back and the PBS Authority regulatory system again used inappropriately.

Attempting to increase biosimilar prescribing with a heavy-handed regulatory approach, without giving time for educational approaches, such as the Government's Biosimilar Awareness Initiative, to have an effect, flies in the face of the Government's own policies to reduce red tape and to use regulatory approaches sparingly and wisely.

There will naturally be increased uptake as, supported by the Biosimilar Awareness Initiative, more biosimilars enter the market in the coming months and years.

The measure is also at odds with PBAC considerations for applying an 'Authority required' restriction. The PBAC guidelines on the Department of Health's website state that:

> *The PBAC considers the appropriateness of an Authority Required benefit on initial listing against two key principles:*
>
> *- There is potential for use in a population in which the proposed medicine is not cost-effective or where the PBAC has not yet determined it to be cost-effective.*
>
> *- There is potential for a high cost per patient or high total opportunity cost to the health system.*
>
> *Other important factors are quality use of the medicine, safety and administrative burden.*

This approach is illustrated in the *PBAC Public Summary Document July 2016* explaining PBAC's decision on Brenzys, the biosimilar equivalent of Enbrel. As the Department will be well aware, Brenzys was the first biosimilar which PBAC approved for substitution of Enbrel at the point of dispensing.

In making its recommendations, PBAC rejected a proposal that the biosimilar brand be differentiated by an 'Authority streamlined' listing because the reason an 'Authority Required' restriction was applied to Enbrel, is equally relevant for Brenzys.

Extracts of the Public Summary Document are copied below (with additional comments and highlights added by the AMA).

> 7.2 <u>The PBAC recommended the restrictions for etanercept (Brenzys) be the same as the restrictions for 50 mg etanercept (Enbrel) for the recommended indications.</u> *[The restriction is Authority Required]*
>
> 7.10 The PBAC noted the proposal from the sponsor in the pre-PBAC response that the PBAC recommend the authority listing of Brenzys (and other etanercept biosimilars) be streamlined, whilst the listing for Enbrel remains a written authority required. The sponsor considered this approach has the following benefits:

- to drive the uptake of both Brenzys and any future biosimilars to etanercept which will generate significant savings for government through price disclosure;
- to provide etanercept biosimilars a point of differentiation from the originator and thereby give physicians a reason to prescribe biosimilar brands; and
- to maintain the primacy of clinician choice.

7.11 The PBAC did not consider streamlined listings would be appropriate because of the large potential for leakage into less severe disease. The PBAC however acknowledged the ongoing need to examine the uptake drivers for biosimilar medicines, and noted that the introduction of competition in the PBS etanercept market would make this bDMARD more cost-effective than many other bDMARDs currently subsidised for the same indications, making this a potential candidate for first line treatment in a cost-effective prescribing setting. *[Both Brenzys and Enbrel are listed for the same price on the PBS]*

7.12 The PBAC considered the utilisation estimates presented in the submission were reasonable. As Brenzys is likely to only substitute for Enbrel or other future etanercept biosimilars, the PBAC considered the listing of Brenzys would not grow the overall market. The PBAC noted the submission estimated overall net savings to the PBAC of over $150 million over the first five years of listing. This was based on the impact of the statutory 16% price reduction following the listing of a biosimilar brand. The financial estimates did not account for any potential impacts of price disclosure. In addition, the PBAC noted the financial estimates did not take into account the 5% statutory price reduction for etanercept that occurred in April 2016.

Unless a biosimilar brand is listed on the PBS for a significantly cheaper price, there appears no justification for applying different restrictions to the same medicine on the basis of brand.

The very nature of their equivalence re-enforces the lack of logic. If biosimilar brands had their restriction relaxed to 'Authority streamlined' without an obvious price difference, then the reference biological brand should also have its restriction relaxed to the same level.

The AMA understands that the Government can already apply a 'brand premium' to specific brands of PBS listed medicines if they are more expensive than other brands of the equivalent medicine to encourage changes to doctor prescribing and patient preference.

The AMA appreciates the potential for overall savings to the PBS if more biosimilar brands were prescribed and for these savings to be reinvested into new PBS listings.

However, the AMA cannot see how:

- the differential restrictions will result in PBS savings, given the first biosimilar to be approved for substitution at the point of dispensing is costing the Government the same amount as the reference biological;
- a differential application of Authority requirements can be justified based on brand name only.

Without these concerns being addressed, the AMA cannot support this measure which has

nothing to do with safety and quality, and appears mostly to benefit certain pharmaceutical companies.

Summary

The AMA supports the intention to amend prescribing software so that it defaults to the international non-proprietary name, on the basis that medical practitioners are consulted early in the development of these changes to ensure they do not add unnecessary or inappropriate complexity to prescribing processes.

The AMA does not support, as a proposed interim measure, the insertion of a Note in the Schedule of Pharmaceutical Benefits as an added 'restriction' or the current wording of the Note. The Note should not be related to any restriction in the Schedule and should state that prescribing of biosimilar brands is 'encouraged' not 'preferred'.

The AMA does not support the differential application of a PBS Authority requirement dependent on brand name only, based on our understanding of how this will be applied.

The AMA is willing to work with Government to help deliver high quality, more affordable health care, including recognising and implementing appropriate cost saving strategies.

The AMA would be happy to meet with representatives of the Department to discuss these issues further. In the first instance, queries should be directed to Mr Luke Toy via ltoy@ama.com.au or 02 6270 5400.

Yours sincerely

Dr Michael Gannon
President

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