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From the President

3 November 2017

[redacted]

Dear Ms La Rance

Re: Encouraging the uptake of biosimilars in Australia

Thank you for your correspondence dated 29 September 2017 seeking the views of The Royal Australasian College of Physicians (RACP) on the proposed implementation of the policy changes impacting on the prescribing of biosimilar medicines.

The RACP strongly supports policies to reduce the costs of biological medicines and ensure these valuable medicines are affordable and available to Australian patients; including policies to increase the use of biosimilar medicines. However we are concerned with the lack of consultation to date on policy changes affecting the prescribing of these complex medicines. As far as we understand it, there was no consultation with any organisation representing prescribing doctors.

Uptake driver 1: Biosimilars for treatment naïve patients

The RACP is supportive of encouraging biosimilar medicines to be prescribed as first line therapy for treatment naïve patients. This is likely to grow their market share and will potential reduce the number of patients being switched from the reference medicine to the biosimilar for non-clinical reasons. As confirmed in your correspondence, the choice of therapy must remain with the prescribing doctor in consultation with the patient.

We note that at this point in time biosimilars are not necessarily priced lower compared to their reference medicines, for example – Brenzys, a biosimilar, is currently the same price as its reference medicine, Enbrel. However, we acknowledge that the Government's policies are not about short term gains but more of encouraging a greater biosimilar market share to bring about eventual price reductions. We encourage the Government to ensure that sufficient focus is given to policy levers to ensure that the costs of biosimilars are lowered substantially and in a timely fashion.

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To address your specific question on the proposed wording, we suggest that the word 'desirable' is used in place of 'preferred'.

We also note that, for many physicians, the current My Health Record remains difficult to access and of little benefit to use. We urge government to ensure that more attention is given to better identifying the needs of medical specialists and addressing their specific barriers to increasing the uptake of this system. The RACP is a strong advocate for better use of digital technologies, including electronic health records and communications, and for the need for and opportunity to implement a more robust and effective data-driven pharmacovigilance system that would better address concerns over health implications of switching between biologic medicines.

Uptake driver 2: Lower authority for prescribing biosimilars

Whilst we acknowledge that the government has already determined this policy and is seeking our views on its implementation, we do not support this policy.

We believe that all medicines which are deemed to have a similar safety and cost profile should be subject to the same authority level.

Providing differing authority levels between medicines for other reasons risks delivering an inaccurate message to clinicians, that they have different safety profile and effectiveness. This goes against the principles and aims of the authority system which is to ensure access to safe, effective and affordable medicines as well as their quality use.

As it is proposed that the differing authority level is only applied to subsequent prescriptions - not when initiating a patient on a medicine – we are concerned that this policy will encourage patients to be switched from the originator medicine to a biosimilar for a non-clinical reason. We strongly support that once a patient has been stabilized on a medicine, they are not switched unless there is a clinical rationale for this. To do otherwise puts the patient at risk for no clinical benefit.

As raised previously with the PBAC and the department, the RACP has concerns that the evidence on the impact to patients of multiple substitutions between biological medicines – whether between the reference medicine or between multiple biosimilars – remains unclear. Until we have more data on this, the practice of multiple substitutions should be strongly discouraged both by educating clinicians and through government policies.

Other comments

Building confidence in biosimilars is crucial to increasing the uptake of biosimilars in Australia. To date, few biosimilars have been approved without direct clinical evidence demonstrating their safety and efficacy, but based on the extrapolation of efficacy and safety data from one therapeutic indication to another. The government should support the improved collection, analysis and use of real world data from existing registries to address this issue. In addition other unresolved concerns, such as nomenclature, improved pharmacovigilance, and traceability of the source of immunogenicity or other safety-related problems, must also be urgently addressed.

Improved systems to inform, support and monitor any switching between biological medicines and any resulting implications, would significantly increase the ability to quickly identify and address any biosimilar safety-related problems if they arise. Moreover, improved data collection and pharmacovigilance studies would substantially increase our knowledge and understanding of safety signals of the longer-term use of these important medicines.

The RACP would appreciate an opportunity to discuss our concerns with the department, and also to be kept informed of these new policies.

Should you require any further information regarding this response, please contact [redacted].

Yours sincerely

[redacted]

Dr Catherine Yelland PSM