AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Dr Kathleen Dermody
Committee Secretary
Senate Economics Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

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Dear Senate Economics Legislation Committee

Concern at recently announced plans to allow substitution of biologics/biosimilars as a default position

I am writing on behalf of AusBiotech's members who are biologics developers and the broader biotechnology industry to seek clarification at the recently published PBAC advice to allow substitution between biologics and biosimilars as a default position. The proposed provisions appear to allow the substitution in the absence of scientific evidence of safety and efficacy if this is the case, AusBiotech wishes to covey its concern at such a move.

AusBiotech is concerned to clarify the interpretation of the limits of the role of the PBAC and the five conditions allowing substitution in pharmacies, the first of which reads as though the absence of data triggers permission for substitution. Read alone this appears to carry risk and to be a poor fit with evidence-based decision making. It would also put Australia out of step with global best practice.

AusBiotech is Australia's biotechnology organisation and national body for the biotechnology and life sciences industry, representing more than 3,000 members.

New technologies are challenging many of the regulation, development, prescribing and funding models that have been relied upon in the past. For example, the rise of regenerative medicine has caused a re-think of the regulation of autologous stem cell therapies in Australia, which has recently been reviewed by the TGA. Re-imbursement models for these therapies are challenged by a one-dose only treatment, not a comfortable fit with current reimbursement, despite the obvious substantial cost savings to the health system of one-dose treatments versus a life-time of treatment.

So too, the treatment of biosimilars as generics, is neither a comfortable fit, nor a safe way forward for Australian patients at this time. It may well be a viable option in the future, once evidence is sought and assessed, but cannot be justified on our current global experience. Substitution increases the potential for adverse immune reactions in patients, the extent of which is not fully understood. Allowing pharmacy substitution is therefore questionable in the absence of reference to the prescribing clinician.

The TGA recognises, and in fact states, on its website that "While biosimilars have some conceptual parallels with generic versions of medicines containing chemically-derived small molecules as the active substance, this complexity and microheterogeneity mean that the principles relevant to the evaluation and the use of generic medicines cannot be simply extrapolated to biosimilars."

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For this reason the TGA is currently reviewing the evaluation of biosimilars and it would appear to be premature to make decisions about substitution at pharmacy level at this time. A more prudent approach would be to wait for the conclusion of the TGA review and, in light of the outcome, reconsider any discussion regarding substitution.

It is our submission that public safety and efficacy of treatment and changes to treatment are best managed at this stage of known evidence by clinicians and that the TGA should continue to be the ultimate arbiter on safety and efficacy.

AusBiotech would be pleased to contribute to a discussion about an appropriate way forward and I can be contacted at

Yours sincerely

Julie Phillips
Chair of AusBiotech