Personal Submission
National Health Amendment (Pharmaceutical Benefits) Bill 2015 - Biosimilars

Please withhold my name for this submission, as I wish to maintain a small footprint regarding my health in light of my professional career. Opinions expressed are solely my own and do not express the views or opinions of my employer, or any organisation which I am or have been a part of.

I am making this submission as a health consumer, currently taking a biologic therapy, specifically a TNF-α inhibitor listed on the PBS. Although I have no medical background, I am well versed in the issues due to my role as a board member of a health consumer charity, and attend yearly medical conferences, the most recent of which had several in depth discussions about biosimilars from the medical and pharmaceutical communities. I represent only my views and those of the health consumer charity and its' members, I have no vested interest in the medical or pharmaceutical industry other than to maintain my own health, and that of those I care about.

The speed with which this Bill is being rushed through Parliament is very concerning given the complexity of biologics and their biosimilars and bioequivalents, and the possible fallout from proposed changes to both the health of individuals, and the health system as a whole.

Biosimilars are vastly more complicated than generic drugs yet this Bill attempts to put them in the same category, and is being rushed through without adequate consultation of the educated parties and stakeholders, including patients like myself. My understanding of the proposed procedure is that the PBAC would deem a biosimilar to be bioequivalent, which may be putting some if not many patients at risk, and is below the medical standards we expect as patients in an evidence based medicine framework.

Item 3 This item inserts a new subsection 85(9) into section 85 of the Act to the effect of *"Brand or pharmaceutical item that is biosimilar or bioequivalent to listed item is taken to have the same drug"*

I have a personal concern that this section is going to give pharmacists permission to substitute my anti-TNF medication with a biosimilar medication without the consent of my prescribing physician. This may be different enough to either cause me more health issues, may provoke an immune response (immunogenicity) or not even work at all. Then there's a risk the drug may potentially even be switched back and forth between the innovator's original biologic and its biosimilars repeatedly at the discretion of the pharmacist, possibly amplifying these risks, or creating additional problems not yet studied.

The obvious reason this is being done is to save money with the use of biosimilar medication over the original medications. However, there are several reasons this may not be the case.

There are several issues concerning me

1) The potential for adverse reactions, including anaphylaxis may possibly be increased by switching between biosimilars, even if they are bioequivalents. This would most likely include immunogenicity, when the body builds up an immune response to a foreign drug and starts to fight it, already a common problem with existing biologic therapies.

2) If there are higher risks of immunogenicity, patients will incur "strikes" more easily, which under current PBS rules would bar them from future biologic therapies, where the innovator drug may have worked. How will strikes (and re-inductions) be handled if they occur on biosimilars when the original product was (or may be) tolerated successfully. Will transfers (and if necessary re-inductions) between biosimilars of the same drug always be without penalty?

3) The choice of using a biosimilar should be at the discretion of the prescribing physician, not of the pharmacist who often has no continuity of care, or necessarily the understanding of the intracies of biologic therapies.

4) A cheaper biosimilar in a competitive market may mean the pharmaceutical sponsor has less funds available to spend on additional programs. This may result in several issues.

    a. There is a risk of reduced availability of additional compassionate doses for non-responding patients. Although only PBS funded for 8 weekly doses, 6 weekly doses of infliximab (Remicade) are somewhat commonplace now among severe patients, and some are even on 4 weekly doses, ie a double dose. Humira (adalimumab) is also available on a weekly dose, ie a double dose, when supplemented by compassionate doses, where otherwise only fortnightly doses are PBS funded.
    If these compassionate doses are reduced in availability, this will cause increased reliance on state health departments to bridge the gap with additional doses for these patients as in the pre-PBS era of biologic therapy, possibly cancelling out any net saving from the government by choosing a cheaper drug. Alternatively, these patients may be at a higher risk of remaining unable to find an appropriate treatment, as there are limited options for severe patients if they not successful on the biologic therapies available to them. This may put additional strain on the state & federal health systems, likely leading to otherwise avoidable hospital admissions and procedures, and reducing any net financial gain.

    b. Reduced availability from additional infusion centres already opened by the innovator (Janssen, for infliximab), which provide easier accessibility to those in regional areas who otherwise may have to travel hours to their nearest capable infusion centre. For example, a friend used to commute from the Barossa Valley to RAH (Adelaide CBD) but now has a local centre she can visit without requiring a day trip for her and her young child. Some of these infusions may take 6-8 hours, and significant resources have been created to make this is as efficient as possible for patients and staff.

5) It is distressing to find out that this Bill has been passed by the House of Representatives and now before the Senate, and the above and other issues have not been raised. One could be forgiven for thinking this legislation is being rushed through as a cost saving money without consideration to the risks this will expose patients to, many of whom are already struggling to live with a chronic illness.

In conclusion, as a patient researching this Bill, I can only come to the conclusion that accepting this Bill would be to put the safety and ongoing health of patients at risk, contrary to the advice of several key medical bodies. This would all be for a short-sighted cost saving measure that may well turn out to be counterproductive in the long term if any one of these complications are realised.

The committee may contact me directly if they seek any further clarification about any of these points

Yours sincerely,

Name Withheld