National Health Amendment (Pharmaceutical Benefits) Bill 2015

Submission to Senate 17 June 2015

The speed with which this Bill is being rushed through Parliament is very concerning given the complexity of biologics and their biosimilars, 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. The discussion to allow the PBAC to determine whether a biosimilar is safe is contrary to medical standards we expect as patients.

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 biosimilars or bioequivalent to listed item is taken to have the same drug*"[1]

Also in the

2013 – 2014 - 2015
THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA
HOUSE OF REPRESENTATIVES
NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS)
BILL 2015
EXPLANATORY MEMORANDUM[2]

Under Technical amendments

"The Bill also contains technical amendments to support the intended operation of the Act. These include amendments relating to PBS listing for bioequivalent and biosimilar medicines and treating brands as Schedule equivalent."

I would have expected more of an explanation about biosimilars and the differences to bioequivalent and generic - however this did not give any details. If this was the only explanation then our politicians have not been adequately informed.

I have a personal concern that this section is going to give pharmacists permission to substitute my anti-TNF medication with a biosimilars medication without the consent of my prescribing physician. This may be different enough to either cause me more health issues. or may not even work for me, and may potentially even be switched back and forth between the original biologic and its biosimilars repeatedly at the discretion of the pharmacist.

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1 http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fems%2Fr5462_ems_bed5ace3-a226-4b38-b6cb-f02374a4da08%22

2 http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/r5462_ems_bed5ace3-a226-4b38-b6cb-f02374a4da08/upload_pdf/502776.pdf;fileType=application%2Fpdf#search=%22legislation/ems/r5462_ems_bed5ace3-a226-4b38-b6cb-f02374a4da08%22

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.

The issues I can perceive

1. A cheaper biosimilar in a competitive market may mean the pharmaceutical sponsor has less funds available to spend on additional programs that may cause:

(a) risk of reduced availability of additional compassionate doses for non-responding patients. Although only PBS funded for 8 weekly doses, 6 weekly infliximab (Remicade) are somewhat commonplace now among severe patients, and some are even on 4 weekly, 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.

2. This may cause increased reliance on state health to bridge the gap with additional doses for these patients as in the pre-PBS era, 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 reducing any net financial gain.

(a) Reduced availability from additional infusion centres opened for infliximab by Janssen, which provide easier accessibility to those in regional areas, eg 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.

3. 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?

4. Potential for reactions such as allergy or not working. If this occurs is there to be some mechanism where I can be **guaranteed** if there is a problem I can return to the original drug – and if I did have to return to it – is it going to continue to work? There is enough issues with these Anti-TNF medications if stopped and then needing to be restarted **– false economy if changing medications to save money causes people to get sicker because of problems with biosimilars,** and then the original not being able to be given again – hence cost of hospitalisations, risk of surgery to remove diseased bowel because medications haven't worked, this then can lead on to all the usual complications of surgery, and even possible death. If they survive then there may be the inability to be able to work, need to go on disability pension so where have the savings gone.

5. It should be up to the person's Specialist to make the decisions of when medications are substituted no matter the cost involved. At present people are asked if they are prepared to use a generic or the doctors can put on the prescription if it to be a generic or not – why are people on medications where Biosimilars are available going to be **DISCRIMINATED AGAINST because of the cost of their medications due to their chronic illnesses**. We have enough problems with our health let alone our Government now prepared to cause us more Discrimination.

6. Also again I notice there will be exceptions to the bill as in Section 10. Why is the exception only for these medications? Is it because the right people who know about these medications had access to the proposed Bill, whilst others like me only found out by accident this afternoon.

7. It is distressing to find out that this Bill has been before the House of Representatives and now at the Senate and the above and other issues have not been raised and it appears like this legislation is being rushed through so the government can save money. To my knowledge there were still discussions going on about biosimilars for our Anti-TNF drugs.

In conclusion, as a patient researching this Bill, I can only come to the conclusion that the Government is putting the safety and ongoing health of patients at risk for a short-sighted cost saving measure that may well turn out to be counterproductive in the long term.

Could my concerns please be raised in regard to this Bill.

I would be happy to appear as a witness in any hearing.

Katherine Stewart

On Disability Pension due to 30 years of Crohn's Disease – already living with vary little small bowel due to issues with many medications or side effects, thus required 6 bowel resections prior to 2004, and currently using Anti-TNF medications and the chemotherapy medication Methotrexate for my Crohn's Disease and it is just holding me. I can't afford to lose any more small bowel due to more issues with medications.
I have lived daily since 2005 with 3 holes in my abdomen due to complications of my disease and surgery so I do not need anything else to add complications to my life.
Past Registered Nurse
BSc Nursing. MSc Health Policy and Management
Member Crohns and Colitis Australia
Member and President IBD Support Australia Inc.