

Dr Kathleen Dermody
Committee Secretary
Senate Economics Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Via Email: economics.sen@aph.gov.au

Dear Dr. Dermody:

We understand that the Senate Economics Legislation Committee will be receiving submissions on the National Health Amendment (Pharmaceutical Benefits) Bill 2015. I am writing today regarding the provisions in the Bill related to the substitution of medicines - specifically to raise issues in relation to the pharmacy level substitution of biosimilar medicines.

Attached please find a letter sent to the Health Minister, the Hon Sussan Ley, on this matter which we would like this inquiry to consider. As you will see, this letter is signed by 130 fellow patients who feel that this complex issue requires more than a few minutes of a two hour hearing. Stakeholders - patients, physicians, manufacturers, government are prepared to partner to get this right and to build confidence in this important category of medicines.

We respectfully request that biosimilar substitution be pulled out of the discussion and a separate window of time be identified for a multi-stakeholder discussion about the best path forward.

Respectfully,

Naomi Creek, Coordinator
CreakyJoints Australia
Victoria



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8 June 2015

The Hon Susan Ley MP
Minister for Health
PO Box 6022
House of Representatives
Parliament House, Canberra ACT 2600

RE: Changes to the Safety and Substitution Regulations of Biosimilar Medicines

Dear Minister Ley:

CreakyJoints, a part of the not-for-profit Global Healthy Living Foundation (GHLF), is a patient led organisation focusing on education, support, advocacy and patient-centered research, for people with all forms of arthritis and related rheumatic & inflammatory diseases. Founded in the U.S. in 1999, today we represent more than 80,000 patients and their families throughout the world.

CreakyJoints Australia launched in February 2015, building on our strong digital presence in Australia, with on the ground local staff and representation.

We, along with the 130 undersigned Australian patients, write to express our concern regarding the government's recent shift in policy related to the substitution of biosimilars for their reference biologic as the default position of the Pharmaceutical Benefits Advisory Committee (PBAC). Furthermore, we are concerned by the apparent exclusion of the Therapeutic Goods Administration (TGA) from the evaluation process, announced by the Minister for Health on 26 May 2015 and detailed by the PBAC on 27 May 2015.

As major beneficiaries of biosimilar medications, arthritis and rheumatic disease patients strongly welcome the development and introduction of biosimilar medicines - as potential new therapies and as a means to lowering overall prices. CreakyJoints Australia and our members support the addition of biosimilars to the range of available treatment options. However, we believe that to build the necessary trust for physicians and patients to feel comfortable with adopting biosimilars as a product class, safety and choice must be paramount in the policies that structure their inclusion into the treatment landscape.

The government's recent announcements appear to put budget savings above patient safety, a matter of deep concern.

Framing biosimilars as a subset of ordinary generic medicines is erroneous and scientifically inaccurate.

Biologics are made from living cells and are an incredibly complex web of proteins that are often



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1,000 times the size of small molecule synthetic compounds. Biosimilars are designed to mimic the same function as biologics, however due to the complexity of a biologic's structure; it is scientifically impossible to exactly replicate them. On this basis, each biosimilar's safety and efficacy must be scientifically evaluated and approved through the traditional gateways, before being prescribed.

In addition, once a biosimilar is approved, patients who are successfully using biologic medicines should not be forced to substitute, putting their stable treatment at risk. Automatic substitution is not medically appropriate, be it forced or an inadvertent switch, unless scientific evidence can demonstrate safe interchangeability with identical results,

We respectfully call on the government to urgently clarify its intentions regarding biosimilars, and revise its expectation regarding safety and substitution, specifically:

1. Confirm that the TGA will continue to regulate the safety of biosimilar medicines and that only safety and efficacy data will guide decision-making regarding biosimilar approval and access in the Australian market.
2. Confirm that in the absence of clear clinical evidence, that a presumption against allowing substitution will be maintained.
3. Clarify that the PBAC will continue to provide determinations regarding substitution at the pharmacy level, however that in its relevant considerations that the TGA's advice will be sought in each instance.
4. Affirm that if the TGA finds certain biosimilars to be safe for use, that the PBAC will not force automatic substitution and that biologic & biosimilar medicine choice will remain a decision solely between patients and their doctors.
5. Outsource publically funded education on biosimilars to *independent* disease experts and patient organisations.

CreakyJoints believes that biosimilars are important to our patients because their entry into the market provides a wider range of treatment options at potentially lower prices.



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However, if the proposed changes proceed, Australia will be the first country to shift the onus from a medicines safety regulator to a funding authority. This shift could have massive global consequences; lowering patient and physician trust in this new class of products and impeding the proliferation and uptake of these therapies.

We ask the government to consider the intended and unintended consequences of this decision, before proceeding further.

We look forward to your response. Please direct correspondence to:

CreakyJoints Australia
56 Kenneth Street
Longueville, NSW, 2066

Respectfully,

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