Dear Dr Dermody

Please see the attached letter on behalf of the Honorary Secretary of the Australasian College of Dermatologists in relation to the Biosimilar Substitution Legislation, which was sent to the Minister of Health on Monday 15 June.

Can you please forward this letter to the Senate Committee for their Senate Inquiry Hearing today at 12-3pm?

I would be grateful if you could also confirm receipt of this email.

Thank you.

Kind regards

Jennifer McNeillie
Acting Education Manager
STP Program Coordinator

Australasian College of Dermatologists

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15 June 2015

The Hon. Sussan Ley MP
Minister for Health and Minister for Sport
Parliament House
Canberra ACT 2600
Minister.ley@health.gov.au

cc: Andrew Simpson Professor Andrew Wilson

Dear Ms Ley,

Re: PROPOSED AMENDMENTS TO THE NATIONAL HEALTH ACT 1952 - BIOSIMILARS 'SUBSTITUTION'

Regarding proposed amendments to the National Health Act 1952 the Australasian College of Dermatologists wishes to submit to you its position statement on biosimilar substitution:

1. We acknowledge the availability of biosimilars and note they are available for use in several countries

2. There is an economic rationale for their use and making them available in Australia

3. It must be remembered that they are biosimilar not bioidentical and there are limitations in comparing agents

4. We would be very concerned if the requirement for safety and efficacy data was reduced compared with existing approved drugs in class. The safety of the Australian public and confidence in the regulatory process must not be compromised by short term economic savings.

5. If supported by best practice clinical data and head to head studies, we support the availability of biosimilar agents.

6. Individual patients, who have responded to a particular agent and who are tolerating that therapy well, should not be switched from one 'biologic' agent to another biosimiliar

7. We would be concerned and not support point of dispensing substitution of a named drug for a biosimilar. These drugs are not identical (as distinct from generic substitution) and only the named drug should be dispensed unless the prescriber approves substitution.

8. Head to head studies are needed for each specific indication.

9. We do not support and express grave concern at extrapolation across disease indications (ie using data for efficacy and safety in rheumatoid arthritis to justify approval in psoriasis)

Our Scientific Committee is examining this matter in greater detail but we wish to raise these issues with you and register The Australasian College of Dermatologists as an interested party given the large number of patients we treat with 'biologic' agents.

Yours sincerely,

Andrew Satchell
Honorary Secretary ACD