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

18th June 2015

Dear Dr Dermody

I am writing to you with regards to the issue of the use of Biosimilars and its introduction into the Australian market. I am the Inflammatory Bowel Disease (IBD) Lead at the Royal Children's Hospital in Melbourne, in a unit with a long standing experience with the use of Biologics in the treatment of Paediatric IBD. Firstly I welcome the price competition that these products will lead to in our current economic climate.

However my main concern with biosimilars is the issue of its interchangebility with the existing biologics in patients that are already stable and are doing well on the originator drug. In the management of Paediatric IBD the rapidity and efficiency of good disease control is paramount in the long term outcome of these patients. Once control is achieved we strive to maintain a well state in our patients with the regular maintenance infusions of the biologic agent. With the lack of any clinical trials on efficacy and safety in IBD I would be concerned if a switch is made midway through a patient's treatment plan using the biosimilar drug, especially without the knowledge of the treating physician, simply because it is now the approved new "formulation". If a loss of response occurs at that transition stage in a Paediatric patient, we would be losing valuable time to try and recapture control which may in turn compromise time critical events in their life such as growth and puberty.

I strongly feel that the decision to choose a biologic or a biosimilar agent needs to lie in the data of its efficacy and safety in the IBD population and more so specifically in the Paediatric population which is not available currently for the Biosimilars. I would also strongly encourage against any measure that allows a switch between a biologic and a biosimilar at a pharmacy level especially if the patient has been stable and well established on the originator drug, until more data is available.

I sincerely hope you will take this feedback when considering your decision on this important matter.

Yours sincerely

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