7th September 2017

COMMENTS TO THE THERAPEUTIC GOODS ADMINISTRATION

Re: Consultation: Nomenclature of Biological Medicines

Submitted by: CreakyJoints Australia (Part of the Global Healthy Living Foundation, (GHLF))

I am writing to you on behalf of CreakyJoints Australia and patients throughout Australia living with inflammatory arthritis who are or will be prescribed biological medications.

As advocates, it is our role to ensure that patients and physicians are fully aware of the drugs prescribed, that patient safety is the top priority in the health care process, and that medical decisions remain between a doctor and his or her patient.

Option 4: Introduce the use of suffixes to the naming of biological medicines.

CreakyJoints Australia supports this option and with the approach taken by the US FDA.

It is essential that each biological medicine have a distinguishable name so that patients and doctors can easily differentiate between medicines. We believe accurate medical product identification and distinction is a critical component to the safety of any public health system. The addition of a four-letter suffix to a product's INN is an extra safety measure, supplementing existing identification, such as trade name and batch number that can only strengthen pharmacovigilance systems worldwide.

CreakyJoints Australia believes the new 4-letter suffix option should apply retrospectively to all biological medicines. Medicines currently registered still need the same safety monitoring measures and should not be disregarded in this case. To reduce confusion among patients, prescribers, and insurers, we believe that Australia should adopt the 4-letter suffixes already designated by the FDA. This will ensure that the same biosimilar medication does not appear as a distinct entity, while still preserving its independence from the reference product.

We believe the current TGA adverse event reporting system needs be a lot more robust, particularly in the biosimilar landscape. All identifying aspects of a biological medicine, including its INN, trade name and batch number should be made mandatory in the reporting system, not just the INN which is currently the case. This would eliminate the unnecessary follow-up by the TGA to seek the missing information from the reporter. Increased awareness for patients and health professionals of the importance of reporting and how to do so also needs to be improved.

Considerations should also be made to allow the biological medicine ID to be integrated into the Australian electronic 'My Health' framework, so patients and healthcare professionals have an historical record of what medicine was prescribed, dispensed and reported on in the case of an adverse event.

Thank you for the opportunity to comment on this consultation.

Yours sincerely

Naomi Creek
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CreakyJoints Australia