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January 28th, 2022

Ms Sophie Mitchell & Ms Lily Xiao Australian Competition & Consumer Commission – ACCC 23 Marcus Clarke Street Canberra ACT 2601

Re: Interested Party Consultation. Application for authorisation AA1000592 Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd.

Dear Ms Mitchell & Ms Xiang

We write on behalf of Myeloma Australia and our Medical and Scientific Advisory Group (MSAG) to provide comment on the proposed application for authorisation AA1000592.

Our organisation welcomes any activity that will improve the lives of people living with multiple myeloma in Australia. In commenting we must balance the impact of this agreement on competition (only two generic providers, Celgene's impact on pricing, no timeline for other generic providers to enter the marketplace) with the potential benefits (reduced costs for patients, reduced financial burden on the health system and potential for the drugs to be removed from the high cost label and therefore be used in new combinations).

Access to generic versions of the medicines in question (Revlimid and Pomalyst) will reduce financial burden on both patients and the health system as a whole. However without a minimum price of the generics, a price comparator between the original medicine and the generics or the authorised launch date it is difficult for us to comment on the significance of this benefit. The documents provided by the ACCC indicate that authorisation AA1000592 will allow two generic providers to enter the Australian market before patents expire. The earlier the price is reduced, the greater the financial benefit over time.

Ideally there would be competition in the market for these generic medicines, allowing independent entities to set their price without interference from each other or Celgene. We are concerned about the past aggressive behaviour of companies preventing Australian multiple myeloma patients from accessing generic medicines. We note this is an international issue (https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away) with similar agreements in both Canada and the United States.

When generics are in place and cost comes down significantly the Pharmaceutical Benefits Advisory Committee (PBAC) is able to remove the high cost label and restrictions on these medications. This would potentially allow clinicians to prescribe the medications in new combinations. For example Velcade is now a generic medication and this foreshadowed the approval of new combinations such as VRD (Velcade, Revlimid and Dexamethasone). This combination is now part of the optimal care of multiple myeloma patients in Australia

(https://myeloma.org.au/wp-content/uploads/2020/09/MSAG clinical practice update JUL20 final.pdf).

Myeloma Australia and MSAG support the early access to generic versions of Revlimid and Pomalyst however the relative significance of this impact on Australian multiple myeloma patients cannot be determined with the information available.

Sincerely,	
Mr Steve Roach	Professor Simon Harrison MBBS, MRCP (UK), FRCPath (UK), FRACP, PhD
CEO, Myeloma Australia	Chair, Myeloma Australia's Medical and Scientific Advisory Group (MSAG) Director, Centre of Excellence for Cellular Immunotherapy Director of Clinical Aphaeresis, Clinical Haematology Peter MacCallum Cancer Centre and Royal Melbourne Hospital Victorian Comprehensive Cancer Centre Honorary Clinical Professor, Sir Peter MacCallum Dept of Oncology, Melbourne University