From: Murphy, Nick [redacted]
Sent: Thursday, 14 April 2022 2:02 PM
To: Ng, Andrew
Cc: Staltari, Danielle; Kolacz, Miriam; Xiao, Lily; Black, Susie
Subject: Re: ACCC request for information - Juno & Ors application for authorisation [SEC=OFFICIAL]

Hi Andrew,

I am away on leave from this pm until April 27th, so please excuse the brevity of my response (writing between patients in clinic), but some thoughts below in red.
If you would like more detailed information, maybe we should speak again after I return, but that will be after your requested date.

Nick

Nicholas E Murphy MBBS, FRACP, FRCPA
Consultant Haematologist,
Royal Hobart Hospital.
[redacted]

From: Ng, Andrew <Andrew.Ng@accc.gov.au>
Sent: Thursday, 14 April 2022 9:05 AM
To: Murphy, Nick [redacted]
Cc: Staltari, Danielle <Danielle.Staltari@accc.gov.au>; Kolacz, Miriam <miriam.kolacz@accc.gov.au>; Xiao, Lily <lily.xiao@accc.gov.au>; Black, Susie <Susie.Black@accc.gov.au>
Subject: ACCC request for information - Juno & Ors application for authorisation [SEC=OFFICIAL]

OFFICIAL

Dear Nick,

Thank you for your assistance with the Australian Competition Consumer Commission's (**ACCC**) consideration of an application lodged by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd. The ACCC has received two submissions following the draft determination which raise issues relating to the **risk management plan** that sponsors are required to provide to prescribers and pharmacies as a condition (set by the TGA) to supply lenalidomide and pomalidomide in Australia. For further information regarding the application (including the submissions received by the ACCC following the draft), please see our website: https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/juno-pharmaceuticals-pty-ltd-ors

We would be grateful if you could provide a response to the questions below regarding the risk management plan.

Questions:

1. Please explain how Celgene's risk management plan operates and what is required to be done by prescribers / pharmacists in order to prescribe / supply lenalidomide and pomalidomide products? Prescribers need to be registered with the RMP around the teratogenicity of thalidomide (the original IMID for Myeloma) as well as safety measures such as donation of sperm, safe storage of drug, pregnancy avoidance etc. I did this when I was a registrar in about 2006 so it was a long time ago! Pharmacists would have similar requirements i am sure, but do not know for a fact.
2. Would both the prescriber and pharmacy be required to operate the same risk management plan in order for a patient to obtain and dispense their script of the same brand of lenalidomide and pomalidomide? I would think so
3. Would prescribers / pharmacies be willing to switch to, or operate, a second or subsequent generic risk management plan if generic products of lenalidomide and pomalidomide were introduced? What factors would generally be taken into account, and to what extent would additional switching costs, IT interface changes or training costs act as a barrier to prescribers/pharmacies deciding to switch. Honestly, I would expect prescribers would 'cop it' but would resent having to go through another RMP process for what would be the same drug/compound. If this could be avoided, then i think that would be ideal.
4. How many separate risk management plans would prescribers / pharmacies be willing establish and operate at any given time? Please explain why.

Medical specialists want to spend their time seeing patients and helping them with their disease/treatment/problems. We increasingly need to fill in form after form and may times are repeating the same information for PBS (eg for expensive drugs) as well as various manufacurers (eg Celgene RMP) as well as hospital based requirements (eg CPD, safe prescribing skill maintenance). The short answer to Qn 4 is "AS FEW AS POSSIBLE", but we know that the reality is that some extent of paperwork is inevitable..

We would be grateful if you could provide a response by **Friday 22 April 2022**. Alternatively, if you would prefer to make an oral submission, we can schedule a time to discuss over the phone.

We would propose to place your response on the public register (subject to any claims you may wish to make for confidentiality).

If you have any questions, please feel free to contact me.

Kind regards,

Andrew Ng

Analyst | Competition Exemptions | Mergers, Exemptions and Digital
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The ACCC acknowledges the traditional owners and custodians of Country throughout Australia and recognises their continuing connection to the land, sea and community. We pay our respects to them and their cultures; and to their Elders past, present and future.