From: Shutt, Anita M [redacted]
Sent: Thursday, 14 April 2022 3:57 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]

Dear Andrew,

My understanding is that the risk management plan is an agreed risk mitigating approach between the TGA and the sponsor, and forms part of the approval for that product's registration/marketing in Australia (https://www.tga.gov.au/sites/default/files/risk-management-plans-medicines-and-biologicals.pdf). The TGA and/or the Sponsor would be best placed to comment on the specifics of this.

In the case of lenalidomide, my understanding is that the purpose of the risk mitigating approach is to manage the risks associated with the teratogenicity of the agent, primarily ensuring there is no risk of exposing a foetus to this agent. In response to your questions:

1. Celgene offers the i-access online platform, which requires healthcare professionals to undertake training and register to participate in prescribing/dispensing the relevant agents. Each time the product is dispensed, a process must be undertaken to ensure that the patient's most recent blood test results are reviewed and the results are recorded in the i-access system to confirm the suitability/safety at the time of supply.
2. Currently, the risk management plan is supported by the sponsor. I expect most sponsors will not operate a system that supports access to another company's product.
3. Yes. It would be possible to switch to a different system to accommodate a new brand. This would likely involve staff needing to re-train and re-register with a new system. Quantifying the impacts of this changeover is challenging without knowledge of what the new approach might be.
4. I expect most would prefer to maintain a single system, on the basis that significant time could be wasted training, registering and accessing a variety of differing systems. Again this response depends on the functionality and ease of use of the systems involved.

For context, I have provided the link to Celgene's i-access system training https://www.celgene.com.au/product-information/patient-safety/i-access/

Kind regards,

Anita Shutt BPharm(Hons) GradDipPubHealth MSHP
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From: Ng, Andrew <Andrew.Ng@accc.gov.au>
Sent: Thursday, 14 April 2022 9:06 AM
To: Shutt, Anita M [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 Anita,

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?
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?
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.
4. How many separate risk management plans would prescribers / pharmacies be willing establish and operate at any given time? Please explain why.

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.