Pharmacor

6 April 2022

Susie Black
Director – Competition Exemptions
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Ms Black

Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd Application for authorisation AA1000592

We refer to your letter dated 23 March 2022 seeking submissions from interested parties on the Australian Competition and Consumer Commission's (**ACCC**) draft determination in respect of the application for authorisation lodged by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd (**Applicants**) on 3 December 2021 (the **Draft Determination**).

Pharmacor makes this submission in response to that invitation.

1. Introduction

1.1 As you know, the Applicants have sought authorisation of provisions of a settlement and licence agreement with respect to the supply of Juno/Natco's generic lenalidomide and pomalidomide products in Australia.

1.2 Pharmacor is an Australian company that provides a wide range of generic medicines to Australian pharmacies and hospitals, in a range of disease areas. Pharmacor is a wholly owned subsidiary of Alkem Laboratories Ltd, and part of the Alkem multinational group of companies. Pharmacor is interested in marketing in Australia one or more of generic lenalidomide and pomalidomide products for the same indications in respect of which Revlimid® and Pomalyst® are approved, upon the expiry or earlier revocation of any relevant patent rights.

1.3 As a preliminary matter, Pharmacor supports the conclusion reached by the ACCC in the Draft Determination that, in all the circumstances, the conduct for which authorisation is sought would not be likely to result in a benefit to the public that would outweigh the detriment to the public.

1.4 In this submission Pharmacor does not comment on every aspect of the Draft Determination, but wishes to raise a particular issue. Pharmacor submits that the issue is relevant to at least the ACCC's assessment in paragraphs 4.16 and following of the Draft Determination, of the future with and without the Proposed Conduct, and in turn, its assessment of the likely public benefits and public detriments.

2. Risk Evaluation and Management Systems (REMS) for lenalidomide and pomalidomide products

2.1 At paragraphs 4.90 to 4.93 of the Draft Determination, the ACCC notes the lucrative first mover advantage the Proposed Conduct will likely confer on Juno/Natco. In paragraph 4.91 of the Draft Determination, the ACCC refers to the establishment of a risk management program as an additional regulatory requirement.

2.2 Given the extent of the redactions to the Draft Determination, the nature of the information available to the ACCC relating to these risk management programs for lenalidomide and pomalidomide products is unclear.

Suite 803, Level 8, Tower A, The Zenith,
821 Pacific Highway, Chatswood NSW 2067
Phone: 1300 138 805 Fax: +612 9413 4075
www.pharmacor.com.au
ACN: 121 020 835 ABN: 58 121 020 835

2.3 As appears to be accepted, the first mover advantage or "first generic mover advantage" for generic products in pharmaceutical markets generally has been well documented and has been the subject of a number of economic analyses.[1] It arises to a significant extent from the switching costs associated with stocking and supplying multiple generics. Upon the first generic entry, most (if not all) pharmacies and hospitals will stock the generic, to have a cheaper alternative product to dispense, which is bioequivalent to the originator product. The switching costs arise by reason of the need to have "bioequivalence" conversations with patients at the point of dispensing at pharmacy level, the increased inventory costs associated with multiple generics and the tender process in hospitals resulting in long term supply contracts. Any cost savings of a second or subsequent generic product made available at a comparable price point are, however, unlikely to overcome these switching costs.

2.4 In order to supply lenalidomide and pomalidomide products in Australia, the TGA requires the sponsor to provide a Risk Evaluation and Management System (or **REMS**). Lenalidomide and pomalidomide are structurally related to thalidomide. Their use in pregnancy carries particular risk of birth defects.[2]

2.5 In Australia, Celgene has supplied to prescribing doctors, hospital pharmacies and community pharmacy the REVLIMID REMS® through an online portal. The REMS for Revlimid® and Pomalyst® is proprietary to Celgene. Pharmacor has limited information available to it about the Celgene REMS for Revlimid® and Pomalyst®, but understands that prescribing doctors and pharmacists are required to register to use the REMS and that pharmacists are required to undertake training modules and pass a test prior to their registration being accepted.

2.6 Unlike other jurisdictions, such as the United States[3], Celgene is not required to make its REMS available to third party sponsors of lenalidomide and pomalidomide products in Australia. The TGA has stated to Pharmacor that it does not propose to implement any such requirement in Australia. See the email correspondence in **Annexure A**. As a result, each sponsor of generic lenalidomide and pomalidomide products in Australia is required to develop its own REMS to support the supply, prescribing and dispensing of its own generic lenalidomide and pomalidomide products.

2.7 Under the proposed settlement and licence agreement, Juno will supply its own separate REMS[4], with the result that each prescriber and dispenser of lenalidomide and pomalidomide products in Australia will need to acquire, implement, be trained in, operate and maintain two separate REMS software products – one for Celgene's originator product and one for Juno/Natco's generic product.

2.8 Pharmacor is particularly concerned that once these two separate software products have been implemented, are established and have been in operation, particularly over any significant period of time, to support the risk management steps required by the TGA in the prescribing and dispensing of these products, doctors, hospitals and pharmacists will be particularly reluctant to acquire, establish and operate a third (or any subsequent) REMS for each subsequent generic product as it becomes available.

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[1] See e.g., Grabowsk , H.G. and Vernon, J.M. "Brand oya ty, entry and pr ce compet t on n pharmaceut ca s after the 1984 drug act", *Journal of Law and Economics*, (1992) 35(2): 331 350; Grabowsk , H.G. and Vernon, J.M. "Longer patents for ncreased gener c compet t on n the us; the Hatch Waxman act after one decade", *Pharmaco Economics*, (1996) 10: 110 123; Yu, Yu and Gupta, Sach n, "P oneer ng Advantage n Gener c Drug Compet t on", *International Journal of Pharmaceutical and Healthcare Marketing* (2008) 8(2): 126 150.

[2] See the Product Informat on document for Rev m d® at https://www.ebs.tga.gov.au/ebs/p cm /p cm repos tory.nsf/pdf?OpenAgent& d=CP 2010 PI 07861 3&d=20220405172310101.

[3] See further be ow.

[4] See etter from M nterE son to the ACCC dated 18 January 2022, not ng at paragraphs 2.52 and 2.54 that Juno s creat ng a spec f ca y des gned r sk management system (RMS) to screen a pat ents pr or to adm n strat on of those products, as a cond t on of regu atory approva w th the TGA.

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2.9 If the Proposed Conduct is authorised, the price differential between the originator products Revlimid® and Pomalyst® on the one hand and Juno/Natco's generic products on the other hand, is likely to result in rapid uptake of Juno's REMS. However, the additional switching costs, IT interface changes, different user experience, training costs and administrative burden of operating multiple REMS systems for multiple generics are likely to raise significant additional barriers to entry for second and subsequent generic sponsors, over and above the usual factors which give rise to the first generic mover advantage generally.

2.10 In this regard, the ACCC may be aware that in the United States, on 21 May 2021 the US Food and Drug Administration (**FDA**) approved the first generic lenalidomide product for marketing in the US. The FDA required Celgene to transition its branded REVLIMID REMS® to a generic "Lenalidomide REMS Shared System" approved by FDA in September 2020. Generic lenalidomide products were due to become commercially available through a single "Lenalidomide REMS" from 3 March 2022. Thus in the US at least, this additional barrier to generic entry has been mitigated by the requirements of the FDA. As discussed above, however, this is not the case in Australia.

3. Conclusion

3.1 Pharmacor is, therefore, concerned that the settlement and licence agreement proposed to be entered into by the Applicants will confer on Juno a significant first mover advantage which is substantial and is likely to cause uniquely significant barriers to entry for subsequent generic sponsors, including Pharmacor.

3.2 Pharmacor supports the conclusion in the Draft Determination that authorisation should not be granted. If, however, the ACCC proposes to grant authorisation, then Pharmacor submits that it would be appropriate to require, as a condition of authorisation, that Celgene make its REMS available to all sponsors of lenalidomide products in Australia.

Please contact me if you would like to discuss this letter.

Your Sincerely,

Ashish Mallela

CEO

M – [redacted]

Pharmacor

Annexure A

TGA Response

External Communication
Dear Sajjad,

Thank you for your email,
The Risk Management Section have provided the following response:

Thank you for your email. The TGA does not have any plans to implement a shared controlled distribution/pregnancy prevention/REMS program for lenalidomide. Generic sponsors of lenalidomide may wish to approach the innovator to discuss this, but there is no TGA requirement for the innovator to provide any shared access to such a program for lenalidomide. The requirements for additional risk minimisation activities for lenalidomide to address the safety concern of teratogenicity are similar to what are currently in place in the EU. As per the guidance on the TGA website Risk management plans for medicines and biologicals:

> Additional risk minimisation materials for generics should cover the same key safety messages as those for the originator, and any safety concerns specific to the generic. The key safety messages should be included in the Australia-specific annex.
> As the risk minimisation in place in Europe is generally similar to that in Australia, risk minimisation materials implemented in the United Kingdom on the electronic Medicines Compendium website (eMC) website can be a useful source of information relating to the additional risk minimisation activities in place for the originator.

I hope this is of assistance,

Kind regards
Lauren

Lauren Kucka
Case Manager - Application and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health
T | E:
Location: Symonston ACT
PO Box 100, Woden ACT 2606, Australia

Please note the TGA will be shut down for the holiday period from 3pm Friday 24 December 2021 with business resuming Tuesday 4 January 2022

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met
***Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

Pharmacor Email to the TGA requesting the REMS program be made available to Generics

From: Sajjad Khan
Sent: Wednesday, 15 December 2021 10:34 AM
To: PCS Inbox ; SMU Info
Subject: Celgene i-access transition to Generic Lenalidomide

Hi PCS inbox team,

We came across the information that FDA approved a generic Lenalidomide product. This approval will trigger the transition of i-access (a REMS programme available for Revlimid) to the Lenalidomide shared system approved by FDA in Sep 2020.

Please refer enclosed newsletter published by Madison multiple myeloma support group, please refer the publication with this link http://madisonmultiplemyeloma.org/newsletter/November_2021_MM.pdf or enclosed pdf (refer Yellow highlighted section).

On May 21, 2021, the Food and Drug Administration (FDA) approved a generic Lenalidomide product. This approval will trigger the transition of REVLIMID REMS® to the Lenalidomide REMS Shared System approved by FDA in September 2020. Generic Lenalidomide is not yet commercially available but will become available through Lenalidomide REMS on March 03, 2022.

Please advise if similar plan under review or going to be approved by TGA as well and whether TGA is in process to implement the shared REMSfor Lenalidomide in AU.

Your guidance in this regard will be greatly appreciated.

Regards,
Sajjad

Dr Sajjad Khan

Snr. Regulatory Affairs Associate

Suite 803, Level 8, Tower A, The Zenith,
821 Pacific Highway Chatswood NSW 2067
M: **P:** **| F:**
W: www.pharmacor.com.au **| E:**