

18 January 2022

Danielle Staltari
Director, Competition Exemptions
Australian Competition & Consumer Commission
Level 17, 2 Lonsdale St
Melbourne VIC 3000

BY EMAIL: danielle.staltari@accc.gov.au

Dear Danielle

Additional information - Application for authorisation of conduct - Settlement and Licence Agreement between Celgene Corporation, Celgene Pty Ltd, Natco Pharma Limited and Juno Pharmaceuticals Pty Ltd

1. Introduction

- 1.1 MinterEllison acts for Juno Pharmaceuticals Pty Ltd (**Juno**) and Natco Pharma Limited (**Natco**) (**Juno / Natco**).
- 1.2 Thank you for your information and document request dated 16 December 2021 with respect to the application for authorisation dated 3 December 2021 (the **Application**).
- 1.3 This letter comprises Juno / Natco's response to the information requested. Defined terms in this letter have the same meaning as set out in the Application.
- 1.4 This letter is accompanied by an electronic copy of documents requested. An index of these documents is attached at **Annexure A**.

2. Juno / Natco's response

For each Generic Product and indication that will be supplied under the Agreement please provide an estimate of the cost savings to the Commonwealth Government that will result from the First New Brand Statutory Price Reduction on the PBS. Please outline when the New Brand Statutory Price Reduction will take effect and over what time period the cost savings will result. Please provide documents to support your response, including any analysis undertaken by the Applicants.

- 2.1 Please see accompanying confidential spreadsheet (20220113_PBS impacts of launch) which estimates the cost savings to the Commonwealth Government that will result from the First New Brand Statutory Price Reduction, which occurs upon the PBS listing date of the Generic Products. Please note that there is no indication level impact on PBS savings because the PBS works on a molecule level, as such this response estimates the cost savings for each of the Generic Products only (pomalidomide and lenalidomide).
- 2.2 Please note that Juno / Natco does not know the value of the special pricing arrangement (**SPA**). As such, Juno has provided 3 estimates of costs savings, based on a SPA of 0%, 35% and 50%.
- 2.3 Juno has estimated the costs savings to the Commonwealth Government for the year 2022 and 2023. In summary, Juno estimates the following yearly cost savings for lenalidomide in **Table 1** and pomalidomide in **Table 2**:

Table 1: Lenalidomide – PBS savings to the Commonwealth (\$AUD)¹

Year	Cost savings – based on 0% SPA	Cost savings – based on 35% SPA	Cost savings – based on 50% SPA
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Table 2: Pomalidomide – PBS savings to the Commonwealth (\$AUD)²

Year	Cost savings – based on 0% SPA	Cost savings – based on 35% SPA	Cost savings – based on 50% SPA
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

2.4 Juno estimates the monthly costs savings (based on a SPA of 35%) to the Commonwealth Government from the Authorised Launch Date until the date for likely generic launches to be approximately:

- (a) between \$4,728,192 – \$4,870,037 per month for lenalidomide;
- (b) \$933,591 per month for pomalidomide.

2.5 Please note that these estimates are based on the market assumptions and modelling in the accompanying confidential spreadsheets (20211221_pomalidomide and 20211221_lenalidomide). This modelling includes key assumptions outlined on the first sheet ('Overview') and involves a number of key assumptions about future matters and the actual outcomes may vary materially from the model including among other reasons because outcomes will depend on actions of other market participants that are independent of Juno and Natco.

Please contact us if the ACCC requires further information.

Yours faithfully

MinterEllison

Contact: Alice Waterston T: [REDACTED]

Partner: Geoff Carter T: [REDACTED]

¹ Price reduction calculated from Authorised Launch Date of [REDACTED]
² Price reduction calculated from Authorised Launch Date of [REDACTED]

Annexure A – Index of relevant documents

	Document description	Document date	Document ID
1.	20220113_PBS impacts of launch (confidential PBS cost savings estimates)	13 January 2022	JUN.5000.0001.0070
2.	20211221_pomalidomide (confidential forecasts for pomalidomide)	21 December 2021	JUN.5000.0001.0071
3.	20211221_lenalidomide (confidential forecasts for lenalidomide)	21 December 2021	JUN.5000.0001.0072