From: Xiao, Lily

Sent: Thursday, 16 December 2021 10:03 AM

To: Geoff Carter; Smith, Prudence J.

Cc: Deano, Sharon; Mitchell, Sophie; Black, Susie; Staltari, Danielle; Ng, Andrew;

Saponaro, Marcello; Bull, Matthew D.; McIntyre, Dylan G.; Alice Waterston; Tatum

Joseph

Subject: RE: Juno, Natco and Celgene application for authorisation AA1000592

[SEC=OFFICIAL] [ACCC-ACCCANDAER.FID3039132]

OFFICIAL

Dear Geoff and Prudence

In addition to the letters dated 16 December 2021, we have an additional request for information and documents. We have sent this request separately to the letters as you may wish to consult on a joint response. The definitions used in the letters are also applicable to the below request.

1. 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.

We request the information and documents in response to this request by 17 January 2022.

Subject to our consideration of any request for exclusion from the public register, a public version of your response to this request will be placed on the ACCC's public register. This correspondence will also be placed on the public register.

Kind regards

Lily

Lily Xiao

(she/her)

Senior Analyst | Competition Exemptions
Australian Competition & Consumer Commission
Level 18 | 2 Lonsdale Street Melbourne 3000
T: 03 9910 9413

www.accc.gov.au

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.

From: Mitchell, Sophie <sophie.mitchell@accc.gov.au>

Sent: Wednesday, 15 December	ber 2021 12:37 PM	
To: Geoff Carter	; Smith, Prudence J.	
Cc: Deano, Sharon <sharon.d< td=""><td>eano@accc.gov.au>; Black, Susie <susie.black@accc.gov.< td=""><td>.au>; Staltari, Danielle</td></susie.black@accc.gov.<></td></sharon.d<>	eano@accc.gov.au>; Black, Susie <susie.black@accc.gov.< td=""><td>.au>; Staltari, Danielle</td></susie.black@accc.gov.<>	.au>; Staltari, Danielle
<danielle.staltari@accc.gov.a< p=""></danielle.staltari@accc.gov.a<>	au>; Xiao, Lily <lily.xiao@accc.gov.au>; Ng, Andrew <andı< td=""><td>rew.Ng@accc.gov.au>;</td></andı<></lily.xiao@accc.gov.au>	rew.Ng@accc.gov.au>;
Saponaro, Marcello <marcello< td=""><td>o.saponaro@accc.gov.au>; Bull, Matthew D.</td><td>; McIntyre, Dylar</td></marcello<>	o.saponaro@accc.gov.au>; Bull, Matthew D.	; McIntyre, Dylar
G.	; Alice Waterston	
Subject: Juno, Natco and Cela	gene application for authorisation AA1000592 [SEC=OFFI	CIAL] [ACCC-
ACCCANDAER.FID30391321		

OFFICIAL

Dear Geoff and Prudence

By way of update, the application for authorisation and associated public documents are now live on the <u>public register</u> and public consultation has commenced.

As previously requested, could you please provide details of any licensing agreements for the lenalidomide and pomalidomide ingredients that Celgene has entered into with other parties internationally. Please explain whether these agreements have been notified to or approved by other international regulators. If so, please identify the relevant regulator. We would be grateful for a response to this question by close of business Monday 20 December 2021.

A copy of this email will be placed on the ACCC's public register.

Kind regards Sophie

Sophie Mitchell

Assistant Director (a/g) | Competition Exemptions Branch Australian Competition & Consumer Commission Level 27, 135 King Street, Sydney NSW 2000 T: + 61 2 9230 3843

www.accc.gov.au

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.