# FURTHER RESPONSE TO ACCC INFORMATION REQUEST DATED 16 DECEMBER 2021[1]

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## 1. Rationale / Industry Background Information

Generic products

1.1 ***Explain Celgene's strategy in relation to actions taken in response to the proposed launch of any generic products that will compete with Celgene's originating products, either generally in relation to any generic products or in relation to Juno/Natco's products specifically, and either in Australia or in locations including Australia.***

Please refer to Celgene's previous response dated 9 February 2022.

1.2 **For each Celgene Product and indication provide the following:**

(a) ***annual sales volumes in Australia for the past 3 financial years;***

(b) ***projected sales volumes in Australia for the first 3 financial years under the Agreement;***

(c) ***total revenue in Australia for the past 3 financial years; and***

(d) ***projected revenue in Australia for the first 3 financial years under the Agreement.***

***Please provide Documents to support the response to this question.***

Please refer to Celgene's previous response dated 9 February 2022.

The agreement

1.3 ***Explain the rationale, including the benefits and disadvantages, for entering into the Agreement. Please provide Documents to support the response to this question.***

At the time of signing the Agreement, the Applicants were engaged in litigation in the Federal Court of Australia concerning infringement and validity of the Celgene Patents (the Proceedings and Cross Claim). In parallel, JH Corporate Services Pty Ltd, acting as agent for both Natco/Juno, filed with the Australian Patent Office requests for re-examination of certain of the Celgene Patents in the Australian Patent Office (the Re-Examination Requests) (see paragraphs 2.18 and 2.19 of the Authorisation Application).

[1] All capitalised terms used in this response have the definition given to them in the ACCC Information Request or the ACCC authorisation application dated 3 December 2021 made by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, and Celgene (**Authorisation Application**) unless otherwise indicated.

Celgene considers that the Agreement represents a fair compromise of the litigation, given (amongst other things) the uncertainties, costs and burdens associated with the litigation and the other benefits described in the Authorisation Application. The Agreement will allow the Applicants to invest the time and resources that would have been directed towards the litigation in the Federal Court of Australia to other business-as-usual functions.

The Agreement provides Celgene with more certainty as to the launch date of the Generic Products than if Natco/Juno were to launch 'at risk' or alternatively if, contrary to Celgene's expectations, Natco/Juno were to obtain a favourable judgment in the Federal Court Proceedings and subsequently launch the products, which although not 'at-risk', would nonetheless involve uncertainty as to the launch date given that it is impossible to predict the timing of a judgment. In this regard, whilst as noted above, Celgene's expectation is that it will be successful in the proceeding, it nevertheless accepts that all complex litigation is inherently uncertain, and therefore it cannot entirely rule out the possibility that Natco/Juno may succeed in whole or in part in the litigation.

The certainty afforded by the Agreement also allows Celgene to better plan and prepare for generic entry, including having regard to the 25% First New Brand Statutory Price Reduction.

The Agreement will avoid further burdens on Celgene's business and resources (both at first instance and on any appeal), including:

- considerable direct legal and other costs in continuing the Federal Court Proceedings (e.g. solicitor fees, barristers fees and expert witness fees); and

- indirect legal and other costs of Celgene litigation management time in continuing the Federal Court Proceedings (e.g. providing instructions and assistance to external legal representatives in relation to: (i) overall strategy; (ii) preparation of pleadings, evidence and submissions; (iii) complying with any discovery orders; and (iv) other interlocutory or litigation related processes).

The key disadvantage to Celgene is that the Agreement allows for entry earlier than the expiry of the Celgene Patents (assuming the Federal Court Proceedings were to continue and Celgene were to succeed, which Celgene expects will be the case, including in any appeal, if there is no launch 'at risk').

[Redacted]

1.4 ***Provide the following information in relation to the Agreement and provide any Documents which support the responses to the following requested information:***

(a) ***any business case and cost-benefit analysis undertaken to assess whether to enter into the Agreement;***

(b) ***quantify the financial value of the Agreement for Celgene;***

(c) ***quantify the financial value to Celgene of Juno and Natco starting to supply the Generic Products by the Authorised Launch Dates;***

[Redacted]

## 2. Impact on Competition

Celgene Products

2.1 ***Provide a list of wholesale and retail prices for Celgene Products for each indication.***

Celgene confirms that there are no sales to the wholesale channel for Revlimid® and Pomalyst®. Celgene's distributor in Australia, Healthcare Logistics (Australia), currently sells to Pharmacies at the prices set out in Table 4 below. The retail price information in Table 4 below is publically available and has been collated from the PBS/ Medicare websites for Revlimid® and Pomalyst®.

**Table 4: Retail prices for Celgene Products**

| Product | Public PBS Price[2] | Indication |
|---|---|---|
| Pomalyst Cap 3mg Blst 21 | $9,975.00 | relapsed and refractory multiple Myeloma (**RRMM**) |
| Pomalyst Cap 4mg Blst 21 | $9,975.00 | RRMM |
| Pomalyst 3mg CAP 14 Blst | $6,650.00 | RRMM |
| Pomalyst 4mg CAP 14 Blst | $6,650.00 | RRMM |
| | | |
| Revlimid 05mg Cap 14 | $2,996.81 | MM |
| Revlimid 10mg Cap 14 | $3,136.28 | MM |
| Revlimid 15mg Cap 14 | $3,657.73 | MM |
| Revlimid 25mg Cap 14 | $3,952.49 | MM |
| | | |
| Revlimid 5mg Cap Blst 21 | $4,495.22 | MM |
| Revlimid 10mg Cap Blst 21 | $4,704.42 | MM |
| Revlimid 15mg Cap Blst 21 | $5,486.60 | MM |
| Revlimid 25mg Cap Blst 21 | $5,928.74 | MM |
| | | |
| Revlimid 5mg Cap Blst 28 | $5,993.62 | MM Maintenance |
| Revlimid 10mg Cap Blst 28 | $6,272.56 | MM Maintenance |
| Revlimid 15mg Cap Blst 28 | $7,315.46 | MM Maintenance |

Revlimid® is not commercially available in Australia for the treatment of mantle cell lymphoma and accordingly no pricing is available for this indication.

From 1 January 2022, patients may pay up to $42.50 as a co-payment for most PBS medicines or $6.80 with a concession card. After reaching the annual safety net threshold ($326.40 for concession card holders and $1,542.10 for all other patients), general patients pay for any further PBS prescriptions at the concessional co-payment rate and concession card holders receive PBS prescriptions at no further charge for the remainder of that calendar year.[3]

[2] The Public PBS Price is the 'dispensed price for maximum quantity' (DPMQ) on the PBS register.

[3] https://www.pbs.gov.au/info/about-the-pbs

2.2 ***How does the price of Celgene Products compare to the products and suppliers identified in Table 1 of the Application at 4.14(a)?***

Please see attached the document titled "*ex-manufacturer-prices-efc-2022-01-01*", which shows the approved ex-manufacturer price (AEMP) for the pricing quantity of each PBS listed pharmaceutical item in Table 1 of the Authorisation Application.

Potential entrants

2.3 ***What impact will the Agreement have or be likely to have on or in relation to parties who enter or seek to enter with their own generic version of the Celgene Products before the Celgene Patents expire?***

Celgene is not in a position to speculate on how third parties, including generic manufacturers, may respond to any particular event or disclosure of information.

Celgene notes, however, that the fact of the Agreement (as disclosed through the Authorisation process) has revealed publicly that Natco/Juno are entitled to an "early launch" of a generic version of Revlimid® and Pomalyst® prior to the expiry of the Celgene Patents, (although the Authorised Launch Dates remain confidential).

The Authorised Launch Dates will become publicly known on the relevant date if Natco/Juno PBS list or otherwise enter the market on or after that date.

2.4 ***What other parties is Celgene aware of who may consider or may have considered an 'at risk' launch of the generic version of the Celgene Products? Please outline what monitoring Celgene has undertaken with regard to third parties' 'at risk' launch of generic versions of the Celgene Products and to the extent available, provide as much detail of the parties, proposed launch date(s), products, indications, PBS listings, patent licences, and pending or anticipated litigation in relation to each launch.***

Celgene is not generally in a position to speculate on whether other parties may consider a launch 'at risk'. Nor is it in a position to comment on who may have considered a launch 'at risk'. Celgene does not have any insight into the actual or potential plans of generic manufacturers.

However, Celgene notes that on or about 10 July 2021, Dr Reddy's Laboratories (Australia) Pty Ltd (**DRL**), obtained registration on the ARTG, as the sponsor of lenalidomide products indicated for multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma.

Subsequently, Celgene demanded that DRL proffer *inter alia* an undertaking that it would not, without a licence from Celgene, exploit the invention that is the subject of the Celgene Patents in respect of Revlimid® prior to their expiry, including by making, importing, selling, offering to sell or supplying its lenalidomide products registered on the ARTG. [Redacted] DRL refused to give the undertaking and instead proffered an undertaking to the effect that it would not, without a licence from Celgene, exploit the invention that is the subject of the Celgene Patents in respect of Revlimid® prior to their expiry including by *inter alia* making, importing, selling, offering to sell or supplying its lenalidomide products registered on the ARTG, without giving Celgene not less than three months' advance written notice of its intention to do so.

In light of DRL's refusal to provide the undertaking sought by Celgene, on 18 November 2021, Celgene Corporation and Celgene Pty Ltd filed proceeding no VID 678 of 2021 in the Federal Court of Australia against DRL for threatened infringement of certain claims of the Celgene Patents and alleged breaches of the Australian Consumer Law (**DRL Proceedings**).

Celgene notes that ARTG registration is required for inter alia marketing and supply of any pharmaceutical product in Australia. Celgene notes however that while registration permits

the launch of a product in Australia, it does not indicate whether or not (or if so, when) the generic intends to launch 'at risk'.

In addition to Natco/Juno and DRL, Celgene notes that the following generic manufacturers are currently sponsors on the ARTG of products containing lenalidomide as the active pharmaceutical ingredient:

- Sandoz Pty Ltd (**Sandoz**), indicated for multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma;
- Teva Pharma Australia Pty Ltd (**Teva**) indicated for multiple myeloma and myelodysplastic syndromes;
- Cipla Australia Pty Ltd (**Cipla**) indicated for multiple myeloma and myelodysplastic syndromes; and
- DRL indicated for multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma.

The lenalidomide products registered on the ARTG by the above companies are not listed on the PBS nor, to the best of Celgene's knowledge based on the current available information, are they currently being marketed or supplied in Australia.

Celgene undertakes regular monitoring of the ARTG to identify registrations for generic Revlimid® or Pomalyst® products.

In addition to monitoring the ARTG, Celgene also:

- reviews the Pharmaceutical Benefits Advisory Committee (PBAC) Meeting Agendas;
- reviews media reports (e.g. Pharma in Focus, BioPharmaDispatch, HealthIndustry Hub, FiercePharma, Myeloma Australia); and
- gathers intelligence from healthcare professionals, pharmacy customers and third party logistics providers / distributors.

For completeness, Celgene's monitoring activities have not revealed any ARTG registrations (or PBS listings) in respect of pomalidomide (other than Natco/Juno).

2.5 ***To the extent known, other than Natco and Juno, what parties may or are likely to enter the market in the next 10 years with a generic version of the Celgene Products or a substitute to the Celgene Products. For each of these parties, please state when entry is likely to occur if known?***

Celgene's response is limited to responding to the question as it relates to generic versions of the Celgene Products. It is not in a position to comment on potential substitutes for the Celgene Products.

[Redacted]

Otherwise, Celgene is not in a position to know whether any other generic manufacturer of lenalidomide and pomalidomide products intends to enter the market in the next 10 years.

Further, Celgene notes that the Celgene Patents are due to expire over the course of 2022, 2023 and 2027 and by 2 August 2027, the last of the Celgene Patents will have expired. Any generic manufacturer is free to enter the market without potential liability associated with "at risk" entry once the patent(s) that cover the supply of the generic product expire(s) (as identified in the response to question 1.3 above).

2.6 ***Does Celgene have any agreement or arrangement with any of the parties identified in response to 2.4 or 2.5 to supply products in Australia? If so, please provide a copy of the agreement.***

Please see the response given to question 2.5 above.

2.7 **Having regard to the Proposed Conduct, please explain the rationale for including [Redacted]. *Please respond from the perspective of Celgene, as well as the perspective of Natco and Juno if known.***

Celgene is not able to comment from the perspective of Natco/Juno.

[Redacted]

In summary, the Agreement allows for Natco/Juno to enter with generic versions of Celgene's Revlimid® and Pomalyst® earlier than would otherwise be the case in light of the expiry dates of the Celgene Patents (other than 'at risk').

The comments below are not to be taken as a comprehensive, detailed summary of the provisions.

[Redacted]

## 3. Counterfactual

3.1 ***Outline Celgene's strategy and proposed steps in relation to the Generic Products (and other generic versions of the Celgene Products) if ACCC authorisation is not granted and the Agreement does not come into effect. Please provide Documents to support the response to this question.***

[Redacted]

3.2 ***Outline Celgene's likely strategy if Natco and Juno or another third party were to proceed with an 'at risk' launch of generic versions of the Celgene Products. Please provide Documents to support the response to this question.***

In relation to Natco/Juno, Celgene refers to the response to question 3.1 above.

[Redacted]