Our ref: AA1000592
Contact officer: Gavin Jones
Contact phone: 03 9290 1475

6 June 2022

Geoff Carter
Partner
MinterEllison

Dear Mr Carter

**Juno Pharmaceuticals Pty Ltd & Ors applications for authorisation AA1000592 – Extension to statutory timeframe and request for further information**

I refer to the above application for authorisation lodged by Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) (the **Applicants**). I note that on 27 May 2022, the Applicants each consented to the relevant period by which a decision must be made in relation to this application being extended by 8 weeks, to **29 July 2022**.

The purpose of this letter is to outline the circumstances necessitating an extension to the statutory timeframe and to request further information from Juno/Natco that is expected to be important to the ACCC's assessment of the claimed public benefits and detriments arising from the proposed conduct. A similar letter has been sent to Celgene but given the different information we are seeking from each Applicant, the Applicants have received different sets of questions in these requests for information, each of which are discussed broadly below.

**Extension to the statutory timeframe**

The Applicants each provided a substantial volume of material in response to the draft determination. This included material that the ACCC considers raises new issues or provides new information in relation to issues that were considered in the draft determination. For example, there is a greater focus in the new material on claimed public benefits arising from secondary price reductions and in-market discounting that are said to be likely to arise from result of generic competition.

On 4 May 2022, the ACCC proposed a 5-month extension to the statutory timeframe to make a determination (which would have required a decision by 2 June 2022), which it considered to be necessary for it to have sufficient time to consider, test, and consult on the further information provided by the Applicants. While Celgene consented to an extension to the relevant period of 5 months, Juno/Natco did not consent to an extension of this length and only consented to an extension of 8 weeks. The 5-month extension was proposed in circumstances where:

- The ACCC must not grant authorisation unless it is satisfied in all the circumstances that the proposed conduct would result, or is likely to result, in a benefit to the public and the benefit would outweigh the detriment to the public that would result, or be likely to result, from the proposed conduct.

- There are extensive confidentiality claims that the ACCC needs to process before we could begin testing the information with interested parties. As stated in the draft determination, the extent of confidential information under consideration in this matter has limited the ACCC's ability to test, and therefore be satisfied of the likelihood, nature and/or extent of claimed public benefits and claimed lack of detriments.
- To properly test this new information, the ACCC considered it would be necessary to consult with interested parties, including consulting with the Department of Health regarding the Applicants' claimed PBS savings and secondary price reductions.
- The ACCC also anticipated that it would need to make further information requests of the Applicants and other interested parties, including seeking information from generic pharmaceutical companies, which is likely to be key to the assessment of public benefit claims regarding the early launch of generic products.
- The Applicants provided their responses to the draft determination after the due date[1] and have provided late responses to each of the ACCC's other substantive requests for responses or information.[2] There have also been lengthy delays in resolving confidentiality issues,[3] which has materially reduced the time available to the ACCC for assessing the application, and which has made it difficult for the ACCC to progress its assessment to date in a timely manner.
- Celgene provided general information that is critical to the assessment of claimed public benefits and claimed lack of detriments 2 months after the application was lodged [redacted]. Celgene has since then provided selective and incomplete new information about [redacted] but has not disclosed fulsome details that would enable to ACCC to assess and evaluate the extent of likely public benefits and detriments.

In the circumstances described above, the ACCC emphasises the importance of the Applicants responding to this current request, and any future requests fulsomely and expeditiously, including in relation to each Applicant's confidentiality requests.

## Request for information

### *Celgene*

At the time of the draft determination, the ACCC was uncertain of the nature of generic competition that may occur without the Proposed Conduct, which is critical to the ACCC's assessment.[4] As indicated in the draft determination, this uncertainty arose largely because of [redacted]. Despite this, [redacted]

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1 The ACCC's deadline for responses was 20 April 2022. Juno/Natco provided its response on 27 April 2022, Celgene provided its response on 13 May 2022.

2 In relation to the ACCC's request for information of 16 December 2021, Juno/Natco provided its response 1 day after the ACCC's deadline, and Celgene provided its response 25 days after the deadline. In relation to the Applicants' responses to interested party submissions prior to the draft determination, Juno/Natco provided its response 2 days after the ACCC's deadline, and Celgene provided its response 6 days after the deadline. These examples do not include the time taken to resolve the parties' confidentiality claims.

3 For example, the ACCC sought consent to disclose the authorised launch dates to the Department of Health/PBS on 27 January 2022. Juno/Natco provided consent on 23 February 2022; Celgene resolved its confidentiality issues in relation to this request on 29 April 2022.

4 ACCC, Juno Pharmaceuticals Pty Ltd & Ors, Draft Determination 23 March 2022, [4.80].

5 See for example, ACCC, Juno Pharmaceuticals Pty Ltd & Ors, Draft Determination 23 March 2022, Executive Summary p 2-3.

6 Statutory Declaration of Prudence Smith, 4 May 2022.

*Lenalidomide*

Regarding lenalidomide, the Statutory Declaration of Prudence Smith[7] states that:

[redacted]

The submissions made in the Statutory Declaration of Prudence Smith after the draft determination [redacted]

*Pomalidomide*

Regarding pomalidomide, the Statutory Declaration of Prudence Smith states that [redacted]

[redacted]

In order to inform the ACCC's assessment of the potential impact of the Proposed Conduct, we have included a request for further information and documents from Celgene that the ACCC considers is important to its assessment. Without this information, the Commission may not be satisfied that the authorisation test is met.

Regarding any confidentiality obligations applicable to the disclosure of this information, the ACCC expects that Celgene will [redacted] required to enable it to disclose the information, including information the ACCC is seeking to test with the Department of Health.

***Juno/Natco***

Separately, we have also requested further information from Juno/Natco (**Attachment A**) in relation to Risk Management Plans and its pricing strategy in relation to generic entry, to provide further context and substantiation of its submissions in response to the draft determination on the potential detriments arising from a 'first mover advantage' and benefits arising from secondary price reductions and in-market discounting.

Your response is required by **5pm (AEST) 15 June 2022**.

Please note that we may have further information requests for the Applicants, particularly in respect of their respective responses to interested party submissions following the draft determination.

A copy of this letter will be placed on the ACCC's public register once a response to the information request is received.

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7 Statutory Declaration of Prudence Smith, 4 May 2022, [10]-[11].

8 Statutory Declaration of Prudence Smith, 4 May 2022, [14].

If you wish to discuss any aspect of this matter please do not hesitate to contact me on 03 9290 1973 or lyn.camilleri@accc.gov.au or Gavin Jones on 03 9290 1475 or gavin.jones@accc.gov.au.

Yours sincerely

Lyn Camilleri
General Manager
Competition Exemptions

**Attachment A: Request for further information**

1. Provide the three most recent supply contracts Juno has entered into with each of the following categories of customers:
    a. public hospitals;
    b. private hospitals;
    c. pharmacies;
    d. state procurement entities; and
    e. any other customer category Juno/Natco considers relevant,

    where those supply contracts include a 'price refresh' clause and/or 'market dynamics' clause.[9]
2. Juno/Natco's economic expert report submits that [redacted]. Provide Juno/Natco's commercial strategy for pricing its generic lenalidomide products. For lenalidomide, describe how this strategy changes in the following circumstances:
    a. Juno/Natco is the only generic manufacturer who enters on the authorised launch date;
    b. Juno/Natco enters with one other generic manufacturer on the authorised launch date;
    c. Juno/Natco enters with two other generic manufacturers on the authorised launch date;
    d. Juno/Natco enters with three or more other generic manufacturers on the authorised launch date.
3. Does the response to questions 2(b)-(d) differ if the other generic(s) enter after the Juno/Natco authorised launch date?
4. Juno/Natco's economic expert report submits that [redacted]. Provide Juno/Natco's commercial strategy for pricing its generic pomalidomide products. For pomalidomide, describe how this strategy changes in the following circumstances:
    a. Juno/Natco is the only generic manufacturer who enters on the authorised launch date;
    b. Juno/Natco enters with one other generic manufacturer on the authorised launch date;
    c. Juno/Natco enters with two other generic manufacturers on the authorised launch date;
    d. Juno/Natco enters with three or more other generic manufacturers on the authorised launch date.
5. Does the response to questions 4(b)-(d) differ if the other generic(s) enter after the Juno/Natco authorised launch date?
6. [redacted] and in circumstances where there is [redacted]; please advise whether or not you still consider that an alternative settlement could not be reached in the counterfactual, and why this is the case?

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[9] As defined in the Expert report of George Siolis, 22 April 2022, [68].

[10] Expert report of George Siolis, 22 April 2022, [55]

[11] Expert report of George Siolis, 22 April 2022, [55]