

21 July 2022

## PUBLIC VERSION

Gavin Jones  
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Australian Competition & Consumer Commission

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Dear Gavin

### **Juno Pharmaceuticals Pty Ltd & Ors applications for authorisation AA1000592 – response to public submissions**

The following colour coding denotes confidential information and the associated disclosure restrictions:

■ is confidential to Juno/Natco (not to be shared with Celgene or the public)

■ is confidential to Celgene (not to be shared with Juno/Natco or the public)

#### **1. Introduction**

- 1.1 We act for Juno Pharmaceuticals Pty Ltd (**Juno**) and Natco Pharma Limited (**Natco**) (**Juno/Natco**).
- 1.2 We refer to the Australian Competition and Consumer Commission's (**ACCC**) email dated 19 July 2022 with respect to the application for authorisation dated 3 December 2021 (the **Application**) noting that two further public submissions had been received.
- 1.3 The ACCC has since published these submissions including the Department of Health (the **Department**) and Aged Care's response dated 15 July 2022 to the ACCC's questions regarding Celgene's expert report and additional questions in the ACCC's email dated 29 June 2022 (**DOH Submission**).
- 1.4 The purpose of this letter is to respond to the DOH Submission.

#### **2. DOH Submission supports the public benefits claimed by the Applicants**

- 2.1 Juno/Natco consider that the DOH Submission clearly substantiates and gives significant weight to the Applicants' claimed public benefits, particularly when combined with the confidential submissions of the Applicants. In particular the DOH Submission supports the Applicants' claims that the Proposed Conduct would:
  - (a) ■ result in the 25% first generic brand statutory price reduction<sup>1</sup>;
  - (b) result in public benefit by virtue of increased market density through Juno's generic entry leading to greater downward pressure on price on the basis of the general principle that the

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<sup>1</sup> DOH Submission, response to Q1 regarding Celgene's expert report.

greater the market density for a given pharmaceutical, the greater the expected downward pressure on the PBS price<sup>2</sup>;

- (c) this downward pressure will be more pronounced when multiple generic brands are listed on the PBS at or about the same time<sup>3</sup>, [REDACTED]
- (d) increase the likelihood of the first price disclosure price reduction occurring at an earlier stage and generating price reductions in excess of the 10 percent statutory threshold<sup>4</sup>;
- (e) result in cost savings to the PBS as a result of these price reductions<sup>5</sup>, which will take effect at an earlier time as a result of the Proposed Conduct;
- (f) result in lower prices and thus retained income for customers / purchasers even if the discount does not exceed the 10 percent statutory threshold<sup>6</sup>; and
- (g) have the potential to improve patient access via new PBS indications and increased affordability where administered outside the PBS reimbursement environment, although the Department does not express a view on whether these benefits would eventuate for the reasons set out in its response to Question 4 of the ACCC's additional questions dated 29 June 2022<sup>7</sup>.

### 3. Additional submissions

3.1 Juno/Natco make the following additional submissions:

3.2 The Department's reservations about the Gregory O'Toole report do not qualify the Department's support for the general proposition that generic entry results in PBS savings as a result of statutory price reductions and/or price disclosure related price reductions, lower prices paid by customers and retained income for customers for PBS listed medicines. The Department only qualifies its support regarding the Gregory O'Toole report's approximation of the specific timing and extent of price disclosure related price reductions for lenalidomide<sup>8</sup>. [REDACTED]

3.3 A 'benefit to the public' for the purposes of section 90 of the *Competition and Consumer Act 2010* (Cth) is not limited to benefits directly accruing to public institutions. Therefore the benefit to private hospital groups of Juno/Natco's early entry in the markets for pomalidomide and lenalidomide that would occur if the Proposed Conduct is authorised (in the form of price reductions) should be characterised as a public benefit, notwithstanding the Department's description of these as private benefits<sup>9</sup>.

3.4 The Department's response regarding litigation by the Commonwealth<sup>10</sup> is of no relevance to this Application. There is currently no interlocutory injunction in place, nor any extant application for such relief, that could (if supported by an undertaking as to damages) provide the necessary

<sup>2</sup> DOH Submission, response to Q3 regarding Celgene's expert report and O'Toole declaration at paragraph [57].

<sup>3</sup> DOH Submission, response to Q3 regarding Celgene's expert report.

<sup>4</sup> DOH Submission, response to Q3 regarding Celgene's expert report.

<sup>5</sup> DOH Submission, response to Q8 regarding Celgene's expert report in which the Department notes it "considers it appropriate to quantify the potential cost savings to the PBS using the percentages by which a medicine's price is reduced." See also the DOH Submission, response to Q4 of the ACCC's additional questions dated 29 June 2022.

<sup>6</sup> DOH Submission, response to Q3 of the ACCC's additional questions dated 29 June 2022.

<sup>7</sup> DOH Submission, response to Q4 of the ACCC's additional questions dated 29 June 2022, where the DOH confirms that generally speaking price competition can result in those outcomes.

<sup>8</sup> DOH Submission, responses to Q4 and Q9 regarding Celgene's expert report. The Department still supports the proposition that there is a likely association between the number of competing PBS brands and both the occurrence of price disclosure reductions and the likely magnitude, and timing of, the first price disclosure reduction (DOH Submission, response to Q7 regarding Celgene's expert report).

<sup>9</sup> DOH Submission, response to Q3 of the ACCC's additional questions dated 29 June 2022.

<sup>10</sup> DOH Submission, response to Q5 of the ACCC's additional questions dated 29 June 2022.

foundation for such a claim.



#### **4. Conclusion**

4.1 The DOH Submission clearly substantiates the Applicants' claimed public benefits, and in the absence of any public detriments, Juno/Natco submit that the ACCC should be satisfied that the net public benefit test is met.

Please contact us if the ACCC requires further information.

Yours faithfully

**MinterEllison**

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[REDACTED]

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<sup>11</sup> Affidavit of Mark Crotty, paragraph [109]. See further Juno/Natco's response to the Draft Determination dated 22 April 2022, at paragraph [6.26].