RESPONSE TO PUBLIC SUBMISSIONS[1]

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1. Overview

1.1 As explained in the Authorisation Application, authorisation should be granted because the Proposed Conduct has no public detriments and has clear and substantial public benefits compared to any other counterfactual that would enable Natco/Juno to launch the Generic Products free from the risk of being exposed to substantial damages (namely, Natco/Juno waiting to launch until after the expiry of the term of the Celgene Patents or after the conclusion of the Proceedings, including any appeals, and only were it to be successful).

1.2 The third party submissions and file notes of meetings on the ACCC's public register as at the date of this response (**Submissions**)[2] do not suggest that authorisation should not be granted or alter the conclusion in the Authorisation Application that a clear net public benefit is likely to arise from the Proposed Conduct and, accordingly, authorisation should be granted.

1.3 On the contrary, the vast majority of Submissions acknowledge factors that are likely to constitute public benefits arising from the early entry of the Generic Products into the Relevant Markets (including additional benefits to those relied on by the Applicants, in the form of savings to State and Territory governments as funders and operators of public hospitals and the potential for extension of PBS funding to new drug combinations and additional indications for lenalidomide and pomalidomide). Celgene notes that the limited concerns that have been expressed in the Submissions are not relevant to the ACCC's assessment of the Authorisation Application.

1.4 The Submissions confirm that, given the absence of structural impediments for hospitals, pharmacies, prescribers and patients to access the Generic Products, there will be public benefits from the Proposed Conduct in the form of:

(a) cost savings to the Commonwealth through PBS price reductions;

(b) cost savings for State and Territory governments through competitive public hospital tender processes;

(c) the possibility of new PBS listed drug combinations involving lenalidomide and pomalidomide and/or broader indications for lenalidomide and pomalidomide, delivering benefits to patients who may be able to access additional treatments; and

(d) alternative sources of supply and treatment options for patients who self-fund treatment with lenalidomide and pomalidomide.

1.5 Celgene has provided more detailed comments in respect of the key aspects of the Submissions below. For completeness, the fact that this response does not address all matters raised in the Submissions does not indicate that Celgene agrees with those matters, but rather that Celgene has confined its response to only addressing relevant and key points in a concise manner to assist the ACCC with its assessment of the Authorisation Application.

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

[2] See attached Annex 1 containing a full list of the Submissions.

2. Myeloma Australia submission and file note

2.1 Myeloma Australia expressly acknowledges the benefit that '*access to generic versions of the medicines in question (Revlimid and Pomalyst) will reduce financial burden on both patients and the health system as a whole*.'

2.2 The above statement is consistent with the Applicants' position that the early introduction of generic versions of lenalidomide and pomalidomide will result in significant savings to the Commonwealth under the PBS, both via the mandatory statutory 25% price reduction and also as a result of additional and ongoing price reductions from price disclosure processes (see in particular paragraphs 5.15 and 5.18 of the Authorisation Application). There will also be further savings for public hospitals from increased competition in tender processes.

2.3 Myeloma Australia may not be able to quantify the magnitude of those savings. However, Myeloma Australia does, nonetheless, acknowledge that savings will arise – which, as noted in the Authorisation Application, constitute a public benefit.

2.4 Myeloma Australia notes that, following the expected reduction in the cost to the PBS of lenalidomide and pomalidomide products on generic entry, the Pharmaceutical Benefits Advisory Committee (**PBAC**) may revise PBS listings. This would allow clinicians to prescribe lenalidomide and pomalidomide in new combinations. This potential increased choice for clinicians in their prescription decisions would represent a public benefit, including by allowing clinicians to further customise treatment to meet individual patient therapeutic needs.

2.5 For completeness, Myeloma Australia states that '*Ideally there would be competition in the market for these generic medicines*'. [Redacted]

3. Tasmanian Department of Health file note

3.1 The Tasmanian Department of Health refers to public benefits that are likely to arise from the Proposed Conduct due to '*the drop in the cost price which will reduce the cost to the PBS, state, or individuals. This will have flow on benefits for public health*.' Celgene agrees with this statement and the description of the public benefits.

3.2 The Tasmanian Department of Health refers to the tender process that it engages in for the supply of pharmaceuticals to public hospitals. The Tasmanian Department of Health notes that it will enter into a contract with a generic supplier if appropriate, including based on price. The Agreement therefore permits Natco/Juno to contract with the Tasmanian Department of Health and supply the Generic Products to public hospitals earlier than would otherwise be the case without the Agreement. In addition, where the cost of the Natco/Juno generic product is discounted vis-a-vis Celgene's product, the Department is afforded an opportunity to save costs earlier than without the Proposed Conduct.

3.3 The Tasmanian Department of Health notes that there are further public benefits that will result from the price reduction to patients following generic entry, specifically increased access by patients who self-fund to a significant number of non-PBS listed lenalidomide and pomalidomide treatments:

> *The Department is aware of around 15 other indications for lenalidomide and 3-4 other indications for pomalidomide that are not PBS funded. If the price for these products reduces as a result of generic entry, this could open up the benefits for patients who could self-fund these medicines and receive them more freely through government-funded systems.*

3.4 Celgene agrees that the expected reduction in the price of lenalidomide and pomalidomide products arising from generic entry would also benefit self-funded patients.

3.5 In addition, as a result of the expected reduction in the price of lenalidomide and pomalidomide products following generic entry, PBS funding may be extended to additional indications (based on a favourable cost/benefit assessment by the PBAC). There is a public benefit from increased indications being listed on the PBS. Importantly, this means that more patients will be able to access lenalidomide and pomalidomide at heavily subsidised / discounted prices in more treatment scenarios. Furthermore, this increased / broader access is brought forward with the Proposed Conduct and represents a significant public benefit.

3.6 Celgene also notes that these public benefits would be similarly enjoyed by each of the Australian States and Territories.

3.7 The Tasmanian Department of Health states that '*in the high-cost oncology space, it has previously seen originators pull out of the market when generics enter*'. [Redacted]

4. The Society of Hospital Pharmacists of Australia file note

4.1 The Society of Hospital Pharmacists of Australia notes that:

> *If a high-priced medicine becomes significantly less expensive due to generic entry, that may improve access for inpatients, as there are generally less budgetary restrictions on lower-cost medicines for inpatient use.*

4.2 Celgene notes that the Society of Hospital Pharmacists of Australia represents members who supply the majority of multiple myeloma medicines in Australia. Celgene considers that a public benefit arises when hospital pharmacies commence supplying generic products as, having obtained the product more cheaply, they will be able to apply savings in hospital budgets to providing other health improvement outcomes. Celgene also considers that lower prices through increased competition will increase access by non-PBS subsidised patients to these important medicines and notes that this will occur earlier with the Proposed Conduct, leading to a significant public benefit.

5. Dr Nick Murphy submission

5.1 Dr Nick Murphy refers to a number of public benefits arising from generic entry, noting it will '*save the PBS money*' and '*Price reductions will also impact in-patient prescriptions, which are not funded by the PBS.*'

5.2 Dr Murphy's statements support the Applicants' position that public benefits arise from the reduction in the PBS price. It also raises an additional public benefit regarding prices for non-PBS subsidised patients (as do a number of the other submissions, as noted above).

5.3 Dr Murphy notes that '*patients may decide to fund one of the unsubsidised drugs to add to an existing combination. Generic entry (and associated price reduction) may make it more accessible for these patients.*'

5.4 Celgene agrees that this can occur where practitioners have medical evidence to prescribe such combinations for a patient's therapeutic benefit. Celgene also notes that Natco/Juno's entry will necessarily lead to increased competitive pricing pressures through additional supply. While self-funded patients represent a small proportion of the total number of lenalidomide and pomalidomide users, it will result in a substantial benefit for those users and have other flow on effects.

5.5 Dr Murphy also notes that '*Some patients and prescribers may be apprehensive to switch from a branded product to a generic*'. To the extent that such "apprehension" does arise, this is only a possibility where patients are already being treated with lenalidomide or pomalidomide, as opposed to new patients. Celgene submits that the possibility of a limited pool of patients continuing to use Revlimid® or Pomalyst® after generic entry does not undermine the public benefits referenced by Dr Murphy in his submission or those relied on by the Applicants.

6. The Pharmacy Guild of Australia file note

6.1 The Pharmacy Guild of Australia states that '*Higher cost drugs take a lot longer to reduce in price as a result of discounting.'*

6.2 It is not clear to Celgene precisely the comparison that is intended by the Pharmacy Guild of Australia. If the Pharmacy Guild of Australia is suggesting that headline discounts are smaller for higher cost drugs relative to lower cost drugs, then Celgene would note that even a smaller relative discount to a higher cost drug would result in a high overall reduction in price (with significant public benefits). Indeed, in many cases, such savings may exceed those which would flow from a higher level of discount for a lower cost drug.

6.3 Celgene further notes that the price disclosure regime that applies following generic PBS listing progressively reduces the price for PBS medicines which are subject to competition, ensuring better value for money from these medicines. Specifically, companies are required to disclose details of their pricing practices, including discounts and incentives, which are then used to calculate the price of the particular medicine. Reductions occur on 1 April and 1 October each year, based on the weighted average price of each of the supplied products. The price disclosure regime will reduce the dispensed price of the products with increased competitive supply, including by way of price discounts and incentives to customers and pharmacists.

6.4 The Pharmacy Guild of Australia has also noted that: '*The volume of patients is not there – therefore, there is no economies of scale that they can absorb at the wholesale level'*. Celgene notes that the Pharmacy Guild of Australia represents community or retail pharmacies. Multiple myeloma is a comparatively rare condition, with medicines commonly dispensed in hospital or by hospital pharmacies, which tend to hold more stock than a community or retail pharmacy. Therefore, while this statement may be correct at the community/retail pharmacy level (where the Pharmacy Guild of Australia notes that '*Community pharmacies will generally not keep stock of Revlimid and Pomalyst unless they have patients on these medicines'*, save for those associated with a hospital), it is not the case for hospital pharmacies. As the Society of Hospital Pharmacists of Australia notes: '*The state procurement bodies will go out to market and tender for medicines under a state-wide contract (enables hospitals to draw on economies of scale)*'. Celgene agrees with this statement and considers that it reflects the reality that hospitals do have economies of scale, which the community/retail pharmacies may not.

7. IP Australia submission

7.1 IP Australia has provided '*further information about the re-examination of Celgene Patents*'. Celgene considers that the matters raised in IP Australia's submissions do not warrant substantial consideration by the ACCC in its assessment of the Authorisation Application.

7.2 The mere fact that the Commissioner *may* elect to re-examine a patent at any time, including after a third party withdraws a re-examination, merely reflects a statutory right afforded to the Commissioner. However, the exercise of this power may lead to the Commissioner issuing a decision that the scope of the protection of a patent be altered or revoked, either partially or fully, or equally to a decision affirming validity. Celgene notes that each of the Celgene Patents were granted by IP Australia itself following an examination process.

7.3 In this regard, Celgene endorses paragraph 2.5 of the response to the public submission submitted by Natco/Juno to the ACCC dated 4 March 2022. For the record, Celgene considers that paragraphs 2.6(a) to (c) of that response do not accurately characterise the Celgene Patents nor accurately describe the nature of the adverse report in relation to the '484 patent.

7.4 Celgene also notes that, where an adverse report is issued against a patent through re-examination (as is the case with only one of the Celgene Patents that are the subject of re-examination requests, namely AU2010201484), the patentee is afforded the right to respond (including by filing evidence, submissions, and requesting a hearing) in order to overcome the adverse report, thereby affirming validity. Those processes will not end prior to the Authorised

Launch Date and indeed are unlikely to end prior to expiry of the last of the Celgene Patents. Furthermore, a decision to revoke a patent following re-examination is a decision against which an appeal lies to the Federal Court of Australia as of right (section 101(4) of the Patents Act).

8. Conclusion

8.1 The Submissions support the Applicants' position that there are substantial public benefits (and, indeed, reference additional public benefits) compared to any other counterfactual that would enable Natco/Juno to launch the Generic Products free from the risk of being exposed to substantial damages (namely, Natco/Juno waiting to launch until after the expiry of the term of the Celgene Patents or after the conclusion of the Proceedings, including any appeals, and only were it to be successful).

8.2 It is also clear from the Authorisation Application and the Submissions that no public detriments are likely to arise from the Proposed Conduct.

8.3 As a result, Celgene continues to consider that authorisation should be granted.

Annex 1 – List of submissions

1. Submission from IP Australia dated 14 January 2022
2. Submission from Myeloma Australia dated 28 January 2022
3. File note of meeting with Myeloma Australia dated 10 February 2022
4. PBS data from the Department of Health dated 11 February 2022
5. File note of meeting with Dr Nick Murphy, a Consultant Haematologist at Royal Hobart Hospital dated 11 February 2022
6. File note of meeting with The Pharmacy Guild of Australia dated 14 February 2022
7. File note of meeting with The Society of Hospital Pharmacists of Australia dated 16 February 2022
8. File note of meeting with the Tasmanian Department of Health dated 21 February 2022