Department of Health and Aged Care's responses to the ACCC's questions regarding Celgene's expert report

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In considering the matters presented in the report of Celgene's expert, Mr Gregory O'Toole, the ACCC has requested the Department's assistance with the following matters:

1. **Confirm whether the description of statutory price reductions at paragraphs 29-31 is accurate.**

With a few exceptions, the description of the statutory price reductions (SPR) contained in paragraphs 29-31 is accurate.

The first exception concerns Mr O'Toole's statement that 'the 15th anniversary statutory price reduction increases to 30% **from** 1 April 2027' (emphasis supplied). By virtue of amendments introduced by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021* (Cth) ('Amendment Act'),[1] certain drugs will be subject to a 30% 15th anniversary SPR **on** 1 April 2027.

It is worth noting that the anniversary price reductions detailed in paragraph 30 are agreed by the Australian Government with key stakeholders in the medicines industry, Medicines Australia and the Generic Biosimilar Medicines Association. The anniversaries that trigger reductions as well as the magnitude of those reductions are not static and may change based on the terms of the agreement that are effective at any one time. In addition to the reductions listed by Mr O'Toole, a reduction of 1.48% may apply to drugs on their 15th anniversary of listing under the newly introduced section 99ACP.

The description in paragraph 31 of a 25% discount applying to both the first new brand and the first listed brand of the pharmaceutical is generally correct. A 25% reduction on the existing approved ex-manufacturer price (AEMP) applies in these circumstances where price reductions from 1 January 2016, or if the pharmaceutical item listed after 1 January 2016, from the date of listing, totals 35%. This discount may not occur in circumstances where the approved ex-manufacturer price on 1 January 2016, or if listed after 1 January 2016, from the date of listing, has been reduced by 60% or more. Additionally, the first new brand statutory price reduction remained 16% until 1 October 2018.

Additional Information:

Lenalidomide was first listed on the Pharmaceutical Benefits Scheme (PBS) on 1 November 2009. It was subject to a 10% 10 year anniversary SPR on 1 April 2020. Following the commencement of the Amendment Act, lenalidomide will be subject to a 26.1% 15 year anniversary SPR on 1 April 2025, provided no generics are listed before this date. Should a generic list prior to 1 April 2025, and lenalidomide has not been subject to any additional reductions, a 25% price reduction to the effective price (as opposed to the AEMP) will apply. Subsequently, a reduction of 1.48% will apply to lenalidomide on 1 April 2025 under section 99ACP of the Amendment Act.

Pomalidomide was first listed on the PBS on 1 August 2015. It was subject to a 5% 5 year anniversary SPR on 1 April 2021. Following the commencement of the Amendment Act, pomalidomide will be subject to a 5% 10 year anniversary SPR on 1 April 2026, provided no generics are listed before this date. Should a generic list prior to 1 April 2026, and pomalidomide has not been subject to any additional reductions, a 25% price reduction to the effective price will apply.

2. **Confirm whether the description of the price disclosure reductions at paragraphs 37-39 is accurate.**

[1] Section 99ACKB of the *National Health Act 1953* (Cth), introduced by s. 75 of the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021* (Cth). This provision commenced on 1 July 2022.

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All suppliers of F2 pharmaceuticals are required to disclose in relation to price disclosure, except for suppliers of brands listed for exempt items.[2] The description of the price disclosure price reductions (PDPR) mechanism at paragraphs 37–38 is otherwise accurate.

Paragraph 39 states that from 1 July 2022, 'sales to public hospital pharmacy will be included in the price disclosure obligation and WADP calculation after an F2 pharmaceutical has undergone six price disclosure cycles', with reference to the 2022-2027 Strategic Agreement with Medicines Australia. Amendments have been introduced to take effect from 1 April 2023[3] and will apply to price disclosure data collection periods from 1 October 2022 onwards.

In addition to the changes mentioned in paragraph 39, the Department notes that other changes to PDPR resulting from the strategic agreements with the medicines industry (2022-2027) will take effect from 1 July 2022. These changes will be given effect by the Amendment Act and include, among other things, the introduction of floor prices for certain brands, as well as changes to the threshold for applying price disclosure price reductions.[4]

3. Does the PBS have any comment on Mr O'Toole's submissions at paragraph 57 and does the PBS anticipate that this submission would be applicable in this Application?

The Department agrees with the submissions made by Mr O'Toole at paragraph 57. In particular, the Department agrees that, all other things being equal, the greater the market density for a given pharmaceutical, the greater the expected downward pressure on the PBS price. This downward pressure would be expected to be more pronounced when multiple generic brands are listed on the PBS at or about the same time. In the Department's experience, the first price disclosure price reduction is more likely to occur at an earlier stage and to generate price reductions in excess of the 10 percent statutory threshold in these circumstances.

Whether, and the extent to which, those observations are applicable to the current Application depends on when subsequent generics seek access to the market, assuming the proposed conduct is authorised by the ACCC. The applicability of those submissions also depends on how Celgene responds to any attempts by subsequent generics to enter the market prior to Celgene's patents expiring.

A more fulsome discussion of these issues is provided in the Department's response to question 9, which concerns the same issues.

4. Does the PBS have any comment on the methodology described at paragraphs 59, 67-70, 76-77 and how does the methodology adopted impact the analysis and conclusions in the report? In particular:

a. The grouping of the data into three categories as described in paragraph 70.

b. The use of the number of brands, rather than the number of generic manufacturers/sponsoring companies, as a measure of the number of competitors.

[2] *National Health (Pharmaceutical Benefits Scheme-Exempt items - Section 84AH) Determination 2017* (https://www.legislation.gov.au/Details/F2021C01068).
[3] *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021* (https://www.legislation.gov.au/Details/F2021L01797).
[4] For further information, see Australian Government Department of Health, *Price Disclosure Reforms under the New Strategic Agreement – Fact Sheet*, 2022: https://www.pbs.gov.au/industry/pricing/price-disclosure-spd/fact-sheet-new-strategic-agreement-price-disclosure-reforms.pdf.

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The methodology described in Mr O'Toole's report uses the information extracted from the relevant AEMP spreadsheets for 39 drugs listed on the PBS between 1 January 2015 and 1 April 2022. The information is represented in two ways: 1) by grouping the 39 drugs into three sub-groups defined by the number of PBS listed brands (Annexure GIO-1); and 2) by individually analysing 29 drugs (Annexure GIO-2).

We understand that Mr O'Toole adopted this methodology for the purpose of demonstrating his general observations at paragraph 57.[5] We accept that the methodology is reasonably appropriate for this purpose. However, the Department has reservations about using this methodology to predict the possible price reductions for lenalidomide, as Mr O'Toole does in paragraph 109. That is because, as Mr O'Toole notes in paragraph 105, 'individual pharmaceuticals will exhibit individual behaviours having regard to matters such as the nature of the pharmaceutical, the market for that pharmaceutical and the capacity of individual companies to compete in the market.' Mr O'Toole's approach of grouping drugs by the number of listed brands only does not allow consideration of whether these differences might have an impact, and if so what it would be.

In paragraph 109, Mr O'Toole suggests that the timing and extent of AEMP price reductions for lenalidomide 'will approximate the curve for the median cumulative price disclosure reduction for pharmaceuticals with 7 or more listed brands' (as depicted by the yellow curve on p. 2 of Annexure GIO-1), with 'the 1st price disclosure reduction taking place in cycle 1 and a cumulative percentage reduction of AEMP of 80% after 10 price disclosure cycles.' That suggestion is made despite the fact that there are a number of material differences between lenalidomide and the eleven drugs with 7 or more listed brands as of 1 April 2022.

In that regard, we note that lenalidomide is:

- Listed on the Highly Specialised Drugs Program (HSDP) under s. 100 of the *National Health Act 1953* (Cth) ('Act'), for administration in public and private hospitals;
- Available in encapsulated form;
- Subsidised for the treatment of:
    - Multiple myeloma as a:
        - Monotherapy;
        - Dual combination therapy (with dexamethasone);
        - Triple combination therapy (with dexamethasone and bortezomib).
    - Myelodysplastic syndromes.

We also note Mr O'Toole's observation at paragraph 60 that 'the PBS prescribing criteria [for lenalidomide] are complex in that prescribers are required to make a written authority request with a substantial volume of supporting patient information.'

None of the eleven drugs with seven or more PBS listed brands as of 1 April 2022 (represented on p. 5 of Annexure GIO-1) share all of these attributes and none are indicated for the treatment of any of the abovementioned conditions. Only one drug (bosentan) is listed on the HSDP with the same manner of administration. Two other drugs, ganciclovir and zoledronic acid, are listed under the HSDP, but have a different method of administration. Zoledronic acid is also listed on the General Schedule under s. 85 of the Act.[6]

[5] See paragraphs 58-9 and 66-7 of Mr O'Toole's report.
[6] The under-representation of drugs listed under the HSDP extends to the broader cohort of drugs analysed by Mr O'Toole. Of the 29 drugs considered in the analysis at the individual level, 22 medicines are listed on the

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With few exceptions, drugs listed on the HSDP are primarily dispensed in public and private hospital settings and there are important differences between the procurement of drugs by hospital pharmacies, on the one hand, and by community pharmacies, on the other. As such, it may have been more appropriate to analyse price disclosure reductions generated by generic drugs listed on the HSDP within the period adopted by Mr O'Toole. The fact that, to date, sales to public hospitals have been excluded from price disclosure data in relation to all of the drugs in the sample also adds to the difficulty in comparing the data.

For these and other reasons discussed in our response to question 12, we would approach with caution the conclusions reached by Mr O'Toole at paragraph 109.

Regarding the methodology more generally, it is not clear to us why the rationale for excluding 10 drugs from the analysis at the individual level (as mentioned at paragraph 76) did not also result in the exclusion of those same drugs from the grouped analysis (described at paragraph 70).

Finally, in conjunction with the analysis involving the number of brands per drug, an analysis by manufacturers/sponsors (known under the Act as the Responsible Person (RP)) corresponding to those brands could also be informative regarding the number of competitors. This is important given the fact that in some instances, an RP can be the supplier of more than one generic brand of a medicine listed on the PBS and these brands may be priced at the same level.

5. Is there any relationship between the number of brands and the number of generic manufacturers/sponsoring companies?

As stated in the response to question 4, an RP can be the supplier of one or multiple brands of a PBS listed medicine. In some instances, an RP can be the supplier of both the originator and a generic brand of the drug.

6. Is it possible to identify the sponsoring company from the public data?

Yes, the RP of a brand of a pharmaceutical item listed on the PBS can be located within the AEMP spreadsheets available on the PBS website. For example, the AEMP for lenalidomide (rows 5603 – 5659 and pomalidomide (rows 7677 – 7684) (excluding the Efficient Funding of Chemotherapy Program) corresponding to each strength dosage and pack size can be accessed at: https://www.pbs.gov.au/industry/pricing/ex-manufacturer-price/2022/ex-manufacturer-prices-non-efc-2022-06-01.xlsx. Celgene Pty Ltd is listed as the RP for both Revlimid and Pomalyst (see column 'I').

In addition, the National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010) outlines the conditions and circumstances under which lenalidomide and pomalidomide are listed on the PBS, including the RP for Revlimid and Pomalyst.[7]

7. Does the PBS have any comment on Mr O'Toole's submission at paragraphs 105 and 106 that 'individual pharmaceuticals will exhibit individual behaviours having regard to matters such as the nature of the pharmaceutical, the market for that pharmaceutical and the capacity of individual companies to compete in the market'? In the PBS' experience, do these factors have any impact on price disclosure reductions?

General Schedule of the PBS. Only 7 drugs are listed on the HSDP, of which 3 have dual listing under the HSDP and the General Schedule.

[7] National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010): https://www.legislation.gov.au/Details/F2021C00191.

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The Department concurs with the following aspects of Mr O'Toole's statements at paragraphs 105 and 106, that:

- Individual pharmaceuticals will exhibit individual behaviours;
- There is a likely association between the number of competing PBS brands and the occurrence of price disclosure reductions;
- There is a likely association between the number of competing PBS brands and the likely magnitude, and timing of, the first price disclosure reduction.

As noted in our answer to question 3 above, experience demonstrates that these factors individually and collectively impact the operation of the PDPR regime.

7.1 Further, are any other factors relevant to price disclosure reductions, including:

a. The type of medication, including any categories of medication the PBS considers relevant.

b. The mode by which medication is delivered;

c. The number of patients taking the medication;

d. The typical length of program for the medication;

e. The original price of the medication.

The determination of price disclosure reductions does not rely on the classification of pharmaceuticals according to therapeutic classes or groups. The presence of biosimilars and generics may affect the magnitude of applied price disclosure reductions not only due to the direct discounting done by RPs, but also due to a price disclosure mechanism where sales and revenue data for originator brands may be excluded from price disclosure reductions.

Outside of litigation associated with particular drugs the Department has not investigated nor identified any correlation between the factors that you have listed and price disclosure reductions, and so cannot rule in or out the possibility that those factors affect the market share and pricing of generic products which ultimately are determinative of price disclosure reductions.

Other factors that similarly may or may not be relevant include the presence of generic brands marketed by the responsible person for the originator brand; the size of the Australian market for the drug (in terms of volume and/or value); the identity of the particular companies responsible for any generic brands and the breadth of their relationships with pharmacies and hospitals; changes in overall market behaviour (in the pharmaceutical market) over time; the availability of the drug over the counter (outside of the PBS); the addition of a brand price premium to any brand; the delisting of the originator brand from the PBS; and whether generic entry was restrained by a Court before it ultimately occurred. That list is not intended to be exhaustive.

8. Is the quantification of cost savings by reference to percentage price reductions and price cycles appropriate?

The Department considers it appropriate to quantify the potential cost savings to the PBS using the percentages by which a medicine's price is reduced. These include all statutory price reductions to the medicine's AEMP and when a medicine is subject to PDPR, the percentage reduction in the AEMP of a medicine for a given price disclosure cycle. The higher the percentage price reductions, the more the medicine is discounted and the greater the cost savings to the PBS.

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9. Broadly, does the PBS have any comment on the bearing of this report and its conclusions at paragraphs 105-106 and 109 on the ACCC's consideration of this Application?

The Department notes that if the proposed conduct is authorised by the ACCC, Juno would, on the available information, be the only generic authorised to enter the markets for lenalidomide and pomalidomide on the authorised launch dates. The Department further notes that Celgene has demonstrated, at least at this point in time, a willingness to enforce its Australian patent rights to lenalidomide against prospective generic competitors. The Application reaffirms Celgene's opinion that any pharmaceutical company seeking to supply generic lenalidomide or pomalidomide before the expiry dates of Celgene's patents would infringe one or more of those patents absent a licence from Celgene.

The Department therefore notes that if the proposed conduct is authorised by the ACCC:

- Juno is likely to obtain PBS listing for its generic lenalidomide products prior to other generic brands; and
- Celgene may take steps to seek to prevent unauthorised market entry by other generics prior to the expiry date of at least some of its patents.

In those circumstances, if the proposed conduct is authorised by the ACCC, then applying the conclusions reached by Mr O'Toole may result in:

- Juno offering its products at a higher price, than it would offer if multiple brands were listed on or about the same date. It may seek to do so at a price which does not lead to the 10% threshold for price disclosure reductions being exceeded;
- the first price disclosure reduction therefore commencing at a later point in time than would occur if multiple brands of lenalidomide and pomalidomide were listed on the PBS at first generic entry.

It follows that the Department has reservations about the assumption made by Mr O'Toole in paragraphs 108 and 109 that at least eight brands of lenalidomide would list on the PBS on the same day and his consequent assumption that the first price disclosure reduction will take place in the first cycle.

For the reasons discussed in our response to question 4 above and question 12 below, we also have reservations about the conclusions reached by Mr O'Toole in paragraph 109.

10. If there is a price reduction as a result of generic competition, what degree of price reduction (in terms of percentage price reduction) would the PBS consider significant for generic Revlimid® and Pomalyst® and why?

In the Department's view, the more appropriate question is, assuming the proposed conduct is authorised, whether any savings generated by price disclosure reductions would be realised as quickly and to the same extent as would otherwise occur. Given the substantial volume of material redacted from the application and supporting submissions made by the applicants, it is not possible for us to verify this.

11. Has the PBS conducted any similar analysis (i.e. forward-looking or backward-looking analysis of future price reductions through price competition)? If so, what methodologies were used and what conclusions were drawn?

The Department has not undertaken any similar analysis for lenalidomide and/or pomalidomide.

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12. Does the PBS have any comment on the applicability of the price disclosure reductions in Denmark as described in paragraphs 107-108 on the ACCC's consideration of this Application?

Paragraphs 107-108 are not, on our reading, directed to 'price disclosure reductions in Denmark'. Rather, our understanding is that Mr O'Toole has selected Denmark as a comparator market based on similarities between its health system and Australia's and to make assumptions about the potential composition of the Australian lenalidomide market based on the number of brands subsidised in Denmark.

That being said, as discussed above, the Department has some reservations about the conclusions drawn by Mr O'Toole in paragraph 108:

- We do not accept, without qualification, Mr O'Toole's assumption that at least 8 of the 15 currently registered brands of lenalidomide would list on the PBS '*at the same time*' (emphasis supplied).
- That assumption appears to rest on the further assumption that the ACCC decides not to authorise the proposed conduct.
- In circumstances where the ACCC does decide to authorise the proposed conduct, and assuming no other generics seek to enter the market prior to the authorised launch date, Juno would be granted access to the market for lenalidomide prior to the expiry date of several of Celgene's patents and this authorised launch date would not be publicly disclosed in advance of Juno obtaining listing on the PBS. That would obviously result in Juno obtaining PBS listing at an earlier date than other generic brands.
- Whether Juno would be followed into the lenalidomide market by other generic brands depends on the respective appetite for risk of the sponsors of those brands. In that regard, we note that some sponsors have registered 'skinny labels' for their lenalidomide brands, which do not include marketing authorisation for mantle cell lymphoma. That indication is not subsidised by the PBS. It is also the subject of Celgene's latest expiring patent (2007282027) and might indicate that the sponsors of those brands intend to enter the market in mid-2023 (if not earlier), when the last of Celgene's other lenalidomide method of treatment patents expire.
- The timing of subsequent generic market entry also depends on whether Celgene would take steps to prevent sponsors from doing so prior to the expiry of relevant patents and whether those steps are successful.

Department of Health and Aged Care's responses to additional ACCC questions

Please see below the Department's response to the five additional questions enclosed in the ACCC's email to the Department of 29 June 2022.

1. **If a sponsor registers on the ARTG on 2 June 2022, what is the earliest date that sponsor's product could be PBS listed? If relevant, include an explanation of how this earliest date is determined in relation to the PBS listings deadlines calendar for 22-23 FY.**

The PBS listings calendar for the 2022-23 financial year can be accessed at: https://www.pbs.gov.au/industry/useful-resources/pbs-calendar/PBS-listing-calendar-2022-2023.pdf.

The earliest possible PBS listing date for a product registered on the ARTG on 2 June 2022 depends, among other things, on whether the application will result in the listing of a first new brand (FNB) of a listed medicine. Because the listing of an FNB triggers an FNB statutory price reduction, the second column of the calendar from the left determines the relevant PBS application deadlines. For a product registered on the ARTG on 2 June 2022, the earliest PBS application deadline for an FNB is 1 August 2022. A complete submission received by this deadline, would be processed by the Department with an effective listing date of 1 December 2022.

If the listing of the brand will not trigger an FNB statutory price reduction because, for example, one or more generic brands are listed on the PBS for the drug, the relevant application and documentation deadlines are given in the fourth column from the left. In that instance an application lodged by 15 June 2022 could result in a listing effective 1 September 2022.

2. **When do the details the SPA (i.e. the confidential price paid by the Australian Government) become known to sponsors that seek PBS listing for a bioequivalent product?**

The Commonwealth may enter into confidential Special Pricing Arrangements (SPAs) with a sponsor for the supply of a medicinal product formalising a 'published' versus an 'effective' pricing component. The difference between the published price in the Schedule of Pharmaceutical Benefits and the price actually paid by the Commonwealth (the 'effective' price), is managed through a rebate arrangement. The existence of SPAs is made publicly known from the date of the listing of the originator brand (or the date that the SPA takes effect if later); however the content of these individual arrangements is confidential to the Commonwealth and the relevant sponsor.[1]

Under ordinary circumstances, the effective price for a PBS listed drug becomes known to responsible persons (RP) seeking to list an FNB of that drug on the PBS within about 14 days after they make their application for listing. That is because, as a matter of policy, where there is a SPA in force, the Minister is only willing to list a first bioequivalent or biosimilar brand of a medicine if the sponsor of that medicine is willing to agree a price which amounts to at least the percentage reduction from the effective price of the originator brand that would be required if the effective price was a published AEMP. The Commonwealth is authorised under the deed governing the SPA to disclose the effective price in these circumstances.

[1] A template Deed of Agreement can be found at: https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/attachment-b-basic-deidentified-deed.pdf.

3. Referring to paragraphs 6.17-6.21 of Juno/Natco's Legal Submissions dated 22 April 2022, does the PBS have any comment on Juno/Natco's submissions at paragraph 6.17 that:

> ***A further substantial public benefit flows to purchasers of lenalidomide and pomalidomide under the Proposed Conduct. This arises as a result of the time delay between the time at which a new discounted price is negotiated by purchasers of these medicines and the time at which that reported discount (if greater than 10%) triggers a subsequent reduction in the PBS list price. During that time period, customers are reimbursed at the PBS list price, regardless of their actual cost of goods. As such, the extent of the difference between the two figures is retained by the customer.***

For the purpose of responding to this question, the Department assumes that 'purchaser' and 'customer' are used synonymously by Juno/Natco and that when so used, those terms denote public, rather than private, hospitals or their dispensaries, given that differences between the PBS price any discounted price negotiated by private hospitals are more properly characterised as a private benefit.

The Department is unable to assess the evidence relied on by Juno/Natco in support of their submissions at paragraphs 6.17-6.21, given that this evidence has been redacted from the public version of their submission. In particular, the Department is unable to verify whether the alleged public benefit can be characterised as 'substantial'.

For completeness, the Department notes that any difference between the PBS price and the price negotiated by the purchaser, are retained by the purchaser even if the discount does not exceed the ten percent price disclosure threshold. However, in that situation there is no public benefit to the Commonwealth, in the form of savings in PBS expenditure, because there is no price disclosure reduction.

4. Referring to paragraphs 6.33-6.37 of Juno/Natco's Legal Submissions dated 22 April 2022:

a. What are the ways in which the PBS considers that patient access to lenalidomide and pomalidomide can be improved through generic entry?

b. If one of the ways patient access to lenalidomide and pomalidomide can be improved is though price reductions, is it possible to identify what percentage price reduction would be necessary to cause improved patient access and if so, what would that percentage price reduction be in this case?

The Department accepts that, generally speaking, price competition can result in:

- cost savings to the PBS by virtue of statutory price reductions and price disclosure reductions. These cost savings can support the PBS listing of new drugs and the extension of existing listings to new indications where this is recommended by the Pharmaceutical Benefits Advisory Committee (PBAC);
- the drug becoming less expensive and, potentially, more affordable for self-funded hospitals and patients outside the PBS reimbursement environment.

As to whether the proposed conduct would, if authorised by the ACCC, be likely to result in increased patient access to lenalidomide and/or pomalidomide, the Department makes the following observations:

In order for a drug to be listed on the PBS, several conditions would usually be met, including:

- the drug is registered on the Australian Register of Therapeutic Goods (ARTG); and
- the indication, or therapeutic use, for which PBS listing is sought is approved by the Therapeutic Goods Administration (TGA) and registered on the ARTG; and
- the listing of the drug for the specific indication is recommended to the Minister by the PBAC.

With respect to pomalidomide, the Department notes that this drug is currently registered on the ARTG for:

- the treatment of relapsed or refractory multiple myeloma;
    - under two schemes of treatment according to specific treatment criteria:
        - in combination with dexamethasone; and
        - in combination with dexamethasone and bortezomib

Pomalidomide is listed on the PBS under the Highly Specialised Drugs Program (HSDP) for the treatment of relapsed or refractory multiple myeloma under these two TGA approved treatment regimes. Therefore, there are no additional registered indications for which PBS listing of pomalidomide could be sought.

Should a sponsor of pomalidomide wish to extend the PBS listing to a specific new indication, they would be expected to:

- seek TGA approval (and ARTG registration) for that new indication of pomalidomide; and
- make a submission to, and receive a positive recommendation from, the PBAC regarding the listing of pomalidomide on the PBS for that new indication.

With respect to lenalidomide, the Department notes that this drug is currently registered on the ARTG for three indications:

- multiple myeloma;
- myelodysplastic syndromes;
- and for the treatment of relapsed and/or refractory mantle cell lymphoma

Lenalidomide is listed on the PBS under the HSDP for the treatment of:

- multiple myeloma under the treatment regimens approved by the TGA:
    - as a monotherapy;
    - as a dual combination therapy (with dexamethasone); and
    - as a triple combination therapy (with dexamethasone and bortezomib).
- myelodysplastic syndromes.

Lenalidomide is not currently listed on the PBS for the treatment of relapsed and/or refractory mantle cell lymphoma. In considering whether the proposed conduct would, if authorised by the ACCC, facilitate the listing of this indication on the PBS, should it be sought by a sponsor, the Department notes that at its July 2016 meeting, the PBAC rejected an application by Celgene for listing of this indication for the intended population on the PBS. The PBAC reached that decision on the basis of uncertain effectiveness **and** uncertain cost-effectiveness. With respect to the former point, the PBAC

observed that 'based on … issues with the clinical trial … it was difficult to make a reliable estimate of any benefit that lenalidomide would add to the management of relapsed/refractory mantle cell lymphoma patients.'[2] With respect to the latter point, the PBAC pointed to issues with the economic model relied on by Celgene, which was 'based on optimistic assumptions, and therefore unlikely to give a reasonable estimate of the cost-effectiveness of lenalidomide in the relapsed/refractory mantle cell lymphoma population.'[3]

Given the PBAC's reasoning, it follows that any reductions to the AEMP of lenalidomide that might arise as a result of the proposed conduct, would not, without more, facilitate an extension of the listing of lenalidomide on the PBS to treatment of mantle cell lymphoma. A sponsor seeking to list lenalidomide on the PBS for mantle cell lymphoma would, at a minimum, need to make a re-submission to the PBAC that addresses the issues noted by the PBAC regarding the economic model presented in the July 2016 submission.[4]

The Department does not express a view on whether the proposed conduct would, if authorised, make lenalidomide and/or pomalidomide more 'affordable' to self-funded hospitals and patients. 'Affordability' is a subjective measure that depends on the capacity and willingness of purchasers to access these drugs at a reduced price. However, the Department notes that there are currently two drugs listed on the PBS for the treatment of released and/or refractory mantle cell lymphoma: ibrutinib and acalabrutinib.

5. Does the PBS consider that paragraph 2.18 from the ACCC's Draft Determination dated 23 March 2022 accurately details the factual scenario (in a general sense) that would give rise to a Commonwealth claim for compensation against an pharmaceutical originator company.

For greater accuracy, the Department would revise the statement at paragraph 2.18 of the draft determination as follows:

2.18 *If a generic manufacturer is unsuccessful in litigation, that is, the relevant patents are upheld, the generic manufacturer may not be able to enter the market and may be liable for damages if it has launched 'at risk'. On the other hand, if the patent is found invalid or not infringed, ~~then new entry by a number of generic manufacturers may take place. Further,~~* ***and*** *if the patent holder had obtained an interlocutory injunction preventing the generic manufacturer from entering while litigation was on foot,* ***the generic manufacturer may be entitled to damages. T****he patent holder may* ***also*** *be liable to pay ~~significant~~ damages to third parties* ***affected by the interlocutory injunction*** *~~including the Australian Government~~.* ***If the medicine is listed on the PBS*** *~~The Australian Government~~* ***the Commonwealth of Australia*** *may seek to claim an entitlement to* ***such*** *compensation pursuant to the "usual undertaking as to damages", to recover* ***any*** *savings in PBS expenditure forgone as a result of* ***the interlocutory injunction*** *~~the~~ delay****inged the*** *listing of generic medicines on the PBS****.*** *~~following the unsuccessful patent proceedings brought by the patent holder~~* ***Those savings***

[2] Pharmaceutical Benefits Advisory Committee, *Public Summary Document – July 2016 PBAC Meeting*, section 6.02 – Lenalidomide, Oral Capsules, 5 MG, 10 MG, 15 MG, 25 MG, Revlimid®, Celgene Pty Ltd, p. 16 (para. 7.7): https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2016-07/files/lenalidomide-psd-july-2016.pdf.
[3] Ibid., para. 7.10.
[4] Ibid., para. 7.11

might include savings associated with price disclosure reductions that would have resulted from listing by generic manufacturers that would have entered the market following entry by the specific generic brands restrained by the Court.[22]

[22] *Before the Federal Court will grant an interlocutory injunction, the party seeking the order will almost always be required to give to the Court the "usual undertaking as to damages", that is, to compensate any person (including a third party) affected by the operation of the order. – Federal Court of Australia, Usual Undertaking as to Damages Practice Note (GPN-UNDR), 25 October 2016, accessed 9 March 2022.*

In the context of this particular issue, and paragraphs 5.26 and 5.27 of Celgene's submission made in response to the ACCC's Draft Determination, the Department also notes that:

- the Commonwealth's claims against AstraZeneca and Wyeth (a Pfizer subsidiary) were both settled on terms which are confidential, but which permit the Commonwealth to disclose that the settlements involved in each instance a substantial payment to the Commonwealth;
- the decision in the Commonwealth's proceedings against Sanofi was appealed by the Commonwealth, the appeal has been heard, and the parties are waiting for a decision; and
- the first instance decision in the Sanofi proceedings (which is subject to appeal) turned on its facts. There was no finding in that decision that would prevent the Commonwealth pursuing further claims on undertakings as to damages given by pharmaceutical companies in litigation in which the entry of generic brands into the market is restrained on an interlocutory basis.