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**From:** HUBICKI, Stephen [REDACTED]  
**Sent:** Friday, 11 February 2022 2:13 PM  
**To:** Mitchell, Sophie  
**Cc:** Staltari, Danielle; Black, Susie; Ng, Andrew; Saponaro, Marcello; Honeyman, Jane; Xiao, Lily; RODRIGUEZ MORALES, Ilys; Exemptions  
**Subject:** RE: Juno Pharmaceuticals Pty Ltd & Ors application for authorisation [SEC=OFFICIAL] [ACCC-ACCCANDAER.FID3039132]

Hi Sophie and Danielle,

Thanks again for your time on the phone yesterday. As discussed, please find below our responses to the PBS data components of your request. I have emboldened the dot points to which we have responded.

These data will also be included in our submission, which will also address the other points you have raised.

If you have any questions about the responses below or any other matter, please do let me know.

Kind regards,

Stephen

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**From:** Mitchell, Sophie <[sophie.mitchell@acc.gov.au](mailto:sophie.mitchell@acc.gov.au)>  
**Sent:** Wednesday, 22 December 2021 2:07 PM  
**To:** HUBICKI, Stephen [REDACTED]  
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**Subject:** RE: Juno Pharmaceuticals Pty Ltd & Ors application for authorisation [SEC=OFFICIAL] [ACCC-ACCCANDAER.FID3039132]

## OFFICIAL

Dear Stephen

Many thanks to you and your colleagues for your time today.

Following up from our background call, please see below a list of high level topics that we would be grateful for the Department's comments on in a public submission.

- The PBS' role in respect of the entry and supply of new medicines (both originator and generic) in Australia
- Process and timeframes for getting PBS listing for a generic medicine
- Factors manufacturers have regard to when considering launching a generic product
- Process and timeframes in relation to the AEMP when one and/or multiple generics enter the market
- Whether the PBS has regard to patent infringement issues when assessing PBS listing applications
- Advantages of being the first to enter the market with a generic drug (e.g. limited switching by prescribers/patients; long term supply contracts in place)

- Whether the PBS is aware of or expects any other manufacturers to launch generic versions of the Celgene products in the coming years
- The impact of the proposed conduct on other manufacturers seeking to launch generic versions of the Celgene products.

We would also be grateful if PBS could provide us with data on prescriptions of Revlimid and Pomalyst in recent years and the cost of the drugs to the PBS, for example:

- **Percentage breakdown of prescriptions for each Revlimid indication**

In the 2020-21 financial year, 98% of PBS prescriptions for Revlimid® (lenalidomide) were supplied for the treatment of multiple myeloma and 2% of prescriptions were for the treatment of myelodysplastic syndrome.

- **Cost of Revlimid to the PBS per indication**

In the 2020-21 financial year, PBS Government expenditure on lenalidomide was \$216.4 million, including \$212.4 million for the treatment of multiple myeloma and \$3.9 million for the treatment of myelodysplastic syndrome.

*PBS prescriptions and Government expenditure for lenalidomide supplied in 2020-21*

Indication	Number of prescriptions	% of total prescriptions	PBS Government Expenditure
Multiple myeloma	38,779	98%	\$212,423,155
Myelodysplastic syndrome	844	2%	\$3,916,544
<b>Total</b>	<b>39,623</b>	<b>100%</b>	<b>\$216,339,699</b>

Source: PBS online claims data extracted 18 January 2022.

Excludes RPBS prescriptions.

PBS claims data does not include information on private prescriptions (non-PBS).

Data is subject to change due to late claims and adjustments by pharmacies.

- **Percentage breakdown of prescriptions for each Pomalyst indication (including prescriptions of Pomalyst in combination with dexamethasone and/or bortezomib)**

Pomalyst® (pomalidomide) is listed on the PBS for the treatment of multiple myeloma only.

- **Cost of Pomalyst to the PBS per indication**

In the 2020-21 financial year, PBS Government expenditure on pomalidomide was \$43.8 million for the treatment of multiple myeloma.

*PBS prescriptions and Government expenditure for pomalidomide supplied in 2020-21*

Indication	Number of prescriptions	% of total prescriptions	PBS Government Expense
Multiple myeloma	4,267	100%	\$43,823,894

Source: PBS online claims data extracted 18 January 2022.

Excludes RPBS prescriptions.

PBS claims data does not include information on private prescriptions (non-PBS).

Data is subject to change due to late claims and adjustments by pharmacies.

- **Proportion of Pomalyst prescriptions that are made in combination with bortezomib.**

The PBS listing of pomalidomide was extended from 1 October 2021 to include use in combination with bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma in patients who have been previously treated with lenalidomide. Prior to 1 October 2021, PBS prescriptions for pomalidomide were for supply to patients not receiving concomitant PBS-subsidised bortezomib.

Insufficient data is available at this point to report the proportion of PBS prescriptions for pomalidomide made in combination with bortezomib from 1 October 2021. We generally allow at least 2 months after the end of the supply period before reporting PBS data to allow sufficient completeness.

- **Information in relation to when Revlimid and Pomalyst were listed on the PBS and the demand for these drugs**

Lenalidomide was first listed on the PBS on 1 September 2009 for the treatment of multiple myeloma (capsule 5 mg, 10 mg, 15 mg, and 25mg), and 1 October 2013 for the treatment of myelodysplastic

syndrome (capsule 5 mg and 10 mg). Pomalidomide was first listed on the PBS on 1 August 2015 for the treatment of multiple myeloma (capsule 3 mg and 4 mg).

From 1 September 2009 to 30 June 2021, over 178,000 PBS prescriptions for lenalidomide were dispensed for all indications. From 1 August 2015 to 30 June 2021, around 15,600 prescriptions for pomalidomide were dispensed under the PBS. The **attached table** includes a breakdown of historical PBS prescriptions for lenalidomide and pomalidomide by financial year of supply, form/strength and indication.

Further, as mentioned on the call, we are happy to discuss an extension to the deadline for submissions should you need it.

Please do not hesitate to get in touch if you wish to discuss, noting that most of the team will be on leave after today until 10 January 2022. The ACCC Exemptions inbox (in cc) will continue to be monitored throughout this time.

Kind regards  
Sophie

**Sophie Mitchell**

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The ACCC acknowledges the traditional owners and custodians of Country throughout Australia and recognises their continuing connection to the land, sea and community. We pay our respects to them and their cultures; and to their Elders past, present and future.

**PBS prescriptions for lenalidomide and pomalidomide from date of first listing to 30 June 2021**

Ref: 2022-005

Source: PBS online claims data extracted 18 January 2022.

Includes lenalidomide prescriptions supplied from 1 September 2009 and pomalidomide prescriptions from 1 August 2015.

Excludes RPBS prescriptions.

PBS claims data does not include information on private prescriptions (non-PBS).

Data is subject to change due to late claims and adjustments by pharmacies.

DRG_SCHDL_NM	DOS_FYR	INDICATION	FRM_STR_LI_NM	PRSCRPTN_CNT
Lenalidomide	2009-10	Multiple myeloma	Capsule 10 mg	371
Lenalidomide	2009-10	Multiple myeloma	Capsule 15 mg	538
Lenalidomide	2009-10	Multiple myeloma	Capsule 25 mg	1,258
Lenalidomide	2009-10	Multiple myeloma	Capsule 5 mg	152
Lenalidomide	2010-11	Multiple myeloma	Capsule 10 mg	850
Lenalidomide	2010-11	Multiple myeloma	Capsule 15 mg	962
Lenalidomide	2010-11	Multiple myeloma	Capsule 25 mg	2,216
Lenalidomide	2010-11	Multiple myeloma	Capsule 5 mg	242
Lenalidomide	2011-12	Multiple myeloma	Capsule 10 mg	1,095
Lenalidomide	2011-12	Multiple myeloma	Capsule 15 mg	1,189
Lenalidomide	2011-12	Multiple myeloma	Capsule 25 mg	2,347
Lenalidomide	2011-12	Multiple myeloma	Capsule 5 mg	318
Lenalidomide	2012-13	Multiple myeloma	Capsule 10 mg	1,366
Lenalidomide	2012-13	Multiple myeloma	Capsule 15 mg	1,859
Lenalidomide	2012-13	Multiple myeloma	Capsule 25 mg	3,042
Lenalidomide	2012-13	Multiple myeloma	Capsule 5 mg	550
Lenalidomide	2013-14	Multiple myeloma	Capsule 10 mg	1,913
Lenalidomide	2013-14	Multiple myeloma	Capsule 15 mg	2,666
Lenalidomide	2013-14	Multiple myeloma	Capsule 25 mg	4,061
Lenalidomide	2013-14	Multiple myeloma	Capsule 5 mg	758
Lenalidomide	2013-14	Myelodysplastic syndrome	Capsule 10 mg	134
Lenalidomide	2013-14	Myelodysplastic syndrome	Capsule 5 mg	46
Lenalidomide	2014-15	Multiple myeloma	Capsule 10 mg	2,106
Lenalidomide	2014-15	Multiple myeloma	Capsule 15 mg	2,888
Lenalidomide	2014-15	Multiple myeloma	Capsule 25 mg	4,478
Lenalidomide	2014-15	Multiple myeloma	Capsule 5 mg	746
Lenalidomide	2014-15	Myelodysplastic syndrome	Capsule 10 mg	265
Lenalidomide	2014-15	Myelodysplastic syndrome	Capsule 5 mg	157
Lenalidomide	2015-16	Multiple myeloma	Capsule 10 mg	2,520
Lenalidomide	2015-16	Multiple myeloma	Capsule 15 mg	3,292
Lenalidomide	2015-16	Multiple myeloma	Capsule 25 mg	5,625
Lenalidomide	2015-16	Multiple myeloma	Capsule 5 mg	837
Lenalidomide	2015-16	Myelodysplastic syndrome	Capsule 10 mg	385
Lenalidomide	2015-16	Myelodysplastic syndrome	Capsule 5 mg	197
Lenalidomide	2016-17	Multiple myeloma	Capsule 10 mg	2,948
Lenalidomide	2016-17	Multiple myeloma	Capsule 15 mg	3,817
Lenalidomide	2016-17	Multiple myeloma	Capsule 25 mg	7,025
Lenalidomide	2016-17	Multiple myeloma	Capsule 5 mg	987
Lenalidomide	2016-17	Myelodysplastic syndrome	Capsule 10 mg	457
Lenalidomide	2016-17	Myelodysplastic syndrome	Capsule 5 mg	198
Lenalidomide	2017-18	Multiple myeloma	Capsule 10 mg	4,428
Lenalidomide	2017-18	Multiple myeloma	Capsule 15 mg	5,343
Lenalidomide	2017-18	Multiple myeloma	Capsule 25 mg	8,315
Lenalidomide	2017-18	Multiple myeloma	Capsule 5 mg	1,376
Lenalidomide	2017-18	Myelodysplastic syndrome	Capsule 10 mg	482
Lenalidomide	2017-18	Myelodysplastic syndrome	Capsule 5 mg	204

DRG_SCHDL_NM	DOS_FYR	INDICATION	FRM_STR_LI_NM	PRSCRPTN_CNT
Lenalidomide	2018-19	Multiple myeloma	Capsule 10 mg	5,592
Lenalidomide	2018-19	Multiple myeloma	Capsule 15 mg	6,275
Lenalidomide	2018-19	Multiple myeloma	Capsule 25 mg	9,292
Lenalidomide	2018-19	Multiple myeloma	Capsule 5 mg	1,880
Lenalidomide	2018-19	Myelodysplastic syndrome	Capsule 10 mg	523
Lenalidomide	2018-19	Myelodysplastic syndrome	Capsule 5 mg	215
Lenalidomide	2019-20	Multiple myeloma	Capsule 10 mg	7,498
Lenalidomide	2019-20	Multiple myeloma	Capsule 15 mg	7,201
Lenalidomide	2019-20	Multiple myeloma	Capsule 25 mg	10,104
Lenalidomide	2019-20	Multiple myeloma	Capsule 5 mg	2,442
Lenalidomide	2019-20	Myelodysplastic syndrome	Capsule 10 mg	570
Lenalidomide	2019-20	Myelodysplastic syndrome	Capsule 5 mg	317
Lenalidomide	2020-21	Multiple myeloma	Capsule 10 mg	12,756
Lenalidomide	2020-21	Multiple myeloma	Capsule 15 mg	10,110
Lenalidomide	2020-21	Multiple myeloma	Capsule 25 mg	12,241
Lenalidomide	2020-21	Multiple myeloma	Capsule 5 mg	3,672
Lenalidomide	2020-21	Myelodysplastic syndrome	Capsule 10 mg	562
Lenalidomide	2020-21	Myelodysplastic syndrome	Capsule 5 mg	282
Pomalidomide	2015-16	Multiple myeloma	Capsule 3 mg	180
Pomalidomide	2015-16	Multiple myeloma	Capsule 4 mg	1,189
Pomalidomide	2016-17	Multiple myeloma	Capsule 3 mg	421
Pomalidomide	2016-17	Multiple myeloma	Capsule 4 mg	1,855
Pomalidomide	2017-18	Multiple myeloma	Capsule 3 mg	374
Pomalidomide	2017-18	Multiple myeloma	Capsule 4 mg	1,405
Pomalidomide	2018-19	Multiple myeloma	Capsule 3 mg	528
Pomalidomide	2018-19	Multiple myeloma	Capsule 4 mg	1,835
Pomalidomide	2019-20	Multiple myeloma	Capsule 3 mg	783
Pomalidomide	2019-20	Multiple myeloma	Capsule 4 mg	2,758
Pomalidomide	2020-21	Multiple myeloma	Capsule 3 mg	1,070
Pomalidomide	2020-21	Multiple myeloma	Capsule 4 mg	3,197