Response to ACCC Draft Determination dated 23 March 2022

Celgene Corporation & Celgene Pty Ltd and Juno Pharmaceuticals Pty Ltd & Anor

Application for authorisation AA1000592-1

Red	is confidential to the Applicants (not to be shared with the public)
Green	is confidential to Celgene (not to be shared with Juno/Natco or the public)
Blue	is confidential to Natco/Juno (not to be shared with Celgene or the public)

1. Overview

1.1 The Proposed Conduct[1] is clearly pro-competitive. The further information and evidence provided in this submission on the ACCC's Draft Determination (**Submission**) confirms that the Proposed Conduct results in clear and substantial benefits to the public and no detriments to the public. As a result, the ACCC should be satisfied that the Proposed Conduct is likely to result in a net benefit to the public and should grant authorisation.

1.2 There are no detriments to the public. As the ACCC itself acknowledges, prior to the publication of the Draft Determination no interested parties *"raised concerns relating to public detriments likely to arise from the Proposed Conduct*".[2] The detriments to the public identified by the ACCC are speculative and theoretical at best and in some cases based on factual and legal assumptions that are clearly erroneous. For example, the Agreement is simply not a 'pay-for-delay' arrangement. Further, the ACCC itself admits that "*the nature and extent of such detriments is unclear*".[3] On the contrary, the evidence (including from interested parties) establishes that there are no detriments to the public:

(a) the Celgene Patents are prima facie valid and enforceable. No third party could legally supply generic lenalidomide and pomalidomide for the relevant indications in Australia without permission from Celgene. Exploiting the invention of the Celgene patents by for example importing, supplying or offering to supply generic lenalidomide and pomalidomide for the relevant indications without permission, is prima facie unlawful would expose a third party to the risk of significant damages and, [confidential to Natco/ Juno];

(b) the Proposed Conduct does not give Celgene any greater control or certainty in relation to competition than it would have had absent the Agreement. The evidence of Mr MacGregor, BMS Company Managing Director for Australia and New Zealand, [confidential to Celgene];

(c) the Proposed Conduct does not grant Natco/Juno any 'first mover' advantage, or deter other generics from entering the market. The Agreement is a non-exclusive licence and [confidential to the Applicants]. In addition, the evidence of Ms Smith states that, [confidential to Celgene]. Accordingly, there is no evidence to support the ACCC's alleged first mover detriment, which is speculative and theoretical and does not reflect the likely commercial outcome; and

[1] All capitalised terms used but not defined in this Submission have the meaning given to them in the ACCC Draft Determination dated 23 March 2022 (**Draft Determination**) or the ACCC authorisation application dated 3 December 2021 made by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, and Celgene (**Authorisation Application**) unless otherwise indicated.

[2] Paragraph 4.78 of the Draft Determination.

[3] Paragraph 4.107 of the Draft Determination.

(d) the ACCC has misunderstood the terms of the Agreement. The Agreement allows for early entry and is plainly pro-competitive. The Agreement does not contain any [confidential to the Applicants].

1.3 On the contrary, as this Submission explains, the Proposed Conduct results in clear and substantial benefits to the public. These benefits do not need to be quantified in order to be taken into account by the ACCC (as explained by the ACCC Guidelines and confirmed by the Australian Competition Tribunal).[4] Specifically, the Agreement permits early generic entry by Natco/Juno for lenalidomide and pomalidomide on the respective Authorised Launch Dates. [confidential to Natco/ Juno]. The Proposed Conduct likely to result in significant and tangible benefits to the public:

(a) Natco/Juno's entry as the first generic supplier of lenalidomide would trigger an automatic, immediate and substantial (25%) price reduction, which is a significant and tangible benefit to the public regardless of the specific quantum of such savings;

(b) the ACCC should assume [confidential to Celgene]. As a result, a clear benefit to the public arises from the launch of the Natco/Juno pomalidomide product itself as a first competitor to Celgene (i.e. the 25% statutory price reduction);

(c) the Proposed Conduct results in significant ongoing benefits to the public through price reductions under the price disclosure regime [confidential to Celgene]. As Celgene's expert (Mr O'Toole) clearly demonstrates in his evidence: (i) the greater the number of brands, the earlier the cycle at which the first price disclosure reduction will occur; and (ii) the greater the number of brands, the greater the likelihood of a first price disclosure reduction being in excess of 10%.

(d) notably, the ACCC has erred in dismissing the significance of PBS price savings by reference to the prospect of a compensation claim by the Australian Government. The question of the potential for the Australian Government to claim compensation [confidential to Celgene] [confidential to Natco/ Juno] [confidential to Celgene];

(e) the price reductions flowing from the Proposed Conduct make it more likely that specific PBS restrictions and access criteria will be relaxed, and as a result there will be a greater number of patients that will be treated with combinations of products that include lenalidomide or pomalidomide. There will also be a significant number of self-funded patients who are prescribed Revlimid® for the treatment of B-Cell Malignancies (which is an indication for which Revlimid® is not reimbursed) who will benefit from a reduction in the price of lenalidomide; and

(f) additional sources of supply, with independent supply chains, are pro-competitive and a benefit to the public.

1.4 As demonstrated above, the Proposed Conduct results in no detriment to the public on the one hand and clear and substantial benefits to the public on the other hand. As a result, the Proposed Conduct is likely to result in a net benefit to the public and the ACCC should, therefore, grant authorisation.

[4] See for example Application by Port of Newcastle Operations Pty Limited (No 2) [2022] ACompT 1 at [34].

2. The test for authorisation

2.1 The Applicants have sought authorisation for the Proposed Conduct under section 88 of the *Competition and Consumer Act 2010* (Cth) (**CCA**).

2.2 Section 90(7)(b) of the CCA provides that the ACCC must not grant authorisation unless it is satisfied in all the circumstances that: (i) the Proposed Conduct ***would result, or be likely to result***, in a benefit to the public; and (ii) that the benefit would outweigh the detriment to the public that ***would result, or be likely to result***, from the conduct (i.e. the conduct ***is likely*** to result in a net benefit to the public). [emphasis added]

2.3 Celgene notes that the statutory test sets a high threshold for the ACCC to be satisfied as to the benefit to the public and/or detriment to the public resulting from the Proposed Conduct. It must be at least likely to result from the Proposed Conduct. Mere speculation or unsupported inference is not sufficient. The Australian Competition Tribunal has previously noted in this regard:[5]

> "… *for a benefit or detriment to be taken into account, we must be satisfied that* ***there is a real chance, and not a mere possibility, of the benefit or detriment eventuating. It is not enough that the benefit or detriment is speculative or a theoretical possibility. There must be a commercial likelihood that the applicants will, following the implementation of the relevant agreements, act in a manner that delivers or brings about the public benefit or the lessening of competition giving rise to the public detriment***.
>
> [emphasis added]

2.4 In applying the statutory test, the ACCC must compare the ***likely*** future with the Proposed Conduct that is the subject of the authorisation to the ***likely*** future in which the Proposed Conduct does not occur (i.e. the counterfactual). The ACCC states in its Guidelines that this analysis involves comparing the state of competition and the benefits and detriments to the public likely to arise in the future where the conduct occurs, against the future in which the conduct does not occur. According to the Guidelines this enables the ACCC to focus its assessment on the impact of the conduct rather than other effects that would occur irrespective of whether the conduct occurs.[6]

3. ACCC has sufficient information regarding the generic market

The ACCC has sufficient information regarding the generic market

3.1 Paragraph 4.80 of the Draft Determination states that the ACCC is unclear as to the nature of generic competition with and without the Proposed Conduct.

3.2 The evidence provided by Celgene through its solicitor, Ms Smith [confidential to Celgene]:

(a) [confidential to Celgene]

(b) [confidential to Celgene]

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[5] *Qantas Airways Ltd [2004]* ACompT 9 at [156]

[6] ACCC Guidelines for Authorisation (Non-Merger), March 2019 (**Guidelines**) at 6.1.1

3.3 [confidential to Celgene], Ms Smith gives evidence as follows:

(a) Celgene informed the ACCC on 11 February 2022 in its Further Response to the ACCC RFI:

(i) [confidential to Celgene];

(ii) [confidential to Celgene].

(b) Celgene informed the ACCC on 11 February 2022 in its Further Response to the ACCC RFI [confidential to Celgene].

(c) [confidential to Celgene].

3.4 Further, the ACCC now has evidence from Natco/Juno as to their confidential launch plans in various different scenarios.[7] No generic manufacturers have lodged any submissions that call into question the most likely counterfactual as set out below. As a result, Celgene submits that the above facts must be accepted by the ACCC.

3.5 Celgene also submits that having regard to the matters identified above, the ACCC is clearly able to assess the likely state of the markets with or without the Proposed Conduct and to be satisfied that benefits to the public are likely to arise from the Proposed Conduct (without any likely detriment to the public).

4. Detriment to the public

4.1 As previously submitted by the Applicants, the Proposed Conduct does not result in any detriments to the public.

Alleged detriments to the public identified by the ACCC in the Draft Determination are no more than speculative (at best)

4.2 In the Draft Determination, the ACCC has expressed concerns regarding a number of alleged detriments to the public arising from the Proposed Conduct. Celgene considers that there is no factual or other basis for this position. Celgene addresses each of the ACCC's alleged detriments to the public in detail in turn below.

4.3 However, as a significant preliminary matter, Celgene notes that the ACCC's own position is that "*the nature and extent of such detriments is unclear*" (paragraph 4.80 of the Draft Determination). Indeed, the potential that the alleged reduction in competitive tension will result in a detriment to the public is expressed in terms of a "risk". This falls far short of any conclusion that the alleged detriments to the public are "*likely*" to occur as required by the CCA. Detriment to the public is only referred to in terms of "likelihood" in the Executive Summary and the section of the Draft Determination entitled "Balance of public benefit and detriment" the latter being effectively a summary of the detailed analysis on detriment (and benefit) to the public in the preceding paragraphs. But a summary can raise no higher than the analysis on which it is

[7] [confidential to Natco/ Juno]

based (and which analysis, as noted above, refers to the possibility of detriment to the public arising, at its highest, as a "risk").

4.4 Celgene submits that the ACCC's inability to identify the nature and extent of its alleged detriments to the public that are ***likely*** to result from the Proposed Conduct, means that there can be no detriment to the public relevant to the ACCC's assessment (nor indeed at all).

4.5 Further, the ACCC cannot, acting in accordance with its statutory duty, put the possibility of the alleged detriments to the public arising any higher than it has, as the ACCC's position lacks any evidentiary or other support whatsoever and is inconsistent with the facts.

4.6 Indeed, as the Draft Determination expressly notes in paragraph 4.78, not a single one of the 8 interested party submissions lodged in respect of the Authorisation Application (prior to the Draft Determination being published) provide any support for the ACCC's position as to alleged detriments to the public. In this regard, Celgene notes that in a number of instances, the ACCC's position is clearly inconsistent with those interested party submissions. For example, Celgene notes that:

(a) the submission of Myeloma Australia dated 18 January 2022 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*". Myeloma Australia does not identify any detriments to the public arising from the Proposed Conduct. Myeloma Australia's submission is discussed in more detail in section 2 of Celgene's response to interested party submissions dated 8 March 2022; and

(b) the ACCC's file note of the meeting with the Tasmanian Department of Health dated 11 February 2022 expressly refers to benefits to the public 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*" and the further benefits to the public 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 Tasmanian Department of Health also does not identify any detriments to the public arising from the Proposed Conduct. This file note is discussed in more detail in section 3 of Celgene's response to Interested Party submissions dated 8 March 2022.

4.7 Additionally, the submission lodged in response to the Draft Determination by the Generic and Biosimilar Medicines Association (**GBMA**) expressly and categorically rejects a number of the factual bases for the ACCC's position on detriments to the public in relation to the Proposed Conduct. In particular, the GBMA expressly rejects the ACCC's "*perceived detrimental impact on the ability or incentive for other generics to seek to enter the market 'at risk*". The GBMA considers that "*true 'at risk' entry – that is, being the first generic brand of a drug in respect of which relevant patents remain in force at the time of that entry and where there is no interlocutory injunction in place – is extremely uncommon in Australia presently, and particularly so for PBS-listed medicines (and even more so where those medicines are expensive, as is the case here)*". The GBMA is the peak body representing generic manufacturers in Australia. It is therefore very well-placed to comment on these issues from a broad industry perspective and its views should be given significant weight by the ACCC.

4.8 Further, the evidence of Celgene discussed below (together with that of Natco/Juno) provides a compelling basis to conclude that no detriment to the public arises.

Celgene's Patents are valid and enforceable including against Natco/Juno

4.9 The starting point for the ACCC's assessment of the Authorisation Application must be that *prima facie* the Celgene Patents are valid and enforceable. Further, it is not in dispute that the Celgene Patents together cover each of the therapeutic indications the subject of the licence granted by Celgene under the Agreement (namely, multiple myeloma, myelodysplastic syndrome and mantle cell lymphoma). The Natco/Juno products are indicated on the ARTG for all three conditions.

4.10 Accordingly, any unauthorised launch of a generic lenalidomide or pomalidomide product in Australia for use in the treatment of multiple myeloma, myelodysplastic syndrome or mantle cell lymphoma during the term of the relevant Celgene Patent(s) is unlawful and a breach of Celgene's statutory patent rights. This fact has significant implications for the ACCC's assessment of alleged detriments to the public (as explained below).

Patents afford statutory rights

4.11 The Proposed Conduct arises in the context of an arm's length commercial agreement entered into between the Applicants, which provides for the settlement of Federal Court litigation concerning a suite of patents held by Celgene Corporation (i.e. the Celgene Patents), and the grant of a licence to those patents. Accordingly, the statutory rights afforded to Celgene under the *Patents Act 1990* (Cth) (**Patents Act**) in respect of each of the Celgene Patents are at the heart of the Proposed Conduct and should likewise be paramount in the ACCC's analysis of the Authorisation Application.

4.12 Section 18 of the Patents Act defines "*patentable invention*" to mean an invention that is a manner of manufacture, novel, involves an inventive step, is useful, and was not secretly used. Section 40 prescribes further requirements in relation to the disclosure of the invention in the specification and claims. The owner of an invention that satisfies these requirements is entitled to the grant of a patent for a term of 20 years (unless extended by up to 5 years under the patent term extension regime).

4.13 Section 13 gives a patentee the exclusive right to "*exploit*" the invention claimed in a patent (or to authorise such exploitation) to the exclusion of all others for the term of the patent. Section 119(5) defines "*exploit*" as follows:

> *where the invention is a product--make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or*
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> *where the invention is a method or process--use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.*

4.14 Pursuant to the Patents Act, a party that engages in unauthorised exploitation of the invention claimed in a patent infringes the statutory rights of the patentee (except for limited exceptions that are not presently relevant as discussed below at paragraph 4.67), and thus engages in conduct made unlawful by the Patents Act.

4.15 Such unlawful conduct entitles the patentee to a range of remedies including seeking a permanent injunction restraining infringing conduct for the duration of the patent. The grant of a permanent injunction is commonplace in patent cases (i.e. it is granted save for in exceptional circumstances that have rarely arisen in this jurisdiction) including in those involving disputes between originators and generics. In addition, the patentee is entitled to claim damages or an account of profits (at its election) in respect of infringement of its patent rights. A recent example of an award of significant damages following a finding of infringement of a patent for a pharmaceutical product (albeit not in relation to PBS-listed products) is *Bayer v Generic Health* [2017] FCA 250.

Patents are prima facie valid

4.16 In short, a patent is granted by IP Australia, an agency of the Australian Government. The process for obtaining a grant of a patent includes evaluation of the application for a patent in a process referred to as 'examination' and in the event that the application is accepted for grant ("allowed"), a 3-month opposition period during which any party (without any requirement to show standing) is able to challenge the decision that the patent application ought proceed to grant. A successful opposition will preclude the patent application from proceeding to grant (subject to any appeal).

4.17 The Federal Court has recognised the rigorousness of the pre-grant process in considering any presumption of validity to be afforded to granted patents. For example, in *GenRx Pty Ltd v Sanofi-Aventis* (2007) 73 IPR 502, at [5], Gyles J stated as follows:

> *Counsel for GenRx submits that that analysis is weakened, if not eliminated, by the type of examination prior to grant discussed in F Hoffman-La Roche AG v New England Biolabs Inc (2000) 99 FCR 56; 176 ALR 108; 50 IPR 305; [2000] FCA 283 especially at [48]–[57]. In my opinion, that decision is controversial. Even if correct, however, it does not detract from the proposition that* ***the Commissioner is charged with the responsibility of examining the validity of a patent before grant, including any relevant question of anticipation or lack of novelty.*** [emphasis added]

4.18 More recently in *Samsung Electronics Co Ltd v Apple Inc* (2011) 217 FCR 238, at [75], the Full Court of the Federal Court of Australia approved of the primary judge's summary of the applicable legal principles as to the respect to be afforded to patents, as follows:

> *Where, in a patent infringement case, the defendant asserts that the patent sued upon is invalid, the court should bear in mind that a granted patent is prima facie evidence of validity.* ***In order to proceed to registration, the patent has to survive the processes undertaken by the registering authority. These include the process of examination of the patent and the opportunity for interested persons to oppose the grant. The system has a degree of stringency built into it. These matters give rise to a presumption of validity in favour of registered patents. This presumption can be displaced but cannot be ignored.*** *It forms part of the plaintiff/patentee's prima facie case. These propositions are supported by Martin Engineering Co v Trison Holdings Pty Ltd (1988) 81 ALR 543; 11 IPR 611 and other cases referred to by the primary judge at [25]–[28] of her reasons.* [emphasis added]

4.19 Accordingly, Celgene submits that the ACCC's assessment of the Authorisation Application ought to properly begin with the presumption that the Celgene Patents are valid and enforceable including as against Natco/Juno's supply of its generic products. This is all the more so given that the Celgene Patents have remained on the register for close to the full patent term despite the ability of the Commonwealth Government and any third party to challenge validity. In this regard, Celgene refers to its response dated 8 March 2022 to the submission lodged by IP Australia on 14 January 2022.

4.20 The recognition of the validity and enforceability of the Celgene Patents inextricably leads to the conclusion that a party cannot (absent permission, for example by grant of a licence) prior to the expiry dates of the patents lawfully launch a lenalidomide or pomalidomide product for multiple myeloma, myelodysplastic syndrome or mantle cell lymphoma and also that any unauthorised launch should be assumed to constitute an infringement of the Celgene Patents, and is therefore *prima facie* unlawful (and liable to be enjoined by order of the Court).

4.21 As a corollary, any concession by the patent owner that authorises third parties to enter into competition with the patentee by launching a competing product ahead of patent expiry is self-evidently a benefit to the public (as discussed further below).

Future with and without the Proposed Conduct

4.22 The ACCC has misunderstood the Proposed Conduct and erroneously taken into account irrelevant counterfactuals. As noted in paragraph 2.4 above, in assessing the application the ACCC is to consider the market with and without the Proposed Conduct.

4.23 Celgene addresses the Proposed Conduct and the ACCC's misunderstanding in this regard in paragraphs 4.294.31 to 4.41 below.

4.24 As to the counterfactuals, Celgene's position is that (even [confidential to Natco/ Juno][8], [confidential to Natco/ Juno] [confidential to Celgene].

4.25 Notably however, the Draft Determination at paragraph 2.18 refers to circumstances in which a generic may enter the market. One example given is where the patent is found invalid or not infringed and "*new entry by a number of generic manufacturers may take place*".

4.26 To the extent that the ACCC is of the view that a relevant counterfactual in the present application is one in which the validity of the Celgene Patents has been determined adverse to Celgene (i.e. all patents are invalidated), this is a manifest error. As the evidence of Natco/Juno [confidential to Natco/ Juno].[9] Celgene of the view that [confidential to Celgene].

4.27 Further, [confidential to Celgene], the ACCC must proceed on the basis that any challenge to the validity of the Celgene Patents would fail.

4.28 At paragraph 4.33, the Draft Determination references the validity of the Celgene Patents in the context of identifying "potential counterfactuals", as follows:

> *The ACCC considers there are several potential counterfactual scenarios that may apply to the Proposed Conduct, including the Proceedings (whether it continues and the likely outcome of litigation) and the expiry dates of the relevant Celgene patents.*
> *…* ***The ACCC is not in a position to form views on the validity of the Celgene Patents, or the likely outcome of the Proceedings, as that is the role of the Federal Court of Australia or what action the Australian Government may undertake.*** [emphasis added]

4.29 The statement in bold appears to reflect an acknowledgment by the ACCC that, in the absence of a Court revoking a patent (or IP Australia doing so by way of re-examination proceedings), it has no basis to question the validity of the Celgene Patents. This is consistent with the Court's clear statements (as at 4.18 above) as to the *prima facie* validity of patents. Despite this apparent acknowledgement, however, the ACCC's analysis of benefit and detriment to the public makes assumptions that are inconsistent with this acknowledgement.

4.30 In particular, to the extent that in considering the state of competition in the market for lenalidomide, the ACCC has indicated in the Draft Determination that it is appropriate to take into account any contribution to competition by a third party (or indeed Natco/Juno), launching at risk, it was manifestly in error.

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[8] [confidential to Natco/ Juno].

[9] [confidential to Natco/ Juno].

4.31 In any case, the evidence clearly shows that [confidential to Natco/ Juno].[10]

4.32 Relevantly, Celgene's position as set out in the declaration of Mr MacGregor [confidential to Natco/ Juno] [confidential to Celgene]. Celgene submits that [confidential to Celgene]:

(a) [confidential to Celgene];

(b) [confidential to Celgene];

(c) [confidential to Celgene].

4.33 [confidential to Celgene] [confidential to Natco/ Juno].[11] [confidential to Celgene].

4.34 The GBMA submission [confidential to Celgene]. [confidential to Celgene], it clearly refers to the speculative nature of 'at risk' entry. For example, the submission states as follows:

> *In particular, the ACCC has placed considerable emphasis on a perceived detrimental impact on the ability or incentive for other generics to seek to enter the market 'at risk'. However, the GBMA considers that true 'at risk' entry – that is, being the first generic brand of a drug in respect of which relevant patents remain in force at the time of that entry and where there is no interlocutory injunction in place – is extremely uncommon in Australia presently, and particularly so for PBS-listed medicines (and even more so where those medicines are expensive, as is the case here).*
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> *The key reason for this is that if the generic supplier is ultimately found to have infringed the patent/s, its damages exposure will include the 25% statutory price reduction that is triggered by generic entry, which will represent lost margin to the patentee and will be applicable to every sale of the medicine (by patentee or generic) during the period of infringing conduct. In any market that is of sufficient size to warrant generic competition, that amount will be substantial.*
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> *That of course changes once a first generic brand has entered the market, because the risk of being held to account for the 25% price reduction has been removed. In that scenario, the prospect of 'at risk' entry by further generic brands necessarily increases.*

4.35 [confidential to Celgene].

4.36 Although the GBMA submission suggests that after the first generic brand lists, the prospect of launch at risk increases, [confidential to Celgene].

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[10] [confidential to Natco/ Juno].

[11] [confidential to Natco/ Juno].

4.37 Further, in light of the matters set out above in relation to the respect to be afforded to the validity and enforceability of the patents, it ought to be assumed that Celgene could enjoin any launch at risk.

4.38 Celgene also reiterates its position that such conduct is unlawful and ought not be considered as part of any counterfactual.

4.39 Accordingly, [confidential to Celgene]. [confidential to Celgene], the Proposed Conduct, which provides for authorised launch by Natco/Juno for both lenalidomide and pomalidomide products several months ahead of patent expiry, clearly results in a competitor entering the market earlier than in any likely counterfactual. This increase in competition is in itself a benefit to the public, [confidential to Celgene].

The Proposed Conduct is clear

4.40 If authorised, the Proposed Conduct, will enable Natco/Juno to enter and supply the Generic Products on and from the Authorised Lenalidomide Launch Date and the Authorised Pomalidomide Launch Date (as defined in the Agreement), as applicable, earlier than the expiry date of the relevant Celgene Patent(s).

4.41 As Natco/Juno noted in its response, the Proposed Conduct is inherently pro-competitive (not distortive of competition) in that "*it introduces competition into a market in which there is presently none or, in the event of other early entry by one or more other generic suppliers of lenalidomide under licence, it introduces further generic competition into the market*". Celgene agrees with this position.

No reduction of uncertainty or first mover concerns

4.42 At paragraph 4.107 of the Draft Determination the ACCC identifies the basis on which it considers that detriment to the public may arise from the Proposed Conduct by reducing competitive tension, as follows:

(a) providing Celgene with greater control and commercial certainty over the timing of generic entry by Natco/Juno;

(b) conferring on Natco/Juno a first mover advantage;

(c) possibly deterring generic entry and [confidential to the Applicants]; and

(d) removing elements of commercial risk, affecting Celgene's response to any generic entry.

4.43 For the reasons set out above, each of these conclusions is speculative and theoretical and not supported by any evidence. It is also noted that the reasoning in the Draft Determination is clearly internally contradictory. As is discussed further below, the ACCC declines to accept that [confidential to Celgene] the ACCC's position is that the Proposed Conduct confers on Natco/Juno a first mover advantage. Clearly, if Natco/Juno were conferred first mover status as the ACCC assumes in its analysis of detriment to the public, [confidential to Celgene].

4.44 As a preliminary matter, the Draft Determination is premised on the approach summarised in paragraph 4.36 of the Draft Determination as to the need to consider not just the conduct of the Applicants, but also the "*broader markets in which the relevant products are sold*". Whilst not accepting that this is the appropriate analysis, Celgene nevertheless submits that, even adopting this erroneous approach, no detriment to the public arises from the Proposed Conduct vis-à-vis any other relevant counterfactual.

Control/uncertainty

4.45 Whilst the Proposed Conduct permits Natco/Juno to launch on the authorised dates, it does not give Celgene any greater certainty in any relevant sense. It is entirely a matter for Natco/Juno when it launches. In any case, patent expiry occurs on a date that is certain, and so at best the agreement brings forward possible launch dates to earlier dates.

4.46 As Mr Neil MacGregor, Managing Director BMS Australia & New Zealand states, [confidential to Celgene].

4.47 The Draft Determination at paragraph 4.81 also states that the Proposed Conduct gives Celgene "control" compared to the counterfactual. The Draft Determination does not provide any further information as to what is meant by this. To the extent it relates to the purported first mover advantage, this is without merit for the reasons discussed at paragraphs 4.52 to 4.57 below.

4.48 In any case, as Natco/Juno's evidence [confidential to Natco/ Juno].[12] [confidential to Natco/ Juno]. Further, the Agreement merely gives to Natco/Juno permission to launch on the applicable authorised launch dates.

4.49 [confidential to Celgene].

4.50 [confidential to Celgene]. At paragraph 4.83 of the Draft Determination, the ACCC states that the threat of generic entry occurring, including at risk, is a key driver of competition.

4.51 [confidential to Celgene].

First mover advantage

4.52 The ACCC states at paragraph 4.90 of the Draft Determination that:

> "*the Agreement appears intended to make Juno/Natco the first supplier of generic lenalidomide and pomalidomide in the relevant markets and the only generic supplier for a period until other generic manufacturers enter (whether through 'at risk' entry or after the relevant patents expire). The Agreement appears to allow Juno/Natco to achieve a, potentially very lucrative, first mover advantage which gives a "potentially very lucrative first more advantage*".

4.53 However, the ACCC also acknowledges at paragraph 4.91 that "*without information from other generic manufacturers, it is uncertain what benefit the first mover advantage is likely to provide to Juno/Natco*". As explained below, this potential concern is speculative and does not reflect commercial reality. Specifically, the Proposed Conduct does [confidential to Celgene] and does not grant any period of exclusivity.

[12] [confidential to Natco/ Juno].

4.54 In this regard, with respect the ACCC has misunderstood the Agreement. The Agreement simply does not operate to confer any such "first mover" right on Natco/Juno in relation to lenalidomide or pomalidomide. Not only is it a non-exclusive licence, [confidential to the Applicants]. This fact alone is sufficient to conclude that the Proposed Conduct confers no actual or de-facto first mover advantage on Natco/Juno.

4.55 As to pomalidomide, Celgene refers to the evidence of Ms Smith above in paragraph 3.3. On the basis set out therein, Celgene [confidential to Celgene]. There is a clear benefit to the public in having a generic competitor, and a further benefit to the public due to the 25% mandatory price reduction triggered by PBS listing of Natco/Juno's pomalidomide product.

4.56 [confidential to Celgene].

4.57 In any case, as the Natco/Juno evidence demonstrates, there is no first mover advantage as a matter of fact.[13] This is also confirmed by [confidential to Celgene] and Celgene's expert Gregory Ian O'Toole dated 29 April 2022. In addition, the assertion by the ACCC that a first mover advantage *may* affect the investment decisions of other generics is entirely without foundation and so general as to be meaningless. There is no evidence to support this speculation and it is not reflective of commercial reality.

The ACCC has misunderstood the Agreement

4.58 Finally, and significantly, it appears that the ACCC has fundamentally misunderstood the operation of the Agreement in asserting that the Proposed Conduct [confidential to the Applicants].

4.59 [confidential to the Applicants].

4.60 Accordingly, Celgene submits that the position is identical with or without the Proposed Conduct – [confidential to the Applicants]. These clauses are in fact pro-competitive in that in the unlikely event that there is a launch at risk (see above) that Celgene fails to enjoin, [confidential to Celgene].

[13] [confidential to Natco/ Juno].

Agreement is not 'pay-for-delay'

4.61 Certain of the third-party submissions speculate that the Agreement is a so called 'pay-for-delay' agreement (see, for example, submissions lodged by the Northern Territory Department of Health and Sven Gallasch). This is not the case. It is established in both Europe and the United States that a pay-for-delay settlement generally involves the following, as part of the settlement of a patent dispute:

(a) an originator/patent holder making a large, unexplained monetary payment (or providing some other significant non-monetary benefit) to a generic pharmaceutical manufacturer;

(b) in exchange for the generic manufacturer agreeing to limit or delay the entry of a generic product into a market.

4.62 In paragraph 2.20 of the Draft Determination, the ACCC states that pay-for-delay generally refers to a practice whereby patent holding companies (i.e. originator/innovator companies) pay or incentivise generic companies to keep their products off the market beyond the scope of a patent.

4.63 The Agreement does not contain any of the characteristics that courts or the ACCC have identified as reflecting an anti-competitive pay-for-delay agreement between an originator/innovator and a generic:

(a) [confidential to the Applicants]. As noted in the 2013 the Supreme Court decision in *FTC vs. Actavis*, large, unexplained reverse payments between brand-name drug companies and generic manufacturers "*bring with it the risk of significant anticompetitive effects*." Courts have identified various tactics that allow companies to disguise the nature of the transfer, such as promises to promote or market other medicines, licensing agreements or agreements to share R&D tasks in future projects, [confidential to the Applicants];

(b) there is no exclusivity over other generics afforded to Natco/Juno – as noted in paragraph 3.2, [confidential to Celgene];

(c) the Agreement is a settlement – parties are entitled to settle their dispute and doing so benefits both the parties and society; and

(d) the Agreement does not involve any delay – as noted in the Authorisation Application and at paragraph 4.40 above, the Proposed Conduct facilitates competition from Natco/Juno earlier than would otherwise be the case with the Celgene Patents. The Agreement does not therefore provide any delay or seek to prevent or hinder the entry of generics.

Pre-launch activities do not result in a detriment to the public, they are pro-competitive

4.64 It appears that the ACCC may have also misunderstood the pre-launch activities rights granted to Natco/Juno by the Agreement. These are without question pro-competitive – they are designed to permit [confidential to the Applicants].

4.65 In short, [confidential to the Applicants].

4.66 It is beyond question that importation of the products, a perquisite to supply in Australia [confidential to Natco/ Juno], is an infringement of the Celgene Patents (and is expressly referred to in the definition of 'exploit' reproduced above at 4.154.13). As Natco/Juno's response indicates, an inability to import its products ahead of PBS listing would mean significant delays in supply (and may result in breach the assurance of supply). Likewise sales and marketing ("offering to supply" in the definition of "exploit") would be an infringement of the Celgene Patents absent the Agreement.[14]

4.67 In addition, while section 119A of the Patents Act exempts acts engaged in for obtaining regulatory approval from the ambit of the Act (i.e. an exemption to infringement), the law is unclear as to whether the act of registration itself falls within the exemption. In any event, the courts have accepted that ARTG registration may constitute a threat to infringe patent rights sufficient to found an application for interlocutory relief restraining such launch.

5. Benefits to the public

PBS Cost Savings

Natco/Juno entry will lead to sustained PBS Cost Savings

5.1 In the Executive Summary of the Draft Determination, the ACCC has stated as follows in respect of the claimed benefits to the public arising from savings under the PBS:

> *The ACCC does not have sufficient evidence, including from the Applicants or the PBS, as to the significance of any potential PBS savings. Based on information currently available, the ACCC considers it is uncertain whether, and if so the extent to which, the settlement and licence agreement is likely to result in cost savings to the Australian Government under the Pharmaceutical Benefits Scheme.* [confidential to Celgene]. [emphasis added]

5.2 In addition, the ACCC states at paragraph 4.48 of the Draft Determination as follows:

> *While the ACCC accepts that PBS cost savings to the Australian Government as a result of the early launch of generic products could theoretically constitute a public benefit for consideration, in the absence of sufficient information, the PBS cost savings are uncertain.* [confidential to Celgene].

[14] Paragraph 103 – 106 of the Affidavit of Mark Crotty.

5.3 As a preliminary matter, Celgene understands that when the ACCC refers to "*the PBS savings*" that is said to be likely to be diminished by [confidential to Celgene], it is referring to the 25% statutory price reduction upon the listing of a first generic brand.

5.4 As noted in paragraph 4.55 above, the ACCC should assume that [confidential to Celgene]. In this situation, a clear benefit to the public arises from the launch of the Natco/Juno pomalidomide product itself as a first competitor to Celgene – the 25% statutory price reduction. This is addressed in Natco/Juno's Legal Submission in response to the Draft Determination dated 22 April 2022 at paragraphs 6.6 – 6.8, which [confidential to Celgene].

5.5 In this respect, Celgene notes that the estimated savings to the Commonwealth prepared by Natco/Juno are based on a number of SPA rebates (as this information is not available to Natco/Juno or its advisers). Although the fact that an SPA is in place is a matter of public record, as the evidence of Celgene's expert shows, the details of an SPA are highly confidential and the subject of confidentiality obligations owed by Celgene to the Commonwealth of Australia. [confidential to Celgene].

5.6 Natco/Juno's entry as the first generic supplier of lenalidomide would also trigger an automatic, immediate and substantial (25%) price reduction, which is a significant and tangible benefit to the public regardless of the specific quantum of such savings. Celgene refers to Natco/Juno's evidence in this regard. The significance of this benefit to the public is also expressly recognized in the GBMA submissions.

5.7 As Natco/Juno submits, even if other generics have been granted the right to enter on the same date as Natco/Juno, the Proposed Conduct provides greater certainty that the 25% price reduction will occur on the Authorisation Launch Date which is itself a benefit to the public.

5.8 As stated in the Authorisation Application, in addition to the automatic, immediate and substantial (25%) reduction, there will be other significant cost savings via the secondary price savings to the Commonwealth over time through the operation of the price disclosure regime.

5.9 Celgene submits that the ACCC has not had adequate regard to the savings which arise over time through the operation of the price disclosure regime. These savings will arise independently of the 25% price reduction (once this reduction has occurred).

5.10 Specifically, for the reasons that follow, Celgene submits that significant PBS cost savings, in the form of price disclosure reductions following generic entry, are likely to arise [confidential to Celgene]. In support of its submissions, Celgene refers to the statutory declaration of Gregory Ian O'Toole dated 29 April 2022.

5.11 As Mr O'Toole explains, the price disclosure regime operates as follows:

> *F2 pharmaceuticals are subject to price disclosure. On a rolling six-monthly data collection cycle, all suppliers of F2 pharmaceuticals are required to disclose data to the Commonwealth Department of Health of the total number of units sold and the total revenue generated for each listed brand. This obligation is referred to as the continuous price disclosure obligation. Over a further six-month period following the conclusion of each six-month data collection period, the Department of Health then calculates the effective in-market price (weighted average disclosed price (**WADP**)) relative to the PBS listed price for each F2 pharmaceutical across all brands.*

When the WADP for an F2 pharmaceutical is lower than the PBS listed price by a threshold margin specified in legislation (presently 10% for pharmaceuticals that have seen less than six data collection cycles), a price disclosure reduction is triggered to bring the PBS listed price to the WADP. Currently the price reductions are applied twice a year, namely on 1 April (corresponding to the data collected of sales made in the preceding 1 April to 30 September period) and 1 October (corresponding to the data collected of sales made in the preceding 1 October to 31 March period).

5.12 Mr O'Toole was asked by Jones Day to analyse the publicly available historical monthly PBS prices for pharmaceuticals with respect to the operation of the price disclosure regime and what implications, if any, the number of PBS listed brands may have for the pharmaceuticals' PBS price over time.

5.13 Based on his analysis, Mr O'Toole concludes that notwithstanding that each pharmaceutical will exhibit individual behaviour, the analysis demonstrates:

(a) a likely association between the number of competing PBS brands and the likely timing of price disclosure reductions. That is, the greater the number of brands, the earlier the cycle at which the first price disclosure reduction will occur; and

(b) a likely association between the number of competing PBS brands and the likely magnitude of the first price disclosure reduction. That is, the greater the number of brands, the greater the likelihood of a first price disclosure reduction being in excess of 10%.

5.14 Mr O'Toole also notes at paragraph 62 of his declaration

Upon reviewing the ARTG, I identified 15 generic brands for lenalidomide registered by 6 sponsors as follows:

a) Cipla Australia Pty Ltd, with three registered brands;
b) Dr Reddy's Laboratories (Australia) Pty Ltd, with four registered brands;
c) Juno Pharmaceuticals Pty Ltd, with three registered brands;
d) Luminarie Pty Ltd, with two registered brands;
e) Sandoz Pty Ltd, with one registered brand; and
f) Teva Pharma Australia Pty Ltd, with two registered brands.

5.15 Based on the information set out at paragraph 62 of his declaration, at paragraph 108 of his declaration Mr O'Toole makes the following statement:

I assumed that at least 8 of the 15 TGA registered brands referred to in paragraph 62 above would list on the PBS and also assumed that all 8 brands would list at the same time.

5.16 Based on the matters discussed at paragraphs 5.14 and 5.15 above, Celgene submits that the ACCC can adopt as working assumptions for the purposes of its final determination that [confidential to Celgene].

5.17 On the basis of the above, the ACCC's conclusion that PBS savings are [confidential to Celgene].

Australian Government's Ability to Obtain Compensation not guaranteed

5.18 In its Draft Determination, the ACCC has made a number of comments regarding the ability of the Australian Government to seek compensation for the delayed entry of generic products and draw conclusions that show that the ACCC has misunderstood this issue (Executive Summary and paragraphs 2.18, 4.33 and 4.51 of its Draft Determination).

5.19 The situation regarding compensation is misstated by the ACCC in a number of material respects in the Draft Determination.

5.20 The potential for the Australian Government to make a claim for compensation [confidential to Celgene] [confidential to Natco/Juno][15] [confidential to Celgene]. [confidential to Celgene], the legal position of the Australian Government regarding the circumstances giving rise to the government being able to assert a claim for damages [confidential to Celgene] set out in paragraph 2.18 of the Draft Determination (extracted below). [confidential to Celgene]:

> *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,* ***if the patent holder had obtained an interlocutory injunction preventing the generic manufacturer from entering while litigation was on foot, the patent holder may be liable to pay significant damages to third parties, including the Australian Government. The Australian Government may seek to claim an entitlement to compensation pursuant to the "usual undertaking as to damages", to recover savings in PBS expenditure forgone as a result of the delayed listing of generic medicines*** *on the PBS following the unsuccessful patent proceedings brought by the patent holder.*[16] [emphasis added]

5.21 Paragraph 2.18 references footnote 22 which states:

> *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.*

5.22 Plainly the context being referred to in the passages above is an undertaking as to damages given by the patentee in support of the grant of an interlocutory injunction.

5.23 There is no injunction in place in the Proceedings and Celgene has made no application for one. Further, as discussed above, [confidential to Celgene].

5.24 [confidential to Celgene].

5.25 Further, it is well-known that the Australian Government has commenced at least four such actions, namely in *Commonwealth v Sanofi* (***Sanofi***), *Sigma v Wyeth* (***Wyeth***), *AstraZeneca v Apotex* (***AstraZeneca***) and *Otsuka v Generic Health* (***Otsuka***).

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[15] [confidential to Natco/ Juno].

[16] Paragraph 2.18 of the Draft Determination.

5.26 In *Sanofi* at first instance, which is the only judicial determination to date on such a claim by the Australian Government, the Court held that claim failed. In *Wyeth* and *AstraZeneca*, the claims were settled and in *Otsuka* the claim is continuing in the Federal Court.

5.27 Accordingly, even if contrary to Celgene's position, circumstances arose in which the Australian Government claimed damages under an undertaking given by Celgene, the Government's entitlement to such recovery is uncertain at best, and in light of *Sanofi*, Celgene submits that the ACCC ought assume that no such entitlement exists on the present state of the law [confidential to Celgene].

5.28 Celgene also refers to the following statement in the Draft Determination:

> *The ACCC also notes that in the event that the litigation is recommenced absent the settlement and licence agreement and it resulted in a favourable outcome for Juno/Natco,* ***it is still open to the Australian Government to seek damages against Celgene to recover PBS expenditure*** *which would affect the extent of any PBS savings that can be attributed to the agreement. This further demonstrates that it is uncertain whether, and if so the extent to which, the Proposed Conduct is likely to result in cost savings under the Pharmaceutical Benefits Scheme.*
>
> [emphasis added]

5.29 To the extent that the ACCC is suggesting by this statement that it has a right to recover damages should the Natco/Juno proceedings conclude in an outcome unfavourable to Celgene, this is plainly incorrect. Australian law has never recognised such an entitlement. In any case, [confidential to Natco/ Juno].[17]

5.30 The ACCC has reached a view that the prospect of a claim by the Australian Government sufficiently complicates the analysis and calculation of PBS savings such as to create uncertainty as to whether it is possible to conclude that the Proposed Conduct would confer a benefit to the public. However, given the matters explained above, it is clear that the ACCC is in error in its views in this regard because the question of the potential for the Australian Government to claim compensation [confidential to Celgene].

The Agreement represents the best available commercial compromise between the Applicants

5.31 The ACCC states in the Draft Determination that "*the information provided by the Applicants does not establish that the Applicants would refuse to settle based on alternative terms (e.g. removing some or all of the provisions in respect of which authorisation is sought)*". On this basis, the ACCC considers that "*a counterfactual which assumes that the Agreement represents the only terms on which the Applicants would be prepared to settle the proceedings*" is a "*questionable premise*".[18]

5.32 As Celgene has previously stated, Celgene considers that the terms of the Agreement are "*a fair compromise of the litigation*".[19] The Agreement represents a commercial bargain struck between the Applicants [confidential to Celgene] conducted in the shadow of complex court proceedings. Any assertion that the Applicants would be prepared to settle the proceedings on alternate terms is pure, unsupported speculation.

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[17] [confidential to Natco/ Juno].

[18] Paragraph 4.34 of the Draft Determination.

[19] Celgene's Response to ACCC RFI dated 16 December 2021 at 1.3.

Savings to State & Territory Governments

5.33 Celgene's position as to savings arising to State & Territory governments are supported by a number of interested third party submissions. For example:

(a) the submission of the GBMA dated 8 April 2022 states:

> *It is beyond doubt that the first entry of a generic brand into the Australian market for these products, by Juno/Natco as a result of the settlement, will trigger immediate and quantifiable PBS savings due to the statutory price reduction mechanisms described above. Those savings will be material for lenalidomide and pomalidomide given their high cost. It is incorrect to consider that these are speculative and/or not capable of being verified. If the date of Juno/Natco's planned market entry is known to the ACCC then the PBS savings from the automatic 25% price reduction can easily be estimated by reference to the (known) patent expiry date. Juno/Natco's entry would also trigger the PBS price disclosure regime. The subsequent PBS savings generated through the price disclosure regime are also likely to be significant.*

(b) the submission of the Northern Territory Government Department of Health dated 15 March 2022 states:

> *early entry of generic Lenalidomide and Pomalidomide, with subsequent PBS listing, will result in an immediate decrease in the cost price i.e. the AEMP…*
>
> *Further AEMP reductions will occur through mandatory price disclosures following change in the PBS Formulary Allocation from F1 to F2 with the early entry of the generics.*

(c) the submission of an Interested Party dated 23 February 2022 refers to two separate types of PBS savings that result from generic entry as follows:

> *The arrival of generic/biosimilar competitor brands once a new medicine's patent expires typically significantly reduces the price of the medicine. This price reduction is driven both by competition and the Commonwealth's legislated price disclosure mechanism that implements cycles of mandated reductions in the price the Commonwealth pays for a medicine.*

Legal Cost Savings for society

5.34 The ACCC recognises in the Draft Determination that "*resolving litigation without final judicial determination will lessen the burden on the court system*" but states that "*the size of these benefits is uncertain and the ACCC has not been provided with the information necessary to estimate their size*".

5.35 As the first ACCC authorisation to substantively deal with patent ligation settlements, it is crucial that the ACCC does not make a final determination which discourages parties from resolving legal proceedings through timely settlement arrangements. As noted by the GBMA, there would be a "*chilling effect*" on patent settlements if generics were "*denied access to an efficient route to market*" through the authorisation process, and were instead required to seek final judicial determination, putting further strain and costs on the court system.[20]

[20] Generic and Biosimilar Medicines Association, Submission to the ACCC, 8 April 2021, p 2.

5.36 While it is not necessary to precisely quantify the benefit that flows from avoiding the cost to the court system of every innovator/generic dispute being adjudicated by the Court, Celgene refers to the Australian Government Productivity Commission's Report on Government Services released on 18 January 2022, summarised in the table below.

Category of data	Cost to the court system
First instance civil lodgements[21]	18,726 lodgements
First instance civil finalisations[22]	19,138 finalisations
Pending civil case load[23]	16,872 pending cases
Real recurrent annual expenditure for civil matters[24]	$3.47 billion
Average cost per finalisation[25]	$13, 957
Judicial officers per finalisation[26]	7.6 judicial officers
FTE staff per finalisation[27]	48.6 FTE staff

5.37 As can been seen from the above, there are significant cost burdens imposed on the court system by litigation, which would increase if the ACCC were to deny authorisation. In that case there is a real risk that some parties may be less willing (or not willing at all) to reach a settlement and would instead be required to seek a judicial determination from the courts as the only viable path for generics to enter the market prior to patent expiry.

5.38 The GBMA has also made this point in their submissions noting that: "*competition between originators and generic suppliers will be adversely impacted as there would be a potential chilling effect on patent settlements. Generic suppliers would be denied access to an efficient route to market, with resultant lost PBS cost savings, to the detriment of the Commonwealth, taxpayers and patients*".

[21] First instance (i.e. non appeal) civil court lodgements (i.e. formal commencement) in Australia in Supreme and Federal Courts.

[22] First instance (i.e. non-appeal) civil court finalisations (i.e. formal completion) in Australia in Supreme and Federal Courts.

[23] The back log (i.e. pending case load) of first instance (i.e. non-appeal) civil matters in Australia in Supreme and Federal Courts.

[24] The real recurrent expenditure (excluding payroll tax) in civil matters in Australia in Supreme and Federal Courts.

[25] The cost per finalisation (i.e. formal completion) (measured by dividing total real recurrent expenditure (excluding payroll tax) with the total number of finalisations) in civil matters in Supreme and Federal Courts on average across Australia.

[26] The number of judicial officers required per finalisation (i.e. formal completion) (measured by dividing the total number of judicial officers within each court for the financial year by the total number of finalisations for the same period, and multiplying by 1000) of a civil matter in Federal Courts on average across Australia.

[27] The number of FTE staff required per finalisation (i.e. formal completion) (measured by dividing the total number of FTE staff employed by courts for the financial year by the total number of finalisations for the same period, and multiplying by 1000) of a civil matter in Federal Courts on average across Australia.

Security of Supply

5.39 The Draft Determination contains a statement that "*an additional source of supply does not necessarily result in greater security of supply in the circumstances, as the ACCC does not have evidence of any supply issues in the past and the patient cohort being treated with these products is unlikely to change significantly in the foreseeable future*"[28]. The ACCC also notes in its Draft Determination that *"Information from interested parties suggests that no supply issues have arisen in the context of lenalidomide and pomalidomide in the past*".

5.40 The absence of supply shortages in the past is no guarantee that there are not likely to be any such shortages in the future.

5.41 The extent of current supply shortages for medicines in Australia has been addressed by Natco/Juno. The examples referred to by Natco/Juno derive from the TGA's medicine shortage reports database which shows that, as at 8 April 2022:

(a) there were 254 medicines affected by shortages in Australia, some due to an unexpected increase in demand and others due to transport, logistical and/or storage capacity issues; and

(b) there were 28 critical shortages in Australia, which includes Cipla's generic bleomycin (this belongs to a group of chemotherapy medicines, which interferes with the growth of cancer cells).

5.42 Indeed, the mere fact that the TGA maintains such a database is ample demonstration of the significance and prevalence of supply issues in the Australian pharmaceutical market.

5.43 The potential for disruptions to pharmaceutical supply chains has been recognised by the Australian Government Joint Standing Committee on Foreign Affairs, Defence and Trade (**Committee**). The Committee, in its Final Report, referred to evidence from various interested parties as to the impact of COVID-19 on pharmaceutical supplies, including the submission of Dr Andrew Dowse AO of Edith Cowen University and Dr Sascha Dov Bachmann of the University of Canberra, which stated that the pandemic has "*highlighted vulnerabilities in our imports – that is, the critical dependencies on our supply chains on foreign sourced materials. The most obvious and direct example of this has been in medicines and medical equipment*".[29]

5.44 The Committee accepted that the pandemic highlighted the extent to which the global market for pharmaceuticals and other medical supplies is exposed to disruptions. In support of this, the Committee referred to evidence given by the Institute for Integrated Economic Research that:

> *Australia imports over 90% of medicines and is at the end of a very long global supply chain making the nation vulnerable to supply chain disruptions. The Therapeutic Goods Administration (TGA), in 2019 discussion paper, noted that Australia is particularly vulnerable to medicine shortages arising from factors outside our control. They stated that these factors could include manufacturing problems, difficulties in procurement, political instability pandemics, another global economic crisis and a range of natural disasters.*[30]

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[28] Paragraph 4.58 of the Draft Determination.

[29] Australian Parliament, Joint Standing Committee on Foreign Affairs, Defence and Trade, *Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade*, December 2020, paragraph 3.16: https://parlinfo.aph.gov.au/parlInfo/download/committees/reportjnt/024552/toc_pdf/InquirvintotheimplicationsoftheCOVID-19pandemicforAustralia%e2%80%99sforeignaffairs,defenceandtrade.pdf;fileType=application%2Fpdf.

[30] Australian Parliament, Joint Standing Committee on Foreign Affairs, Defence and Trade, *Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade*, December 2020, paragraphs 4.77 – 4.80: https://parlinfo.aph.gov.au/parlInfo/download/committees/reportjnt/024552/toc_pdf/InquirvintotheimplicationsoftheCOVID-19pandemicforAustralia%e2%80%99sforeignaffairs,defenceandtrade.pdf;fileType=application%2Fpdf.

5.45 The ACCC itself has recognised the potential for medical supply chain issues as a result of COVID-19. Since March 2020, the ACCC has granted various authorisations to medical and pharmaceutical providers due to supply chain and other difficulties caused by COVID-19. Specifically, in its Final Determination granting authorisation to Medicines Australia, the ACCC made the following comments regarding supply chain difficulties for pharmaceutical products during COVID-19:

> *The ACCC recognises the significant challenges occurring as a result of the COVID-19 pandemic… At some stages of the pandemic, there has been a risk of Australia's health services being put under significant stress, including through the unavailability of sufficient supplies of certain medicines and devices. The identification of this risk and the need for collective and coordinated action by competitors gave rise to the need for applications for authorisation such as the one from MA.*[31]

5.46 If there were to be any future lenalidomide or pomalidomide shortages as a result of the kind of system wide shocks that can occur during a pandemic or conflict, any additional source of supply would provide a clear benefit to the public by making supply more secure. As the GBMA notes, "*the supply of a high quality generic medicine from a reputable supplier like Juno/ Natco will also provide additional supply chain assurance to purchases by providing another reliable source of supply*".

5.47 The ACCC also noted that [confidential to Celgene]. Celgene submits that, irrespective of the number of other potential generic suppliers in the market, additional sources of supply and independent supply chains are always preferable. The increased security associated with Natco/Juno's separate supply chain is a standalone benefit to the public.

5.48 Given the critical nature of medical supply chains and their inherent vulnerability to systemic shocks (as acknowledged by the ACCC), the increased security of supply resulting from the Proposed Conduct constitutes a clear benefit to the public.

Other Benefits to the public

Alternative Sources of Supply and Treatment Options and New Combinations

5.49 The evidence of Mr Cook demonstrates the potential for the Natco/Juno triggered price drop (and contribution to subsequent price reductions) to open up the possibility of additional combinations involving lenalidomide.

5.50 Mr Cook refers to bortezomib, a Celgene product for the treatment of multiple myeloma noting that:

> *There was only a very limited number of specific indications reimbursed under the PBS prior to the entry of generic brands. However, once generic bortezomib products were able to list on the PBS, the specific access criteria were revised and a streamlined indication of multiple myeloma was substituted for the previously existing criteria. This change in access criteria made bortezomib more accessible to patients in that treating doctors were able to prescribe it for the treatment of multiple myeloma more generally, including in combination with other products, in the knowledge that patients would be reimbursed under the PBS.*

[31] ACCC, Final Determination – Medicines Australia, 24 September 2020, paragraph 2.1: https://www.accc.gov.au/system/files/public-registers/documents/Final%20Determination%20-%2024.09.20%20-%20PR%20-%20AA1000486%20MA.pdf.

5.51 In Mr Cook's view, drawing on the experience with bortezomib, applications to list combination treatments that include lenalidomide or pomalidomide will be seen as more cost-effective than prior to the listing of generic lenalidomide and pomalidomide products. This will make it more likely that specific PBS restrictions and access criteria will be relaxed, and as a result there will be a greater number of patients that will be treated with combinations of products that include lenalidomide or pomalidomide.

5.52 Mr Cook's evidence also shows that there are a significant number of self-funded patients who are prescribed Revlimid for the treatment of B-Cell Malignancies (which is an indication for which Revlimid is not reimbursed) who will benefit from a reduction in the price of lenalidomide. This alone is a significant benefit to the public.

6. Other matters raised by the ACCC

Market definition

6.1 In the Draft Determination, the ACCC states that "*[f]or the purposes of assessing the Proposed Conduct the ACCC considers it appropriate to define separate markets for each active ingredient, rather than a market for a broader group of different active ingredients that may be used to treat multiple myeloma, myelodysplastic syndromes or mantle cell lymphoma*".[32]

6.2 While Celgene maintains that the indications based market definition put forward by the Applicants remains appropriate, it accepts that it is open to the ACCC to adopt the above active ingredient market definition for the purposes of assessing this authorisation application.

6.3 The ACCC has briefly considered the appropriate geographic scope of the markets but observed that it "*does not consider that a definitive view needs to be reached… in order to assess the application for authorisation*".[33] Relevantly, the ACCC has previously acknowledged that the supply and distribution of pharmaceutical products is on a national basis in multiple public competition assessments.[34] Celgene considers that the distribution issues which led to ACCC finding national markets for the supply of pharmaceuticals remain relevant and appropriate and that the relevant markets are national in scope.

[32] Paragraph 4.10 of the Draft Determination.

[33] Paragraphs 4.14 and 4.15 of the Draft Determination.

[34] ACCC, Public Competition Assessment, Mylan – proposed combination with Pfizer's Upjohn Inc. division, 4 December 2020, paragraph 30: https://www.accc.gov.au/system/files/public-registers/documents/Mylan%20Upjohn%20-%20Public%20Competition%20Assessment_0.pdf and ACCC Public Register, Informal Merger Reviews, Arrow Pharmaceuticals Pty Ltd - proposed merger with Apotex Pharmaceuticals Pty Ltd, September 2018: https://www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/arrow-pharmaceuticals-pty-ltd-proposed-merger-with-apotex-pharmaceuticals-pty-ltd.

7. Conclusion

7.1 The Proposed Conduct does not result in any detriments to the public. The ACCC's preliminary concerns about Celgene having greater control and commercial certainty over the timing of generic entry, the Proposed Conduct conferring on Natco/Juno a first mover advantage, possibly deterring generic entry and [confidential to the Applicants] and removing elements of commercial risk for Celgene are theoretical and speculative and not supported by any evidence.

7.2 On the contrary, there are substantial benefits to the public in the form of PBS price reductions (both initial and ongoing through the price disclosure regime), additional sources of supply, savings to State and Territory governments, increased potential for new PBS indications and combinations of lenalidomide and pomalidomide and additional access for self-funded patients. These benefits to the public are supported by evidence of experts with considerable experience and do not need to be quantified in order to be taken into account by the ACCC.

7.3 Overall, there are no detriments and substantial benefits to the public. As a result, the ACCC should be satisfied of the net benefit test and should grant authorisation for the Proposed Conduct, which is fundamentally a pro-competitive Agreement which facilitates increased competition and price reductions.

PUBLIC VERSION

Response to Interested Party Submissions

Celgene Corporation & Celgene Pty Ltd and Juno Pharmaceuticals Pty Ltd & Anor

Application for authorisation AA1000592-1

Red	is confidential to the Applicants (not to be shared with the public)
Green	is confidential to Celgene (not to be shared with Juno/Natco or the public)
Blue	is confidential to Natco/ Juno (not to be shared with Celgene or the public)

Response to Interested Party Submissions

1. Overview

1.1 The ACCC will appreciate that the majority of the interested party submissions received after the ACCC's Draft Determination dated 23 March 2022 (Additional **Interested Party Submissions**) support the position of the Applicants that the Proposed Conduct is likely to result in substantial benefits to the public.

1.2 In particular, the Generic and Biosimilar Medicines Association (**GBMA**) is in favour of authorisation being granted and provides yet further evidence (in addition to that provided by the Applicants) as to the compelling and substantial benefits to the public of the Proposed Conduct. The GBMA also categorically rejects the ACCC's unfounded speculation as to alleged detriments to the public. The GBMA is the peak industry body of the generics industry in Australia and is very well placed to comment on the ACCC's Draft Determination from the perspective of generic manufacturers. As a result, its views should be given considerable weight.

1.3 Other Interested Party Submissions raise theoretical or speculative issues that are irrelevant to the application, are factually incorrect, misunderstand the Proposed Conduct (e.g. incorrectly alleging that the Agreement is a 'pay-for-delay' arrangement) or put forward positions that are expressly contradicted by evidence filed by the Applicants, (such as the alleged impact of the REMS system (which is entirely contradicted by the Natco/Juno evidence[1]).

1.4 Celgene has provided more detailed comments in respect of the key aspects of the Additional Interested Party Submissions below. For completeness, the fact that this Response does not address all matters raised in the Additional Interested Party 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 Final Determination of the Authorisation Application.

2. GBMA

2.1 The GBMA is the peak representative body of generic suppliers in Australia which represents companies accounting for "*82% of all generic medicines sold in Australia*". Its views should, therefore, be regarded as representative of the view of the vast majority of generic manufacturers operating in Australia. As a result, this submission should be given considerable weight by the ACCC.

2.2 The GBMA submission addresses the fact as noted at paragraph 3.3 of the Draft Determination that, at that time, the ACCC had "*received no submissions from pharmaceutical manufacturers*".

2.3 GBMA supports authorisation being granted and confirms a number of the substantial benefits to the public which the Applicants identified in the Authorisation Application are likely to arise from the Proposed Conduct. In addition, the submission rejects the ACCC's preliminary findings in the Draft Determination that the Proposed Conduct may give rise to detriments to the public.

2.4 Significantly, the GBMA submits that denying authorisation is in fact likely to result in a significant detriment to the public by decreasing competition in the market for pharmaceuticals because it is likely to hinder settlements between originators and generics. The GMBA notes:

[1] 7.47 – 7.55 of the Juno/Natco Submission on Draft Determination dated 22 April 2022 (**Natco/Juno Response**)

competition between originators and generic suppliers will be adversely impacted as there would be a potential chilling effect on patent settlements. Generic suppliers would be denied access to an efficient route to market, with resultant lost PBS cost savings, to the detriment of the Commonwealth, taxpayers and patients.

2.5 These comments support Celgene's Response to ACCC Draft Determination dated 23 March 2022 (**Submission**) that the act of permitting any generic to enter a market by granting a licence under a patent is inherently pro-competitive.

2.6 In respect of the ACCC's position regarding the possibility of generic manufacturers launching at risk and, specifically, the conclusion that the Proposed Conduct results in a "*perceived detrimental impact on the ability or incentive for other generics to seek to enter the market 'at risk*", the GBMA submission rejects this as follows:

> *true 'at risk' entry – that is, being the first generic brand of a drug in respect of which relevant patents remain in force at the time of that entry and where there is no interlocutory injunction in place – is extremely uncommon in Australia presently, and particularly so for PBS-listed medicines (and even more so where those medicines are expensive, as is the case here).*
>
> *The key reason for this is that if the generic supplier is ultimately found to have infringed the patent/s, its damages exposure will include the 25% statutory price reduction that is triggered by generic entry, which will represent lost margin to the patentee and will be applicable to every sale of the medicine (by patentee or generic) during the period of infringing conduct. In any market that is of sufficient size to warrant generic competition, that amount will be substantial.*

2.7 [**confidential to Celgene**].

2.8 GBMA's submission also explicitly supports the Applicant's position on continuity of supply, namely: "*the supply of a high quality generic medicine from a reputable supplier like Juno/ Natco will also provide additional supply chain assurance to purchases by providing another reliable source of supply*".

2.9 Celgene also refers to its comments regarding the GBMA submission in its Submission.

3. Northern Territory Government Department of Health (NT DoH)

3.1 The NT DoH submission states that a substantial benefit to the public in the form of initial and ongoing PBS savings would result from the Proposed Conduct. For example NT DoH states that:

> *early entry of generic Lenalidomide and Pomalidomide, with subsequent PBS listing, will result in an immediate decrease in the cost price i.e. the AEMP. …*
>
> *Further AEMP reductions will occur through mandatory price disclosures following change in the PBS Formulary Allocation from F1 to F2 with the early entry of the generics.*

3.2 These statements support Celgene's position (as set out at paragraphs 5.6 and 5.7 of the Submission) that Natco/Juno's entry as the first generic supplier of lenalidomide and pomalidomide, would trigger an automatic, immediate and substantial (25%) price reduction (or at least provides greater certainty this reduction will occur).

3.3 In addition, consistent with Celgene's evidence, the submission identifies other significant cost savings to the Commonwealth over time through the operation of the price disclosure regime.

3.4 NT DoH also explains the non-PBS price benefits that would result from authorisation and the resultant early entry:

> *A decrease in AEMP as a result of early entry of a generic Lenalidomide and Pomalidomide does benefit hospitals and jurisdictions that are currently subsidising costs to patients via state-government funded mechanisms for off-label or non-PBS indications.*
>
> *Consumers who would be directly impacted are those accessing these treatments privately for indications that are not subsidised by the PBS i.e. self-funded treatment.*
>
> *In Australia, reduction in PBS expenditure, and resulting cost savings, could be utilised to subsidise treatment for new agents. It is expected that the number of patients who can self-fund their treatment to be small.*

3.5 Celgene agrees with the NT DoH's statements which support the clear benefits to the public that would result from the Proposed Conduct. These statements are consistent with the evidence of Dr Gregory Cook who as BMS' Senior Director of Access, Policy & Advocacy is well-placed to comment on these matters. The NT DoH notes the following:

(a) the Proposed Conduct would directly impact self-funded patients. Dr Cook notes that Celgene supplied 51 patients with Revlimid® for the treatment of B-Cell Malignancies in 2021 on a 'co-pay' basis (where the patients funds the cost of the first two months of treatment, following which Celgene provides the product free of charge to the patient). Given the lifesaving nature of the treatments in question making Revlimid® more affordable to these and other patients in similar need in the future, is a significant benefit to the public.

(b) the savings from the reduction in PBS expenditure could be utilised to subsidise treatment for new agents. In this regard, Dr Cook states that, based on past experience with other drugs, it is reasonable to expect that the PBS access criteria for lenalidomide are likely to be relaxed once generic competition enters the market. Once those criteria are relaxed, Dr Cook expects that the PBAC is more likely to consider funding new combinations of drugs which include lenalidomide or pomalidomide.

3.6 As stated above, both of these statements support the Authorisation Applications and Submission in support of authorisation.

3.7 Insofar as the NT DoH characterises the Settlement and Licence Agreement as a pay-for-delay arrangement, Celgene submits that such comments are based on a fundamental misunderstanding of the Agreement. In this regard:

(a) the principal thesis of the NT DoH is that competition will be thwarted by limited entry to the market and eliminating any incentive for the single permitted entrant to reduce prices. As discussed in paragraphs 4.61 to 4.63 of the Submission, this characterisation of the Settlement and Licence Agreement is incorrect. Put simply, the Agreement is not a 'pay for delay' arrangement. It does not contain any of the features widely understood in the United States and Europe to constitute 'pay-for-delay'. Nor does it meet the ACCC's own definition of 'pay-for-delay' in paragraph 2.20 of the Draft Determination. Further, as the ACCC is aware, [**confidential to the Applicants**]. Accordingly, the NT DoH's submissions in this regard are not relevant and should not be taken into account by the ACCC; and

(b) NT DoH inappropriately speculates about Celgene's behaviour. NT DoH refers to a risk of medication shortages in the event that Revlimid® and Pomalyst® are removed from the market before maturation of the generic supply chain. The evidence of Mr Neil. MacGregor, Managing Director, Australia and New Zealand (BMS Company) [**confidential to Celgene**].

4. Dr Sven Gallasch

4.1 This submission discusses patent rights and patent settlement agreements at a high level. It makes only passing reference to the Proposed Conduct. The submission does not provide factual evidence or material which the ACCC could rely on in deciding whether to grant authorisation. The submission, therefore, provides no assistance to the ACCC in its assessment of the application.

4.2 In addition, insofar as the submission makes a number of theoretical and speculative comments regarding "pay for delay". For the reasons explained in 1.19(a) above, these comments represent a fundamental misunderstanding of the nature of the Agreement.

4.3 Similarly, the Proposed Conduct does not grant Natco/Juno any sort of 'first mover' advantage. As the evidence of Natco/Juno and Mr MacGregor of BMS [**confidential to Celgene**] and does not grant any period of exclusivity.

5. Pharmacor

5.1 Pharmacor states that it is "*interested in marketing in Australia one or more of generic lenalidomide and pomalidomide products for the same indications in respect of which Revlimid® and Pomalyst® are approved' upon the expiry or earlier revocation of any relevant patent rights*".

5.2 Pharmacor thereby acknowledges that it considers that Celgene's Patent rights are valid and that it will not launch 'at risk'. This is yet further evidence that there is no likelihood (or prospect) of launch at risk which contradicts the speculative position that underpins the ACCC's public detriment analysis.

5.3 The majority of the Pharmacor submission is directed towards two specific concerns. The first relates to the need to implement a risk evaluation and management system (**REMS**), if it is to enter the market. The second is that it perceives that Natco/Juno is conferred preferred status as the sole and exclusive licensee, thereby handing Natco/Juno a first mover advantage. Pharmacor's specific submission in this regard is that the Proposed Conduct) "*is likely to raise significant additional barriers to entry for second and subsequent generic sponsors, over and above the usual factors which give rise to the first generic mover advantage generally*".

5.4 Both of these concerns are fundamentally flawed for the following reasons:

(a) in relation to the aspect of the submission that concerns REMS, Natco/Juno, who are very well-placed to comment on entry requirements, provide clear evidence that establishing a REMS is a straight-forward process which Juno has had no difficulty carrying out and that a REMS is merely a cost of doing business. Given Juno does not view a REMS requirement as a barrier to entry[2], it is simply not credible that any of the other larger international generics could consider it to be a genuine barrier to entry; and

(b) in relation to the suggestion that Natco/Juno is conferred first mover status, as explained above at 1.22, Natco/Juno derives no 'first mover' advantage from the Settlement and Licence Agreement.

5.5 Although it is not necessary for Celgene to address (given the matters above dispose of the issue raised by Pharmacor regarding REMS), it is noted that paragraph 2.6 of the Pharmacor submission misstates the position in the United States. In this jurisdiction, Celgene was not required to make its proprietary Revlimid® REMS program available. Rather, Celgene has now

[2] 7.52 Natco/Juno Response.

developed a lenalidomide REMS system that it hosts, and provides, on a fee-for-service basis, to generic lenalidomide manufacturers.

5.6 However, and significantly, generics are not required to use the Celgene system, and can elect to develop and obtain FDA approval of their own REMS systems. Indeed, certain generics have done so.

5.7 In particular, the FDA has approved separate generic REMS programs for lenalidomide (and pomalidomide) including those from Dr Reddy's Laboratory (ANDA 209348) and Eugia Pharma, Breckenridge and Mylan jointly (ANDA 210249, 210111, 210275).

5.8 Indeed, this is further evidence that Pharmacor's submission that the REMS requirement is a barrier to entry is without merit.

6. An interested party (5 April 2022)

6.1 The anonymous Interested Party Submission dated 5 April 2022 deals with essentially the same subject matter as the Pharmacor submission. Celgene has no additional comments to make over and above its comments in respect of the Pharmacor submission.

7. An interested party (23 February 2022)

7.1 The anonymous Interested Party submission dated 23 February 2022 supports the two separate types of PBS savings that result from generic entry (as discussed at 1.14 above):

> *The arrival of generic/biosimilar competitor brands once a new medicine's patent expires typically significantly reduces the price of the medicine. This price reduction is driven both by competition and the Commonwealth's legislated price disclosure mechanism that implements cycles of mandated reductions in the price the Commonwealth pays for a medicine.*

7.2 However, the remainder of the unredacted submission makes comments which are broad, speculative and of minimal (if any) relevance to the ACCC's assessment of the Proposed Conduct. As a result, Celgene consider that these comments should be given very little weight by the ACCC.

Commonwealth of Australia

STATUTORY DECLARATION

Statutory Declarations Act 1959

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

Red is confidential to the Applicants (not to be shared with the public)

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

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

I, Prudence Jane Smith, of Level 41, 88 Phillip Street, in the state of New South Wales, solicitor, make the following declaration under the *Statutory Declarations Act 1959*.

Background and experience

1. I am a solicitor and partner at Jones Day in the competition group. I joined Jones Day in May 2014.

2. Jones Day acts for Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) in relation to the application for authorisation from the Australian Competition and Consumer Commission (**ACCC**) under section 88 of the *Competition and Consumer Act 2010* (Cth) (**CCA**) to enter into and give effect to certain provisions of a settlement and licence agreement with Natco Pharma Ltd (**Natco**) and Juno Pharmaceuticals Pty Ltd (**Juno**) (**Natco/Juno Agreement**) in relation to the pharmaceutical products Revlimid® and Pomalyst® lodged on 3 December 2021 (AA1000592) (the **Authorisation Application**).

3. The Authorisation Application is made jointly by Celgene, Natco and Juno (together, the **Applicants**).

4. I am a solicitor admitted to practise in the Supreme Court of New South Wales and the High Court of Australia.

5. I was employed as an officer of the ACCC between 1999 – 2014 in various roles including for a period as a principal lawyer in the then Enforcement and Compliance Unit and Trade Practices and Litigation Unit (Mergers and Adjudication Sub-Unit).

6. I act for Celgene on the Authorisation Application.

7. Unless I expressly state to the contrary, I have not been instructed to waive legal professional privilege over any communications passing between me or Jones Day and Celgene (or its parent company, Bristol Myers Squibb) or third parties and I do not intend to do so by means of this declaration.

8. I make this declaration from my own knowledge, unless stated otherwise. Where I refer in this declaration to being informed of matters, I believe those matters to be true. I understand the importance of the ACCC being provided with true and accurate information.

9. In making this declaration I do so as an officer of the Court. I am also aware of the consequences of an authorisation granted on the basis of evidence or information that was false or misleading in a material particular under section 91B(3) of the CCA and the repercussions of making a false or misleading statement to a Commonwealth Officer under section 90B of the *Crimes Act 1914* (Cth).

Lenalidomide

10. [redacted]

11. [redacted]

Pomalidomide

12. Celgene informed the ACCC on 11 February 2022 in its Further Response to the ACCC RFI:

    a. [redacted]

    b. [redacted]

13. Celgene informed the ACCC on 11 February 2022 in its Further Response to the ACCC RFI [redacted]

[redacted]

14. I am instructed that in the current circumstances, including as at the date of this declaration, [redacted]

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

Declared at Sydney, NSW on 4 May 2022.

Before me,

Charlie Guerit
Legal Practitioner
Aurora Place
Level 41, 88 Phillip Street
Sydney, NSW 2000 Australia

Commonwealth of Australia

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, Neil MacGregor, of Level 2/4 Nexus Ct, Mulgrave, in the state of Victoria, Managing Director Australia & New Zealand, Bristol Myers Squibb Company, make the following declaration under the *Statutory Declarations Act 1959:*

Introduction

1. Since December 2018, I have been employed as Managing Director for Australia & New Zealand, Bristol-Myers Squibb Company (**BMS Company**). In this role, I oversee the operations of the following corporate entities: Bristol-Myers Squibb Australia Pty Ltd, Celgene Pty Limited, Bristol-Myers Squibb (NZ) Limited, Celgene Limited (NZ), Abraxis Bioscience Australia Pty Ltd, Myokardia Australia Pty Ltd and Forbius Pty Ltd (collectively **BMS).** The BMS entities are each subsidiaries of BMS Company.

2. In November 2019, BMS Company acquired Celgene Corporation. Since that time, Celgene Corporation has been a wholly owned subsidiary of BMS Company. The Australian operating entity of Celgene Corporation is Celgene Pty Limited (together, **Celgene**).

3. I make this declaration in connection with an application which Celgene and Natco Pharma Ltd/Juno Pharmaceuticals Pty Ltd (**Natco/Juno**) have jointly made to the Australian Competition and Consumer Commission (**ACCC**) for Authorisation of a confidential settlement and licence agreement between them relating to lenalidomide and pomalidomide, dated 3 December 2021.

4. Unless otherwise indicated, this statutory declaration is made on the basis of my own knowledge. Where the information is based on information provided by others, I believe the information to be true. In making this statutory declaration, I am not intending and am not authorised to waive privilege on behalf of BMS in relation to any matter set out in this statutory declaration (or otherwise).

5. I request that the highlighted paragraphs be treated as confidential and not disclosed to Natco/Juno or placed on the ACCC public register. These paragraphs contain commercially sensitive information that if disclosed contrary to this request could cause harm to BMS including in providing a commercial advantage to competitors.

Qualifications and experience

6. In 2002, I obtained a Bachelor of Science (Hons), Biology from the University of Aberdeen, Scotland.

7. In 2005, I obtained the qualification of 'Chartered Management Accountant' from the Chartered Institute of Management Accountants, United Kingdom.

8. Between September 2003 and May 2012, I was employed by AstraZeneca PLC. AstraZeneca PLC is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology; Cardiovascular, Renal & Metabolism; and Respiratory & Immunology.

9. During my tenure at AstraZeneca PLC I held the following roles:

    - Liaison Accountant, based in the UK (2003 – 2004);
    - Tax Analyst, based in the UK (2004 – 2005);
    - Senior Business Analyst, Group Business Planning & Reporting, based in the UK (2005 – 2007);
    - Head of Finance Planning & Analyses, based in Japan (2007 – 2009); and
    - Chief Financial Officer South Africa & Sub-Saharan Africa, based in South Africa (2010 –2012).

10. I have been employed with BMS since 2012. Prior to being appointed to my current position as Managing Director, I was employed at BMS as:

    - Chief Financial Officer Australia & New Zealand, based in Melbourne, Australia (2012 – 2015); and
    - Chief Financial Officer Japan, Korea & Taiwan, based in Tokyo, Japan (2015 - 2018).

11. As Managing Director, Australia & New Zealand, I am responsible for all aspects of BMS' Australian and New Zealand business operations and oversee approximately 300 staff (based in Melbourne for headquarters staff and across most states for field based staff). The Heads of Haematology, Oncology, and Innovative Medicines report directly to me, along with the Head of Access, Policy & Advocacy and the Head of Strategy & Operations.

12. Since October 2019, I have been a member of the Board of Medicines Australia. Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. BMS is a member of Medicines Australia.

13. A copy of my *curriculum vitae* is annexed to this declaration and marked **Annexure NM-1.**

BMS and its Australian product portfolio

14. BMS Company is a global innovative biopharmaceutical company. It is engaged in the discovery, development, licensing, manufacture, marketing and distribution of biopharmaceuticals and related healthcare products.

15. BMS Company operates primarily in the therapeutic areas of Immuno-Oncology, Haematology, Immunology, Cardiology and Fibrosis.

16. BMS Company's mission is to "transform patients' lives through science".

17. Consistent with this, in my opinion, what distinguishes BMS in Australia and globally is its commitment to and focus on providing a high quality product to patients by developing breakthrough treatments for devastating and sometimes terminal diseases with new, innovative, 'best in class' pharmaceuticals.

18. In Australia, BMS Company has a large product portfolio which includes products sponsored on the ARTG by Celgene Pty Ltd containing lenalidomide (Revlimid®), pomalidomide (Pomalyst®) and thalidomide (Thalomid®), as follows:

- REVLIMID lenalidomide 25mg capsule blister pack
- REVLIMID lenalidomide 20mg capsule blister pack
- REVLIMID lenalidomide 15mg capsule blister pack
- REVLIMID lenalidomide 10mg capsule blister pack
- REVLIMID lenalidomide 7.5mg capsule blister pack
- REVLIMID lenalidomide 5mg capsule blister pack
- REVLIMID lenalidomide 2.5mg capsule blister pack
- POMALYST pomalidomide 4 mg capsule blister pack
- POMALYST pomalidomide 3 mg capsule blister pack

- POMALYST pomalidomide 2 mg capsule blister pack
- POMALYST pomalidomide 1 mg capsule blister pack
- THALOMID thalidomide 200 mg hard capsule blister pack
- THALOMID thalidomide 150 mg hard capsule blister pack
- THALOMID thalidomide 100 mg hard capsule blister pack
- THALOMID thalidomide 50 mg hard capsule blister pack

19. **Annexure NM-2** lists other products currently registered on the ARTG that are sponsored by companies in the BMS Company group.

Multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma

20. Revlimid® is indicated on the ARTG for the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma (each of which may be described at a high level as a malignancy (cancer) of the blood).

21. Pomalyst® is indicated on the ARTG for the treatment of multiple myeloma.

22. Multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma are devastating disorders that are ultimately terminal. Treatment with Revlimid® and Pomalyst® is safe and efficacious and significantly improves average patient survival rates.

Generic lenalidomide and pomalidomide products

23. As at the date of making this declaration, I am aware that 6 generic manufacturers have obtained ARTG registration for products containing lenalidomide, namely:

- Cipla Australia Pty Ltd
- Teva Pharma Australia Pty Ltd
- Dr Reddys Laboratories Australia Pty Ltd
- Juno Pharmaceuticals Pty Ltd
- Sandoz Pty Ltd
- Luminarie Pty Ltd

24. I am also aware that the only generic pomalidomide products registered on the ARTG are sponsored by Juno Pharmaceuticals Pty Ltd.

25. [redacted]

26. [redacted]

27. [redacted]

Comments on Draft Determination

28. I have reviewed the public version of the Draft Determination issued by the ACCC on 23 March 2022.

29. I have been asked by Jones Day to comment on paragraphs 4.81 to 4.83 of the Draft Determination, extracted below:

> *4.81. The ACCC considers the Proposed Conduct gives Celgene greater control and certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage' may deter generic entry, and, [redacted]. The Proposed Conduct replaces the competitive tension among current or future generic manufacturers of lenalidomide and pomalidomide which are looking to enter the market, by seeking to establish Juno/Natco as the first generic manufacturer and distributor in Australia for these products. It also affects Celgene's response to generic entry by removing elements of commercial risk, which, in the absence of the Proposed Conduct, might generate a more competitive response to the actions of generic manufacturers. There is a risk that affecting the structure of the relevant markets for the supply of lenalidomide and pomalidomide in this way will result in public detriment. The ACCC considers the nature and extent of this public detriment is unclear.*
>
> *4.82. The ACCC has considered whether the Proposed Conduct changes the dynamics in the relevant areas of competition and whether other generic manufacturers may have a reduced incentive or ability to enter 'at risk' (i.e. before the relevant patents expire, and potentially before the specified launch dates).*

This would ultimately impact the wider community, including patients, hospitals and buying groups, and the Australian Government.

4.83. Without the Proposed Conduct, the ACCC considers that generic manufacturers (including Juno/Natco) could seek to launch lenalidomide or pomalidomide products 'at risk', that is, enter before the relevant patents expire, which could be before the specified launch dates. The ACCC considers the threat of generic entry occurring, including the possibility of 'at risk' entry and any response to entry, can be a key driver of competition in the supply of products and is likely to exert pressure on Celgene. The ACCC is concerned that the Proposed Conduct compromises this competitive threat and could affect the way in which Celgene responds to generic entry, which may not be in the interests of competition.

30. I note that I was not asked to comment on any other part of the Draft Determination. Accordingly, the fact that I do not do so should not be taken to reflect that I agree or disagree (in whole or in part) with any of the other matters raised therein.

31. I understand that at a high level, the reference to the "*Proposed Conduct*" in paragraphs 4.81 to 4.83 is to the agreement between Celgene and Natco/Juno that permits launch of generic lenalidomide and pomalidomide from the authorised launch dates. I also understand that these paragraphs purport to discuss the competitive landscape in Australia with and without the Proposed Conduct.

32. I have been asked by Jones Day to briefly comment on how BMS will respond to loss of exclusivity (**LOE**) for Revlimid® and Pomalyst®. [redacted]

33. [redacted]

34. [redacted]

35. [redacted]

[redacted]

36. [redacted]

37. [redacted]

38. [redacted]

39. [redacted]

[redacted]

40. [redacted]

41. [redacted]

42. [redacted]

43. [redacted]

44. Juno is currently the only manufacturer with an ARTG registration for pomalidomide products.

45. The next possible PBS listing date for generic pomalidomide is 1 October 2022. That is, no generic can PBS list on an earlier date.

46. [redacted]

47. [redacted]

- [redacted]
- [redacted]

48. I refer to the statement in paragraph 4.81 of the Draft Determination as follows:

> *The Proposed Conduct replaces the competitive tension among current or future generic manufacturers of lenalidomide and pomalidomide which are looking to enter the market, by seeking to establish Juno/Natco as the first generic manufacturer and distributor in Australia for these products.*

49. [redacted]

50. [redacted]

51. [redacted]

Juno Pharmaceuticals

52. [redacted]

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

[redacted]

Neil MacGregor
Managing Director Australia and New Zealand
[redacted]

Declared at Mulgrave, Victoria on Thursday 5th of May 2022

Before me,

1. [redacted]

2.
Alexander Hagan
Solicitor
Level 41, 88 Phillip Street
Sydney, NSW 2000 Australia

3. [redacted]

This declaration was made in accordance with the *Coronavirus Economic Response Package (Modifications – Statutory Declarations and Notices of Intention to Marry) Determination 2021*

Note 1 A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years — see section 11 of the *Statutory Declarations Act 1959*.

Note 2 Chapter 2 of the *Criminal Code* applies to all offences against the *Statutory Declarations Act 1959* — see section 5A of the *Statutory Declarations Act 1959*.

A statutory declaration under the *Statutory Declarations Act 1959* may be made before–

(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

Architect	Chiropractor	Dentist
Financial adviser	Financial Planner	Legal prac itioner
Medical prac itioner	Midwife	Migration agent registered under Division 3 of Part 3 of the *Migration Act 1958*
Nurse	Occupational herapist	Optometrist
Patent attorney	Pharmacist	Physiotherapist
Psychologist	Trade marks attorney	Veterinary surgeon

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or

(3) a person who is in the following list:

Accountant who is:

a) a fellow of the National Tax Accountants' Association; or

b) a member of any of the following:

i. Chartered Accountants Australia and New Zealand;

ii. the Association of Taxation and Management Accountants;

iii. CPA Australia;

iv. the Institute of Public Accountants

Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public

APS employee engaged on an ongoing basis with 5 or more years of continuous service who is not specified in another item in his list

Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the *Consular Fees Act 1955*)

Bailiff

Bank officer with 5 or more continuous years of service

Building society officer with 5 or more years of continuous service

Chief executive officer of a Commonwealth court

Clerk of a court

Commissioner for Affidavits

Commissioner for Declara ions

Credit union officer with 5 or more years of continuous service

Employee of a Commonwealth authority engaged on a permanent basis with 5 or more years of continuous service who is not specified in another item in this list

Employee of the Australian Trade and Investment Commission who is:

(a) in a country or place outside Australia; and

(b) authorised under paragraph 3 (d) of the *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Employee of the Commonwealth who is:

(a) at a place outside Australia; and

(b) authorised under paragraph 3 (c) of he *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Engineer who is:

a) a member of Engineers Australia, other than at the grade of student; or

b) a Registered Professional Engineer of Professionals Australia; or

c) registered as an engineer under a law of the Commonwealth, a State or Territory; or

d) registered on the National Engineering Register by Engineers Australia

Finance company officer with 5 or more years of continuous service

Holder of a statutory office not specified in another item in this list

Judge

Justice of the Peace

Magistrate

Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the *Marriage Act 1961*

Master of a court

Member of the Australian Defence Force who is:

a) an officer

b) a non-commissioned officer within the meaning of the *Defence Force Discipline Act 1982* with 5 or more years of continuous service

c) a warrant officer within the meaning of that Act

Member of the Australasian Institute of Mining and Metallurgy

Member of the Governance Institute of Australia Ltd

Member of:

a) the Parliament of the Commonwealth

b) the Parliament of a State

c) a Territory legislature

d) a local government authority

Minister of religion registered under Subdivision A of Division 1 of Part IV of the *Marriage Act 1961*

Notary public, including a notary public (however described) exercising functions at a place outside

a) the Commonwealth

b) the external Territories of the Commonwealth

Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office providing postal services to the public

Permanent employee of

a) a State or Territory or a State or Territory authority

b) a local government authority

with 5 or more years of continuous service, other han such an employee who is specified in another item of this list

Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made

Police officer

Registrar, or Deputy Registrar, of a court

Senior executive employee of a Commonwealth authority

Senior executive employee of a State or Territory

SES employee of the Commonwealth

Sheriff

Sheriff's officer

Teacher employed on a permanent full- ime or part-time basis at a school or tertiary education ins itu ion

Annexure NM-1

NEIL MACGREGOR

Location: Melbourne, Australia

Personal Profile:

International Executive with a proven track record of influencing and implementing strategies in both mature and emerging markets. Strengths include ability to drive change management in complex business contexts, motivating diverse teams to achieve high levels of productivity whilst re-energising commercial culture to deliver financial targets.

Professional Experience:

Bristol-Myers Squibb Plc (May 2012 – Present)

Bristol-Myers Squibb Company is global biopharmaceutical company. It undertakes the discovery, development, licensing, manufacture, marketing and distribution of biopharmaceuticals and related healthcare products. The company, and its 30,000 employees, focus on the Therapeutic Areas of Immuno-Oncology, Haematology, Immunology, Cardiology and Fibrosis.

- **Managing Director Australia & New Zealand (Melbourne Dec'18 – present)**
  - Accountable for strategy and commercialisation of BMS portfolio across the AUS & NZ affiliates (Sales $400m in '20 (+10% CER), Costs $50m, ~300 company employees), as well as overarching responsibility for Regional Clinical Operations, Enabling Functions and APAC capability centres based in Melbourne.
  - Established BMS as an industry leader in revenue growth (ranked #1 pharma company in Aus, 4 products in top 20) by successfully accelerating pipeline assets (17 regulatory submissions), navigating new product launches (13 PBS listings) through Health Technology Assessment (HTA), continued growth of core portfolio with globally leading shares, and the management of patent expirations.
  - Successfully lead M&A integration of both Celgene (2019) and MyoKardia (2020) businesses across all elements of the value chain whilst navigating the numerous and unique challenges of the COVID pandemic.
  - Developed and executed a people strategy that has generated a psychologically safe environment where people thrive to achieve, perform with excellence, and feel valued as we innovate our ways of working to enhance both customer and employee experience. Continue to be a passionate talent developer and exporter (5 LT/LT-1 in '21)
  - Launched and embedded BMS' Reconciliation Action Plan (RAP) commitments which lay foundations for lasting impact as allies in advancing reconciliation in Australia with Aboriginal and Torres Strait Islanders.
  - Appointed to Industry Association Board (Medicines Australia) by peers and co-led negotiations with Government on Strategic Agreement (Policy & Funding Framework for Healthcare). Key highlights include; $5Bn envelope for funding new medicines; First review of HTA system in 30 years; Enhanced Consumer Engagement Process (ECEP)
  - Industry representative and advocate on National Oncology Alliance Board.

- **Chief Financial Officer Japan, Korea & Taiwan (Tokyo, Japan '15 - '18)**
  - Responsible for 5 Functions (Finance, Supply Chain, Procurement, IS/IT, Business Insight & Analytics) across Japan, Korea and Taiwan (Sales $1.7bn in '17 (+1% CER), Costs $285m, ~2200 company employees, 83 reports). Korea and Taiwan responsibilities added in January 2017.
  - Executed fastest ever product launch in Japanese Pharma market (Daklinza/Sunvepra – HCV), before dynamically flexed organisational resources and capital allocation towards next wave growth in Oncology.
  - Global financial lead for the Ono-BMS Oncology alliance, where we launched innovative Immuno-Oncology products (Opdivo, Yervoy) into 6 tumor types, navigated public "price toxicity" concerns, R&D pipeline harmonisation and generated a complimentary biomarker strategy.
  - Successfully negotiated Japanese Income Tax and Payroll audits with National Tax Agency (NTA), whilst inserting sustainable structures and controls ahead of Base Erosional Profit Shifting (BEPS) legislation in 2018.
  - Lead the assessment and strategic design of APAC Finance operating model (In-market & Centre of Excellence) as part of a wider Enabling Function transformation
  - Implemented new Business Performance management "Data Lake" to centralise multiple internal and external data sources, facilitate focused "push-and-pull" reporting and allow for customised close loop analytics.
  - Chaired APAC Finance Talent Development forum that assesses, mentors and facilitates active career mapping for a select talent pool across Asia. Concurrently built "Asia as a Career Accelerator" program to attract HQ talent into the region.

- **Chief Financial Officer Australia & New Zealand (Melbourne, Australia (: '12 – '15)**
  - Responsible for 7 Functions (Finance, Business Development, Facilities, SHE, Supply Chain, Procurement & Legal) across Australia and New Zealand (Sales $220m in '14 (+27% CER), Costs $60m, ~320 company employees, 19 reports)
  - Rebased company performance following strategic divestment of Sanofi JV business in 2012, before embarking on ambitious growth strategies in 2013 to launch an unheralded 6 new product and become fastest growing Pharma Company in Australia.
  - Successfully lead the world's fastest divestment transition of all value chain elements associated with our Diabetes franchise to AstraZeneca (12 weeks from NYSE Announcement) in 2014.
  - Optimization of the distribution activities in Australia to deliver cost savings of $2.7M/yr (~35%), working capital benefit of $0.5m, enhanced operational service flexibility and transparency as well as contract simplification
  - Led global benchmarking project to evaluate alternative go-to-market business models as company assesses "the next best practice" through continuous improvement
  - Outsourced transactional finance to Centre of Excellence in China and refreshed financial focus towards Business Partnering through resourcing/structural changes and implementation of the balance scorecard.
  - Reinvigorated an underperforming Finance function through a 3 year Learning & Development program to achieve best employer scores within AON Hewitt Best Employer survey

AstraZeneca Plc (Sept 2003 – May 2012)

AstraZeneca is a global, innovation-driven, integrated biopharmaceutical company employing over 61,000 employees across +100 countries. Listed on the FTSE, AstraZeneca discover, develop, manufacture and market prescription medicines across 6 major therapeutic areas.

- **Chief Financial Officer South Africa & Sub-Saharan Africa (SSA) (Johannesburg, South Africa (: '10 –'12)**
  - Responsible for 8 Functions (Finance, Business Development, IS/IT, SHE, Supply Chain, Procurement, Legal & Compliance) in 20 emerging markets across the Anglophone & Lusophone areas of Africa (Sales $200m in '11 (+16% CER), Costs $45m, 420 employees, 10 reports)
  - Led the strategic sizing and prioritisation of the "Africa Opportunity" - focusing on the quantification of the opportunity, barriers to entry and risk management (inc. legal entity & supply chain set up, employment models, strategic partner choice and tax planning).
  - Outsourced transactional finance to Genpact (Morocco)
  - Other achievements in South Africa; successfully defended Transfer Pricing audit ('05-'08), led Industry Association evaluation of International Benchmark Pricing alternatives, facilitated a Corporate HQ review of a local M&A target and divestment of a non-core brand.
  - Other achievements in SSA; launched new companies in Angola and Nigeria, reduced product lead times by 50% through set up of 2 new consignment stock Distribution Centres (Kenya & Ghana), inserted new Financial Governance & Control framework across 13 strategic partners and optimised cash cycles away from Letters of Credit towards internal Re-insurance.

- **Head of Finance Planning & Analyses Japan (Osaka, Japan (: '07 – '09)**
  - Developed strategic plans and optimisation of resources across the Japanese Marketing Company (Sales $2.0bn in '08 (+18% CER), Costs $525m, 2,500 company employees, 7 reports), including 9 months in 2008 as Acting CFO of the Commercial business.
  - Initiated organisational restructuring and cost reduction project (-150 FTE, -$25m savings YoY) as part of leading 2008 budgeting process
  - Introduced Sales and Operating Plan and associated forecasting tools into monthly Business Unit review to drive improved forecast accuracy. AZ Japan exceeded target in 2009 (102%) for the first time in 5 years.
  - Successfully realigned cost architecture and associated cost management processes to implement Global-forecasting platform (APEX).
  - Introduced Finance Academy to my direct reports (9 FTEs) to drive long-term finance organisational capability.

- **Senior Business Analyst, Group Business Planning & Reporting (London, UK '05 – '07)**
  - Senior analytical support to Group Chief Financial Officer & Investor Relations (Sales 2007 $29.6bn, Operating Profit $8.1bn, 67,400 company employees) – including the creation of all external/internal Finance presentations to senior stakeholders.
  - Maintained numbers and narratives underpinning Group Operating Profit forecasts ('05-'10) & Global Balance Scorecard across 10 geographically remote sub-forecasts.

- Undertook cross functional review of people, processes and systems underpinning Central Admin area ($1bn) as part of companywide push on G&A (subsequent savings ~$100m YoY)
- Project managed (~20 FTEs) the automation of External Sales reporting and the associated complexities

- **Tax Analyst, Group Taxation (Manchester, UK '04 – '05)**
  - Devised methodology in line with new tax legislation for calculating UK R&D Tax Credit (~$50m savings YoY) as part of preparation of 2004 AZUK Ltd. tax computation
  - Systematised product profitability analytics & subsequent statutory cost recharge as part of Transfer Pricing policy review
  - Financial Modelling / Commercial Support to product licensing deals

- **Liaison Accountant, Operations (Bristol, UK '03 - '04)**
  - Liaison Accountant on an Active Ingredient manufacturing site
  - Led maintenance benchmarking project vs. asset replacement value.

Other Relevant Employment

- **Aegon Asset Management ('02-'03)**: Credit controller in Corporate Risk Renewals
- **MacGregor's C.A. ('99-'01)** Insolvency practitioner's assistant in trust deed/sequestrations

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Education:

- Chartered Management Accountant (ACMA, CGMA)
- University of Aberdeen ('98-'02): BSc Biology (Hons)

Interests / Skills

- Married to Johanna (Australian), Daughter Lucy (9), Son Robin (7)
- Active sportsman: AFL, Soccer, Cricket & Golf
- Basic French & Japanese

References: (available on request)

Annexure NM-2

Annexure NM-2

The following is a list of products currently registered on the ARTG that are sponsored by companies in the BMS Company group.

- ABRAXANE nanoparticle albumin-bound paclitaxel 250 mg powder for injection (suspension) vial;
- ABRAXANE nanoparticle albumin-bound paclitaxel 100 mg powder for injection (suspension) vial;
- Azactam 1g powder for injection vial;
- AZAFURIDINE azacitidine 100mg powder for injection vial;
- AZAMYELIDINE azacitidine 100mg powder for injection vial;
- BARACLUDE entecavir 0.5mg film coated tablet blister pack;
- BARACLUDE entecavir 1.0mg film coated tablet blister pack;
- CEENU 10mg capsule bottle;
- CEENU 40mg capsule bottle;
- CELAZADINE azacitidine 100mg powder for injection vial;
- ELIQUIS apixaban 2.5mg film-coated tablet blister pack;
- ELIQUIS apixaban 5mg film-coated tablet blister pack;
- EMPLICITI elotuzumab 300mg lyophilized powder for IV infusion vial;
- EMPLICITI elotuzumab 400mg lyophilized powder for IV infusion vial;
- EVOTAZ atazanavir/cobicistat 300mg/150mg film coated tablets bottle;
- HYDREA hydroxycarbamide (hydroxyurea) 500mg capsule bottle;
- Istodax (romidepsin) 10mg powder for injection vial, and solvent for reconstitution vial;
- MONOPRIL fosinopril sodium 10mg tablet (ARTG ID 46475);
- MONOPRIL fosinopril sodium 10mg tablet (ARTG ID 46751);
- NULOJIX belatacept (rch) 250mg powder for IV infusion vial;
- ONUREG azacitidine 200mg film-coated tablet blister pack;
- ONUREG azacitidine 300mg film-coated tablet blister pack;
- OPDIVO nivolumab 100mg in 10 mL (10mg/mL) concentrated solution for IV infusion vial;
- OPDIVO nivolumab 240mg in 10 mL (10mg/mL) concentrated solution for IV infusion vial;
- OPDIVO nivolumab 40mg in 4 mL (10mg/mL) concentrated solution for IV infusion vial;

- ORENCIA abatacept (rch) 125mg single dose ClickJect prefilled autoinjector;
- ORENCIA abatacept (rch) 125mg single dose syringe subcutaneous injection flange extender;
- ORENCIA abatacept (rch) 125mg single dose syringe subcutaneous injection needle guard;
- ORENCIA abatacept (rch) 125mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender;
- ORENCIA abatacept (rch) 250mg powder for IV infusion vial;
- REBLOZYL luspatercept 25mg powder for injection vial;
- REBLOZYL luspatercept 75mg powder for injection vial;
- REYATAZ atazanavir (as sulfate) 300mg capsule bottle;
- REYATAZ atazanavir 200mg capsule bottle;
- SPRYCEL (dasatinib) 100mg tablet blister pack;
- SPRYCEL (dasatinib) 100mg tablet bottle;
- SPRYCEL (dasatinib) 20mg tablet blister pack;
- SPRYCEL (dasatinib) 20mg tablet bottle;
- SPRYCEL (dasatinib) 50mg tablet blister pack;
- SPRYCEL (dasatinib) 50mg tablet bottle;
- SPRYCEL (dasatinib) 70mg tablet blister pack;
- SPRYCEL (dasatinib) 70mg tablet bottle;
- VIDAZA azacitidine 100mg powder for injection;
- WINGLORE ipilimumab (rch) 200mg in 40mL (5mg/mL) concentrate solution for IV infusion vial;
- WINGLORE ipilimumab (rch) 50mg in 10mL (5mg/mL) concentrate solution for IV infusion vial;
- YERVOY ipilimumab (rch) 200mg in 40mL (5mg/mL) concentrate solution for IV infusion vial;
- YERVOY ipilimumab (rch) 50mg in 10mL (5mg/mL) concentrate solution for IV infusion vial;
- ZEPOSIA ozanimod 230 microgram and 460 microgram capsules blister wallet composite pack (250 microgram);
- ZEPOSIA ozanimod 230 microgram and 460 microgram capsules blister wallet composite pack (500 microgram);
- ZEPOSIA ozanimod 920 microgram capsules blister pack.

Commonwealth of Australia

STATUTORY DECLARATION

Statutory Declarations Act 1959

1 *Insert the name, address and occupation of person making the declaration*

I, Gregory Ian O'Toole, of 31 Bland Street, Ashfield, in the state of New South Wales, consultant, make the following declaration under the *Statutory Declarations Act 1959:*

2 *Set out matter declared to in numbered paragraphs*

Background and experience

1. I am currently Principal of Concord Pharmaceutical Consulting, a business which I founded in November 2020. In this role, I provide consulting services in relation to the operation of the Pharmaceutical Benefits Scheme (**PBS**). My work is primarily concerned with advising pharmaceutical companies of the ways in which government policies and processes in the pharmaceutical sector will impact their existing products and products under development. A particular emphasis of my work in advising clients concerns the impacts of government policies and processes on the pricing of their pharmaceutical products.

2. I have undertaken and completed recent projects articulating the impacts of new and amended policies arising from the 2022-2027 Strategic Agreement between Medicine Australia (on behalf of the research-based pharmaceutical industry) and the Commonwealth Government, including impending changes to the price disclosure regime (which I discuss further at paragraph 39 below).

3. In 2000, I obtained the degree Bachelor of Pharmacy from the University of Sydney.

4. Between 2000 and 2010, I worked as a pharmacist in a number of clinical roles, including in community pharmacies, nursing homes, and medical centres. In these roles, I was engaged in dispensing pharmaceuticals to patients and counselling patients in relation to their use of pharmaceuticals.

5. In addition, aspects of these roles involved pharmacy management which included negotiating with pharmaceutical companies for the purchase of pharmaceutical products including generic brands of products, and the pharmacy's claim for reimbursement from the PBS for pharmaceutical products dispensed in the centres in which I worked. This work also involved counselling patients on the potential for adverse reactions from the use of pharmaceuticals (including generic brands of pharmaceutical products) that I dispensed and the circumstances in which they

should seek further medical advice from their doctor. I also counselled patients on the appropriate use of over-the-counter medicines.

6. In addition to the work described in paragraph 5 above, between 2008 and 2010, I held a joint appointment at the University of Sydney's Faculty of Pharmacy and the Pharmaceutical Society of Australia. This work, in which I was engaged three days per week, focused on the training and education of undergraduate pharmacy students and intern pharmacists undertaking pre-registration training following the completion of their undergraduate degree. This work involved running clinical tutorials for student pharmacists and developing training and testing materials for intern pharmacists for their first supervised year of practice. These clinical tutorials and training included segments on the practical operation of the PBS, including pricing of pharmaceuticals at the time of initial listing and mechanisms for the revision of those prices over time.

7. From 2010 to 2012, I was Director of PBS Listings & Advisory Section and Senior Pharmaceutical Advisor at the Australian Department of Human Services. In this role, I was responsible for the administration of the PBS. This included the administration of the PBS Authorities scheme under which prescribers must obtain authority approval prior to prescribing high-cost pharmaceuticals. The role also involved supporting and advising on AUD $11.8 billion worth of pharmacy reimbursement claims annually and included attending Pharmaceutical Benefits Advisory Committee (**PBAC**) meetings to provide advice on the criteria to be applied in considering and granting PBS authority applications. In addition, I advised on or directly managed monthly updates to the PBS including price changes and the addition and removal of medicines from the PBS, based on advice from the PBAC.

8. From 2012 to 2017, I worked for the Commonwealth Department of Health in a variety of PBS-related roles including 4 years as the Secretary of the PBAC in the final 2 of which I was also Director of Health Technology Assessment.

9. I was involved with negotiations with pharmaceutical companies following a positive PBAC recommendation to agree the projected financial impact on the Commonwealth of listing new pharmaceuticals on the PBS.

10. In these roles, I oversaw the management of Health Technology Assessment processes for the PBAC, a reimbursement process representing hundreds of millions of dollars in new government spending every year. I was key liaison between Government and the pharmaceutical industry on the lodgement and

evaluation of reimbursement submissions. I advised on, supervised, or was personally responsible for the evaluation of over 1,500 PBAC submissions.

11. These evaluations routinely required addressing a company's request for a Special Pricing Arrangement (**SPA**). Under an SPA, the pharmaceutical product is listed on the PBS at a published price, however, pursuant to a confidential agreement between the pharmaceutical company and the government, the company rebates an agreed percentage of the cost of each supply back to the government. These confidential agreements are normally formalised in a five-year deed of agreement, which corresponds to the five-year Budget forward estimates period.

12. The rationale for SPAs is to enable the negotiations between the pharmaceutical company and the Commonwealth government in relation to the price at which a pharmaceutical supplied in Australia will be reimbursed, to be kept confidential. Confidentiality enables the Commonwealth government to negotiate a price for the supply of pharmaceuticals in Australia unimpeded by comparison with the price paid by other countries for the supply of that product. A number of countries take international prices into account when negotiating local prices for the same pharmaceutical or brand (International Reference Pricing (**IRP**), also referred to as External Reference Pricing). Under such a system, the country (for example, South Korea) may insist on a price comparable to that at which the company has supplied other developed countries. For some pharmaceuticals, the sponsoring company may be unwilling to supply the product at the low price required by the Commonwealth government because of the price consequences for the supply of that product in other countries. Therefore, the implementation of an SPA enables the Commonwealth government to secure the supply of pharmaceuticals at a price lower than the pharmaceutical company would be willing to supply the product in the absence of such arrangements. I note that the PBS provides a rationale for SPAs on its website at https://www.pbs.gov.au/info/industry/listing/elements/deeds-agreement/b-background as follows:

> *SPA*
>
> *The Commonwealth may enter into confidential Special Pricing Arrangements with a sponsor for the supply of a medicinal product formalising a 'published' versus '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 main reason for the Commonwealth to enter into a SPA for the supply of a medicine is so that Australia is able to have access to medicines at a lower cost-effective price without affecting the price for the product in other markets.

13. Another routinely employed mechanism to manage financial risk to the Commonwealth in respect of the PBS is called a Risk Share Agreement (**RSA**). Under an RSA, the pharmaceutical product is listed on the PBS pursuant to a confidential agreement between the pharmaceutical company and the government. This agreement establishes specific annual expenditure caps for a pharmaceutical. When the actual cost of the pharmaceutical exceeds the agreed cap in an agreed 12-month period, the company becomes liable to reimburse the government for the additional expenditure. These confidential agreements are also normally formalised in a five-year deed of agreement, which corresponds to the five-year Budget forward estimates period.

14. In my role as PBAC Secretary, I advised and supported the team negotiating the financial implications of a new pharmaceutical with the sponsoring pharmaceutical company. My purpose was to ensure that any RSA and associated expenditure caps aligned with the PBAC's advice to government.

15. My work with the PBAC also related to downstream drug pricing implications both for single-branded drugs and drugs operating in competitive environments (including both on-patent and multi-branded (genericised) pharmaceuticals). This required knowledge of the full range of PBS pricing mechanisms (namely, statutory price reductions, administrative price reductions, and reductions under the price disclosure regime) and close cooperation with the PBS Pricing Section. I provided detailed policy advice on PBS matters to internal and external parties ranging from Ministerial submissions to materials published on the PBS website.

16. In addition, during 2016 – 2017, I worked on projects involving the authority criteria for high-cost pharmaceuticals which had extremely detailed eligibility requirements. This involved in-depth analysis of 12 – 24 months of the use of the pharmaceutical to prepare reports for the PBAC. Another project in which I was also involved required managing the review of the activity-based costing model and financial analysis for the Commonwealth Department of Health's recovery of costs from industry for PBAC submissions.

17. From 2017 to 2020, I was a Reimbursement Strategy Specialist at AstraZeneca Australia & New Zealand. In this role, I advised the company on pricing scenarios for both new products and those operating under Price Disclosure. In terms of the latter, where an AstraZeneca product was identified by the Commonwealth Department of Health as being a candidate for a price disclosure reduction, it was

my role to review PBS pricing data with a view to arriving at AstraZeneca's own conclusion regarding the Department's calculation. In the event that AstraZeneca's independent calculations revealed a plausible basis for disagreeing with the Department's calculations, it was my role to support the company in making appropriate submissions to the Department.

18. I have presented at an international conference in Singapore in 2018 at the request of an industry peak body on various Australian drug pricing matters and policies, including health technology assessment and PBS pricing mechanisms (statutory price reductions, price disclosure reductions and administrative price reductions). I presented on the same matters to an international conference in Hanoi, Vietnam in 2019 and 2021 at the request of the Vietnamese Ministry of Health.

19. In 2021, I obtained a Master of Business Administration (Technology) from the Australian Graduate School of Management. My studies in corporate finance further developed on my experience with the Commonwealth Department of Health on activity-based costing models and review of financial data.

20. Unless otherwise indicated, this statutory declaration is made on the basis of my own knowledge. Where the information is based on information provided by others, I believe the information to be true. In making this statutory declaration, I am not intending and not authorised to waive privilege on behalf of Celgene Corporation and Celgene Pty Ltd in relation to any matter set out in this statutory declaration.

21. I declare that I have made all the inquiries that I believe are desirable and appropriate (save for any matters identified explicitly in this report), and no matters of significance which I regard as relevant have, to my knowledge, been withheld.

PBS pricing framework

Price on PBS listing

22. I have been asked to describe in general terms the framework relating to the pricing of pharmaceuticals reimbursed by the Commonwealth government under the PBS.

23. When a pharmaceutical (as a new molecule or as a new indication for an existing molecule) is first listed on the PBS, its listing price is arrived at by considering its cost effectiveness compared to existing PBS listed pharmaceuticals or alternative therapies. Pharmaceuticals for which a price premium is sought over existing PBS listed options must demonstrate commensurate superiority in effectiveness and/or

safety. The pharmaceutical's effectiveness and safety relative to currently listed pharmaceuticals or alternative therapies is evaluated by the PBAC upon request for PBS listing of a pharmaceutical by a pharmaceutical company.

24. As well as looking at effectiveness and safety, the PBAC considers the likely patterns as to how the pharmaceutical is expected to be prescribed by doctors and used by patients as well as the overall budget impacts of the proposed PBS listing.

AEMP, PTP, DPMQ

25. Every PBS listed pharmaceutical has a government regulated maximum price that may be paid to the manufacturer (or sponsor) of the product in Australia. This is called the Agreed Ex Manufacturer Price (**AEMP**).

26. The price to pharmacy (**PTP**) comprises the AEMP plus the government regulated wholesaler mark-up. This is the price at which the pharmacy purchases the pharmaceutical.

27. The Dispensed Price for Maximum Quantity (**DPMQ**) comprises the PTP plus the government regulated pharmacy fees and mark ups. This is the price upon which pharmacy reimbursement is based.

28. Based on the matters I have discussed in paragraphs 25 - 27 above, in the event that the pharmacist is able to purchase the product from the wholesaler at a discount to the AEMP, then having regard to the fact that the pharmacist will be reimbursed under the PBS at the DPMQ, the lower purchase price represents a financial windfall to the pharmacy.

Statutory price reductions

29. Pharmaceuticals listed on the PBS are subdivided into two formularies, being 'F1' and 'F2'. F1 pharmaceuticals are those with only a single PBS listed brand and F2 pharmaceuticals are those with multiple PBS listed brands.

30. F1 pharmaceuticals are subject to a statutory price reduction upon their 5th, 10th and 15th anniversaries of PBS listing. From 1 July 2022, these anniversary statutory reductions are 5% on the 5th and 10th anniversaries, and 26.1% on the 15th anniversary. The 15th anniversary statutory price reduction increases to 30% from 1 April 2027.

31. On the same day that the first new brand of a pharmaceutical (bioequivalent or for biologic medicines, biosimilar) lists on the PBS, it is listed at a 25% discount on the existing brand, and the price of the existing (originator) brand is discounted

accordingly to match that price. This is referred to as the first new brand statutory price reduction. The pharmaceutical in question is moved to the F2 formulary at the same time. For completeness, I note that the first new brand statutory price reduction was 16% prior to 1 June 2018.

Dispensation settings

32. Prescription pharmaceuticals may be dispensed in community pharmacy, private hospital in-patient pharmacy, private hospital out-patient pharmacy, public hospital in-patient pharmacy, or public hospital out-patient pharmacy. A very small minority of PBS prescription claims are for prescriptions dispensed by a medical practitioner when no approved pharmacy is nearby.

33. Pursuant to current agreements between the Commonwealth government and the States and Territories (except for NSW and the ACT), the cost of pharmaceuticals dispensed by public hospital pharmacies to outpatients, non-admitted patients, or day-admitted patients are reimbursed from the PBS. The cost of any pharmaceuticals provided to patients admitted to hospital are covered by the State or Territory.

34. Public hospital pharmacies operate with formularies of pharmaceuticals available to be prescribed by the hospital. These formularies are set by expert committees either state-wide or on a hospital-by-hospital basis. Formulary submissions are made by pharmaceutical companies and include a clinical and financial analysis of the likely costs and benefits of the use of a particular pharmaceutical in the hospital setting. Following a positive recommendation by the expert committee, a new pharmaceutical may be added to the hospital formulary. Once a pharmaceutical is included in the hospital formulary, it is available to be prescribed by medical practitioners within the hospital. Except in NSW and the ACT, pharmaceutical products that are dispensed by the hospital pharmacy are typically reimbursed under the PBS.

35. State and Territory health departments routinely make use of tender processes to secure advantageous pricing terms for public hospital formulary pharmaceuticals. When multiple brands are available, the hospital formulary will typically include one of those brands for supply in and from the hospital. To the extent that the State and Territory health departments are able to procure pharmaceutical products under tender arrangements at a price less than the PBS price, this will represent a saving to the hospital pharmaceutical budget.

36. All supplies of PBS listed pharmaceuticals dispensed by community pharmacies and private hospital pharmacies are reimbursed by the PBS.

Price disclosure reductions

37. F2 pharmaceuticals are subject to price disclosure. On a rolling six-monthly data collection cycle, all suppliers of F2 pharmaceuticals are required to disclose data to the Commonwealth Department of Health of the total number of units sold and the total revenue generated for each listed brand during that data collection period. This obligation to provide data is referred to as the continuous price disclosure obligation. Then, over a further six-month period (referred to as the processing period) following the conclusion of each six-month data collection period, the Department of Health then calculates the effective in-market price (weighted average disclosed price (**WADP**)) relative to the AEMP for each F2 pharmaceutical across all brands. In this declaration, I refer to each 6-month period as 1 price disclosure cycle.

38. When the WADP for an F2 pharmaceutical is lower than the AEMP by a threshold margin specified in legislation (presently 10% for pharmaceuticals that have seen less than six data collection cycles), a price disclosure reduction is triggered to bring the AEMP to the WADP. Currently the price reductions are applied twice a year, namely on 1 April (corresponding to the data collected of sales made in the preceding 1 April to 30 September period) and 1 October (corresponding to the data collected of sales made in the preceding 1 October to 31 March period).

39. The price disclosure obligation and therefore the WADP calculation currently includes only sales to community pharmacy and private hospital pharmacy. Until 30 June 2022, sales to public hospital pharmacy are excluded from the price disclosure obligation and WADP calculation. 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. This is pursuant to clause 10.2.3 of the 2022-2027 Strategic Agreement between Medicines Australia (as representative for the research-based pharmaceutical industry) and the Commonwealth Government available at https://www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/MA-Strategic-Agreement-Signed.pdf.

Competition on generic entry

40. Jones Day asked me to describe the dynamics of market competition once the first new brand of a pharmaceutical is listed on the PBS.

41. A pharmaceutical company seeking to list a new brand of an existing pharmaceutical makes its application directly to the Commonwealth Department of Health. The brand is listed on the PBS some 12 weeks after application, if successful.

42. As described in paragraph 31 above, the new (generic) brand is listed at a 25% discount to the existing AEMP of the pharmaceutical and the price of the originator brand is reduced to that amount.

43. Pharmaceutical companies sponsoring generic brands of PBS listed pharmaceuticals must obtain an adequate share of PBS prescriptions for that pharmaceutical in order for the new (generic) brand to be financially viable.

44. There are a number of pharmaceutical companies sponsoring generic brands of pharmaceuticals in Australia including: Alphapharm, Apotex, Amneal, Generic Health, Sandoz, and Teva Pharma. Some such companies maintain a narrow portfolio of generic brands of only four to five pharmaceuticals while others maintain portfolios of dozens of products. Some companies which did not historically market generic brands have done so in recent years including MSD and Amgen.

45. Whereas companies sponsoring originator brands focus the majority of their marketing activities on medical practitioners and other prescribers with a minority focus on pharmacists, companies sponsoring generic brands focus their marketing activities predominantly on pharmacists.

46. Marketing of originator brands focuses on patient support, scientific education by reference to published clinical trials and learned articles, and by conducting professional conferences. Marketing of generic brands focuses on the financial benefit to the dispensing pharmacy by way of discounts off the PBS wholesale price and other financial benefits such as free or bonus stock.

47. Pharmaceutical companies marketing generic brands may employ a volume-based strategy to incentivise pharmacists to substitute a higher proportion of their generic brand. For example, the company may offer a higher percentage discount off the PTP when the pharmacy has demonstrated a willingness and ability to increase the rate at which it substitutes that company's generic brand for any other listed brand.

48. Storage space in a typical pharmacy dispensary limits the range of PBS listed brands that can be kept in stock. As a result, pharmacies typically purchase a limited number of generic brands or may stock only a single generic brand of each

pharmaceutical at a given time. However, the pharmacy's preference for a particular brand would be subject to change depending on factors including a more attractive price from another company. Committing to a single generic brand may also improve the pharmacy's financial performance by way of higher discounts as discussed above at paragraph 47.

49. As discussed above in paragraph 27, the pharmacy is reimbursed the PTP plus pharmacy fees and mark ups for each supply of a pharmaceutical. This price is predicated on the assumption that the pharmacy purchased the pharmaceutical at the full PTP. When a generic brand is sold to the pharmacy at a discount off the PTP, the pharmacy still receives the full reimbursement and the lower purchase cost represents additional revenue to the pharmacy.

50. Based on the matters discussed at paragraphs 41 - 49 above, supplying generic pharmaceuticals at a discount to the PTP is a key factor in generic companies obtaining market share.

51. Prior to 2007, the amount of discounts which generic companies offered pharmacists off the PTP were opaque to the Commonwealth. As a result, the Commonwealth introduced the price disclosure regime as a savings measure to return those discounts to the taxpayer. As discussed above in paragraph 37 - 39, the market share and effective in-market discount are used to calculate the WADP and to reduce the price of the pharmaceutical over time where market behaviour reveals that a pharmaceutical can be supplied to the pharmacy at lower cost.

Price movements following generic competition

52. Jones Day asked whether I have experience regarding the AEMP movements for specific pharmaceutical products following generic competition, and if so, to comment upon that experience.

53. In my experience in community pharmacy, I noted that following generic entry for sodium valproate (a common medicine prescribed for epilepsy and bipolar disorder), AEMP reduced over a 15-year period, namely for 500 mg sodium valproate a reduction in AEMP from $25.61 as of 1 July 2007 to $10.81 as of 1 April 2022. At that time, the data collection period for each price disclosure cycle extended over 12 months as opposed to the present duration of 6 months.

54. In my experience in government service, I noted many examples of pharmaceuticals undergoing substantial price disclosure reductions. Most notably, two chemotherapy agents, docetaxel and paclitaxel underwent significant reduction in AEMP as a result of price disclosure as follows:

a) On 1 July 2007 the AEMP for docetaxel 80 mg was $1,174.21. As of 1 April 2022, its AEMP was $24.12, a reduction of approximately 98%.

b) On 1 July 2007, the AEMP for paclitaxel 300 mg was $1,706.47. as of 1 April 2022, its AEMP is $49.66, a reduction of approximately 97%.

55. In my experience in industry, I assisted AstraZeneca in formulating its strategy when its brand of rosuvastatin (Crestor®) was subject to two separate price disclosure reductions during 2020. Crestor® is used in the treatment of hyperlipidaemia (high cholesterol) and is available in 4 different strengths. While I was employed by AstraZeneca, rosuvastatin took two price disclosure reductions, the first price of which took effect on 1 April 2020 and applied to the 5 mg, 20 mg and 40 mg strengths with the AEMP being reduced by between 30.00% to 30.10%. The second price disclosure reduction took effect on 1 October 2020 and applied to the 10 mg strength only with the AEMP being reduced by 38.52%.

56. Based on my experience and knowledge of the legislation and mechanics of price disclosure, in my view generic competition consistently exerts significant downward pressure on the price of PBS listed pharmaceuticals.

57. It has also been my observation that the greater the market density (that is, the more numerous the PBS listed generic brands of a pharmaceutical), the greater the downward pressure on the PBS price. In practice, a pharmaceutical operating in a market with numerous PBS listed generic competitors is more likely to have its first price disclosure reduction occur at an earlier stage and also to experience price reductions in excess of the statutory discount threshold of 10% compared to pharmaceuticals with fewer PBS listed generic competitors.

PBS price data

58. Following my comments in paragraph 57 above, Jones Day asked me if I could identify market examples that demonstrate those observations.

59. I suggested to Jones Day that one way of demonstrating these matters was to access publicly available historical monthly AEMP for a number of pharmaceuticals from the PBS website and observe both the number of brands available and the rate at which the AEMP changed over time following the listing of the first generic brand of the pharmaceuticals (that is, after the application of the first new brand statutory price reduction). These data are available from the PBS website at the following URL https://www.pbs.gov.au/info/industry/pricing/ex-manufacturer-price.

60. Jones Day then informed me that the pharmaceutical of interest is lenalidomide (Revlimid®). I was aware of this product having been considered on multiple occasions by the PBAC. I was also aware that the principal indication was in the treatment of multiple myeloma and that the PBS prescribing criteria are complex in that prescribers are required to make a written authority request with a substantial volume of supporting patient information. I was also aware that Revlimid® represents a cost to the PBS in excess of $100 million annually and was in the top 10 of PBS listed pharmaceuticals by cost to the government in the 2020-21 financial year.

61. Jones Day informed me that although there are no generic brands of lenalidomide currently listed on the PBS, a number of generic brands have been registered on the Australian Register of Therapeutic Goods (**ARTG**). I therefore consulted the ARTG to determine the number of generic brands that have been registered by the Therapeutic Goods Administration as of 18 April 2022.

62. Upon reviewing the ARTG, I identified 15 generic brands for lenalidomide registered by 6 sponsors as follows:

    a) Cipla Australia Pty Ltd, with three registered brands;

    b) Dr Reddy's Laboratories (Australia) Pty Ltd, with four registered brands;

    c) Juno Pharmaceuticals Pty Ltd, with three registered brands;

    d) Luminarie Pty Ltd, with two registered brands;

    e) Sandoz Pty Ltd, with one registered brand; and

    f) Teva Pharma Australia Pty Ltd, with two registered brands.

63. I also note that the PBS website lists lenalidomide at 4 different strengths, each of which have a published AEMP as follows:

    - 5 mg capsule – AEMP of $2,996.81;
    - 10 mg capsule - AEMP of $3,136.28;
    - 15 mg capsule - AEMP of $3,657.73; and
    - 25 mg capsule - AEMP of $3,952.49,

    although the PBS website indicates that a confidential rebate is in place for this product.

64. In addition, I note that the total PBS expenditure on lenalidomide (prior to the deduction of the confidential rebate(s)) in the 2021 calendar year was $233,722,015. I retrieved this expenditure figure from the Services Australia website at http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp.

65. I am aware that even though the ARTG shows registrations as I have described in paragraph 62 above, in practice not all registered brands are guaranteed to pursue a PBS listing. However, there are examples of PBS listed pharmaceuticals for which a single company has maintained more than one generic brand listed on the PBS at the same time. Indeed, some of the materials which I present in this declaration illustrate this behaviour. While the impact on price disclosure outcomes of a company listing multiple generic brands is difficult to demonstrate based on published information, in theory this approach could allow a company to offer differential discounts off AEMP for its brands of a pharmaceutical. This may have implications for the calculation of the Weighted Average Percentage Discount and consequently for the operation of the price disclosure regime while still allowing the company to present sufficiently attractive discounts to pharmacy to secure additional market share.

66. Jones Day then asked me if I could undertake the work that I describe in paragraph 59 keeping in mind that the pharmaceutical ultimately of interest in the analysis is lenalidomide.

67. Adopting the methodology described in paragraph 59 above, I identified all pharmaceuticals that had the listing of their first generic brand after 1 January 2015 and before 1 April 2022, of which there were 39 in total. I selected the start date for this period as 1 January 2015 as it was the start of the first full calendar year after which the current data collection periods of 6 months (as opposed to 12 months previously) came into effect, and in order to limit the scope of the analysis to a manageable number of pharmaceuticals.

68. I then downloaded the monthly published AEMP for all identified products (available in Microsoft Excel format) from 1 January 2015 up to 1 April 2022. I also downloaded the number and identity of the generic brands listed for each month for the same period (available in the same Microsoft Excel spreadsheets).

69. I determined that one way to represent this information would be to consider:

    a) percentage AEMP movements for a group of pharmaceuticals; and

    b) absolute and percentage AEMP movements for individual pharmaceuticals,

which occurred for these pharmaceuticals following the listing of the first generic brand (that is, after the application of the first new brand statutory price reduction) and represent this information in graphical form against the number of PBS listed brands over the course of a selected number of price disclosure cycles. Where a pharmaceutical is PBS listed in multiple strengths with different AEMPs, I included only one presentation with one AEMP on the basis that all strengths of a pharmaceutical would be equally affected by price disclosure.

70. I chose to group the pharmaceuticals by those with:

    a) 3 or less brands listed as of 1 April 2022;

    b) 4 – 6 brands listed as of 1 April 2022; and

    c) 7 or more brands listed as of 1 April 2022.

    In selecting these groupings, my intention was to create groupings of reasonably consistent size in terms of the number of pharmaceuticals whilst still having sufficient number of pharmaceuticals in each group for analysis.

71. Attached as Annexure **GIO-1** are the graphical representations which I have described in accordance with the method described in paragraphs 59 to 70 above.

72. Page 1 of Annexure GIO-1 contains a graph representing the percentage change in AEMP for each of the 39 pharmaceuticals over time resulting from price disclosure reductions.

73. Page 2 of Annexure GIO-1 contains a graph representing the median percentage change in AEMP grouped by the number of brands listed for each pharmaceutical as of 1 April 2022 (i.e., 3 or less, 4 – 6 or 7 or more brands listed as of 1 April 2022).

74. The curve for the overall median percentage change in AEMP across all 39 pharmaceuticals is also represented on this graph on page 2 (being the blue-coloured curve).

75. Pages 3, 4 and 5 of Annexure GIO-1 represent the individual percentage change in AEMP for the same groupings referred to in paragraph 73 above, that is grouped by pharmaceuticals with: 3 or less brands listed; 4 – 6 brands listed; and 7 or more brands listed.

76. I then proceeded to exclude 10 of the 39 pharmaceuticals referred to in paragraph 67 above because after reviewing the data relevant to those pharmaceuticals, I formed the view that market behaviour or government action was likely to have

affected the pharmaceutical's AEMP owing to one of the following circumstances, and I had no information to suggest that such market behaviour or government action would be relevant to lenalidomide:

a) The pharmaceutical is PBS listed in multiple formulations, only some of which have competing brands that have taken price disclosure reductions. This applied to aripiprazole, buprenorphine, voriconazole, valganciclovir, and tobramycin;

b) The originator brand of the pharmaceutical was de-listed from the PBS by its sponsoring company upon generic entry. This applied to erlotinib rituximab, and trastuzumab (IV formulation); and

c) The pharmaceutical has been granted a price increase by the Commonwealth Department of Health indicating a level of government intervention in the movement of its AEMP. This applied to dutasteride and cefuroxime

77. To further explain the basis on which I excluded the above pharmaceuticals based on their circumstances described in sub-paragraphs 76(a) to (c) above, I make the following observations. The generic sponsors of lenalidomide products referred to in paragraph 62 above have registrations on the ARTG across the full range of strengths and formulations of Revlimid®. Based on this, I consider it highly likely that generic competition will affect the full range of strengths and formulations of Revlimid® and therefore the circumstances in 76(a) would not apply. I have no reason to believe that the sponsor of Revlimid® intends to de-list this brand from the PBS upon generic entry and I therefore assume that it will remain in the market after generic entry and therefore consider that the circumstances in paragraph 76(b) would not apply. Thirdly, in relation to paragraph 76(c), the examples in this group of pharmaceuticals which received price increases had a low unit cost compared to lenalidomide and had been in price disclosure for a number of years. These are not circumstances that apply to lenalidomide and I therefore excluded pharmaceuticals affected by price increases from the analysis.

78. I have annexed as **Annexure GIO-2** the individual graphs of the 29 pharmaceuticals which I produced by the methodology that I described in paragraph 77 above.

79. Jones Day asked me to explain what each of the graphs in Annexure GIO-1 and GIO-2 shows.

80. The curve overall median (coloured in blue) in the graph on page 2 of Annexure GIO-1 titled '*Cumulative median percentage reduction in AEMP due to Price Disclosure vs number of Price Disclosure cycles since generic entry – breakdown by market density*' shows the first price disclosure reduction occurring in cycle 2 with a cumulative median AEMP reduction of approximately 50% over the course of 10 cycles.

81. The median curve for the group of pharmaceuticals with 3 or less listed brands in this same graph shows the first price disclosure reduction taking place in cycle 3 with a cumulative median AEMP reduction of approximately 40% over the course of 9 cycles then reaching a median of approximately 50% in the 10th cycle.

82. The median curve for the group of pharmaceuticals with 4 – 6 listed brands in this same graph shows the first price disclosure reduction taking place in cycle 3 with a cumulative median AEMP reduction of approximately 45% over the course of 10 cycles.

83. The median curve for the group of pharmaceuticals with 7 or more listed brands in this same graph shows the first price disclosure reduction taking place in cycle 1 with a cumulative median AEMP reduction of approximately 80% over the course of 10 cycles.

84. Based on the information that I have extracted in paragraphs 80 to 83 above, in my opinion a pharmaceutical with 7 or more brands listed is more likely to have its first price disclosure reduction in an earlier cycle than the overall market median and its cumulative median AEMP reduction is more likely to be larger than the market median.

85. The graph at page 3 of Annexure GIO-1 titled '*Percentage change in AEMP vs number of PD cycles since generic entry – Individual pharmaceuticals with 3 or fewer PBS-listed brands as of 1 April 2022*' represents the following features:

    a) 6 drugs, namely nortriptyline, cefuroxime, ibuprofen, dorzolamide, nicorandil, and bivalirudin have taken zero price disclosure reductions up to five cycles after generic entry;

    b) 3 drugs, namely ganciclovir, rituximab, and erlotinib triggered a price disclosure reduction in their first cycle in price disclosure;

    c) pegfilgrastim took no price disclosure reductions for 5 cycles but by the start of cycle 7 had reached a cumulative 70% reduction in AEMP; and

d) the trajectory of AEMP for each pharmaceutical in this group of pharmaceuticals with 3 brands or less over the observed period varied significantly from the median for the same group, as demonstrated in the graph discussed in paragraph 81 above appearing at page 2 of Annexure GIO-1, and did not follow a consistent gradient.

86. Given the wide dispersion of the curves describing the change in AEMP over time for pharmaceuticals with 3 or fewer brands, I consider it is not possible to rely upon the data presented for the purposes of predicting the future change in AEMP over time for a given pharmaceutical with 3 or fewer brands.

87. The graph at page 4 of Annexure GIO-1 titled '*Percentage change in AEMP vs number of PD cycles since generic entry – Individual pharmaceuticals with 4 – 6 PBS-listed brands as of 1 April 2022*' represents the following features:

a) 3 pharmaceuticals, namely ursodeoxycholic acid, nebivolol, and itraconazole have avoided price disclosure reductions until at least 5 cycles after the listing of the first generic brand. I note itraconazole had a 44% reduction to its AEMP on 1 December 2016. However the price disclosure outcomes published on the PBS website at https://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd do not reference a price disclosure reduction for itraconazole on this date. In my opinion, this reduction may relate to direct negotiations between the Commonwealth and one or more of the sponsors involved, however, there is no published information available to me to clarify the reason for this price reduction; and

b) 2 pharmaceuticals, namely valganciclovir and trastuzumab took a price disclosure reduction at the start of their second cycle;

c) except for the pharmaceuticals mentioned in sub paragraphs (a) and (b) above, which I consider to be outliers, the majority of pharmaceuticals with 4 – 6 brands experienced reduction of their AEMP over time within a reasonably narrow range for the first 5 cycles.

88. Notwithstanding the outlier results which I have identified in paragraph 87(a) and (b) above, it is my opinion that, this graph has some value for the purposes of predicting the future change in AEMP over time for a given pharmaceutical with 4 – 6 brands. However, these data do not have predictive value in terms of anticipating how many cycles after generic entry will elapse before the first price disclosure reduction occurs.

89. In my opinion, the graph at page 5 of Annexure GIO-1 titled *Percentage change in AEMP vs number of PD cycles since generic entry – Individual pharmaceuticals with 7 or more PBS-listed brands as of 1 April 2022*' represents the following features:

    a) 1 pharmaceutical, namely tobramycin, avoided price disclosure reductions until cycle 7. Tobramycin is PBS listed in multiple dose forms used by multiple manners of administration only some of which have generic brands PBS listed. I therefore consider this pharmaceutical would not be typical of a pharmaceutical with 7 or more brands; and

    b) Out of 11 pharmaceuticals in this group, 10 had taken their first price disclosure reductions on or before 3 price disclosure cycles had elapsed.

90. Notwithstanding the atypical result that I have identified in paragraph 89(a) above, 10 out of the 11 pharmaceuticals experienced reduction of their AEMP over time within a reasonably narrow range of approximately 30% and 60% by the start of the 5th price disclosure cycle. It is therefore my opinion that this graph provides a reasonable basis for predicting the future change in AEMP over the first 5 price disclosure cycles for a given pharmaceutical with 7 or more brands.

91. Based on the sub-division into the 3 groupings as I have described in paragraph 70 above, the graphical representation of pharmaceuticals with 7 or more brands shows that the pharmaceuticals in this grouping are likely to receive their first price disclosure reduction earlier than the market median and to have an overall larger percentage reduction following at least 5 price disclosure cycles.

92. It is also my opinion that notwithstanding the atypical result that I have identified in paragraph 89(a) above, 10 out of the 11 pharmaceuticals experienced their first price disclosure reduction by or before the start of the 3rd price disclosure cycle. Therefore, it is my opinion that this graph provides a reasonable basis to expect that a given pharmaceutical with 7 or more brands is unlikely to endure more than 3 price disclosure cycles before the first price disclosure reduction occurs.

93. I also prepared individual graphs for 29 of the 39 pharmaceuticals referred as referred to in paragraph 78 above and which are at Annexure GIO-2.

94. In this series of graphs, the absolute change in AEMP (in dollar amounts) is compared to the number of listed brands (originator and generic) on a month-by-month basis commencing from the 1st month of generic competition up to 1 April 2022. I also identified each sponsoring company, the number and name of brands marketed by each company, and the date of PBS listing of each brand (for

example azacitadine currently has 5 brands PBS listed, with 2 of those 5 marketed by a single sponsor namely Dr Reddy's Laboratories (Australia) Pty Ltd).

95. I also note that as discussed in paragraph 38 above, a change in AEMP at the commencement of a particular price disclosure cycle is a result of the price disclosure data collected from sales in the 6-month period commencing 1 year earlier than the date of the price disclosure reduction and result from outcomes calculated 6 months prior. For avoidance of doubt, a price disclosure reduction in April of any given year would arise from price disclosure data collected from sales occurring in the 1 April to 30 September period of the previous year. For ease of refence, on each individual graph in Annexure GIO-2 I have highlighted each April and October data point as indicating the commencement of each price disclosure cycle. In addition, I note that where a price disclosure reduction is indicated for any cycle, the reduction occurs from the commencement of that cycle.

96. I note that there are examples of individual pharmaceuticals where multiple competing brands were PBS listed from the very first month of generic entry (for example, pregabalin, bosentan, ezetimibe, and zoledronic acid). In contrast, there are examples of individual pharmaceuticals where multiple generic brands were not PBS listed until 1 to 2 additional price disclosure cycles had elapsed after the first month of generic entry (for example, azacitadine, imatinib, and infliximab). I have selected a series of individual graphs of these individual pharmaceuticals which are contained in Annexure GIO-2 and which I will discuss in the paragraphs that follow.

97. The graph for azacitadine at page 3 of Annexure GIO-2 is an example of a pharmaceutical where only 2 of the 7 brands that would ultimately PBS list were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 June 2016 to 1 April 2022 after the listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

    a) The 1st price disclose reduction occurs on 1 April 2018, being the 4th price disclosure cycle after generic entry (a period of 22 months), with a percentage price reduction of 14% off the AEMP prior to any price disclosure reduction. As discussed at paragraphs 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 April 2017 to 30 September 2017. I note that at the start of that period, only the originator and one generic brand were PBS listed. However, by the conclusion of that period, an additional two generic brands had also PBS listed.

b) A 2nd price disclosure reduction occurred on 1 October 2018, relating to price disclosure data collected of sales made from 1 October 2017 to 31 March 2018, during which period 5 brands were PBS listed.

c) A 3rd price disclosure reduction occurred on 1 April 2019, relating to price disclosure data collected of sales made from 1 April 2018 to 30 September 2018, during which period 5 brands were PBS listed.

d) The 5th price disclosure reduction took place on 1 October 2020 relating to price disclosure data collected from 1 October 2019 to 31 March 2020 during which period the number of PBS listed brands increased from 6 to 7.

e) Over the course of 6 price disclosure reductions spread over 12 price disclosure cycles, the AEMP of azacitadine reduced from $369.44 to its current AEMP of $96.14. The total percentage reduction in the AEMP over this period is 74%.

98. The graph for imatinib at page 13 of Annexure GIO-2 is an example of a pharmaceutical where only 3 of the 10 brands that ultimately PBS listed were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 October 2016 to 1 April 2022 after the listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) The 1st price disclosure reduction occurs on 1 October 2017, being the 2nd price disclosure cycle after generic entry (a period of 12 months), with a percentage price reduction of 19% off the AEMP prior to any price disclosure reduction. As discussed at paragraphs 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 October 2016 to 31 March 2017. I note that at the start of that period, only the originator and two generic brands were PBS listed. However, by the conclusion of that period, an additional two generic brands had PBS listed.

b) A 2nd price disclosure reduction occurred on 1 October 2018, relating to price disclosure data collected of sales made from 1 October 2017 to 31 March 2018, during which period an additional 4 brands were PBS listed.

c) A 3rd price disclosure reduction occurred on 1 October 2019, relating to price disclosure data collected of sales made from 1 October 2018 to 31 March 2019, during which period the number of PBS listed brands remained the same at 9 brands.

d) The 4th price disclosure reduction took place on 1 April 2020 relating to price disclosure data collected of sales made from 1 April 2019 to 30 September 2019, by the end of which period the number of PBS listed brands increased to 10.

e) I note the period from 1 April 2020 until the next price disclosure reduction on 1 October 2021 during which no AEMP reductions took place and during which period the number of PBS listed brands had reduced to 8.

f) Over the course of 5 price disclosure reductions spread over 11 price disclosure cycles, the AEMP of imatinib reduced from $1449.57 to its current AEMP of $290.33. The total percentage reduction in the AEMP over this period is 80%.

99. The graph for infliximab at page 14 of Annexure GIO-2 is an example of a pharmaceutical where 2 of the 4 brands that ultimately PBS listed were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 December 2015 to 1 April 2022 after the listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) The 1st price disclosure reduction occurs on 1 October 2017, being the 4th price disclosure cycle after generic entry (a period of 23 months) with a percentage price reduction of 12% off the AEMP prior to any price disclosure reduction. As discussed at paragraphs 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 October 2016 to 31 March 2017. I note that at the start of that period, only the originator and one biosimilar brand were PBS listed.

b) A 2nd price disclosure reduction occurred on 1 October 2018, relating to price disclosure data collected of sales made from 1 October 2017 to 31 March 2018, during which period 1 additional brand had PBS listed.

c) A 3rd price disclosure reduction occurred on 1 October 2019, relating to price disclosure data collected of sales made from 1 October 2018 to 31 March 2019, during which period the number of PBS listed brands remained the same at 3 brands.

d) To date no further price reductions have taken place, however a 4th brand PBS listed on 1 July 2021.

e) Over the course of 3 price disclosure reductions spread over 11 price disclosure cycles, the AEMP of imatinib reduced from $574.85 to its current

AEMP of $320.71. The total percentage reduction in the AEMP over this period is 44%.

100. The graph for bosentan at page 5 of Annexure GIO-2 is an example of a pharmaceutical where 9 of the 10 brands that were ultimately PBS listed were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 August 2017 to 1 April 2022 after listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) The 1st price reduction occurs on 1 October 2018, being the 1st price disclosure cycle after generic entry (a period of 14 months), with a percentage reduction of 33% off the AEMP prior to any price disclosure cut. As discussed at paragraph 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 October 2017 to 31 March 2018. However, by the conclusion of that period, one brand had de-listed from the PBS.

b) A 2nd price disclosure reduction occurred on 1 October 2019, relating to price disclosure data collected of sales made from 1 October 2018 to 31 March 2019, by the end of which period the number of PBS listed brands increased to 10.

c) A 3rd price disclosure reduction occurred on 1 October 2020, relating to price disclosure data collected of sales made from 1 October 2019 to 31 March 2020, during which period the number of PBS listed brands decreased to 8.

d) 4th and 5th price reductions in consecutive price disclosure cycles in April 2021 and October 2021, during the data collection periods for which the number of brands were 8 and 9 respectively.

e) Over the course of 5 price disclosure reductions spread over 10 price disclosure cycles, the AEMP of bosentan reduced from $2294.43 to its current AEMP of $430.63. The total percentage reduction in the AEMP over this period is 81%.

101. The graph for pregabalin at page 23 of Annexure GIO-2 is an example of a pharmaceutical where 9 of the 12 brands that would ultimately be PBS listed were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 August 2017 to 1 April 2022 after listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) A reduction in AEMP took place on 1 October 2017, however the price disclosure outcomes published on the PBS website at https://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd do not

reference a price disclosure reduction for pregabalin on this date. In my opinion, this reduction may relate to direct negotiations between the Commonwealth and one or more of the sponsors involved, however, there is no published information available to me to clarify the reason for this price reduction.

b) The 1st price disclosure related reduction occurs on 1 October 2018, being the 3rd price disclosure cycle after generic entry (a period of 14 months), with a percentage reduction of 21% off the AEMP prior to any price disclosure reduction. As discussed at paragraph 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 October 2017 to 31 March 2018. Throughout this period, the number of listed brands increased from 9 to 12.

c) A 2nd price disclosure reduction occurred on 1 October 2019, relating to price disclosure data collected of sales made from 1 October 2018 to 31 March 2019, during which period the number of PBS listed brands remained the same at 12.

d) A 3rd price disclosure reduction occurred on 1 October 2020, relating to price disclosure data collected of sales made from 1 October 2019 to 31 March 2020, during which period the number of PBS listed brands decreased to 11.

e) 4th and 5th price reductions in consecutive price disclosure cycles in April 2021 and October 2021, during the data collection periods for which the number of brands increased back to 12.

f) Over the course of 5 AEMP reductions that can be confirmed as price disclosure reductions spread over 10 price disclosure cycles, the AEMP of bosentan reduced from $45.36 to its current AEMP of $12.66. The total percentage reduction in the AEMP over this period is 72%.

102. The graph for zoledronic acid at page 29 of Annexure GIO-2 is an example of a pharmaceutical where 7 of the 10 brands that would ultimately be PBS listed were present at the commencement of the first price disclosure cycle. This graph shows the AEMP from 1 December 2015 to 1 April 2022 after listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) The 1st price disclosure related reduction occurs on 1 April 2017, being the 2nd price disclosure cycle after generic entry (a period of 16 months), with a percentage reduction of 25% off the AEMP prior to any price disclosure cut.

As discussed at paragraph 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 April 2016 to 30 September 2016. Throughout this period, the number of listed brands remained the same at 7.

b) A 2nd price disclosure reduction occurred on 1 April 2018, relating to price disclosure data collected of sales made from 1 April 2017 to 30 September 2017, during which period the number of PBS listed brands remained the same at 7.

c) A 3rd price disclosure reduction occurred on 1 October 2019, relating to price disclosure data collected of sales made from 1 October 2018 to 31 March 2019, during which period the number of PBS listed brands increased to 8.

d) 4th and 5th price disclosure reductions in consecutive price disclosure cycles in April 2020 and October 2020, during the data collection periods for which the number of brands fluctuated between 8 and 10 brands.

e) Over the course of 6 price disclosure reductions spread over 13 price disclosure cycles, the AEMP of zoledronic acid reduced from $326.97 to its current AEMP of $50.24. The total percentage reduction in the AEMP over this period is 85%.

103. The graph for ezetimibe at page 8 of Annexure GIO-2 is an example of a pharmaceutical where all 8 brands that would ultimately be PBS listed were present by the 3rd month after generic entry. This graph shows the AEMP from 1 June 2018 to 1 April 2022 after listing of the first generic brand and the application of the first new brand statutory price reduction. I note that:

a) The 1st price disclosure related reduction occurs on 1 October 2019, being the 2nd full price disclosure cycle after generic entry (a period of 17 months), with a percentage reduction of 29% off the AEMP prior to any price disclosure cut. As discussed at paragraph 38 and 95 above, this reduction is a result of the price disclosure data collected of sales made from 1 October 2018 to 31 March 2019. Throughout this period, the number of listed brands remained the same at 8.

b) A 2nd price disclosure reduction occurred on 1 April 2020, relating to price disclosure data collected of sales made from 1 April 2019 to 30 September 2019, during which period the number of PBS listed brands remained the same at 8.

c) 3rd and 4th price disclosure reductions occurred in consecutive price disclosure cycles in October 2020 and April 2021, during the data collection periods for which the number of brands remained the same at 8.

d) Over the course of 6 price disclosure reductions spread over the course of 8 price disclosure cycles, the AEMP of ezetimibe reduced from $29.44 to its current AEMP of $8.28. The total percentage reduction in the AEMP over this period is 72%.

104. With regard to the timing of the first price disclosure reduction, I note azacitadine, infliximab and imatinib had 2, 2 and 3 listed brands respectively upon first generic entry with the timing of the first price disclosure reduction being 22, 23 and 12 months respectively after first generic entry. I also note pregabalin, zoledronic acid, ezetimibe, and bosentan had 9, 7, 8, and 9 brands respectively upon generic entry with the timing of the first price disclosure reduction being 14, 16, 17, and 14 months after generic entry respectively.

105. Based on these matters and the discussion at paragraphs 91 - 96 above, it is my opinion that notwithstanding 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, the analysis demonstrates a likely association between the number of competing PBS brands and the occurrence of price disclosure reductions. That is, the greater the number of brands listed at first generic entry, the earlier the cycle at which the first price disclosure reduction will occur (an example of which is bosentan, referred to in paragraph 100 above). In addition, even if a small number of brands is listed at first generic entry, the subsequent participation of additional brands increases the likelihood of a price disclosure reduction (an example of which is azacitadine, referred to in paragraph 97 above).

106. With regard to the magnitude of the first price disclosure reduction, in the examples of azacitadine, infliximab and imatinib, these pharmaceuticals underwent AEMP reductions of 14%, 12% and 19% respectively. In the examples of bosentan, pregabalin, zoledronic acid and ezetimibe, these pharmaceuticals underwent AEMP reductions of 33%, 21%, 25% and 29% respectively. Bearing in mind that the minimum price discount required to trigger the price disclosure regime is a 10% discount to the AEMP, the examples of bosentan, pregabalin, zoledronic acid and ezetimibe show a discount that is significantly higher than the 10% threshold. Based on these matters and the discussion at paragraphs 91 - 96 above, it is my opinion that notwithstanding 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, the analysis demonstrates a likely association between the number of competing PBS brands listed at first generic entry and the likely magnitude of the first price disclosure reduction. That is, the greater the number of brands listed at first generic entry, the greater likelihood of a first price disclosure reduction being in excess of 10%.

107. Jones Day asked me whether I could express an opinion as to the likely impact of price disclosure on lenalidomide. One example of a database which I found containing listings of generic lenalidomide products is the Danish Medicines Authority website (https://medicinpriser.dk). In my opinion Denmark's health system has parallels to Australia's health system in terms of arrangements for government-subsidised as opposed to privately-insured pharmaceutical funding arrangements and a transparent and publicly available list of subsidised pharmaceuticals and brands. I identified the following companies listed on the Danish Medicines Authority's website each with one brand of lenalidomide available in Denmark:

    a) Zentiva Denmark;

    b) Viatris ApS;

    c) Sandoz;

    d) Teva (Søborg);

    e) Krka AB; and

    f) Celgene ApS

108. In view of the number of companies marketing brands of lenalidomide in Denmark and in light of the dynamic noted above in paragraph 62 and 65 above, with companies registering multiple brands, I assumed that at least 8 of the 15 TGA registered brands referred to in paragraph 62 above would list on the PBS and also assumed that all 8 brands would list at the same time. Having regard to the matters that I have discussed in paragraphs 62 - 65 above, and my discussion more generally at paragraphs 91 -106 above, I make the following comments:

    a) I consider, given the high published AEMP and the high overall published PBS expenditure for lenalidomide, that there is a significant prospect of companies sponsoring generic brands of lenalidomide being in a position to offer

substantial discounts in order to be able to secure market share while still generating viable levels of revenue.

b) I consider, given the number of brands registered for lenalidomide on the ARTG and mindful of the assumption that at least 8 of these brands would list on the same day, that there is a significant prospect of companies sponsoring those brands being forced to offer substantial discounts in order to secure sufficient market share to generate viable levels of revenue.

109. Given these matters, it is my opinion that when lenalidomide faces generic competition it will be subject to AEMP price reductions by operation of the price disclosure regime, and that the timing and extent of those price reductions will approximate the curve for the median cumulative price disclosure reduction for pharmaceuticals with 7 or more listed brands (represented by the yellow-coloured curve in the graph at page 2 of Annexure GIO-1). This curve indicates the 1st price disclosure reduction taking place in cycle 1 and a cumulative percentage reduction of AEMP of 80% after 10 price disclosure cycles.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

3 *Signature of person making the declaration*

4 *[Optional: email address and/or telephone number of person making the declaration]*

5 *Place*
6 *Day*
7 *Month and year*

Declared at Ashfield, NSW on the 29th of April 2022

Before me,

8 *Signature of person before whom the declaration is made (see over)*

9 *Full name, qualification and address of person before whom the declaration is made (in printed letters)*

Samin Raihan
Legal Practitioner
Aurora Place
Level 41, 88 Phillip Street
Sydney, NSW 2000 Australia

10 *[Email address and/or telephone number of person before whom the declaration is made*

This declaration was made in accordance with the *Coronavirus Economic Response Package (Modifications – Statutory Declarations and Notices of Intention to Marry) Determination 2021*

Note 1 A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years — see section 11 of the *Statutory Declarations Act 1959*.

Note 2 Chapter 2 of the *Criminal Code* applies to all offences against the *Statutory Declarations Act 1959* — see section 5A of the *Statutory Declarations Act 1959*.

]

A statutory declaration under the *Statutory Declarations Act 1959* may be made before–

(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

Architect	Chiropractor	Dentist
Financial adviser	Financial Planner	Legal practitioner
Medical practitioner	Midwife	Migration agent registered under Division 3 of Part 3 of the *Migration Act 1958*
Nurse	Occupational therapist	Optometrist
Patent attorney	Pharmacist	Physiotherapist
Psychologist	Trade marks attorney	Veterinary surgeon

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or

(3) a person who is in the following list:

Accountant who is:

a) a fellow of the National Tax Accountants' Association; or

b) a member of any of the following:

i. Chartered Accountants Australia and New Zealand;

ii. the Association of Taxation and Management Accountants;

iii. CPA Australia;

iv. the Institute of Public Accountants

Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public

APS employee engaged on an ongoing basis with 5 or more years of continuous service who is not specified in another item in this list

Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the *Consular Fees Act 1955*)

Bailiff

Bank officer with 5 or more continuous years of service

Building society officer with 5 or more years of continuous service

Chief executive officer of a Commonwealth court

Clerk of a court

Commissioner for Affidavits

Commissioner for Declarations

Credit union officer with 5 or more years of continuous service

Employee of a Commonwealth authority engaged on a permanent basis with 5 or more years of continuous service who is not specified in another item in this list

Employee of the Australian Trade and Investment Commission who is:

(a) in a country or place outside Australia; and

(b) authorised under paragraph 3 (d) of the *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Employee of the Commonwealth who is:

(a) at a place outside Australia; and

(b) authorised under paragraph 3 (c) of the *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Engineer who is:

a) a member of Engineers Australia, other than at the grade of student; or

b) a Registered Professional Engineer of Professionals Australia; or

c) registered as an engineer under a law of the Commonwealth, a State or Territory; or

d) registered on the National Engineering Register by Engineers Australia

Finance company officer with 5 or more years of continuous service

Holder of a statutory office not specified in another item in this list

Judge

Justice of the Peace

Magistrate

Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the *Marriage Act 1961*

Master of a court

Member of the Australian Defence Force who is:

a) an officer

b) a non-commissioned officer within the meaning of the *Defence Force Discipline Act 1982* with 5 or more years of continuous service

c) a warrant officer within the meaning of that Act

Member of the Australasian Institute of Mining and Metallurgy

Member of the Governance Institute of Australia Ltd

Member of:

a) the Parliament of the Commonwealth

b) the Parliament of a State

c) a Territory legislature

d) a local government authority

Minister of religion registered under Subdivision A of Division 1 of Part IV of the *Marriage Act 1961*

Notary public, including a notary public (however described) exercising functions at a place outside

a) the Commonwealth

b) the external Territories of the Commonwealth

Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office providing postal services to the public

]

Permanent employee of

a) a State or Territory or a State or Territory authority

b) a local government authority

with 5 or more years of continuous service, other than such an employee who is specified in another item of this list

Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made

Police officer

Registrar, or Deputy Registrar, of a court

Senior executive employee of a Commonwealth authority

Senior executive employee of a State or Territory

SES employee of the Commonwealth

Sheriff

Sheriff's officer

Teacher employed on a permanent full-time or part-time basis at a school or tertiary education institution

]

Annexure GIO-1

This and the following 5 pages are the annexure marked "**GIO-1**" referred to in the statutory declaration of **Gregory Ian O'Toole** declared on 29 April 2022.

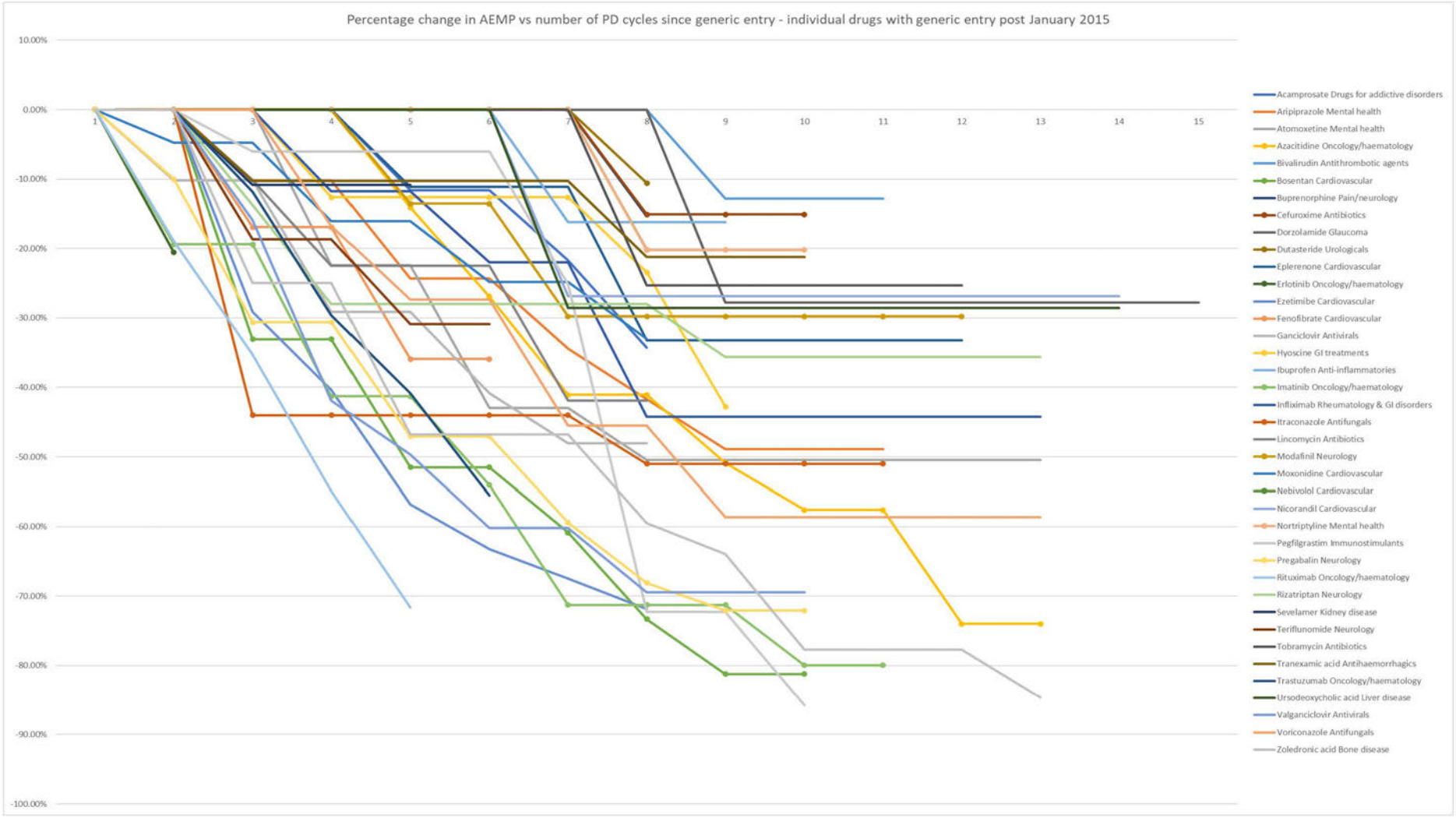
.....

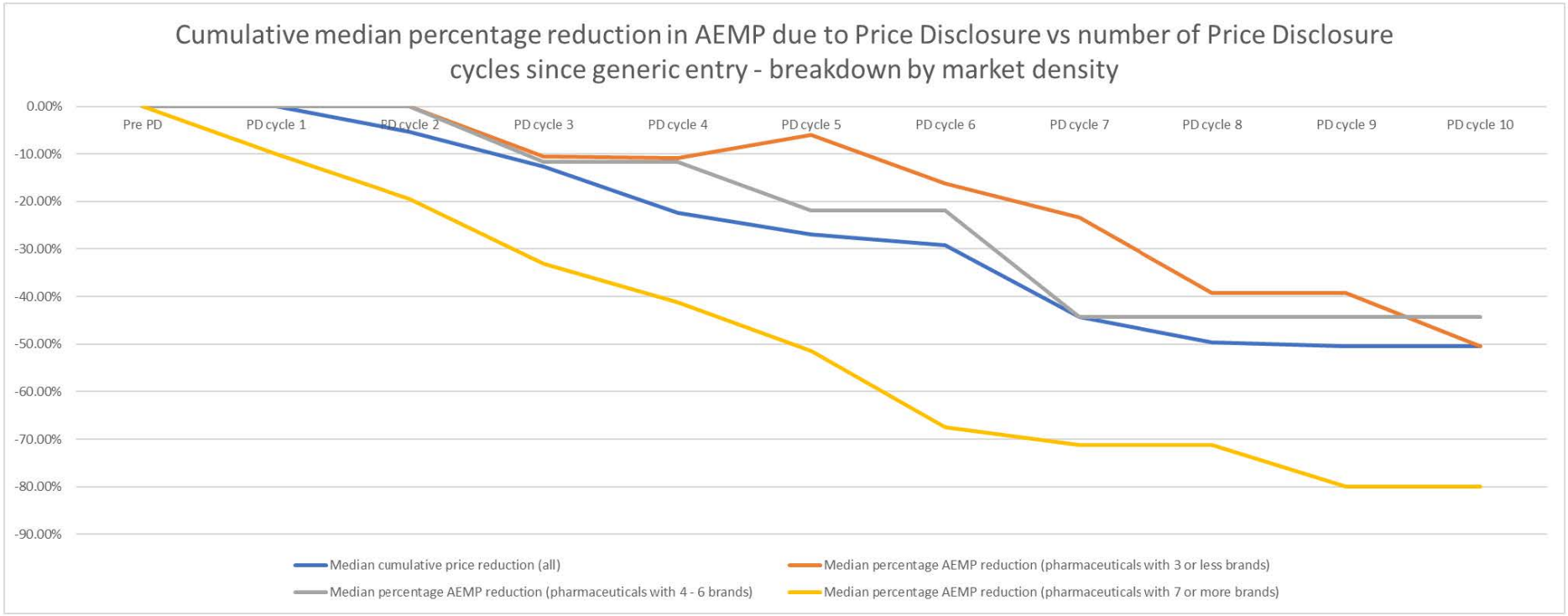
Signature of witness

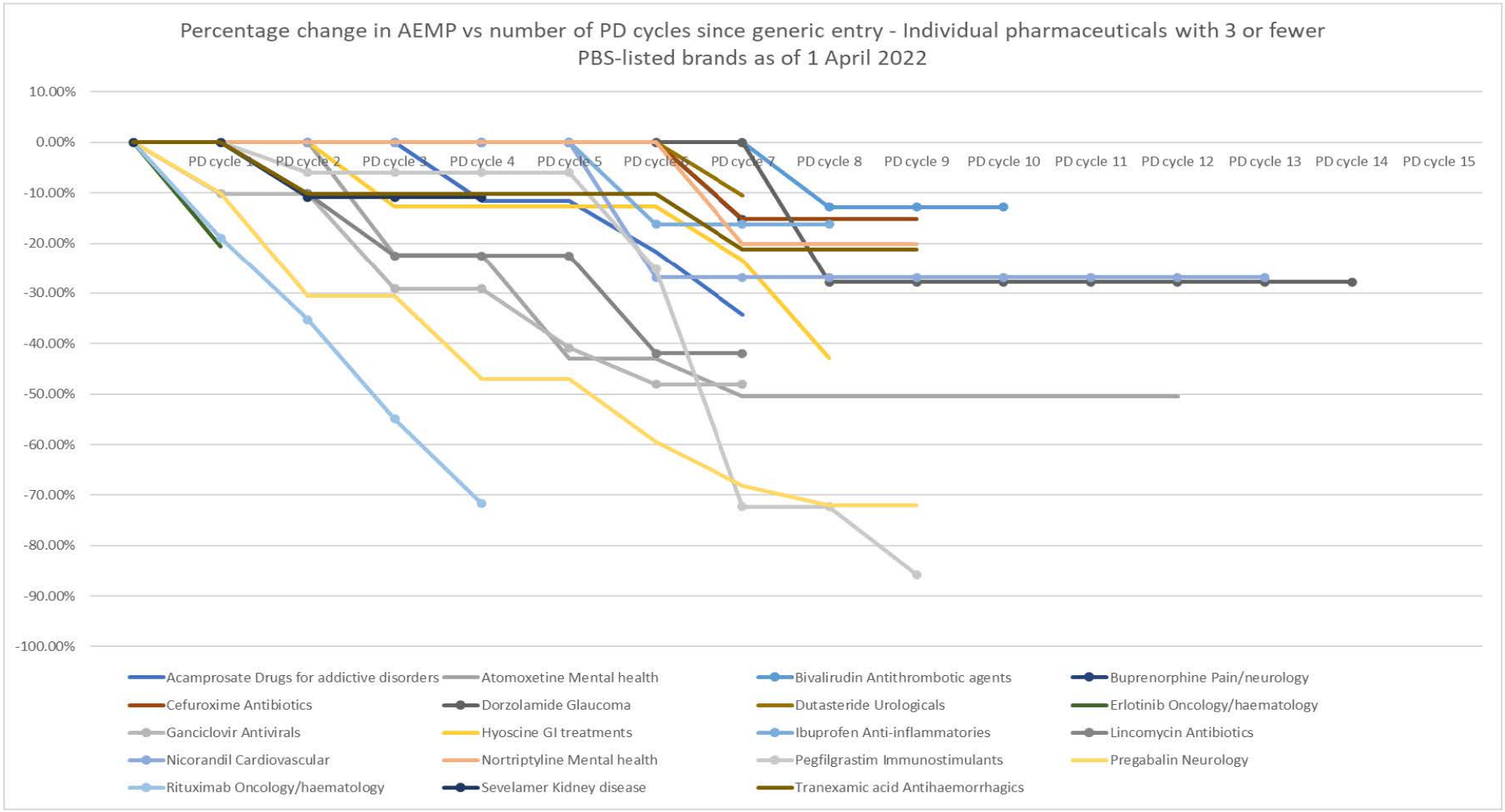
Name of witness: Samin Raihan

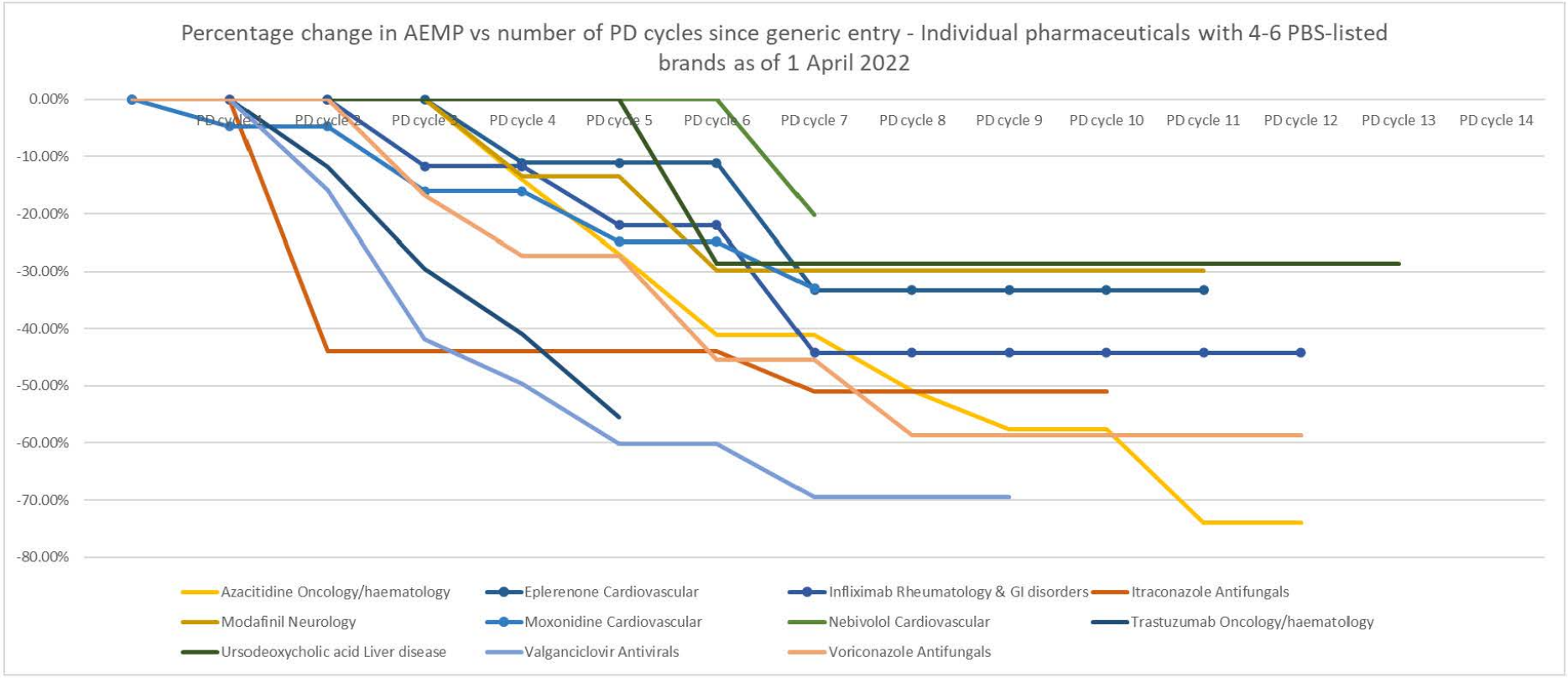
Address of witness: Aurora Place, Level 41, 88 Phillip Street Sydney, NSW 2000 Australia

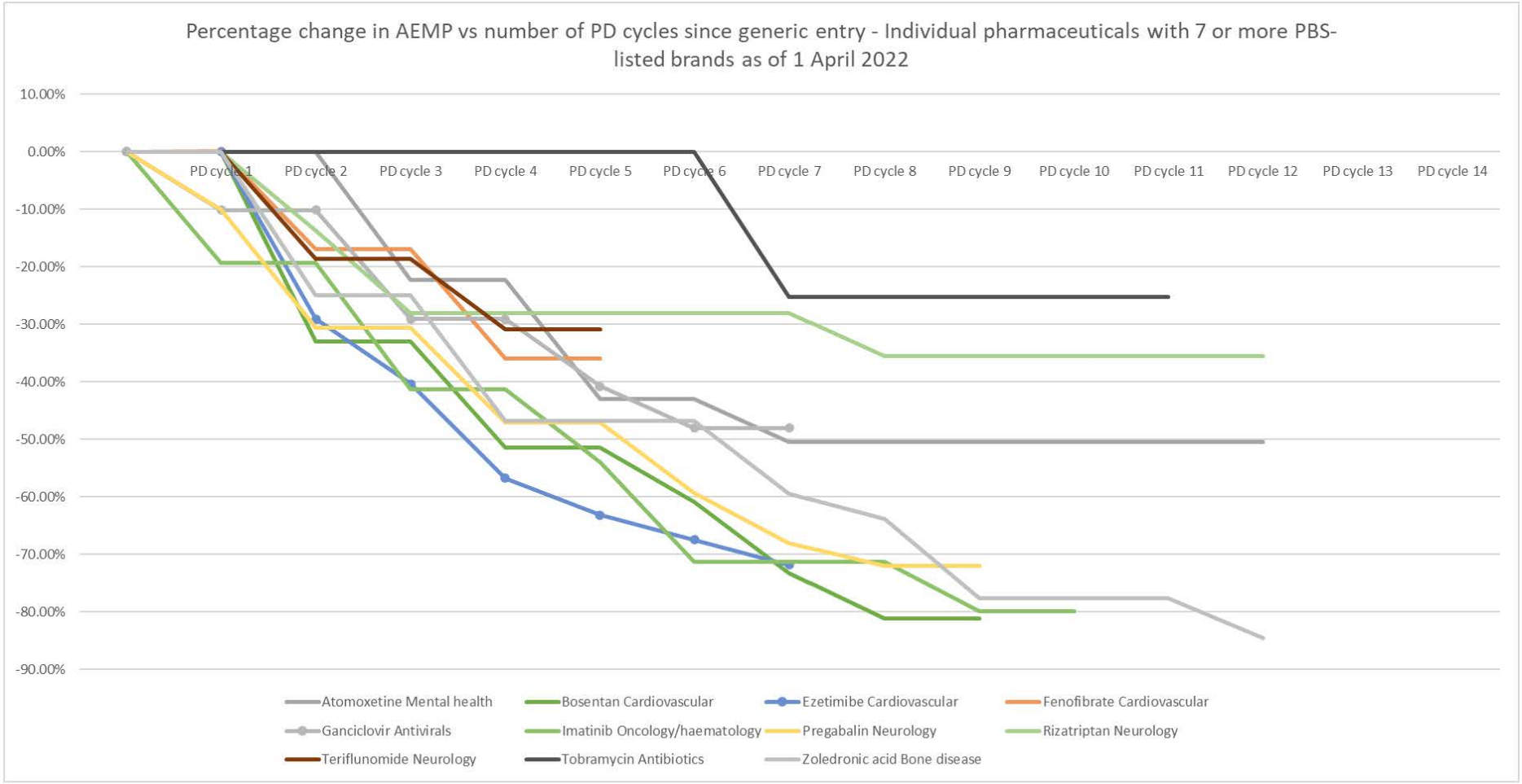
Capacity of witness: Legal Practitioner


Percentage change in AEMP vs number of PD cycles since generic entry - individual drugs with generic entry post January 2015
10.00%
0.00%
-10.00%
-20.00%
-30.00%
-40.00%
-50.00%
-60.00%
-70.00%
-80.00%
-90.00%
-100.00%
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
Acamprosate Drugs for addictive disorders
Aripiprazole Mental health
Atomoxetine Mental health
Azacitidine Oncology/haematology
Bivalirudin Antithrombotic agents
Bosentan Cardiovascular
Buprenorphine Pain/neurology
Cefuroxime Antibiotics
Dorzolamide Glaucoma
Dutasteride Urologicals
Eplerenone Cardiovascular
Erlotinib Oncology/haematology
Ezetimibe Cardiovascular
Fenofibrate Cardiovascular
Ganciclovir Antivirals
Hyoscine GI treatments
Ibuprofen Anti-inflammatories
Imatinib Oncology/haematology
Infliximab Rheumatology & GI disorders
Itraconazole Antifungals
Lincomycin Antibiotics
Modafinil Neurology
Moxonidine Cardiovascular
Nebivolol Cardiovascular
Nicorandil Cardiovascular
Nortriptyline Mental health
Pegfilgrastim Immunostimulants
Pregabalin Neurology
Rituximab Oncology/haematology
Rizatriptan Neurology
Sevelamer Kidney disease
Teriflunomide Neurology
Tobramycin Antibiotics
Tranexamic acid Antihaemorrhagics
Trastuzumab Oncology/haematology
Ursodeoxycholic acid Liver disease
Valganciclovir Antivirals
Voriconazole Antifungals
Zoledronic acid Bone disease


Cumulative median percentage reduction in AEMP due to Price Disclosure vs number of Price Disclosure cycles since generic entry - breakdown by market density
0.00%
-10.00%
-20.00%
-30.00%
-40.00%
-50.00%
-60.00%
-70.00%
-80.00%
-90.00%
Pre PD
PD cycle 1
PD cycle 2
PD cycle 3
PD cycle 4
PD cycle 5
PD cycle 6
PD cycle 7
PD cycle 8
PD cycle 9
PD cycle 10
Median cumulative price reduction (all)
Median percentage AEMP reduction (pharmaceuticals with 3 or less brands)
Median percentage AEMP reduction (pharmaceuticals with 4 - 6 brands)
Median percentage AEMP reduction (pharmaceuticals with 7 or more brands)


Percentage change in AEMP vs number of PD cycles since generic entry - Individual pharmaceuticals with 3 or fewer PBS-listed brands as of 1 April 2022
10.00%
0.00%
-10.00%
-20.00%
-30.00%
-40.00%
-50.00%
-60.00%
-70.00%
-80.00%
-90.00%
-100.00%
PD cycle 1
PD cycle 2
PD cycle 3
PD cycle 4
PD cycle 5
PD cycle 6
PD cycle 7
PD cycle 8
PD cycle 9
PD cycle 10
PD cycle 11
PD cycle 12
PD cycle 13
PD cycle 14
PD cycle 15
Acamprosate Drugs for addictive disorders
Atomoxetine Mental health
Bivalirudin Antithrombotic agents
Buprenorphine Pain/neurology
Cefuroxime Antibiotics
Dorzolamide Glaucoma
Dutasteride Urologicals
Erlotinib Oncology/haematology
Ganciclovir Antivirals
Hyoscine GI treatments
Ibuprofen Anti-inflammatories
Lincomycin Antibiotics
Nicorandil Cardiovascular
Nortriptyline Mental health
Pegfilgrastim Immunostimulants
Pregabalin Neurology
Rituximab Oncology/haematology
Sevelamer Kidney disease
Tranexamic acid Antihaemorrhagics


Percentage change in AEMP vs number of PD cycles since generic entry - Individual pharmaceuticals with 4-6 PBS-listed brands as of 1 April 2022
0.00%
-10.00%
-20.00%
-30.00%
-40.00%
-50.00%
-60.00%
-70.00%
-80.00%
PD cycle 1
PD cycle 2
PD cycle 3
PD cycle 4
PD cycle 5
PD cycle 6
PD cycle 7
PD cycle 8
PD cycle 9
PD cycle 10
PD cycle 11
PD cycle 12
PD cycle 13
PD cycle 14
Azacitidine Oncology/haematology
Eplerenone Cardiovascular
Infliximab Rheumatology & GI disorders
Itraconazole Antifungals
Modafinil Neurology
Moxonidine Cardiovascular
Nebivolol Cardiovascular
Trastuzumab Oncology/haematology
Ursodeoxycholic acid Liver disease
Valganciclovir Antivirals
Voriconazole Antifungals


Percentage change in AEMP vs number of PD cycles since generic entry - Individual pharmaceuticals with 7 or more PBS-listed brands as of 1 April 2022
10.00%
0.00%
-10.00%
-20.00%
-30.00%
-40.00%
-50.00%
-60.00%
-70.00%
-80.00%
-90.00%
PD cycle 1
PD cycle 2
PD cycle 3
PD cycle 4
PD cycle 5
PD cycle 6
PD cycle 7
PD cycle 8
PD cycle 9
PD cycle 10
PD cycle 11
PD cycle 12
PD cycle 13
PD cycle 14
Atomoxetine Mental health
Bosentan Cardiovascular
Ezetimibe Cardiovascular
Fenofibrate Cardiovascular
Ganciclovir Antivirals
Imatinib Oncology/haematology
Pregabalin Neurology
Rizatriptan Neurology
Teriflunomide Neurology
Tobramycin Antibiotics
Zoledronic acid Bone disease

Annexure GIO-2

This and the following 29 pages are the annexure marked "**GIO-2**" referred to in the statutory declaration of **Gregory Ian O'Toole** declared on 29 April 2022.

.....

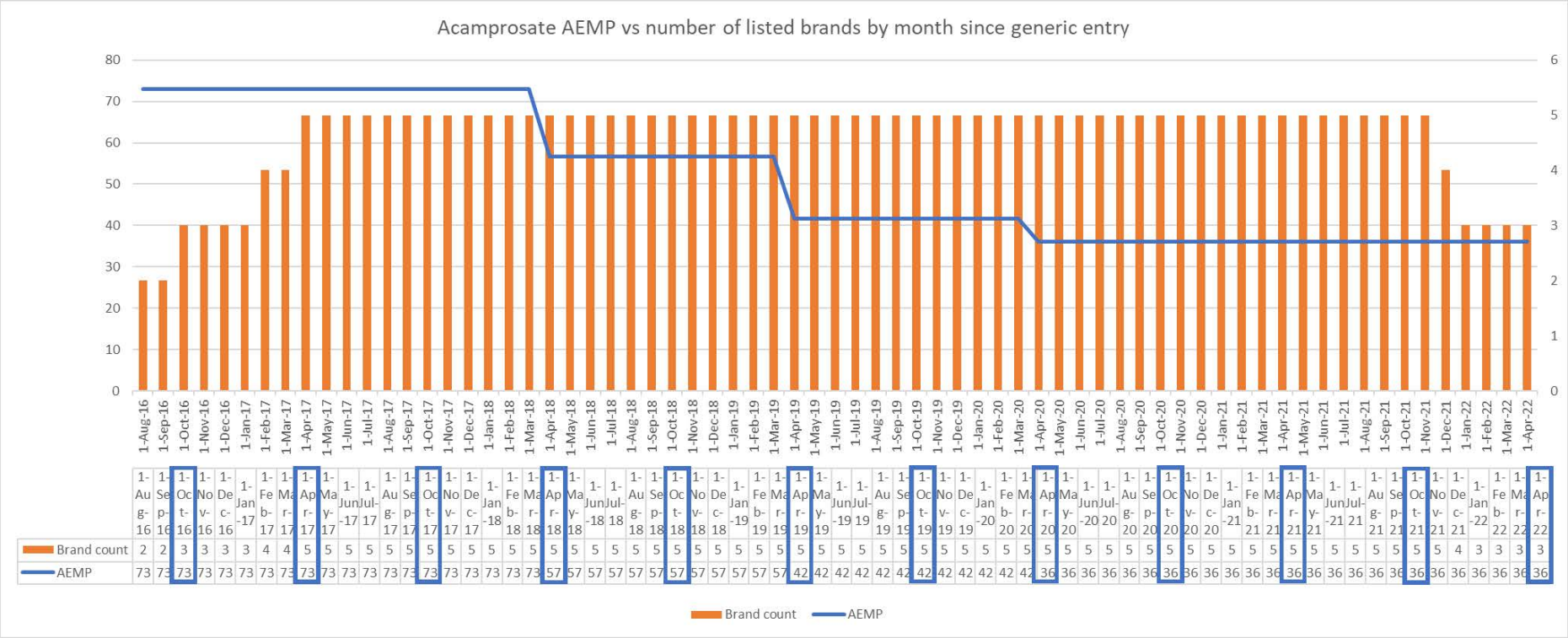
Signature of witness

Name of witness: Samin Raihan

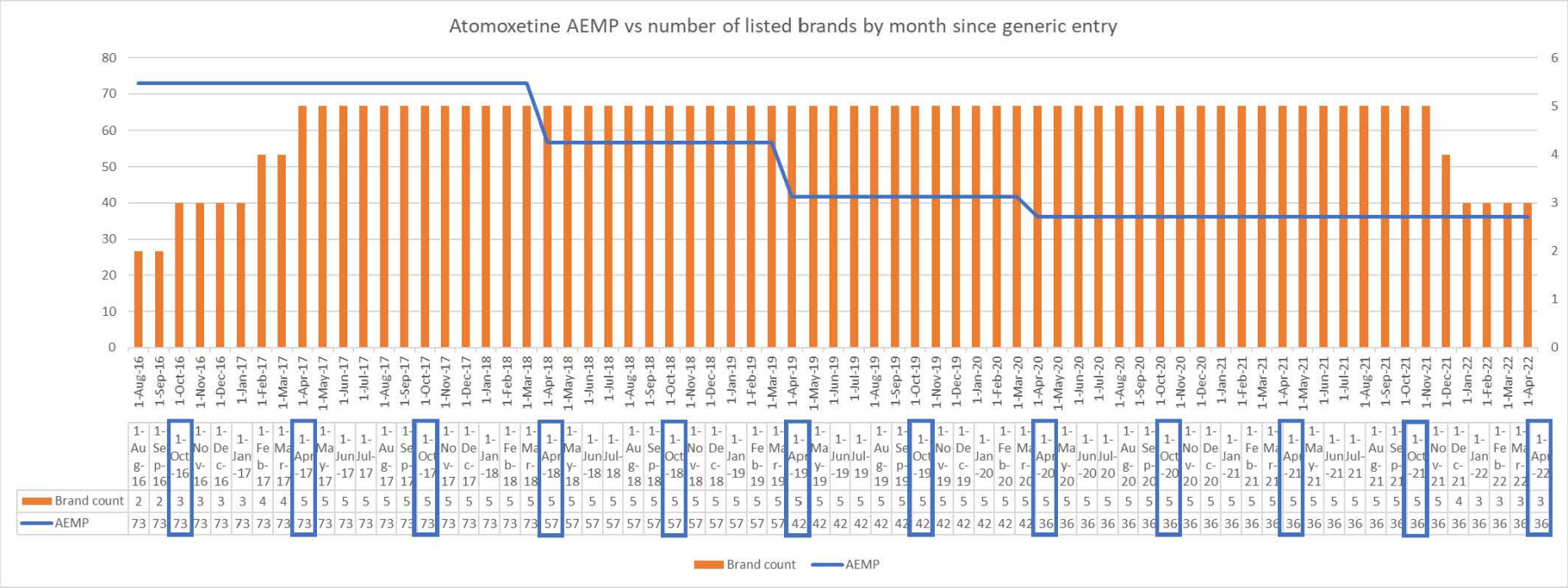
Address of witness: Aurora Place, Level 41, 88 Phillip Street Sydney, NSW 2000 Australia

Capacity of witness: Legal Practitioner

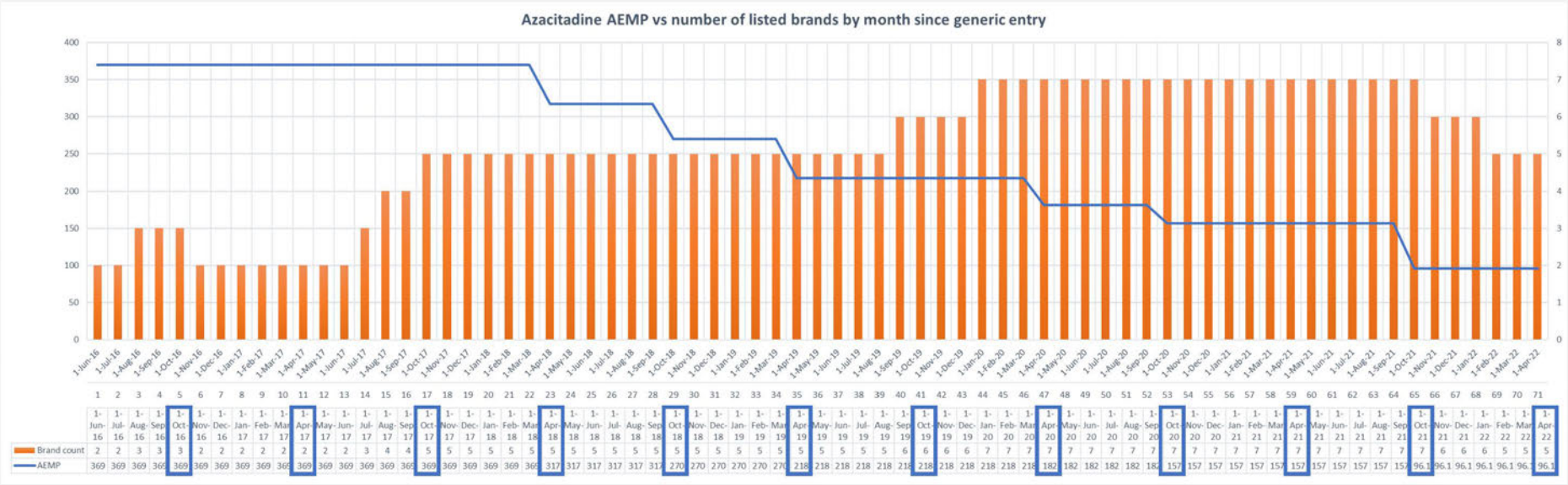
Acamprosate



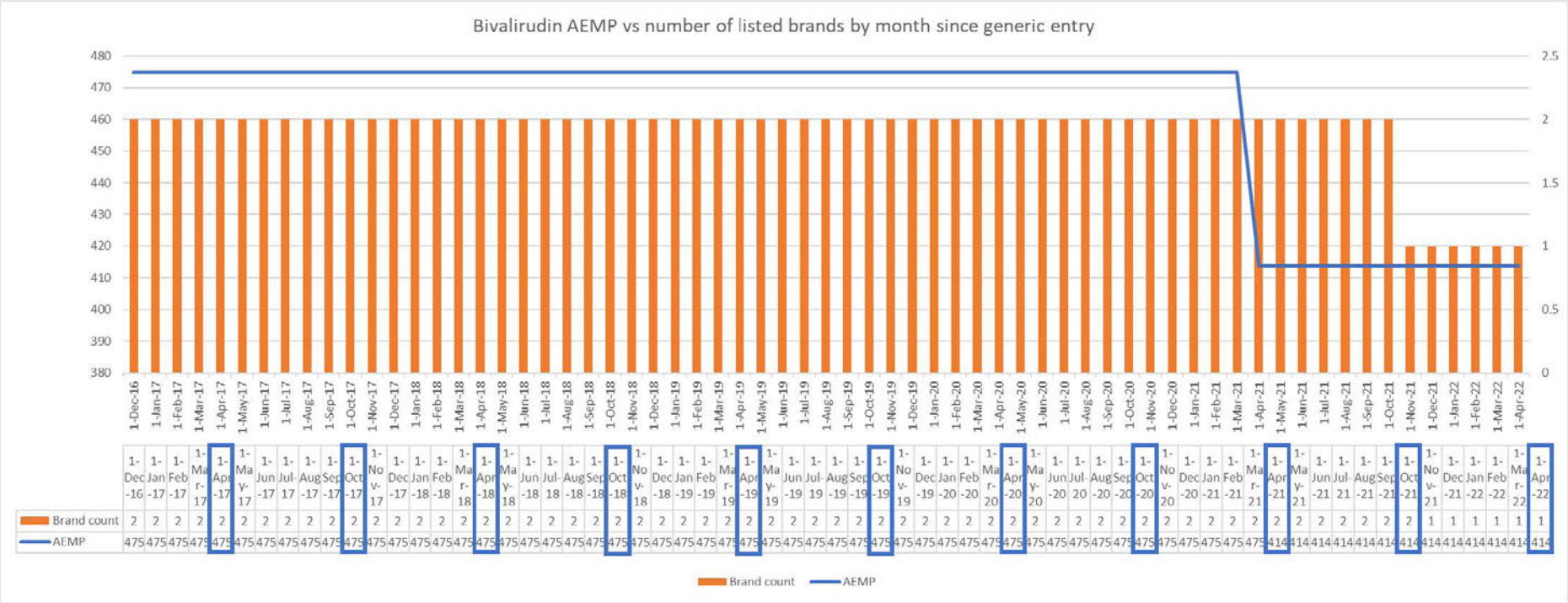
Atomoxetine



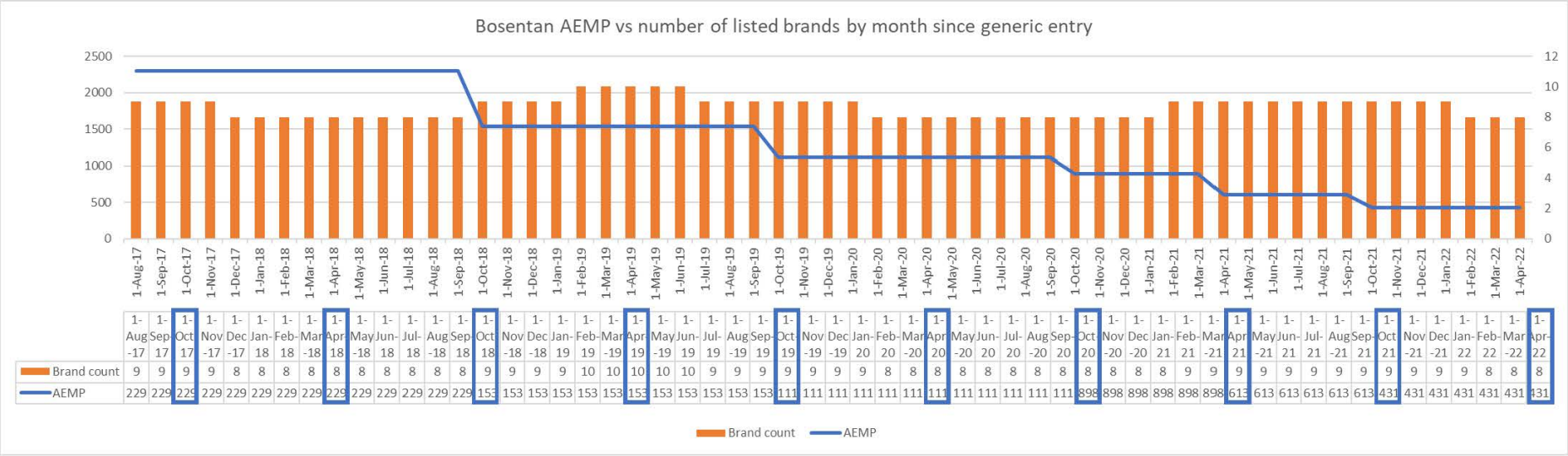
Azacitadine



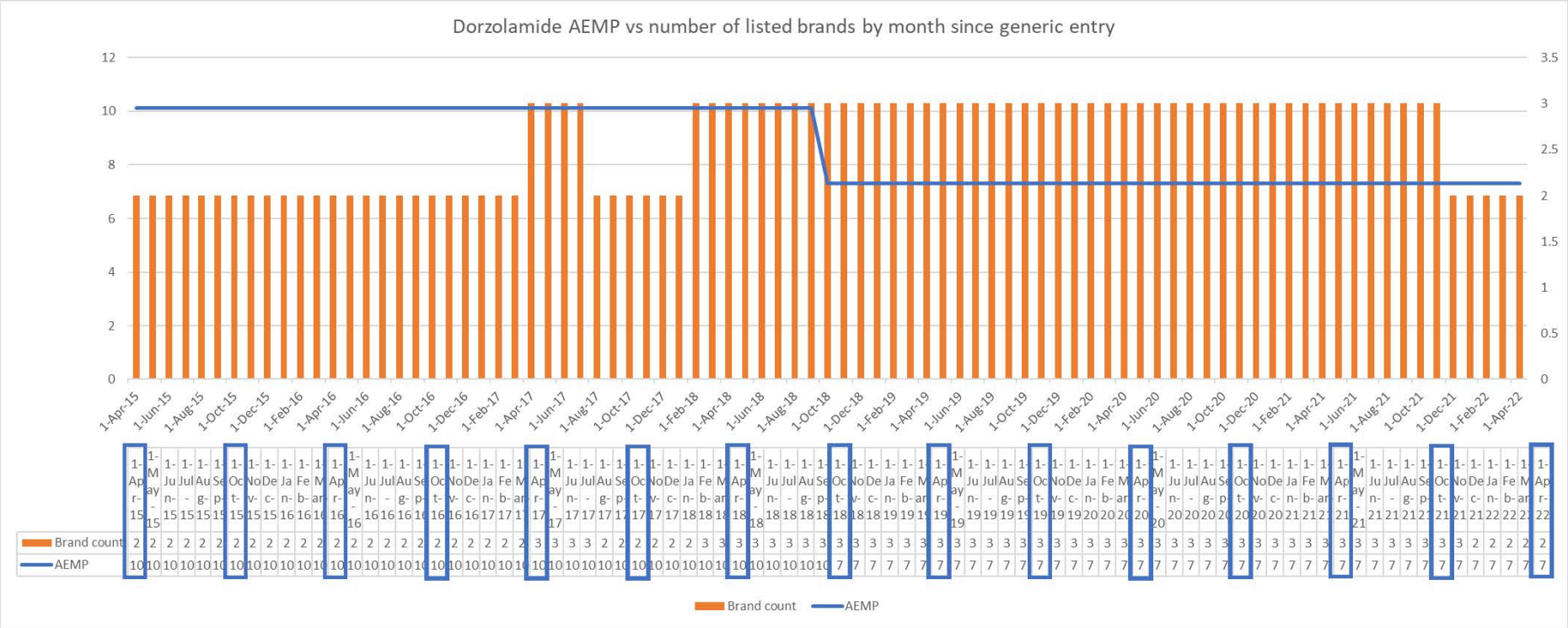
Bivalirudin



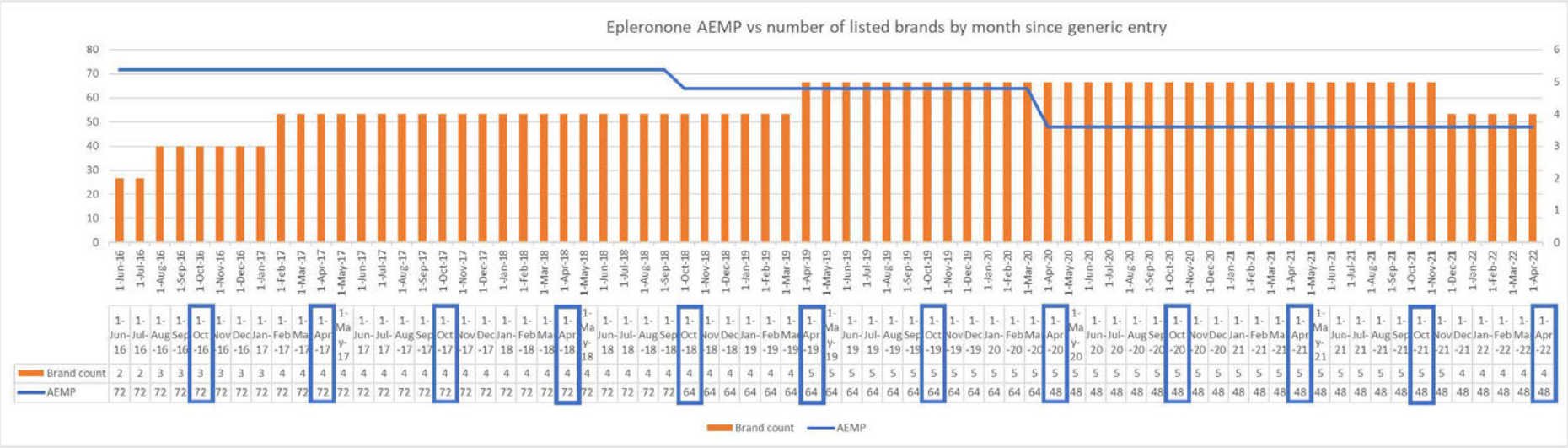
Bosentan


Bosentan AEMP vs number of listed brands by month since generic entry
2500
2000
1500
1000
500
0
12
10
8
6
4
2
0
1-Aug-17
1-Sep-17
1-Oct-17
1-Nov-17
1-Dec-17
1-Jan-18
1-Feb-18
1-Mar-18
1-Apr-18
1-May-18
1-Jun-18
1-Jul-18
1-Aug-18
1-Sep-18
1-Oct-18
1-Nov-18
1-Dec-18
1-Jan-19
1-Feb-19
1-Mar-19
1-Apr-19
1-May-19
1-Jun-19
1-Jul-19
1-Aug-19
1-Sep-19
1-Oct-19
1-Nov-19
1-Dec-19
1-Jan-20
1-Feb-20
1-Mar-20
1-Apr-20
1-May-20
1-Jun-20
1-Jul-20
1-Aug-20
1-Sep-20
1-Oct-20
1-Nov-20
1-Dec-20
1-Jan-21
1-Feb-21
1-Mar-21
1-Apr-21
1-May-21
1-Jun-21
1-Jul-21
1-Aug-21
1-Sep-21
1-Oct-21
1-Nov-21
1-Dec-21
1-Jan-22
1-Feb-22
1-Mar-22
1-Apr-22
Brand count 9 9 9 9 8 8 8 8 8 8 8 8 8 8 9 9 9 9 10 10 10 10 10 9 9 9 9 9 9 9 8 8 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 8 8 8
AEMP 229 229 229 229 229 229 229 229 229 229 229 229 229 153 153 153 153 153 153 153 153 153 153 153 153 153 111 111 111 111 111 111 111 111 111 111 111 111 111 111 898 898 898 898 898 898 613 613 613 613 613 613 431 431 431 431 431 431 431
Brand count
AEMP

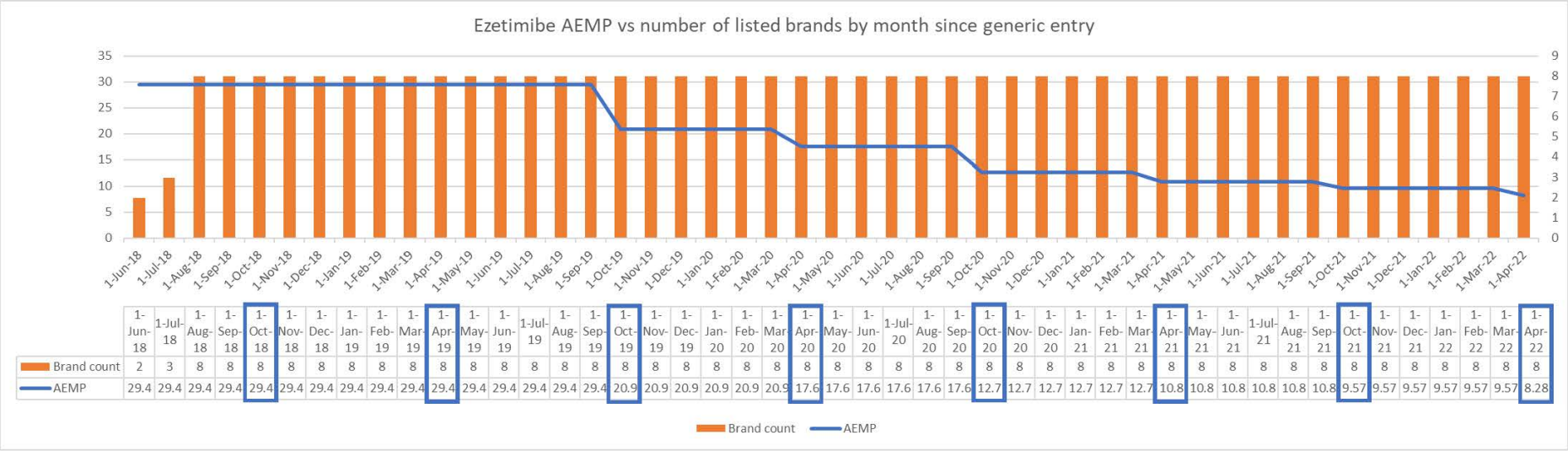
Dorzolamide



Epleronone

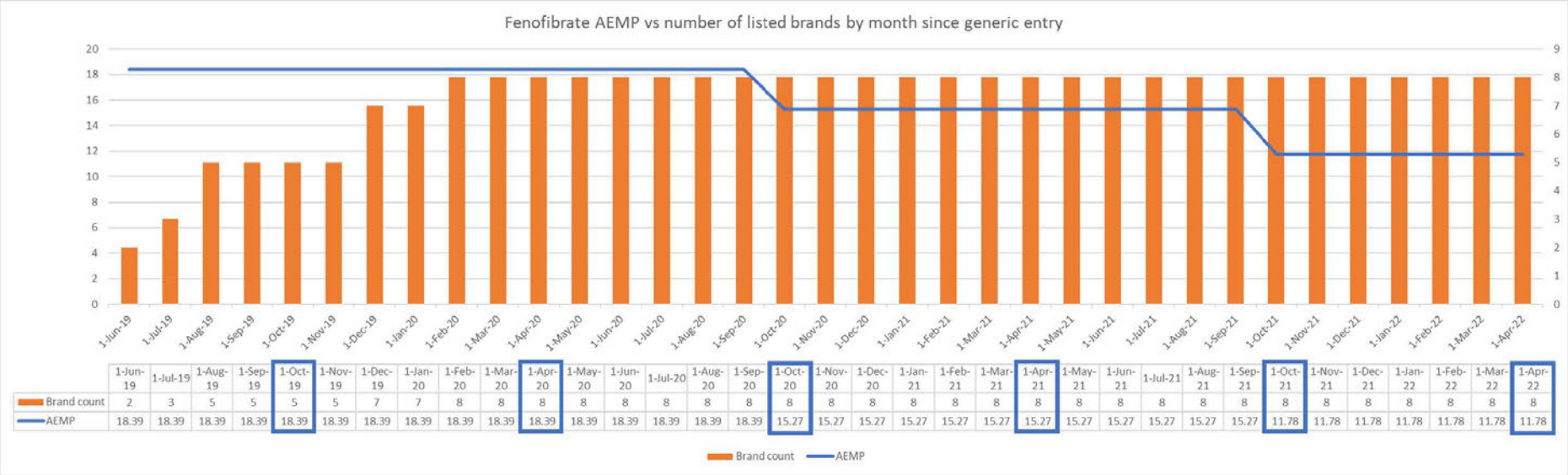

Epleronone AEMP vs number of listed brands by month since generic entry
Brand count
AEMP

Ezetimibe



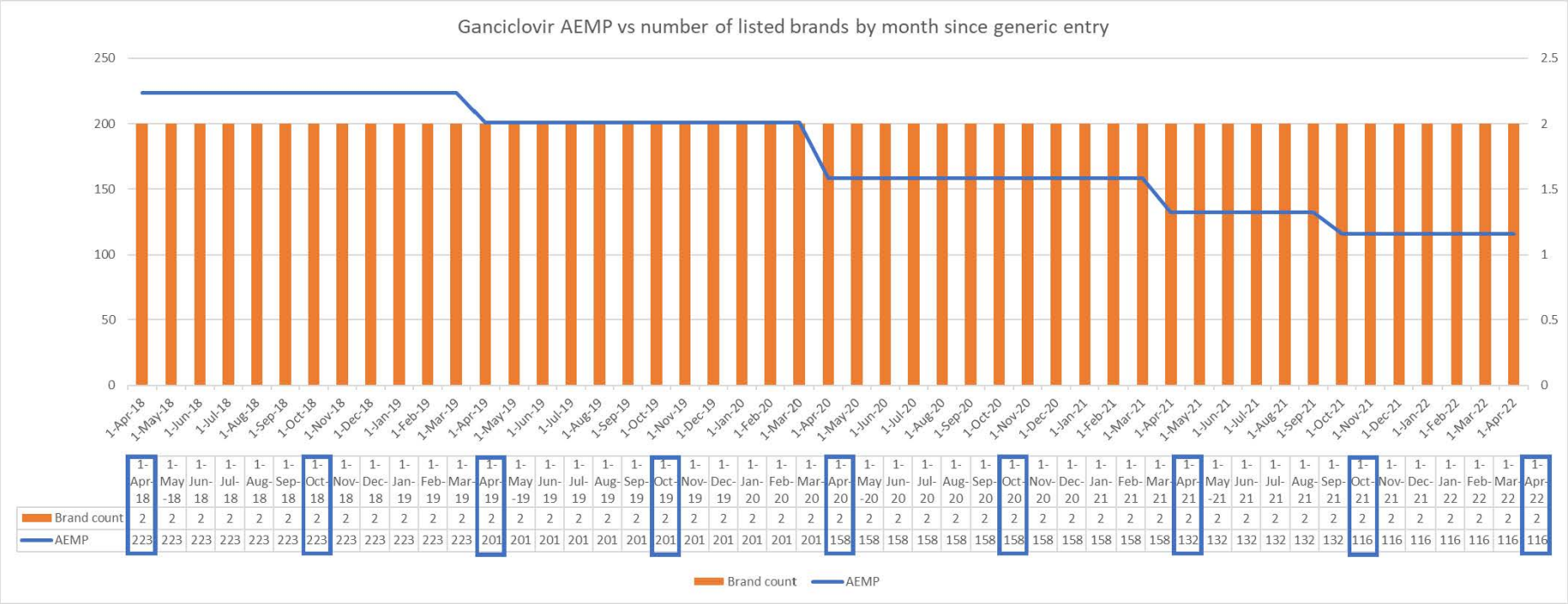
	1-Jun-18	1-Jul-18	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	3	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
AEMP	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	29.4	20.9	20.9	20.9	20.9	20.9	20.9	17.6	17.6	17.6	17.6	17.6	17.6	12.7	12.7	12.7	12.7	12.7	12.7	10.8	10.8	10.8	10.8	10.8	10.8	9.57	9.57	9.57	9.57	9.57	9.57	8.28

Fenofibrate



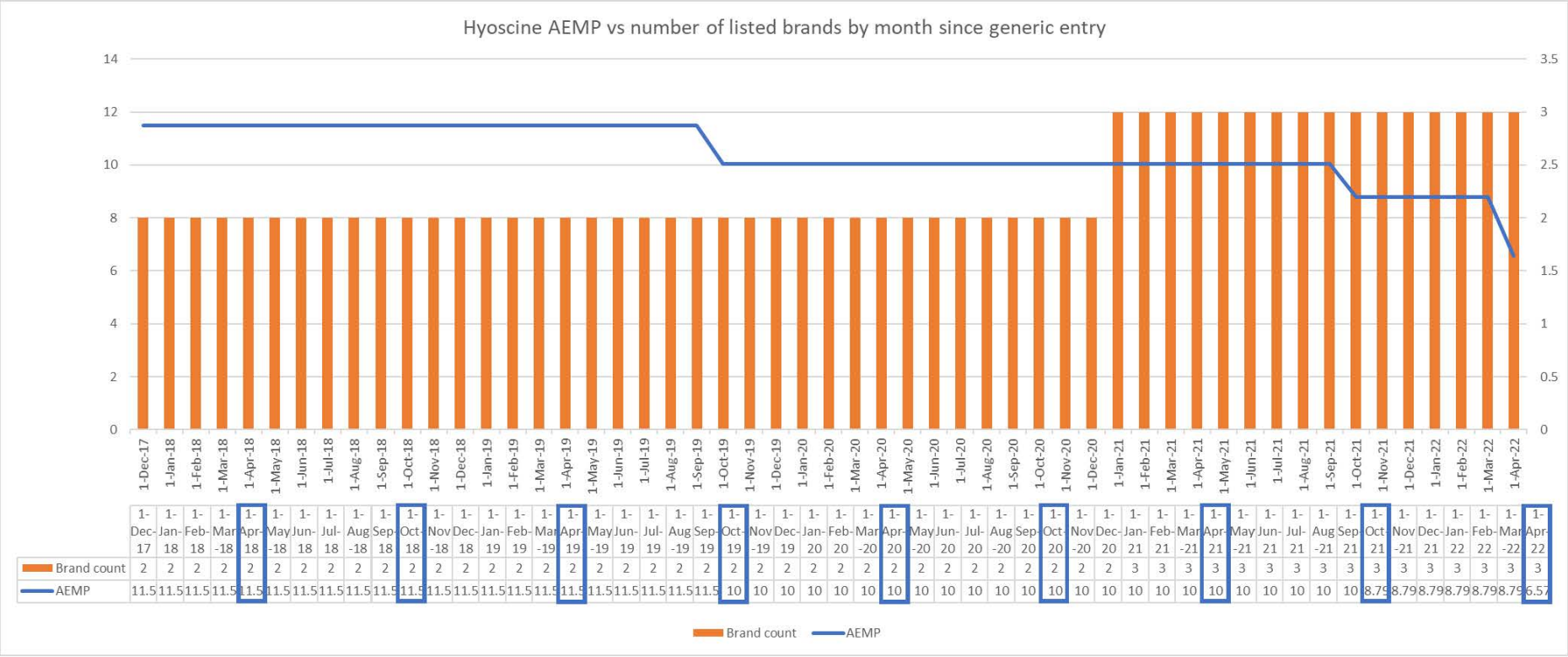
	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	3	5	5	5	5	7	7	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
AEMP	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	18.39	15.27	15.27	15.27	15.27	15.27	15.27	15.27	15.27	15.27	15.27	15.27	11.78	11.78	11.78	11.78	11.78	11.78	11.78

Ganciclovir

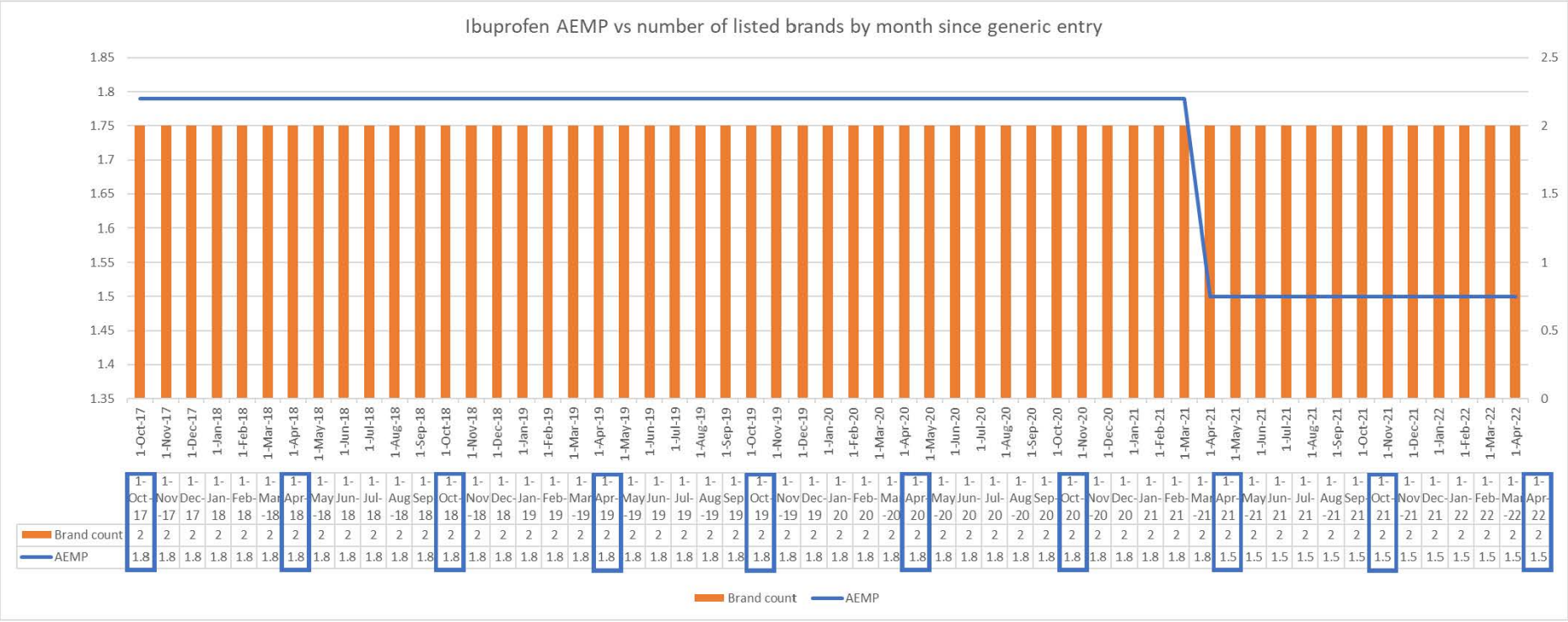


	1-Apr-18	1-May-18	1-Jun-18	1-Jul-18	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
AEMP	223	223	223	223	223	223	223	223	223	223	223	223	201	201	201	201	201	201	201	201	201	201	201	201	158	158	158	158	158	158	158	158	158	158	158	132	132	132	132	132	132	116	116	116	116	116	116	116

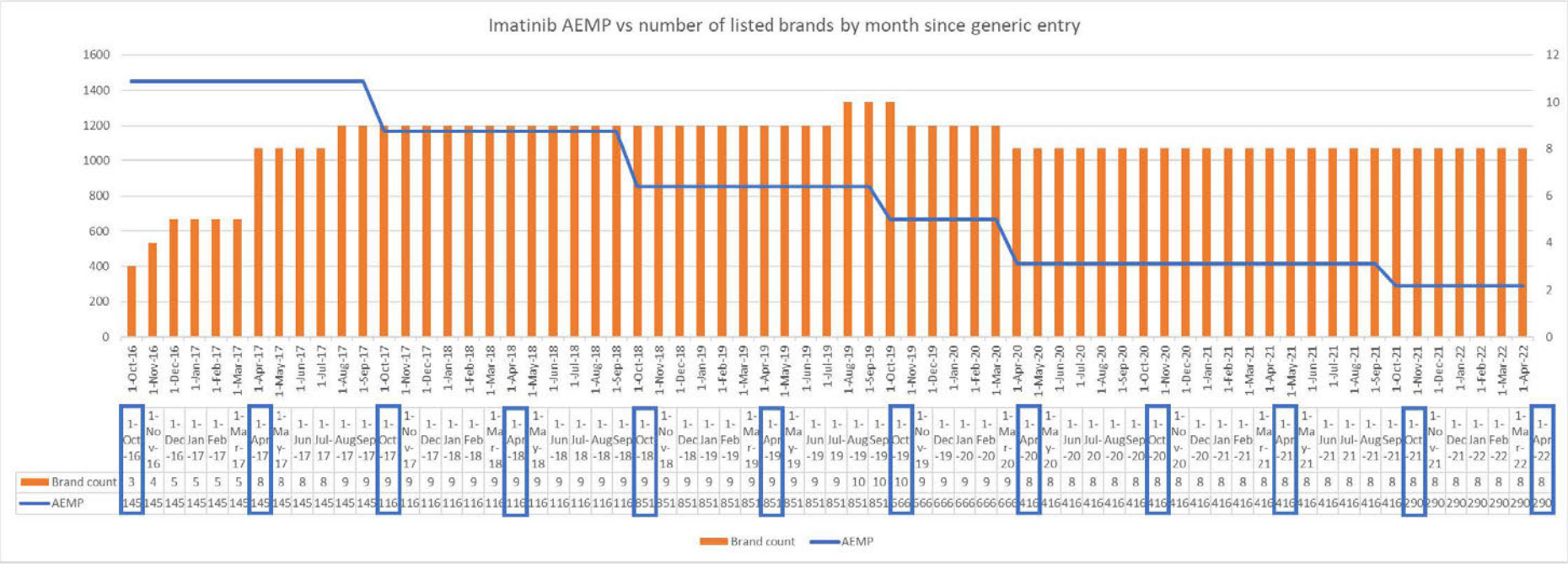
Hyoscine


Hyoscine AEMP vs number of listed brands by month since generic entry
14
12
10
8
6
4
2
0
3.5
3
2.5
2
1.5
1
0.5
0
1-Dec-17 1-Jan-18 1-Feb-18 1-Mar-18 1-Apr-18 1-May-18 1-Jun-18 1-Jul-18 1-Aug-18 1-Sep-18 1-Oct-18 1-Nov-18 1-Dec-18 1-Jan-19 1-Feb-19 1-Mar-19 1-Apr-19 1-May-19 1-Jun-19 1-Jul-19 1-Aug-19 1-Sep-19 1-Oct-19 1-Nov-19 1-Dec-19 1-Jan-20 1-Feb-20 1-Mar-20 1-Apr-20 1-May-20 1-Jun-20 1-Jul-20 1-Aug-20 1-Sep-20 1-Oct-20 1-Nov-20 1-Dec-20 1-Jan-21 1-Feb-21 1-Mar-21 1-Apr-21 1-May-21 1-Jun-21 1-Jul-21 1-Aug-21 1-Sep-21 1-Oct-21 1-Nov-21 1-Dec-21 1-Jan-22 1-Feb-22 1-Mar-22 1-Apr-22
Brand count 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3
AEMP 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 11.5 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 8.79 8.79 8.79 8.79 8.79 8.79 6.57
Brand count
AEMP

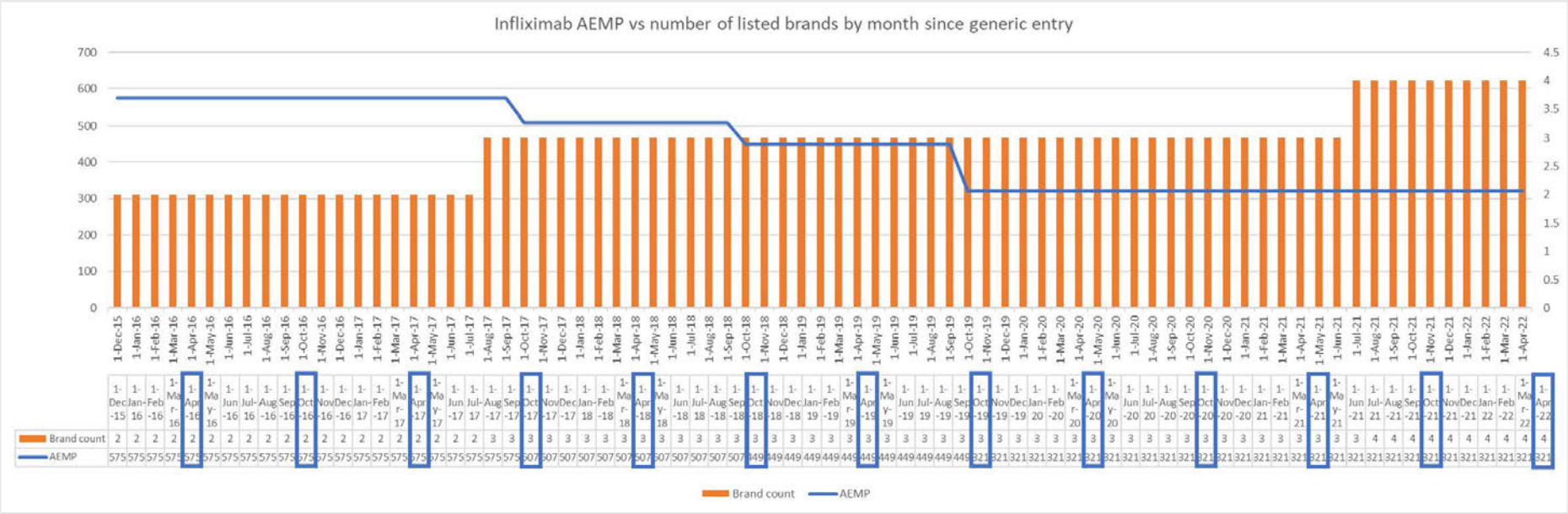
Ibuprofen


Ibuprofen AEMP vs number of listed brands by month since generic entry
1.85
1.8
1.75
1.7
1.65
1.6
1.55
1.5
1.45
1.4
1.35
2.5
2
1.5
1
0.5
0
Brand count
AEMP

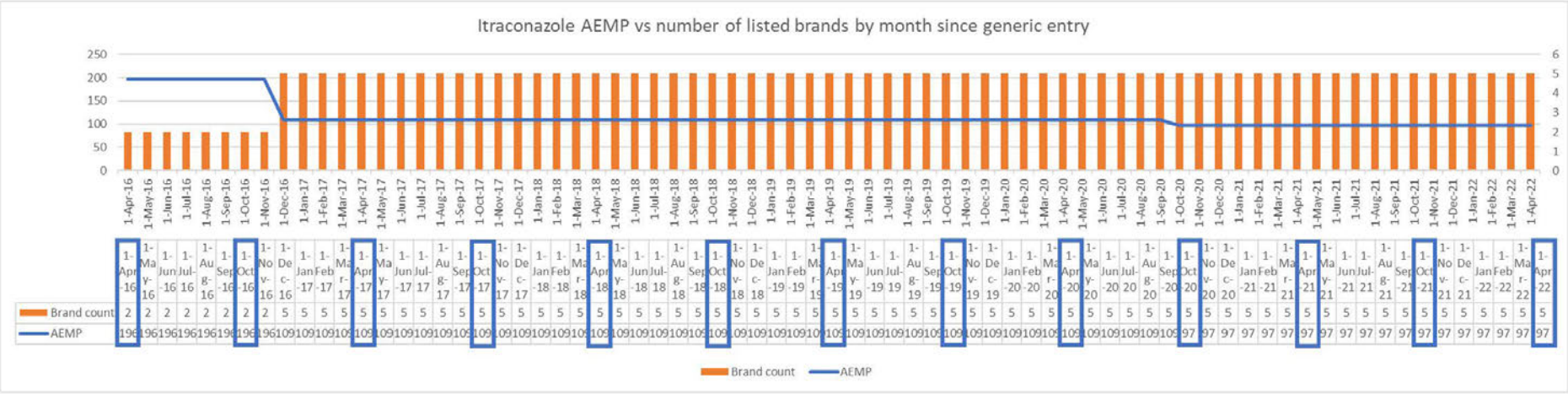
Imatinib


Imatinib AEMP vs number of listed brands by month since generic entry
1600
1400
1200
1000
800
600
400
200
0
12
10
8
6
4
2
0
Brand count
AEMP

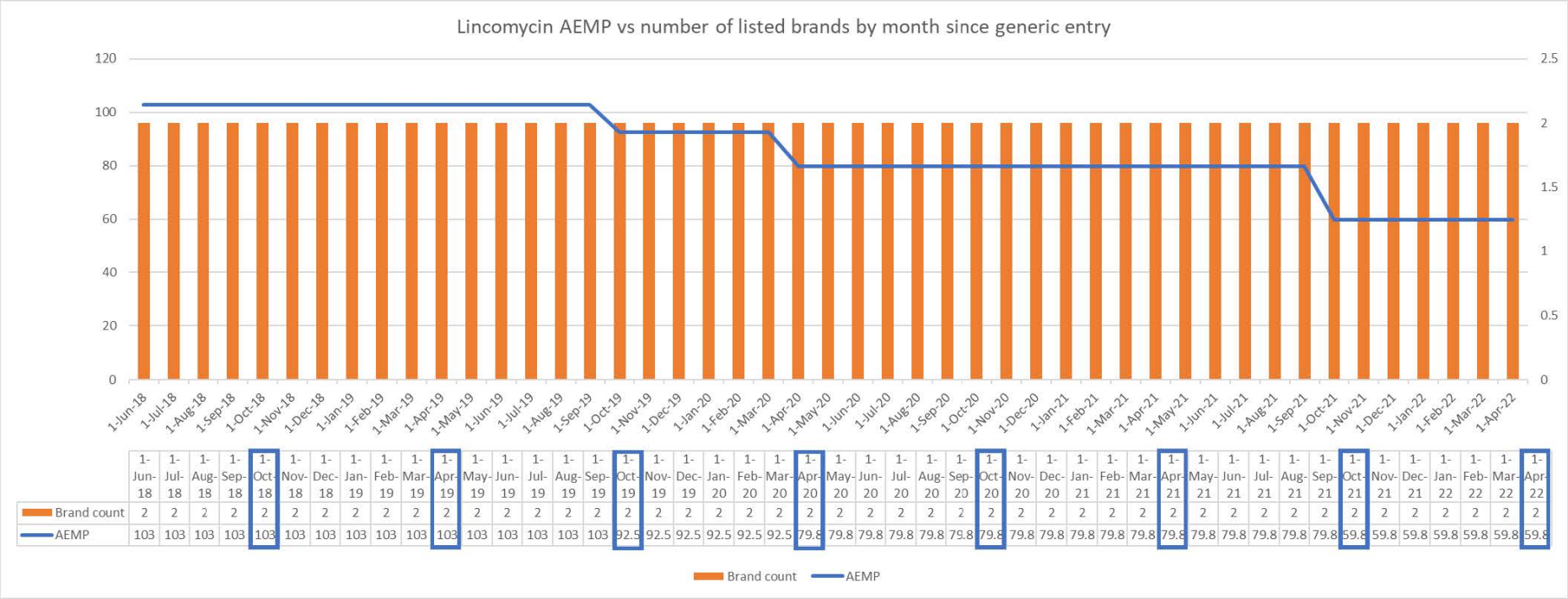
Infliximab


Infliximab AEMP vs number of listed brands by month since generic entry
Brand count
AEMP

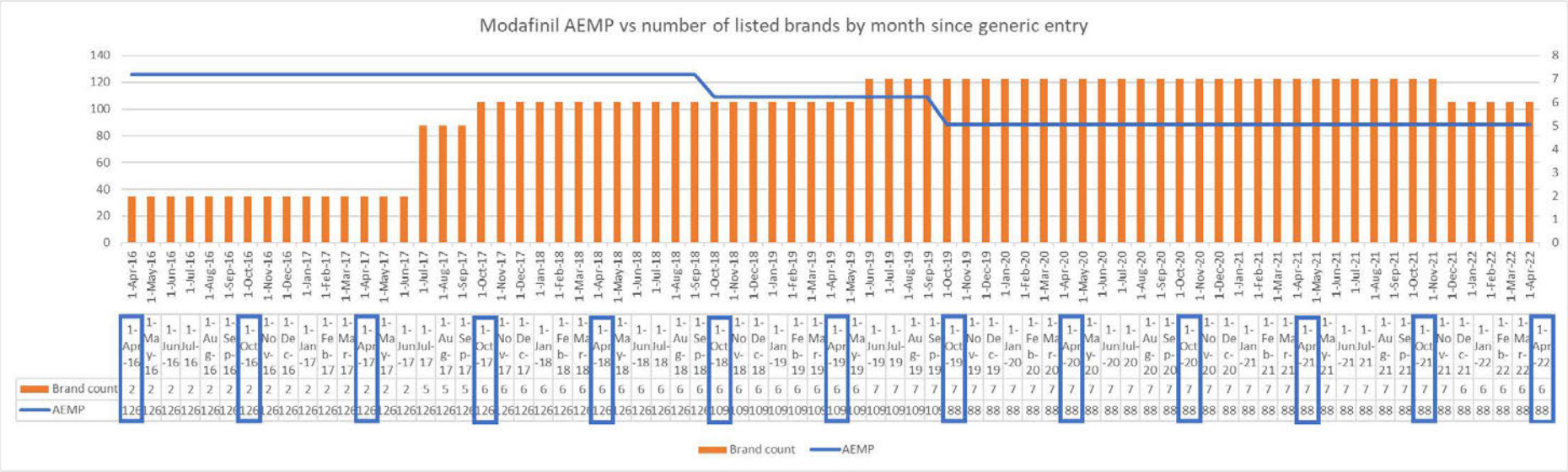
Itraconazole



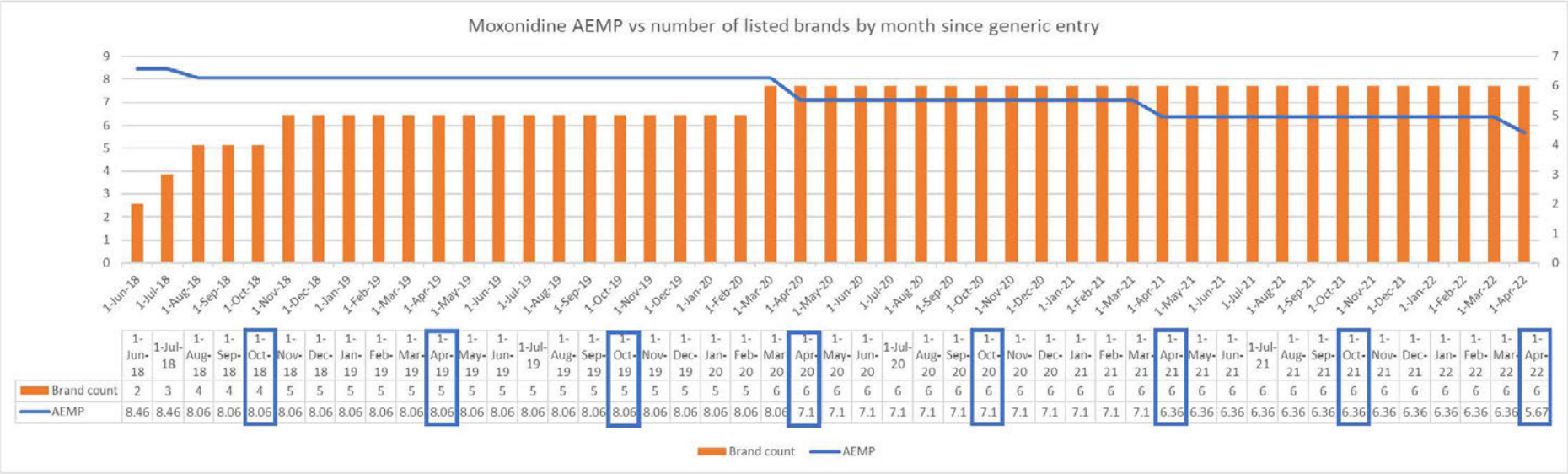
Lincomycin


Lincomycin AEMP vs number of listed brands by month since generic entry
120
100
80
60
40
20
0
2.5
2
1.5
1
0.5
0
1-Jun-18 1-Jul-18 1-Aug-18 1-Sep-18 1-Oct-18 1-Nov-18 1-Dec-18 1-Jan-19 1-Feb-19 1-Mar-19 1-Apr-19 1-May-19 1-Jun-19 1-Jul-19 1-Aug-19 1-Sep-19 1-Oct-19 1-Nov-19 1-Dec-19 1-Jan-20 1-Feb-20 1-Mar-20 1-Apr-20 1-May-20 1-Jun-20 1-Jul-20 1-Aug-20 1-Sep-20 1-Oct-20 1-Nov-20 1-Dec-20 1-Jan-21 1-Feb-21 1-Mar-21 1-Apr-21 1-May-21 1-Jun-21 1-Jul-21 1-Aug-21 1-Sep-21 1-Oct-21 1-Nov-21 1-Dec-21 1-Jan-22 1-Feb-22 1-Mar-22 1-Apr-22
Brand count 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
AEMP 103 103 103 103 103 103 103 103 103 103 103 103 103 103 103 103 92.5 92.5 92.5 92.5 92.5 92.5 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 79.8 59.8 59.8 59.8 59.8 59.8 59.8 59.8
Brand count
AEMP

Modafinil

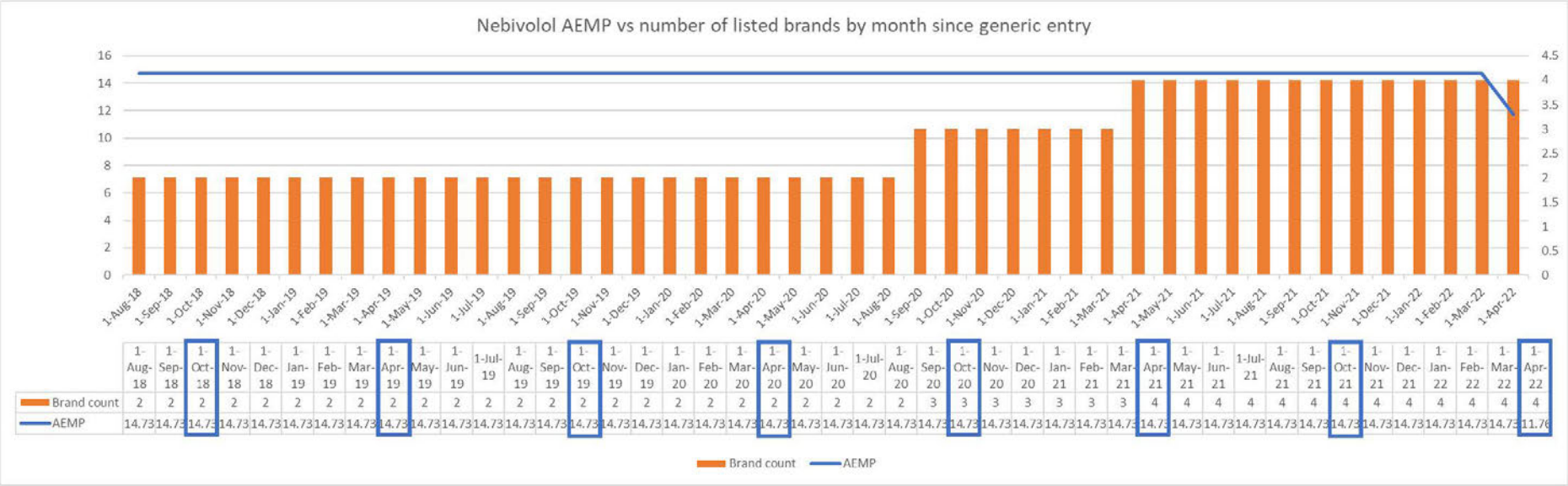

Modafinil AEMP vs number of listed brands by month since generic entry
Brand count
AEMP

Moxonidine



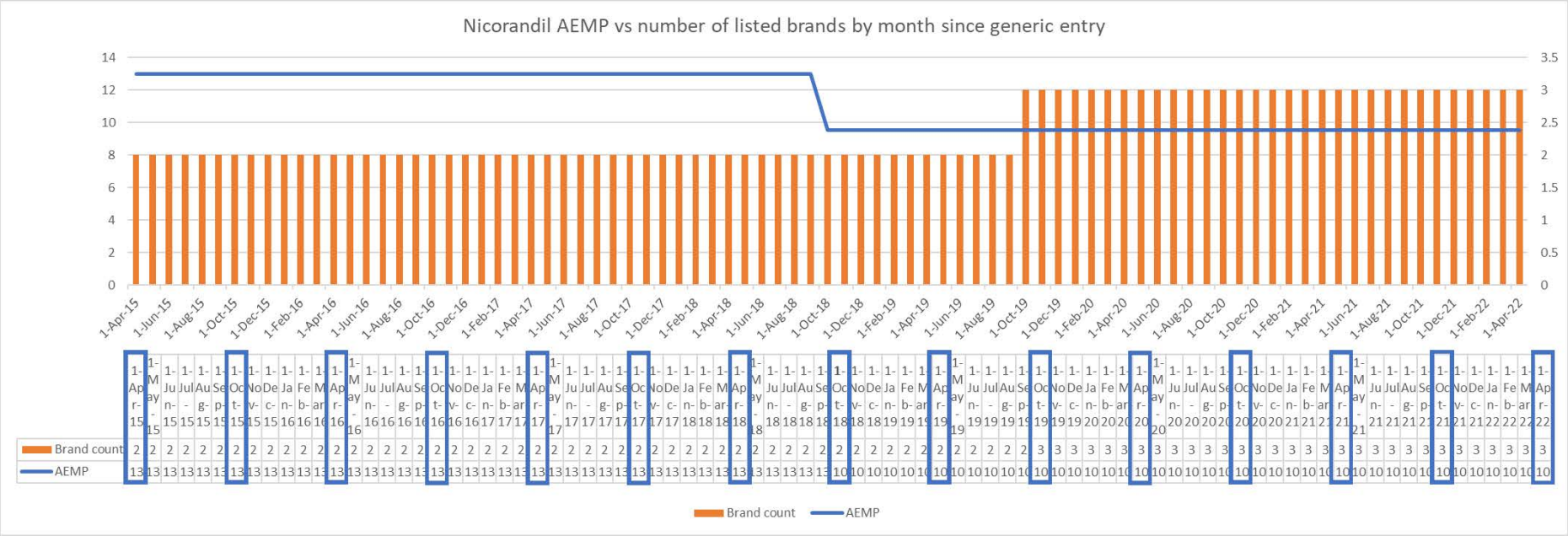
	1-Jun-18	1-Jul-18	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar 20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	3	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
AEMP	8.46	8.46	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	8.06	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	6.36	6.36	6.36	6.36	6.36	6.36	6.36	6.36	6.36	6.36	6.36	5.67

Nebivolol

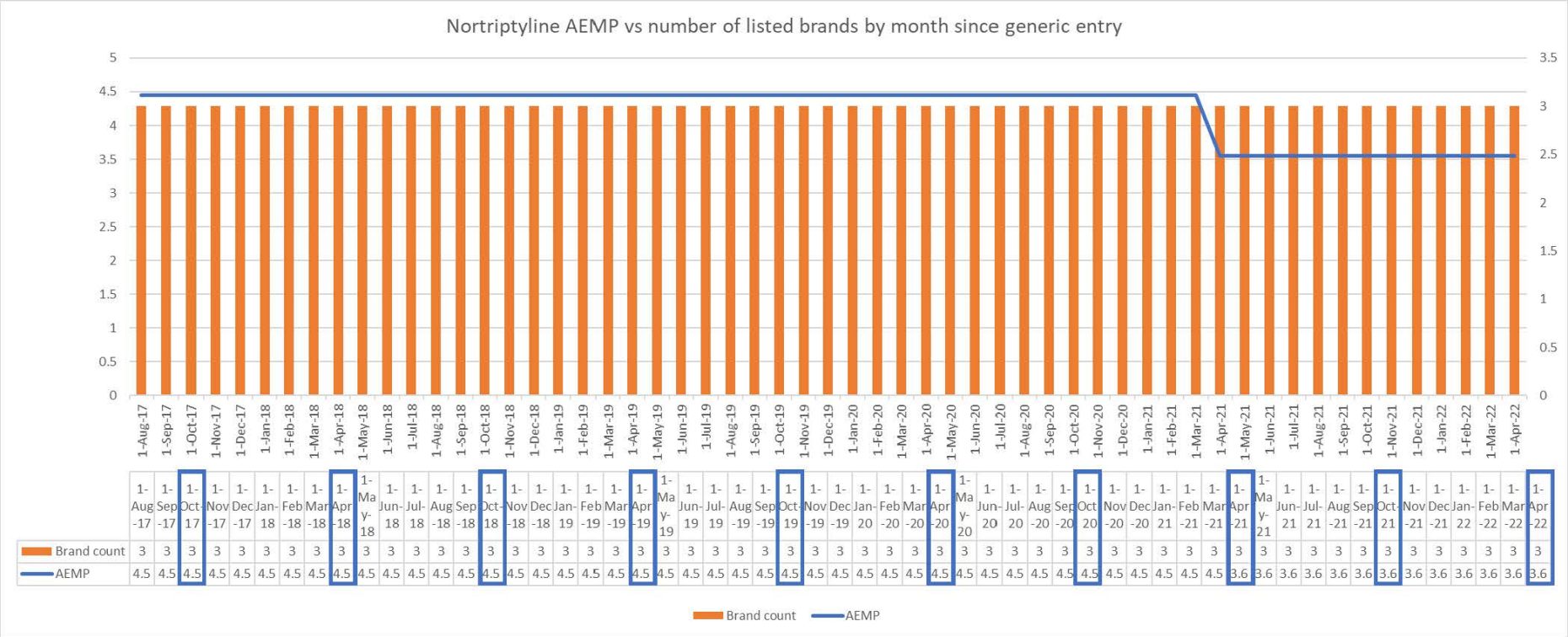


	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4
AEMP	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	14.73	11.76

Nicorandil

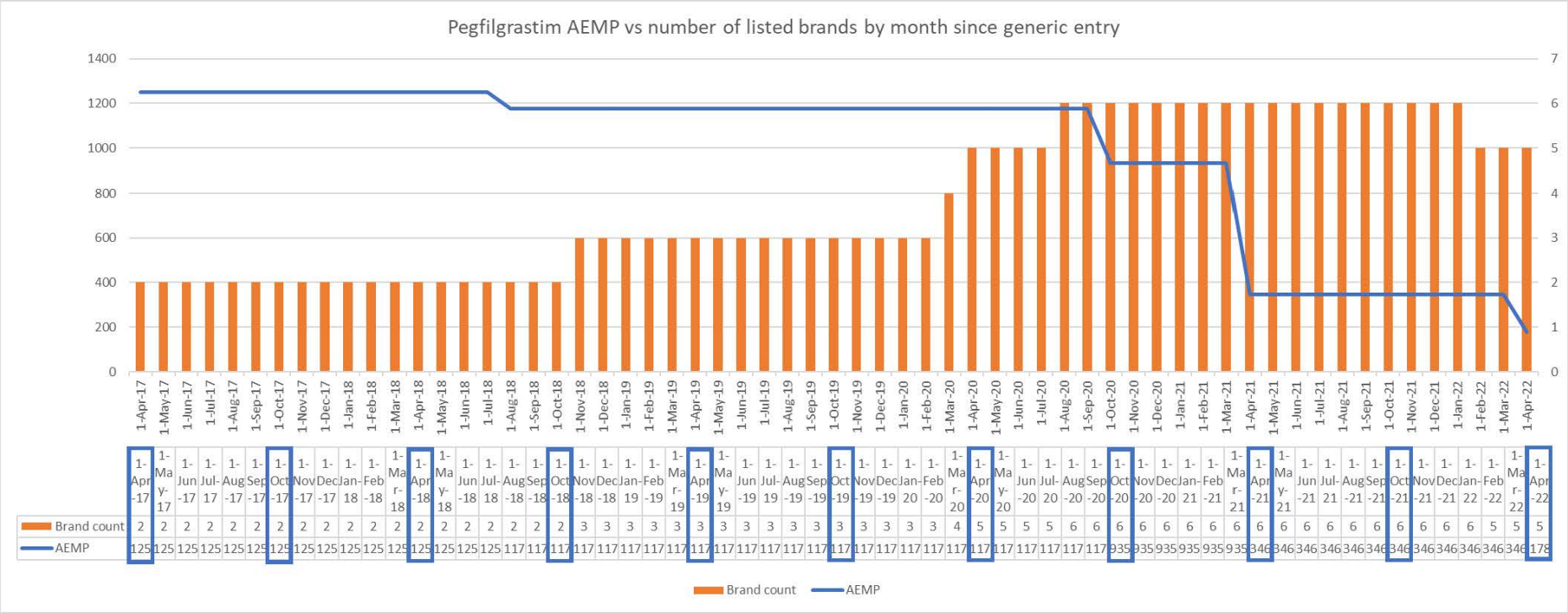

Nicorandil AEMP vs number of listed brands by month since generic entry
Brand count
AEMP

Nortriptyline

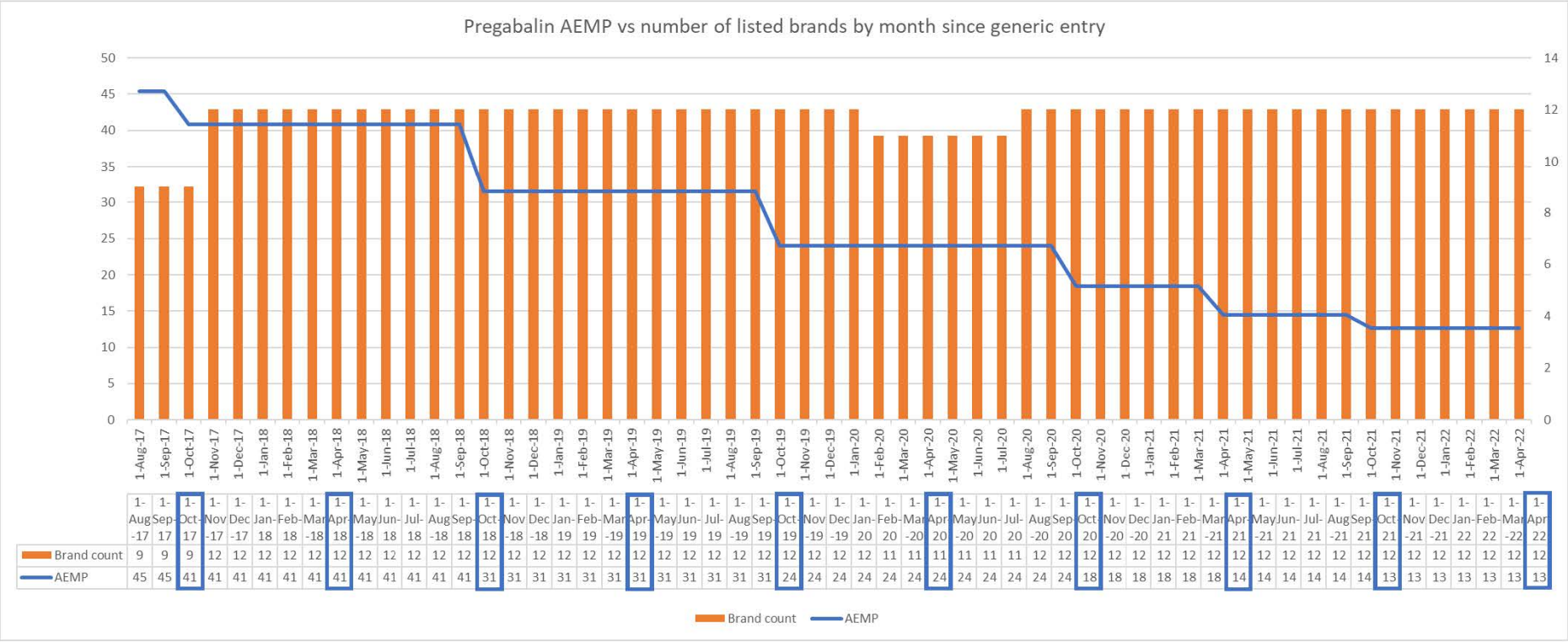


	1-Aug-17	1-Sep-17	1-Oct-17	1-Nov-17	1-Dec-17	1-Jan-18	1-Feb-18	1-Mar-18	1-Apr-18	1-May-18	1-Jun-18	1-Jul-18	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
AEMP	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6

Pegfilgrastim

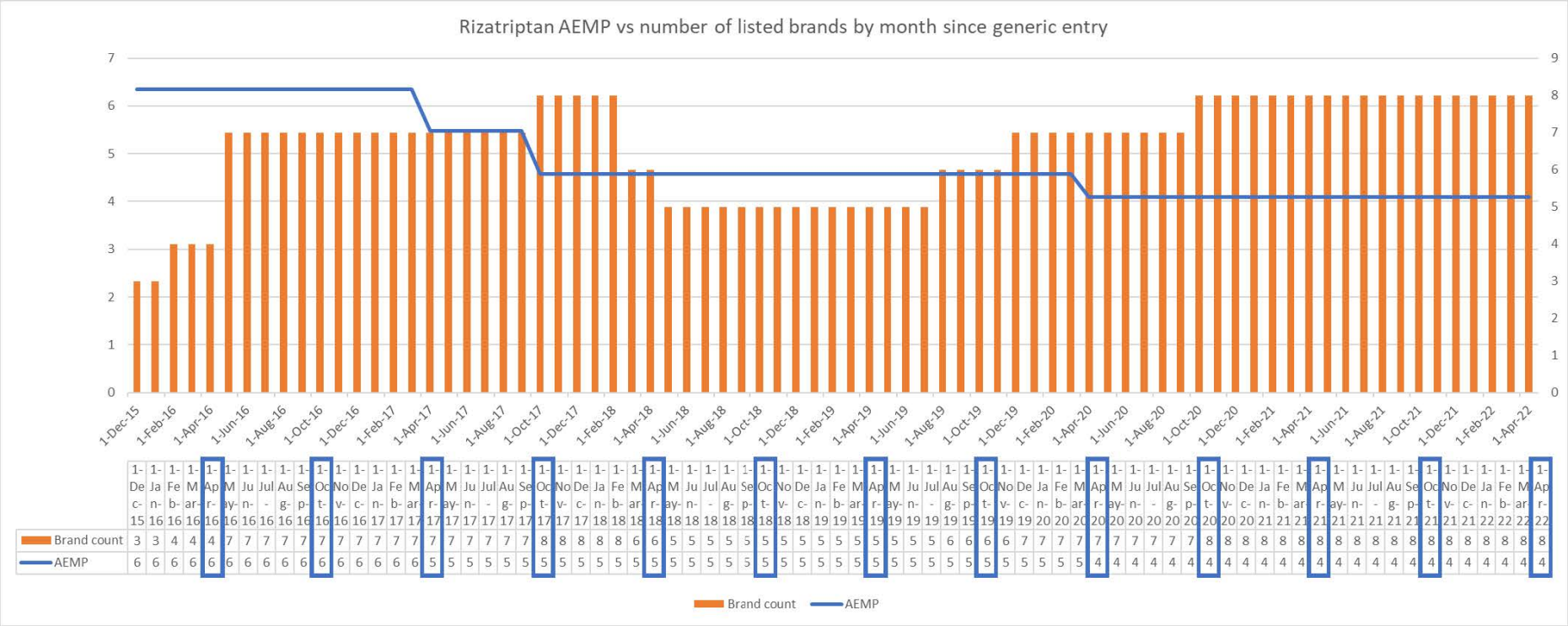


Pregabalin

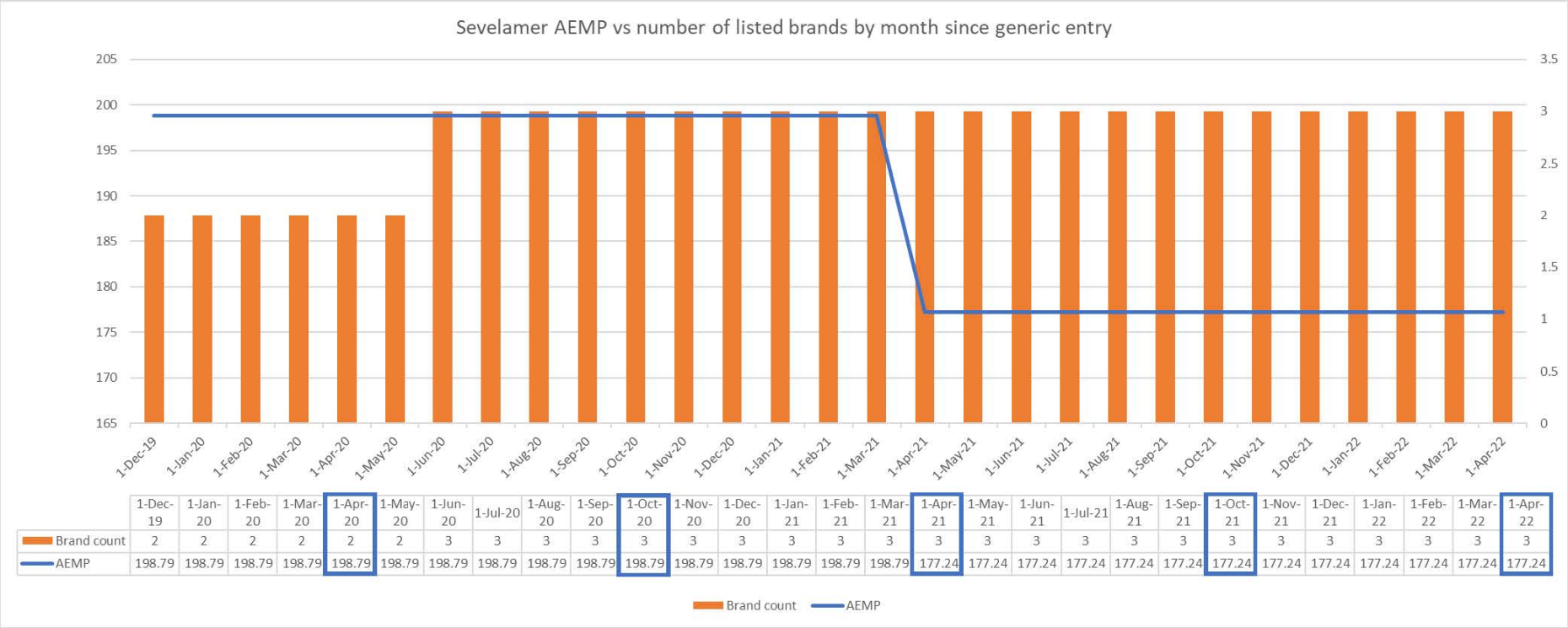


	1-Aug-17	1-Sep-17	1-Oct-17	1-Nov-17	1-Dec-17	1-Jan-18	1-Feb-18	1-Mar-18	1-Apr-18	1-May-18	1-Jun-18	1-Jul-18	1-Aug-18	1-Sep-18	1-Oct-18	1-Nov-18	1-Dec-18	1-Jan-19	1-Feb-19	1-Mar-19	1-Apr-19	1-May-19	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	9	9	9	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	11	11	11	11	11	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
AEMP	45	45	41	41	41	41	41	41	41	41	41	41	41	41	31	31	31	31	31	31	31	31	31	31	31	24	24	24	24	24	24	24	24	24	24	24	24	18	18	18	18	18	18	14	14	14	14	14	14	13	13	13	13	13	13

Rizatriptan

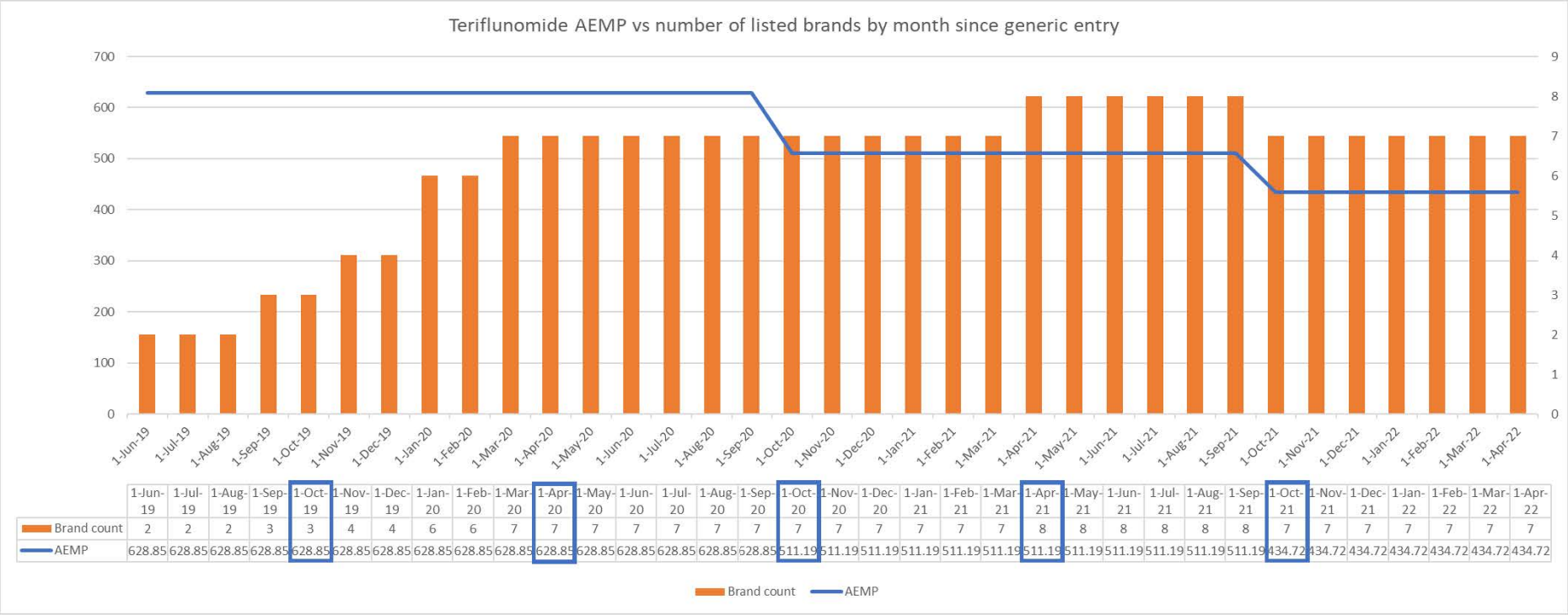


Sevelamer



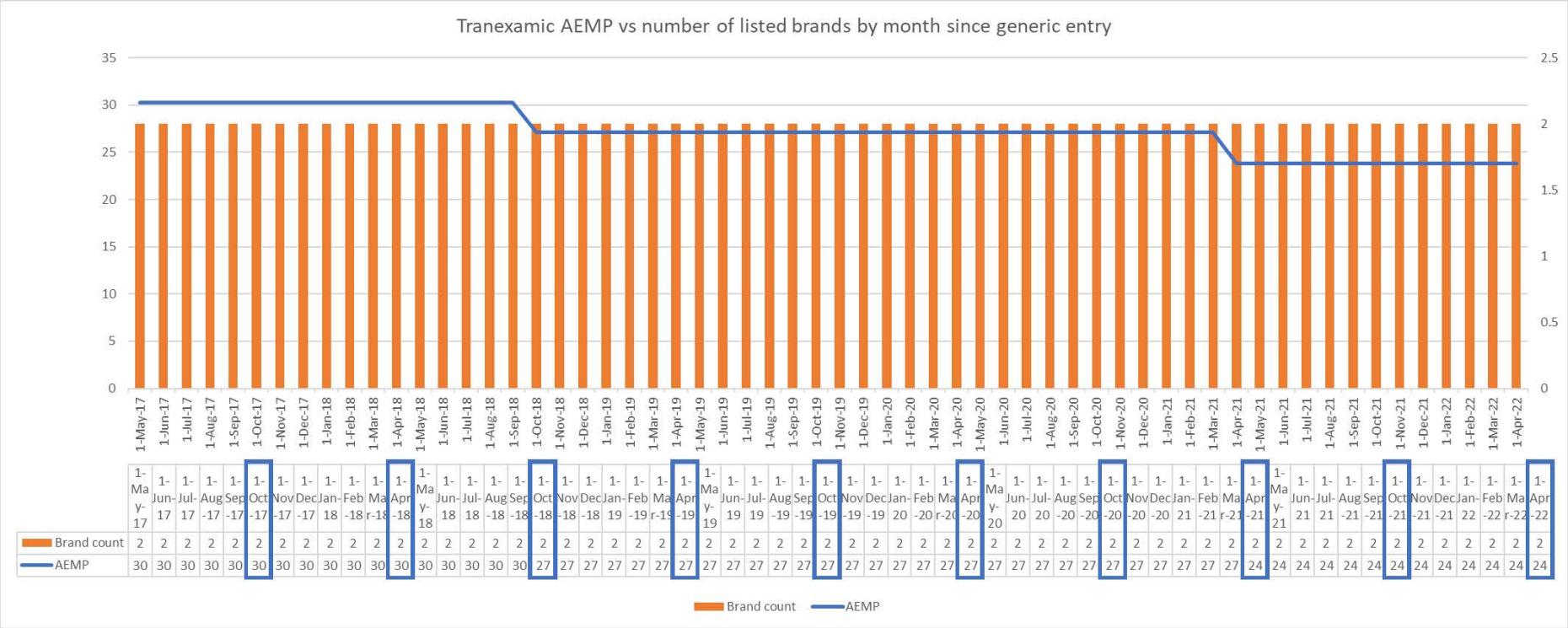
	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	2	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
AEMP	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	198.79	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24	177.24

Teriflunomide

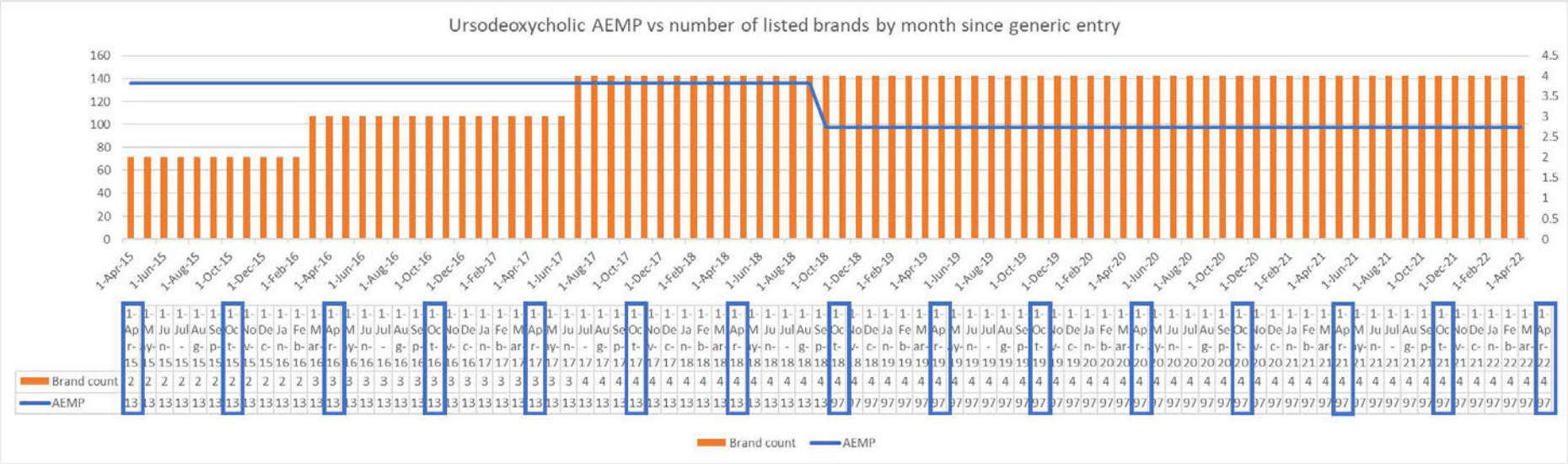


	1-Jun-19	1-Jul-19	1-Aug-19	1-Sep-19	1-Oct-19	1-Nov-19	1-Dec-19	1-Jan-20	1-Feb-20	1-Mar-20	1-Apr-20	1-May-20	1-Jun-20	1-Jul-20	1-Aug-20	1-Sep-20	1-Oct-20	1-Nov-20	1-Dec-20	1-Jan-21	1-Feb-21	1-Mar-21	1-Apr-21	1-May-21	1-Jun-21	1-Jul-21	1-Aug-21	1-Sep-21	1-Oct-21	1-Nov-21	1-Dec-21	1-Jan-22	1-Feb-22	1-Mar-22	1-Apr-22
Brand count	2	2	2	3	3	4	4	6	6	7	7	7	7	7	7	7	7	7	7	7	7	8	8	8	8	8	8	7	7	7	7	7	7	7
AEMP	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	628.85	511.19	511.19	511.19	511.19	511.19	511.19	511.19	511.19	511.19	511.19	511.19	434.72	434.72	434.72	434.72	434.72	434.72	434.72

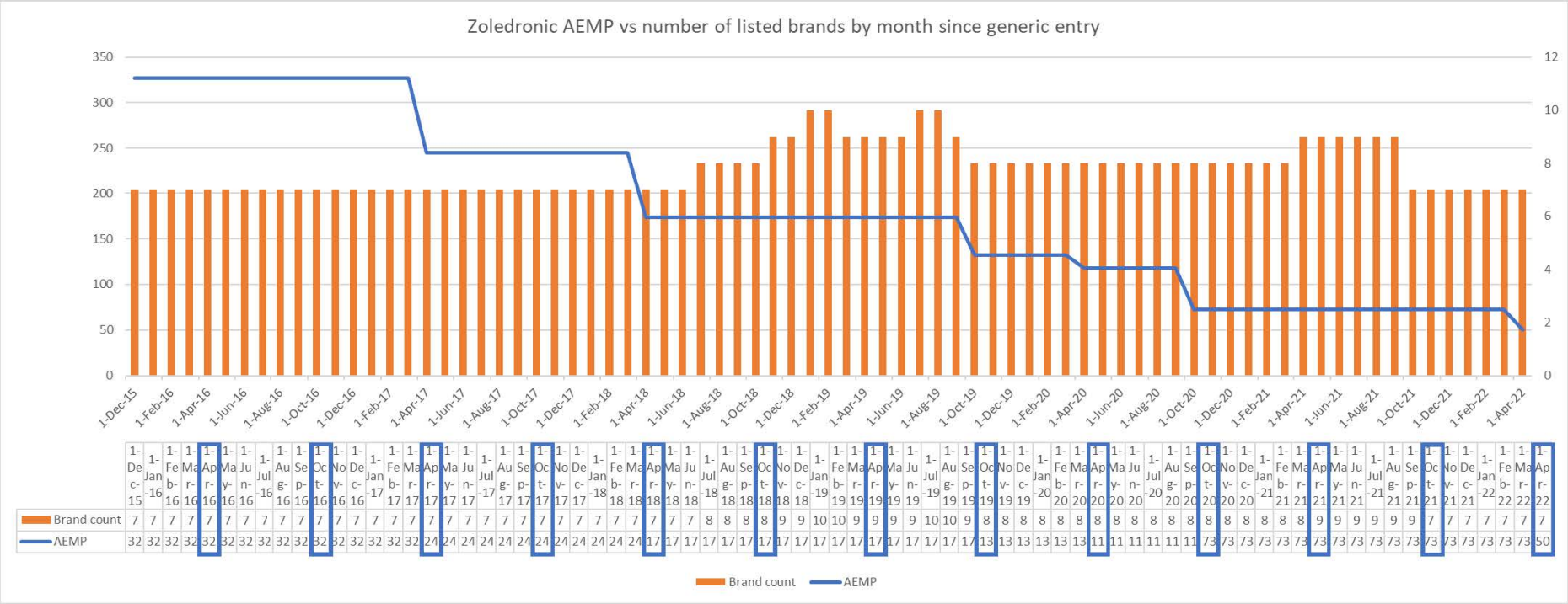
Tranexamic acid



Ursodeoxycholic acid



Zoledronic acid



Commonwealth of Australia

STATUTORY DECLARATION

Statutory Declarations Act 1959

1 *Insert the name, address and occupation of person making the declaration*

I, Gregory Cook, of 2/4 Nexus Circuit, Mulgrave, in the state of Victoria, company executive, make the following declaration under the *Statutory Declarations Act 1959:*

2 *Set out matter declared to in numbered paragraphs*

1. I make this declaration in connection with an application which Celgene and Juno/Natco have jointly made to the Australian Consumer and Competition Commission (ACCC) for Authorisation of a settlement agreement dated 3 December 2021.

2. I am currently Senior Director of Access, Policy & Advocacy at Bristol Myers Squibb Australia Pty Ltd (**BMS**).

3. I was awarded the degrees of Bachelor of Science (Zoology) and PhD (Molecular Biology), by the University of Melbourne in 1988 and 1996, respectively, along with a Graduate Certificate in Drug Development by the University of New South Wales in 1998.

4. In 2000, I left medical research to work for a pharmaceutical consultancy company, Sirius Research, which assisted small to medium Australian pharmaceutical companies with their submissions to the Pharmaceutical Benefits Advisory Committee (**PBAC**) for reimbursement of their medicines via the PBS. After two years at Sirius Research, I moved to BMS where I was employed as a Senor Health Economist. I have worked in the area of health economics/ market access for close to 20 years.

5. As Senior Director of Access, Policy & Advocacy (and in my previous roles referred to above), it is and has been my responsibility to apply for and seek reimbursement for BMS's medicines under (or in accordance with) the Pharmaceutical Benefits Scheme (**PBS**). As Senior Director, the principal emphasis of my responsibility is in the development of strategy specific to obtaining reimbursement of the company's medicines, as well as the management of a team of market access managers who prepare each PBAC submission. Obtaining market access (PBS listing) for a medicine involves a submission to the PBAC to review the clinical and cost-effectiveness of the medicine compared to the main comparator (current standard of care), and post-PBAC approval, negotiations with the Department of Health specific to the final restriction, pricing and financial caps. By the term 'restriction', I mean the clinical indication(s) for which the medicine will be reimbursed. The restriction is determined not only by clinical trial data but also by other factors such as the level

of expenditure for the Commonwealth. Various levels of restrictions (in other words, conditions for access) exist within the PBS codes, for example, authority required, streamlined authority.

6. One area of experience I have gained over my time at BMS is overseeing the pricing evolution of BMS originator medicines once they have lost patent and a generic brand has entered the market. Currently, the entry of a generic medicine triggers a 25% statutory price reduction for the originator brand and also begins the Commonwealth's formal process of potential further price reductions through the price disclosure mechanism. Price disclosure captures any potential discounting, and the value of benefits given as incentives, relative to the PBS price that generics or the originator brand conduct in the marketplace in an attempt to gain market share. After a certain period of time, for example 6 months, the level of discounting (and incentives) in the marketplace is captured and if the weighted average discount price across brands is greater than 10% below the PBS price, then the PBS price is reduced for all medicines, generic and/or originator, to the weighted average discount price beyond 10%. The price disclosure mechanism continues on a six-monthly basis in order to capture any and all discounting practices in the marketplace. In my experience with BMS products, PBS price reductions through price disclosure have been driven through the discounting of the generic medicines.

7. Jones Day asked me if I am able to provide an opinion as to whether, following the launch of generic lenalidomide products, there is likely to be an expansion of the use (i.e. number of patients) of lenalidomide including in combination with other products.

8. The decision whether to recommend reimbursement of new combinations of products lies with the PBAC. The role of the PBAC is to advise the Minister of Health on the clinical and economic justification for the listing of new drugs, new brands of existing drugs and new combinations of drugs on the PBS. When recommending a medicine for listing on the PBS, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value-for-money') compared with other treatments (see https://www.pbs.gov.au/pbs/industry/listing/participants/pbac).

9. In addition, I am aware that in the case of certain drugs, the PBS access criteria are streamlined at the time that generic brands of a pharmaceutical are listed on the PBS. I am aware that in the case of the pharmaceutical bortezomib, a Celgene product for the treatment of multiple myeloma sold under the product

name Velcade®, there was only a very limited number of specific indications reimbursed under the PBS prior to the entry of generic brands. However, once generic bortezomib products were able to list on the PBS, the specific access criteria were revised and a streamlined indication of multiple myeloma was substituted for the previously existing criteria. This change in access criteria made bortezomib more accessible to patients in that treating doctors were able to prescribe it for the treatment of multiple myeloma more generally, including in combination with other products, in the knowledge that patients would be reimbursed under the PBS.

10. At present, I have no information as to whether, and if so how, PBS restrictions and access codes for Revlimid® (lenalidomide) will be treated following generic entry. However, based on my experience outlined above, it is my opinion that following price reductions for lenalidomide and/ or pomalidomide, applications to list combination treatments that include lenalidomide or pomalidomide will be viewed more favourably (that is, seen as more cost-effective) than prior to the listing of generic lenalidomide and pomalidomide products. As was the experience with bortezomib, I believe it will be more likely that specific PBS restrictions and access criteria will be relaxed, and as a result there will be a greater number of patients that will be treated with combinations of products that include lenalidomide or pomalidomide.

11. Jones Day asked me if I am aware of any patients who are currently prescribed Revlimid® and who are required to self-fund their treatment because their use of Revlimid® does not qualify for reimbursement under the PBS.

12. I am aware that Revlimid® is currently prescribed for the treatment of B-Cell Malignancies. The term "B-Cell Malignancies" is used to describe a range of haematological cancers including lymphomas, however the treatment of B-Cell Malignancies is not an indication for which Revlimid® is currently reimbursed under the PBS. Given the nature of the diseases encapsulated by B-Cell Malignancies, and the fact that their treatment is not an indication for which the use of Revlimid® is currently reimbursed, BMS makes Revlimid® available to B-Cell Malignancy patients on a 'co-pay' basis. This involves the patients meeting the cost of the first two months of treatment from personal (or other) funds, following which BMS provides the product free of charge to the patient. I estimate that approximately 50 patients fall into this category each year. Our records show that 51 patients accessed Revlimid® for B-Cell Malignancies via the co-pay program in the last year. BMS reviews all of its access programs every two years and at times more frequently.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

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3 *Signature of person making the declaration*

4 *[Optional: email address and/or telephone number of person making the declaration]*

Mob: [redacted]

5 *Place*
6 *Day*
7 *Month and year*

Declared at [5] Strathmore, Victoria on [6] Friday 29th of [7] April, 2022

Before me,

8 *Signature of person before whom the declaration is made (see over)*

1. 

9 *Full name, qualification and address of person before whom the declaration is made (in printed letters)*

2. Alexander Hagan
Solicitor
Level 41, 88 Phillip Street
Sydney, NSW 2000 Australia

10 *[Email address and/or telephone number of person before whom the declaration is made*

3. 

This declaration was made in accordance with the *Coronavirus Economic Response Package (Modifications – Statutory Declarations and Notices of Intention to Marry) Determination 2021*

Note 1 A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years — see section 11 of the *Statutory Declarations Act 1959*.

Note 2 Chapter 2 of the *Criminal Code* applies to all offences against the *Statutory Declarations Act 1959* — see section 5A of the *Statutory Declarations Act 1959*.

A statutory declaration under the *Statutory Declarations Act 1959* may be made before–

(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

Architect	Chiropractor	Dentist
Financial adviser	Financial Planner	Legal practitioner
Medical practitioner	Midwife	Migration agent registered under Division 3 of Part 3 of the *Migration Act 1958*
Nurse	Occupational therapist	Optometrist
Patent attorney	Pharmacist	Physiotherapist
Psychologist	Trade marks attorney	Veterinary surgeon

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or

(3) a person who is in the following list:

Accountant who is:

a) a fellow of the National Tax Accountants' Association; or

b) a member of any of the following:

i. Chartered Accountants Australia and New Zealand;

ii. the Association of Taxation and Management Accountants;

iii. CPA Australia;

iv. the Institute of Public Accountants

Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public

APS employee engaged on an ongoing basis with 5 or more years of continuous service who is not specified in another item in this list

Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the *Consular Fees Act 1955*)

Bailiff

Bank officer with 5 or more continuous years of service

Building society officer with 5 or more years of continuous service

Chief executive officer of a Commonwealth court

Clerk of a court

Commissioner for Affidavits

Commissioner for Declarations

Credit union officer with 5 or more years of continuous service

Employee of a Commonwealth authority engaged on a permanent basis with 5 or more years of continuous service who is not specified in another item in this list

Employee of the Australian Trade and Investment Commission who is:

(a) in a country or place outside Australia; and

(b) authorised under paragraph 3 (d) of the *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Employee of the Commonwealth who is:

(a) at a place outside Australia; and

(b) authorised under paragraph 3 (c) of the *Consular Fees Act 1955*; and

(c) exercising the employee's function at that place

Engineer who is:

a) a member of Engineers Australia, other than at the grade of student; or

b) a Registered Professional Engineer of Professionals Australia; or

c) registered as an engineer under a law of the Commonwealth, a State or Territory; or

d) registered on the National Engineering Register by Engineers Australia

Finance company officer with 5 or more years of continuous service

Holder of a statutory office not specified in another item in this list

Judge

Justice of the Peace

Magistrate

Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the *Marriage Act 1961*

Master of a court

Member of the Australian Defence Force who is:

a) an officer

b) a non-commissioned officer within the meaning of the *Defence Force Discipline Act 1982* with 5 or more years of continuous service

c) a warrant officer within the meaning of that Act

Member of the Australasian Institute of Mining and Metallurgy

Member of the Governance Institute of Australia Ltd

Member of:

a) the Parliament of the Commonwealth

b) the Parliament of a State

c) a Territory legislature

d) a local government authority

Minister of religion registered under Subdivision A of Division 1 of Part IV of the *Marriage Act 1961*

Notary public, including a notary public (however described) exercising functions at a place outside

a) the Commonwealth

b) the external Territories of the Commonwealth

Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office providing postal services to the public

Permanent employee of

a) a State or Territory or a State or Territory authority

b) a local government authority

with 5 or more years of continuous service, other than such an employee who is specified in another item of this list

Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made

Police officer

Registrar, or Deputy Registrar, of a court

Senior executive employee of a Commonwealth authority

Senior executive employee of a State or Territory

SES employee of the Commonwealth

Sheriff

Sheriff's officer

Teacher employed on a permanent full-time or part-time basis at a school or tertiary education institution