Generic and Biosimilar Medicines Association

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Ms Danielle Staltari
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Australian Competition & Consumer Commission
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Dear Ms Staltari

**Application by Juno / Natco (Authorisation number AA1000592-1) – Draft Determination dated 23 March 2022**

I am writing to express the Generic and Biosimilar Medicines Association's (**GBMA**) support for the above application for authorisation, and to give the ACCC our views on the role of settlement agreements in the context of patent disputes.

Given its role as the peak representative body of generic and biosimilar medicine suppliers in Australia, the GBMA is well placed to provide a sector-wide perspective on the issues raised by the application. Specifically, the GBMA's members ensure that all Australians are offered the highest quality generic and biosimilar medicines in the world whilst providing affordable community health outcomes that benefit all Australians. Our members predominantly manufacture and/or supply generic and biosimilar medicines in the Australian market and/or manufacture such medicines for export. Our members include Accord Australia, Apotex Pty Ltd, Arrow Pharmaceuticals Pty Ltd, Celltrion Healthcare Australia Pty Ltd, Fresenius Kabi Australia Pty Ltd, Juno Pharmaceuticals Pty Ltd, Organon, Sandoz Pty Ltd, Viatris, with Commercial Eyes Pty Ltd and Sinapse Pty Ltd being associate members. Their medicines account for approximately 82% of all generic medicines sold in Australia.

Our members and associate members support the principles of the GBMA. These are to:

- make high quality medicines affordable for all Australians, today and for the future.
- provide ongoing education and professional development to Australian healthcare professionals to support community health outcomes that assists all Australians.
- support high standards in the manufacture of generic medicines; making Australian generic medicines consistently safe, effective, of high quality and a global benchmark.
- ensure high standards of conduct by adhering to a strict Code of Practice.
- adhere to a system of best practice and ethical standards whilst providing pricing benefits to pharmacy, patients and the Australian tax payer.
- respect the intellectual property rights of truly innovative medicines.

The generic and biosimilar medicines sector is a high value-add sector in Australia delivering significant health and economic benefits to the Australian public. Generic and biosimilar medicines are at the heart of the Australian Government's strategy to deliver access to high quality, cost-effective, reliably supplied, lifechanging medicines for the benefit of all Australians. Last year, the GBMA concluded negotiations for a new five year Strategic Agreement[1] with the Australian Government, with patient access to affordable medicines at the core of the agreement.

[1] New 5-year Strategic Agreement | Generic Biosimilar Medicines Association (gbma.com.au)

The availability of generic medicines in Australia helps to deliver:

- timely access to affordable medicines;
- substantial savings to the PBS;
- thousands of highly skilled jobs; and
- domestic manufacturing and annual exports of around $[300] million.

Generic medicines deliver significant savings to the PBS, and thereby to the Australian public. The benefits of entry by generic medicine are twofold: first, by automatically triggering the statutory 25% price reduction and subsequently, via operation of the PBS price disclosure regime, which delivers further savings. Over the past 5 years, the price disclosure regime has delivered savings to the PBS of approximately $4.3 billion[2].

Savings to PBS through generic medicines being introduced not only make access to reimbursed medicines more affordable, they also free up public funds to enable new medicines to be added to the PBS so that they can become widely available and affordable to the public (in circumstances where many medicines are simply too expensive to be purchased by patients privately). Since 2013, there has been, on average, a new or amended listing on the PBS every day.

**Overarching concerns with the Draft Determination**

Our members support the guiding principle that the intellectual property rights of truly innovative medicines should be respected. However, there is nevertheless an imbalance between patentee monopoly interests and public interest considerations in Australia, which creates persistent and inappropriate market entry barriers to the launch and manufacture of generic and biosimilar medicines in Australia, and which do not exist in our closest trading partners.

The GBMA is concerned that if the ACCC were to deny authorisation here, 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.

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).

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.

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.

**Significance of the ACCC's authorisation process**

In September 2019, an exemption for Intellectual Property (**IP**) arrangements in the *Competition and Consumer Act 2010* (**CCA**) was repealed. Parties to IP arrangements, including those entering into patent settlements, can apply to the ACCC to seek authorisation on public benefit grounds for conduct which may have previously been protected by this IP exemption. Authorisation is an important feature of

[2] GMA1955_Infographics_DD03 (gbma.com.au)

the CCA, to ensure that public benefits, including those from IP arrangements such as patent settlements, can be generated while mitigating risk and removing legal uncertainty.

Given the repeal of the intellectual property exemption in the antitrust regime, it is in the public interest to permit and encourage the effective and appropriate use of the ACCC's authorisation process to allow generic medicines companies to settle hard fought litigation positions in a legally certain way. Our members are concerned that the application of the cartel conduct provisions of the CCA is complicated and uncertain and the consequences of unintended breach of those provisions is extremely serious. As the ACCC is of course aware, in addition to large monetary penalties for corporations and individuals, there is the prospect of criminal prosecution including jail terms for individuals.

Our view is that parties to patent settlements that have legitimate concerns about the legal risks they face should be entitled to seek authorisation to mitigate those risks where those patent settlements facilitate early entry and as a result generate net public benefits. In our view, the Applicants' settlement agreement is squarely within the class of patent settlement agreements that should be authorised.

**Public benefits of earlier generic entry for lenalidomide and pomalidomide**

Lenalidomide and pomalidomide are important, lifesaving, but high cost, medicines internationally, and in Australia. These are significant in terms of the overall PBS spend given that lenalidomide is the 8th most expensive drug listed on the PBS, as noted in the Draft Determination.

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.

From the GBMA's perspective, the supply of a high quality generic medicine from a reputable supplier like Juno/Natco will also provide additional supply chain assurance to purchasers by providing another reliable source of supply. Availability of supply of medicines is especially important given the vulnerabilities in global and local supply chains which have been exacerbated by the current COVID-19 pandemic. The GBMA does not consider that the ACCC has given enough weight to this benefit in the Draft Determination. The fact that Celgene has not experienced any supply disruptions to date is not a basis to conclude that this could not occur in the future, given factors internal or completely external to Celgene can impact supply unexpectedly. One or more additional sources of supply from diverse manufacturing sources provides a clear 'insurance' benefit to Australian patients reliant on these lifesaving medicines.

**Response to specific ACCC's concerns**

*No anti-competitive first mover advantage*

The GBMA does not agree with the ACCC's concerns in the Draft Determination relation to an anti-competitive "first mover advantage".

The Applicants' settlement agreement, and other similar non-exclusive settlement agreements do not confer an 'anti-competitive' advantage. Rather, these types of agreements are themselves the product of competitive processes. The potential to obtain legal certainty to be able to launch a generic medicine provides an important economic incentive for generic suppliers to bear the significant cost and risk of procuring or developing a generic product, obtaining necessary regulatory approvals and initiating or defending litigation from the incumbent patent holder. Any commercial "first mover advantage" that may result from such a settlement agreement i.e. the value transfer of market share from the originator supplier, incentivises and, for a transitory period only, compensates the first generic competitor's entry efforts. Crucially, the first generic supplier, whether entering before or after patent expiry, *creates* competition with the original sole supplier of the medicine, which necessarily leads to the benefits described above.

*Certainty of the timing of entry*

The GBMA does not consider it makes a material difference to the ultimate intensity of generic competition whether the first generic product is launched at patent expiry or at an earlier date under licence authorised by a settlement agreement. In either case, the original sole supplier is aware of the likely timing of entry.

*No potential deterrence of generic entry*

Generic products, especially generic brands of high value medicines such as lenalidomide and pomalidomide, are highly competitive. I am not aware of any features of these particular products, or the Applicants' settlement agreement, that would make any first mover advantage afforded to Juno/Natco harmful to competition. While the GBMA is not privy to any of our members' specific commercial plans, based on our experience and general knowledge, we would expect competition to supply lenalidomide and pomalidomide to be vigorous, given the high value of these products. We understand that there are already four other generic suppliers holding ARTG registrations for lenalidomide, and a high level interest by generic suppliers in relation to both products globally. We view the existing ARTG registrations for lenalidomide as indicative of likely entry by a number of other generic suppliers.

The GBMA strongly disagrees with the ACCC's concern that the Applicants' settlement agreement may somehow soften competition from other generic competitors for these products, by either delaying or deterring their entry. There are no features of the agreement that could be expected to result in competitive tension between generic competitors being diminished. To the contrary, it is more likely that the public nature of the Applicants' settlement agreement may bring forward the timing of entry by other generic suppliers.

*Pre-launch activities*

The GBMA considers it to be standard practice for a settlement agreement to permit certain pre-launch activities in order to achieve legal certainty for the generic supplier and give practical effect to the contractually agreed early launch date. In our view no detriment would arise from this.

*Summary*

The GBMA considers that a denial of authorisation for the reasons set out in the Draft Determination would represent a misunderstanding of the competitive dynamics of pharmaceutical markets in which generic suppliers of medicines engender competition as against the sole supplier upon entry and as between all suppliers once further generic suppliers enter. A first mover advantage (if any) conferred by a non-exclusive patent licence would not be expected to prevent or delay subsequent entry by other generic suppliers. It would simply bring a generic competitor to market more quickly than would otherwise be the case, and potentially incentivise other generic competitors to do the same. As set out above, there are clear public benefits arising from generic suppliers being able to enter and ensuring those medicines are available in the market – not only the immediate and subsequent reductions in the price of those medicines but also by assuring reliable supplies and freeing up PBS spend for new medicines to be PBS listed for the first time.

The GBMA respectfully asks the ACCC to reconsider its preliminary views in the Draft Determination and grant final authorisation to the proposed conduct.

Yours sincerely,

Marnie Peterson
Chief Executive Officer
Generic and Biosimilar Medicines Association