



INTERNATIONAL GENERIC AND  
BIOSIMILAR MEDICINES ASSOCIATION

**Submission to the Office of Trade Negotiations,  
Department of Foreign Affairs and Trade,  
Government of Australia**

**Considerations for the Proposed  
Australia–European Union Free Trade Agreement  
as it Pertains to Medicines**

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The International Generic and Biosimilar Medicines Association appreciates the opportunity to make a submission to the Australian Department of Foreign Affairs and Trade (DFAT) with regard to the ongoing negotiation of the Australia-European Union Free Trade Agreement (AEUFTA).

The International Generic and Biosimilar Medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world.<sup>1</sup> The IGBA is at the forefront of preserving sustainable competition within our industries, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines.

IGBA recognizes the importance of trade to generic and biosimilar medicines manufacturers. It is therefore critical to ensure that a new trade agreement between Australia and the EU does not create higher barriers to entry to generic and biosimilar medicines that may negatively impact the legitimate trade of these more affordable medicines.

## **I. General Overview**

Australia, is a country with an increasingly larger aging population. As estimated in the Productivity Commission Inquiry Report “An Ageing Australia: Preparing for the Future”, “Australia's population is projected to rise to around 38 million by 2060, or around 15 million more than the population in 2012. Sydney and Melbourne can be expected to grow by around 3 million each over this period.”<sup>2</sup> Moreover, “[t]he population aged 75 or more years is expected to rise by 4 million from 2012 to 2060, increasing from about 6.4 to 14.4 per cent of the population. In 2012, there was roughly one person aged 100 years old or more to every 100 babies. By 2060, it is projected there will be around 25 such centenarians.”

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<sup>1</sup> A full list of IGBA members is available at <https://www.igbamedicines.org/members>

<sup>2</sup> Australian Government, Productivity Commission, "An Ageing Australia: Preparing for the Future, November 2013", Overview. <https://www.pc.gov.au/research/completed/ageing-australia/ageing-australia-overview.pdf>

Furthermore, as the years go by, there will be fewer economically active Australians, which will make it harder to cover the increasing health care expenditures of older Australians. Given that granting higher intellectual property rights delays the market entry of more affordable generic and biosimilar products, this could be quite costly for the Australian government's budget.

In addition, as stated by the Productivity Commission Inquiry Report on Intellectual Property Arrangements, “Australia is overwhelmingly a net importer of IP and the gap between IP imports and exports is growing rapidly. This means that the costs to consumers and follow-on innovators from higher prices and restricted availability are not offset by increases in Australian producer profits.”<sup>3</sup>

Much has been said about intellectual property (IP) as a key to promote innovation. However, it is important to highlight that IP is only one of the two variables of the equation that fosters innovation, with competition being the other. Both are needed to promote innovation. Indeed, a report of the U.S. Federal Trade Commission (FTC) addresses how to achieve this worthy goal in the following terms: “Competition and patents stand out among the federal policies that influence innovation. Both competition and patent policy can foster innovation, but each requires a proper balance with the other to do so. Errors or systematic biases in how one policy’s rules are interpreted and applied can harm the other policy’s effectiveness.”<sup>4</sup> Furthermore the FTC report clearly states that “[a] failure to strike the appropriate balance between competition and patent law and policy can harm innovation.” The importance of competition was also highlighted in the European context in a 2009 report of the European Commission, which conducted a comprehensive inquiry into obstacles hindering the proper functioning of competition in the pharmaceutical market.<sup>5</sup>

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<sup>3</sup> Australian Government, Productivity Commission “Intellectual Property Arrangements”, September 23, 2016. <https://www.pc.gov.au/inquiries/completed/intellectual-property/report/intellectual-property.pdf>

<sup>4</sup> Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", October 2003.

<sup>5</sup> European Commission, "Competition DG, Pharmaceutical Sector Inquiry. Final Report", July 8, 2019.

While patent policy takes care of the interests of inventors, as stated by the Harper Report “[c]ompetition policy, like other arms of government policy, is aimed at securing the welfare of Australians.”<sup>6</sup> Thus, it is essential that the balance between patent and competition policies be preserved in the AEUFTA.

For the past almost 25 years, since the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO), trade negotiations have, for the most part, made significant emphasis on the adoption of increasingly higher levels of intellectual property policies that have come at the expense of the generic and biosimilar medicines industry. Such additional levels of protection have further delayed the market entry of generic/biosimilar products, negatively impacting consumers and the Pharmaceutical Benefits Scheme (PBS). Therefore, after 25 years of favoring the branded pharmaceutical industry at the expense of generic/biosimilar companies and patients' timely access to more affordable medicines, it is time that trade agreements like the AEUFTA not only not increase the existing imbalance between the branded pharmaceutical and generic/biosimilar industries, **but in fact bring back some much-needed balance.**

As mentioned, for the past 25 years the generic/biosimilar medicines industry has been absorbing increasingly higher levels of intellectual property at a significant cost, first with the adoption of the TRIPS Agreement, then with the Australia-US FTA (AUSFTA), and now the branded industry is once again seeking the inclusion of even higher standards of protection in the AEUFTA. The generic/biosimilar medicines industry cannot continue to face changes in the Australian legal and regulatory framework that consistently delay the entry of its products and expose it to even more lengthy and expensive litigation. This is neither good for Australian consumers nor for the health care budget, which would face higher expenses due to longer and broader monopolies. The Australian Government should seek the adoption of provisions that benefit all

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<sup>6</sup> Professor Ian Harper, Peter Anderson, Su McCluskey, Michael O’Bryan OC, "Competition Policy Review, Final Report," March 2015, Part 1, Overview.

Australians, so the AEUFTA should revert the current trend of yielding to the pressure of powerful interest groups at the expense of taxpayers and the healthcare budget. Below is a quick review of some of the principles on which we base this:

- Australia has one of the highest levels of intellectual property protection in the world that is skewed in favor of the branded pharmaceuticals industry, and which goes well beyond the global standard established by the TRIPS Agreement.
- AUSFTA imposed patent and non-patent forms of protection that went beyond the TRIPS Agreement.
- According to the Productivity Commission Report on Intellectual Property Arrangements,
  - “Australia’s patent system grants exclusivity too readily, allowing a proliferation of low-quality patents, frustrating follow-on innovators and stymieing competition.”<sup>7</sup>
  - “[T]o raise patent quality, the Australian Government should increase the degree of invention required to receive a patent, abolish the failed innovation patent, reconfigure costly extensions of term for pharmaceutical patents, and better structure patent fees.”<sup>8</sup>
  - “Australia is overwhelmingly a net importer of IP, and the gap between IP imports and exports is growing rapidly. This means that the costs to consumers and follow-on innovators from higher prices and restricted availability are not offset by increases in Australian producer profits.”<sup>9</sup> This is consistent with Medicines Australia's submission to the Australian Government with regard to the AEUFTA, which stated:

*“Australia imported over \$7billion worth of medicines and pharmaceutical products from the EU in 2016, an increase of 17% on 2014, representing the top merchandise import from the EU. Reciprocal exports in the same year amounted to approximately \$420 million.”*

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<sup>7</sup> Australian Government, Productivity Commission, Productivity Commission Inquiry Report, Intellectual Property Arrangements, 23 September, 2016

<sup>8</sup> Idem.

<sup>9</sup> Idem

Therefore, as the Governments move forward with this negotiation, it is important to keep in mind that both Australia and the EU have an increasingly aging population with a smaller economic force to sustain it. Indeed, addressing this serious challenge should be a shared goal for both Parties.

With a growing share of very expensive biologic medicines, legal systems that unless amended allow for the granting of low-quality patents that delay competition and maintain artificially high prices, as well as the negotiation of trade agreements, Australia will be paying even more for these expensive drugs. Striking the right balance in these trade negotiations is critical to ensure biosimilar competition, as well as for the development of a healthy biosimilar industry that can contribute to the sustainability of healthcare systems due to their cost savings potential. Indeed, in 2016, it was estimated that biosimilars could generate savings up to EUR 100 billion by 2020 in the five most populous countries in the European Union (Germany, France, Italy, Spain and the United Kingdom) plus the United States.<sup>10</sup> While penetration has been slow, including in the European Union which is ahead in terms of biosimilar approvals, a recent IQVIA report states that "biosimilars are seen as a key means to alleviate financial challenges faced by many stakeholders in the currently constrained European budgetary environment", with "the potential to offer savings of more than €10 billion between 2016 and 2020 in the EU5 countries alone."<sup>11</sup> As to Australia, according to the Budget Review 2018-19 increased uptake of biosimilar medicines is expected to reduce PBS spending by \$335.8 million over five years from 2017–18.<sup>12</sup> Moreover, a mandatory reduction is applied to the government subsidized price for all brands of a biological medicine when the first biosimilar is listed.

Failure to strike a better balance between promoting innovation and competition in the AEUFTA would undermine the availability of more affordable generic/biosimilar medicines and therefore have a significant negative impact on healthcare budgets due to

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<sup>10</sup> OECD, "Health at a Glance: Europe 2018. State of Health in the EU Cycle", 2018.

<sup>11</sup> IQVIA Institute, "Advancing Biosimilar Sustainability in Europe A Multi-Stakeholder Assessment", September 2018. EU 5 countries are France, Germany, the UK, Italy and Spain.

<sup>12</sup> Australia, Budget Review 2018–19, Parliamentary Library, Research Paper Series, 2017–18 23 May 2018, accessed at <https://apo.org.au/sites/default/files/resource-files/2018/05/apo-nid173131-1194851.pdf>

delayed access to these cost saving medicines.

## **II. Specific Provisions**

The European Union has already submitted a proposal to the Australian Government on the intellectual property chapter that would require extending the exclusivity granted to data and broadening current Australian patent term extensions for delays in the regulatory office. It is important to state the obvious, that more is not always better. Indeed, while the European Union has provisions that may go beyond those in force in Australia, that does not mean that it has a better system in place. Indeed, there is no justification for the ratcheting up of intellectual property protections, as the EU draft would require.

Additionally, negotiations should be transparent, and all proposals, including those made by the Government of Australia, should be made public. Indeed, it is critical that the negotiation not be based solely on the text put forward by the EU but also on Australian proposals. If the Government of Australia has not done so yet, it may wish to consider doing it as soon as possible. Moreover, given that access to affordable, safe and effective drugs is so critical to every Australian citizen, the government may wish to think out of the box by not just seeking to prevent the adoption of bad provisions that may reduce access to medicines but by aggressively championing the inclusion of provisions that may ensure the appropriate balance between innovation and access such as the inclusion of a mandatory regulatory exception, the requirement to disclose the best mode in patent applications, incentives to challenge patents and exclusivities to foster the expedited launch of generic and biosimilar products as well as penalties for those who misuse intellectual property rights to prevent competition, to mention a few.

**It is important to recognize that the EU system faces many problems.** The European Union faces serious challenges with regard to access to affordable medicines, many of which were documented by DG Competition in the Pharmaceutical Sector Inquiry, a very comprehensive and voluminous report that listed a number of strategies the branded industry engages in simply to block competition thus allowing it to charge higher prices

for medicines for longer periods of time.<sup>13</sup> Such types of corporate behavior do not promote innovation or economic growth, but do exactly the opposite and lead to the waste of limited resources. Therefore, IGBA believes that the Australian Government should not copy a system that has opened the door to the misuse of intellectual property rights as documented in the Inquiry. Australia is known for its PBS, a unique system that provides patients with much needed medicines, so it should not be put further at risk when negotiating trade agreements that continue to tilt the system in favor of intellectual property holders and at the expense of consumers and the taxpayers.

**Some of the specific provisions in the EU proposal that are of concern to the generic/biosimilar medicines industries and patient access to affordable medicines include:**

### **1 - Patent Term Extensions**

Australia already currently grants an extension of up to 5 years and up to 15 years of effective market life, which is one year longer than in the United States). Nevertheless, this is one of the provisions the originator pharmaceutical industry is championing in the AEUFTA. IGBA does not believe the inclusion of this provision in the AEUFTA is necessary. Moreover, the EU proposal goes beyond Australian law by potentially broadening the scope of patents that may be extended and even granting extensions to medicinal products for which pediatric studies have been carried out.

Furthermore, it is important to keep in mind what the Productivity Commission Inquiry Report says with regard to patent term extensions:

*“Further to the 20-year term applying to all patents, pharmaceutical patents can qualify for an additional five years of protection. Extensions of term (EoT) are capped at an effective market life of 15 years. These bespoke arrangements were intended to attract pharmaceutical research and development investment to*

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<sup>13</sup> European Commission, "Competition DG, Pharmaceutical Sector Inquiry. Final Report", July 8, 2019.

*Australia and to improve incentives for innovation by providing an effective market life for pharmaceuticals more in line with other technologies.*

*However, Australia's EoT scheme has had little effect on investment and innovation; Australia represents a meagre 0.3 per cent of global spending on pharmaceutical research and development. As pharmaceutical companies have acknowledged, the prospect of future returns in such a smaller market (accounting for only 2 per cent of global pharmaceutical revenues) provides little in the way of additional incentive.*

*Moreover, the benefits sought from EoT arrangements have proven largely illusory, resulting in a costly policy placebo. Poor targeting means that more than half of new chemical entities approved for sale in Australia enjoy an extension in patent term, and consumers and governments face higher prices for medicines<sup>14</sup>."*

Therefore, we need to ask ourselves what the purpose of this additional intellectual property monopoly is, but it is clearly not linked to innovation or investment in Australia, which in fact is increasingly an importer of intellectual property rights.

Furthermore, branded products are not the only ones facing delays in the regulatory agency as generic and biosimilar medicines also experience such delays. Hence, if originator companies are compensated for such delays, the generic/biosimilar industries should be compensated as well.

## **2 - Exclusivity for Data Provided in a Drug Marketing Application**

Australia has also adopted TRIPS Plus standards with regard to the protection of data by granting 5 years of data exclusivity, as the WTO agreement does not nominate an exclusivity period.

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<sup>14</sup> Australian Government, "Productivity Commission, Productivity Commission Inquiry Report, Intellectual Property Arrangements," September 23, 2016.

IGBA is deeply concerned that the EU proposal seeks to more than double this already generous exclusivity. Indeed, Article X.45 of the European Union proposal includes a mandatory period of 8 years of exclusivity from the date of a first marketing authorization. In addition, the proposal states that each Party should ensure a period of 10 years from the date of a first marketing authorization in the Party concerned and that this may be extended to 11 years if, during the first 8 years after obtaining the marketing authorization the market authorization holder obtains a marketing authorization for one or more therapeutic indications.

Australia currently grants 5 years of data exclusivity. The EU proposal would extend this to 8 years and add up to 3 additional years of market exclusivity that Australia does not grant today. Moreover, a generic/biosimilar company would not even be able to apply for marketing approval for 8 years. Accepting the EU proposal could entail even longer delays for the entry of competition especially with regard to biologics, the most expensive medicines in the market.

Once again, it is worth drawing attention to the conclusions reached by the Productivity Commission:

*“Pharmaceutical companies have pressed the Australian Government to extend the duration of data protection. They view data protection as an insurance policy to guard against what they see as inadequate patent protection. Most recently, negotiations for the Trans-Pacific Partnership Agreement saw (unsuccessful) calls to extend data protection for biologics from 5 to 12 years.*

*Despite decade-long claims of inadequate patent protection, there is little evidence of a problem. Even if isolated cases were verified as genuine, extending protection to a broad class of products to address exceptional cases would represent a blunt and costly response. As using data protection as a proxy for patent protection has drawbacks. Beyond the obvious absence of disclosure of information to promote further innovation, data protection lacks other important*

*balances that apply to patents. Data protection arises automatically and cannot be challenged in court.*

*As well as there being strong grounds for resisting further calls to extend the period of data protection, there is a case for making data more widely available. At present, not only are follow-on manufacturers prevented from relying on clinical data for a period of five years, the data is kept confidential indefinitely. Allowing researchers access to this data could provide substantial public health benefits<sup>15</sup>.”*

Furthermore, as stated above, the EU faces very serious competition problems in the pharmaceutical sector that results in the waste of much needed limited resources, so Australia should not follow the wrong path that could undermine timely access to affordable medicines for its taxpayers.

In addition, under the EU proposal, the exclusivity could be granted to a broader set of products as it would be conferred to a "medicinal product" which footnote 10 clarifies that it "shall mean at least: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals; or (b) any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

Finally, the exclusivity period should start running from the first approval by a regulatory authority with similar scientific and regulatory standards as the Therapeutic Goods Administration (TGA) and the European Medicines Agency Regulatory Network and not when the marketing approval is granted "in the Party", i.e. the periods should be concurrent. Otherwise, if a company delays its registration in Australia, consumers and payers in Australia would be negatively impacted through no fault of their own but

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<sup>15</sup> Australian Government, Productivity Commission, Productivity Commission Inquiry Report, Intellectual Property Arrangements, September 23, 2016.

simply due to the failure of the company to seek such registration in the country. For instance, if a company takes 6 years after the first marketing approval in the world to seek approval in Australia, Australian patients would not have access to such drug for 11 years (assuming the exclusivity is 5 years). There is no reason why Australia should accept such delays. Some countries like Chile grant a 12-month grace period for companies to register their drugs in the country, as they otherwise would lose the exclusivity.

### **3 - Notification/Linkage**

Medicines Australia is asking the Australian government to include notification requirements for an application to register a generic or biosimilar product on the Australian Register of Therapeutic Goods (ARTG). As spelled out in its submission, the purpose would be to delay the entry of competitors in the market: “Introduce a policy requirement that the Department of Health directly notify the patent holder (sponsor of the product) when a third party submits an application for registration of a generic or biosimilar version of a product on the ARTG, rather than publishing ARTG entry at the time of approval. This improved notification timeframe may allow sufficient time for preliminary injunctions, patent conflict and/or other measures to be resolved.” [emphasis added]

This would be nothing less than a soft patent linkage, which would allow branded companies to transfer the responsibility of protecting their IP property to the government, which ends up being the gatekeeper of their rights. The linkage mechanism is one of the most regressive provisions in terms of access to medicines as it has opened the door to many abuses. The goal is to enable the branded industry to file lawsuits and seek injunctions that will require generic/biosimilar companies to fight in court depleting their limited resources while extending the monopoly of branded pharmaceutical companies. There is absolutely no advantage for Australian consumers or payers. Indeed, this provision unnecessary tilts the system in favor of branded companies at the expense of everyone else. Furthermore, linkage is considered unlawful in the European Union and it

may be argued that it is in violation of the TRIPS Agreement as it discriminates by field of technology.<sup>16</sup>

### **III. Recommendations**

As stated at the beginning of this document, for over 25 years there has been a consistent effort to ratchet up the IP protection granted to pharmaceutical products, thus skewing the balance that must be struck between patent and competition policies to promote innovation and access to medicines. If the AEUFTA includes any type of provisions related to pharmaceuticals, it should not be those that extend and broaden monopolies further tilting the balance, but those that restore it to foster both innovation and access. These would include the following, among others:

#### ***a. Incentives***

Trade agreements invariably provide incentives to foster research and development through the granting of patents and exclusivity protection but for the most part have omitted the granting of incentives to challenge the validity or enforceability of patents to secure early market entry of more affordable generic medicines. Incentives may take different forms<sup>17</sup> but are a critical element to ensure on one hand that only true innovation is rewarded with such monopolies, thus preventing the waste of resources, and on the other hand that patients have timely access to generic and biosimilar medicines.

The competition chapter of the agreement may consider some possible ways to monitor compliance with competition law to avoid abuses of IP as well as to stimulate competition at IP expiry.

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<sup>16</sup>As explained in section 872 of the EU Pharmaceutical Sector Inquiry, "[u]nder EU law, linking the granting of marketing authorisation for a product to the patent status of a branded company's reference product is unlawful. The task of marketing authorisation bodies is to verify whether a medicinal product is safe, effective and of good quality. Their main function is to ensure that the pharmaceutical products reaching the market are not harmful to public health. Other factors, such as the patent status of the product, should therefore not be taken into account when assessing the risk/benefit balance of a medicine."

<sup>17</sup> There are different ways to provide incentives which will vary in their value and viability. These include:

- exclusivity period for successful generic or biosimilar patent challenges
- effective damages for successful generic or biosimilar patent challenges
- pricing and reimbursement policies such as incentive pricing or unregulated prices for a time period
- streamlining regulatory approval process

***b. Disclosure of the best mode in patent applications***

As explained by the U.S. Patent and Trademarks Office, "[t]he best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves."<sup>18</sup>

The disclosure of the best mode is particularly important for the development of complex biosimilar medicines, so it should be included in trade agreements entered into by Australia. The AEUFTA should ensure the inclusion of a mandatory best mode provision and the revocation of the patent if the patent applicant did not provide the best mode at the time of applying for the patent. This is fully consistent with TRIPS and of particular importance given Australia's increasing imports of medicines so the government should propose the inclusion of such language to the EU. Furthermore, the best mode requirement is critical for the development of biologic drugs given their complexity.

***c. Penalties for the misuse of patent rights***

Trade agreements have included detailed sections aimed at ensuring the effective enforcement of intellectual property rights, but only a broad reference, if any at all, to the ability of Parties to adopt measures necessary to prevent anticompetitive practices that may result from the misuse or abuse of the intellectual property rights. i.e. trade agreements have failed to include specific mandatory language to address the misuse or abuse of IP by right holders to block or delay competition. In order to have balanced agreements that foster innovation, the AEUFTA should impose similar penalties to those that infringe intellectual property rights as to those that misuse them to prevent or delay competition. Australia should propose the inclusion of such language in the AEUFTA.

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<sup>18</sup> US Patent and Trademark Office, "Manual of Patent Examination Procedure", Chapter 2100, Section 2165.

Furthermore, in its submission Medicines Australia argued for the elimination or reduction of damages sought by the Commonwealth related "to the Pharmaceutical Benefits Scheme (PBS) savings the Government may have achieved through the mandatory (or statutory) price reduction and price disclosure process if a generic or biosimilar product had been allowed to enter the market, but for the interlocutory injunction. The costs attached to defending against the Commonwealth's claim, plus any resultant damages, are of the size and nature to deter innovator companies from seeking injunctions..."<sup>19</sup>

This submission demonstrates the importance of this provision and the need to maintain it. Without such potential damages (which many argue are not nearly enough), the branded industry could seek many more injunctions simply to delay competition. It is clearly very important to maintain and, if possible, to reinforce this provision, which requires some corporate responsibility on the part of branded companies. IGBA believes that when a branded company has engaged in actions to deliberately delay the market entry of competitors, generic/biosimilar medicines companies should also be properly compensated. Damages should not only be awarded to branded companies in cases of patent infringement, but also to generic/biosimilar medicines companies that face the efforts of branded companies to delay the launch of their products, which require them to engage in costly and lengthy litigation.

Finally, it is well known that branded companies have thwarted generic/biosimilar medicines companies' access to samples of the original medicines to prevent or delay the launch of their products. In order to end this anticompetitive practice, the Australian Government should seek to adopt strong enough penalties to avert such behavior, either in the AEUFTA or in its domestic laws and regulations. The Australian Government should consider introducing language to address this issue in the AEUFTA.

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<sup>19</sup> Medicines Australia, Submission to the Department of Foreign Affairs and Trade with regards to the Australian-European Union Free Trade Agreement (AEUFTA), 24 October 2018.

***d. Regulatory Review Exception (Bolar)***

The regulatory review exception is critical for the launch of generic/biosimilar products immediately after patent expiration. A regulatory review exception allows generic and biosimilar manufacturers to use a patented invention during the period of patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval from health regulatory authorities.

Such a provision is fully consistent with the TRIPS Agreement and was upheld by the Dispute Settlement Body at the World Trade Organization in a dispute between the EU and Canada.<sup>20</sup> It is therefore essential that this very critical provision be included in the AEUFTA in mandatory and broad terms.

***e. Export Manufacturing Waiver***

Trade agreements must ensure that provisions on patent term extensions, where included, allow generic and biosimilar medicines manufacturers to export during the period of additional protection. Enabling generic/biosimilar medicines manufacturers to export during that period would enhance competition by creating a level playing field with manufacturers in countries where patent term extensions do not apply. This is of particular importance for Australia to ensure that its manufacturing plants are fully utilized to supply not only the Australian market but foreign ones as well. This may also contribute to reduce the trade deficit with regard to pharmaceuticals. Both the EU and Canada have implemented such a provision, and text explicitly providing parties with the option to implement such a waiver/exception was included in the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada.

***f. Streamlining Regulatory Requirements and Avoiding Regulatory Duplication***

Trade agreements should seek to increase trade among the Parties involved. In order to achieve this goal, it is essential that the AEUFTA address the need to avoid regulatory duplication and in fact seek regulatory coherence and the streamlining of regulatory

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<sup>20</sup> WTO, DS114: Canada: Patent Protection of Pharmaceutical Products, 2000. The report of the panel may be accessed at [https://www.wto.org/english/tratop\\_e/dispu\\_e/7428d.pdf](https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf)

requirements. With this in mind, it would be very important that the AEUFTA allow companies to leverage their global development processes for generic and biosimilar medicines and provide for the mutual recognition of inspections.

***g. Evergreening***

The Productivity Commission emphasized the need to grant new patents only for genuinely inventive products, warning against strategies pursued by some companies to further extend the commercial life of their products, including through the evergreening of existing patents.<sup>21</sup> Hence, trade agreements should incorporate language to safeguard against such practices.

***h. Border Measures***

In order to foster trade in generic and biosimilar medicines, the AEUFTA should not include border measures that in any way restrict the circulation of products that are in transit on the grounds that they might be violating IP rights conferred in the country of transit.

**IV. Conclusion**

Thank-you for reviewing this submission of the International Generic and Biosimilar Medicines Association with respect to the AEUFTA negotiations. The proposals being pursued by the European Commission in these negotiations would have a negative impact on timely access to affordable medicines in Australia, and we urge the Government of Australia to hold firm against any Commission demands that would require changes to its domestic laws for pharmaceuticals.

The IGBA, the Generic and Biosimilar Medicines Association (GMBA) of Australia and Medicines for Europe are available to provide expert assistance as may be required by the Government of Australia in these negotiations. Please contact [info@igbamedicines.org](mailto:info@igbamedicines.org) should you have any questions with respect to this submission.

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<sup>21</sup> Australian Government, Productivity Commission “Intellectual Property Arrangements”, September 23, 2016. Page 19.