



Medicines
Australia

Better health through
research & innovation

Department of Foreign Affairs and Trade
RG Casey Building
John McEwen Crescent
Barton ACT 0221

24 October 2018

Via email: a-eufta@dfat.gov.au

Dear Sir/Madam,

Department of Foreign Affairs and Trade (DFAT) - Australia-European Union Free Trade Agreement (AEUFTA)

Medicines Australia welcomes the opportunity to provide input into the DFAT consultation on the AEUFTA.

Medicines Australia is the peak industry body for the research-based innovative pharmaceutical industry in Australia. Our members research and develop, manufacture and supply medicines and vaccines that help keep Australians productive, healthy and out of hospital. Our industry provides thousands of high-value jobs for Australians, invests over \$1 billion in research and development (R&D) each year and generates close to \$4 billion in annual exports.¹ Our members have strong business ties to the EU, including imports from and exports to the EU, as well as other key partnerships including in research and development (R&D).

Our support of the principles underpinning free trade agreements is fundamentally about three key principles:

- ensuring all Australians have access to high quality, safe, efficacious and cost-effective medicines;
- ensuring Australia remains competitive internationally to incentivise the presence of industry; and
- recognising the value of our industry in advancing the overall health and wellbeing of Australians.

These principles are guided by, and consistent with the Australian National Medicines Policy.

With global demand for medicines expected to double in a decade, there is a real and significant opportunity to increase the positive impact the innovative pharmaceutical industry has on the health and wealth of Australians. But the right policy settings must be in place. To create a more stable and transparent investment environment these policy settings must reduce trade barriers, for example any such barriers related to rules of origin and inappropriate customs and tariffs.

In this context, Medicines Australia strongly supports Government's proposed free trade agreement (FTA) with the European Union (EU).

For our industry, a successful AEUFTA depends on the inclusion of a bespoke pharmaceutical chapter that incorporates and supports the following:

- acknowledgement of the unique role of innovative pharmaceutical technologies to Australians' health and economic prosperity;

¹ Medicines Australia FactsBook, 4th Edition



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- commitment to a strong and competitive intellectual property (IP) system that recognises and rewards our niche strengths in research and advanced manufacturing, and is consistent with international IP norms;
- harmonisation of regulatory standards across key trading partners;
- inclusion of policy incentives and streamlined processes to attract direct and indirect investment in R&D and the avoidance of policies that detract from innovation; and
- mechanisms to continuously monitor, strengthen and improve trade relations.

We would welcome the opportunity to discuss and collaborate with the Australian Government further on this issue. Please feel free to contact Andrew Bowskill, Manager, Industry Policy and Research on (02) 6122 8513 abowskill@medaus.com.au or Betsy Anderson-Smith, Policy Officer on banderson-smith@medaus.com.au.

Kind regards

Elizabeth de Somer
Chief Executive



Appendix

I. Pharmaceutical Chapter/Principles Based Approach

The Australian innovative pharmaceutical industry has strong links with the EU. A significant number of Medicines Australia members have either headquarters located there, or have investments in manufacturing and associated supply chain components. Australia imported over \$7bn 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.² Reciprocal exports in the same year amounted to approximately \$420m.³ The negotiation of an AEUFTA provides the opportunity to expand the industry in Australia which would drive economic growth through the creation of high value jobs, the reallocation of resources to the highly skilled pharmaceutical industry, and the subsequent improvement of Australia's overall productivity level for the benefit of all Australians.

Acknowledgement of a mutually agreed set of principles is the foundation of successful FTAs. Previously this resulted in a specific chapter on pharmaceuticals being included in the Australian-US Free Trade Agreement (AUSFTA), and a similar chapter was also included in the Korea-EU FTA. Medicines Australia believes it is of benefit to employ a similar approach in the AEUFTA.

In light of this, Medicines Australia suggests the inclusion of principles similar to those below in any AEUFTA:

- recognition of the important role played by innovative pharmaceutical products in delivering high quality health care;
- recognition of the value of innovative pharmaceuticals through the operation of competitive markets, and/or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical;
- cooperation between relevant regulatory bodies in the development of aligned, efficient international practices;
- strengthening of regulations to the highest standards on a global level and improvement of the regulatory framework without compromising patient safety;
- recognition of the importance of R&D in the pharmaceutical industry. Government support for academic and commercial R&D, strong IP systems, and economic incentives that promote innovation; and
- timely and affordable access to pharmaceuticals through transparent, expeditious and accountable procedures, whilst maintaining high standards of quality, safety and efficacy.

II. Intellectual Property

Medicines Australia has long emphasised the need to maintain a strong, stable and predictable IP environment. To encourage pharmaceutical innovation, R&D and commercial translation, Australia's IP environment should be harmonised with international best practice. Strong IP systems have been shown to drive innovation and investment by providing a framework for innovators to share their discoveries and creations in exchange for a period of exclusivity. IP systems that recognise the balance between risk and reward, particularly in highly novel areas and local innovation should be supported. IP rights provide innovators with the incentives needed to conduct the expensive, risky and time-

² DFAT 2017. <https://dfat.gov.au/about-us/publications/trade-investment/business-envoy/Pages/january-2018/australia-eu-trade-statistics.aspx>

³ DFAT. <https://dfat.gov.au/about-us/publications/Pages/trade-statistical-pivot-tables.aspx>



consuming work to discover and bring new medicines to market and find further uses for existing medicines.

Trade agreements that do not adequately support the important role of a strong IP system undermine investment and domestic economic growth. Australia makes up approximately only 1% of the global pharmaceutical market⁴, making it even more important that Australia has globally competitive strengths in areas such as IP to continue to attract pharmaceutical investment and incentivise greater future investment in Australian's overall health outcomes.

IP Harmonisation

To increase Australian patients' access to innovative medicines and vaccines, significantly improve Australia's attractiveness as a destination for foreign investment in R&D and support the growth of Australia's biotechnology sector, Medicines Australia calls on the Australian Government to recognise the important role of IP and ensure Australia's regime is globally competitive.

A key IP policy mechanism for the pharmaceutical industry is regulatory data protection (RDP). As well as encouraging R&D investment and follow-on innovation, RDP recognises the extensive time, effort and cost of drug discovery, development and particularly clinical trials, required to ensure that medicines are of a high quality, safe and effective, by protecting against unauthorised third-party use of data submitted by the innovator for regulatory approval.

Patents are awarded to recognise innovation and provide a period of market exclusivity which in turn fosters further innovation and ensures innovators can recoup up-front investment. In the case of medicines, up-front investment is significant and known to be high risk.⁵ Therefore, RDP becomes particularly important for medicines that are highly specialised, have paediatric indications or indications for diseases impacting a very small patient population, as well as when effective patent durations are limited by lengthy development programs. It is also increasingly important as biological medicines become more complex and uncertain in their patentability. Furthermore, where the period of market exclusivity from a patent cannot be assured, which is more likely for biologics, innovators will rely more heavily on RDP to enable them to recoup up-front investment.

Medicines Australia strongly encourages the Australian Government to align Australia's RDP period, which is currently five years, with at least that of the EU. The EU provides innovators with ten years⁶ of RDP, which can be increased to 11 years for new indications with significant clinical benefit for patients.

In addition, Medicines Australia seeks to align Australia's RDP periods and incentives for orphan drugs, paediatric indications and areas where there is high unmet need (such as the development of new antimicrobial therapies) to that of the EU.

Patent notification

As mentioned above, the innovative pharmaceutical industry relies on a strong, stable and predictable IP regime to invest in R&D, and to bring new and essential medicines to the Australian market. Such a regime underpins innovation and investment in Australia.

⁴ World Trade Organization, Geneva, 2013, International Trade Statistics, Merchandise Trade

⁵ DiMasi, JA., et al, 'Innovation in the pharmaceutical industry: new estimates of R&D costs' J Hlth Ec. V 47, May 2016, p. 20-33.,

⁶ Comprising of eight years data exclusivity, followed by two years "market exclusivity" where a generic company can make use of the pre-clinical and clinical trial data of the originator in their regulatory applications, but still cannot market their product.



Currently, innovator companies are not notified of an application to register a generic or biosimilar product on the Australian Register of Therapeutic Goods (ARTG). They only become aware of the launch of such a product when it is registered on the ARTG or when notified of mandatory price reductions applied by the Commonwealth. As such, most of the legal process for determining the validity of patents currently occurs after the date the generic or biosimilar product is listed on the ARTG (should the patent be found to be invalid). The better approach would be for the Government to ensure earlier notification of an application to facilitate earlier resolution of patent disputes.

As Medicines Australia has said on previous occasions, an effective notification system would enable patent holders to defend their intellectual property in a timely manner and without causing potentially unnecessary delays to generic or biosimilar market entry.

Therefore, as part of the AEUFTA negotiations, Medicines Australia would like to see the trade agreement include an adequate notification period.

This could be achieved by one or more of the following policy or legislative initiatives:

1. **Amend the *Therapeutic Goods Act 1990*** to legislate a requirement for direct notification from the TGA to the patent holder (sponsor of a product) when a third party submits an application for registration of a generic or biosimilar version of a product on the ARTG. This improved notification timeframe may allow sufficient time for preliminary injunctions, patent conflict and/or other measures to be resolved;
2. **Introduce a policy requirement** that the Department of Health directly notify the patent holder (sponsor of a 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; or
3. **Introduce a transparency measure** to publish applications for registration of generic or biosimilar versions of a product on the TGA website at the time of application, 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.

Market size damages

Commonwealth Government policy introduced in 2011 undermines the strength and stability of IP law in Australia. This Australian policy encourages patent challengers and disincentivises innovators from defending their patents.⁷ Under the current system, innovator medicines companies can only defend their patents, in the case of inappropriate generic entry, through taking out an interlocutory injunction to prohibit the marketing of a product whilst the validity of the patent is determined through the courts. Historically, the Commonwealth allowed these legal proceedings to run their course. This position changed in 2011, when the Commonwealth of Australia commenced third party proceedings against a number of innovative medicines companies.

The damages sought by the Commonwealth relate to the Pharmaceutical Benefits Scheme (PBS) savings the Government may have achieved through the mandatory (or statutory) price reduction and price

⁷ 'Spring-boarding' encourages generic pharmaceutical manufacturers to register and potentially market products before patents expire and Australian Commonwealth policies seeking to be a party to damages claims discourages innovators from defending valid IP when early market entrants occur.



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 and consequently reduces their ability to protect their IP rights.

This is particularly concerning for companies with smaller products or those of small to medium size in Australia, where the potential cost of damages outweighs the revenue derived. It is also problematic because under the National Health Act 1953 there are no provisions to restore a price reduction applied to medicine in circumstances where a generic company unlawfully enters the market by infringing a valid patent. This creates an environment where innovator medicines companies are at an inequitable position compared to other litigants because they are compelled to apply for an interlocutory injunction, despite the risk involved with the Commonwealth seeking to be a party to the damages claim. Thus, the Commonwealth's large damages claims against innovator companies may have irreversible and detrimental effects on R&D, foreign direct investment and international trade in Australia through the erosion of IP rights and the destabilisation of the pharmaceutical industry as a whole.

Medicines Australia strongly contends this action to be bad public policy for several reasons:

- Korea and the United Kingdom (UK) have both decided not to pursue a similar policy because it would undermine both countries efforts to encourage growth of their innovative pharmaceutical and medical research sectors. Korea and the UK are direct competitors to Australia for pharmaceutical investment;
- it significantly increases the risk for innovator companies in defending their patents, thereby eroding IP rights. There are greater financial risks in defending IP for innovator companies compared with the risk faced by generic companies when challenging a patent;
- it is a retrospective application of policy that makes innovator pharmaceutical companies potentially liable for significant and unforeseen damages claims which are difficult to quantify; and
- the Government has not implemented key policy settings that would otherwise reduce the exposure of innovator companies to damages. It has:
 - not implemented restorative provisions in relation to pricing of PBS listed medicines where patents are upheld following a generic launch which has caused a price cut; and
 - not implemented adequate notification provisions that would reduce the time between patent challenges and Court outcomes.

In continuing to implement this policy, the Government risks the following for Australia's interests:

- singling out Australia as the only country where Government will seek damages from innovator companies in this way;
- reducing Australia's ability to attract domestic and foreign investment in pharmaceutical R&D and high-tech manufacturing due to sovereign risk;
- placing smaller companies, including Australian biotechs, at risk of being unable to financially account for future liabilities associated with such claims;
- creating friction with key trading partners;
- creating a negative perception about Australia's commitment to a strong and robust IP regime and innovation; and



- deprioritising Australia as a market for innovative new medicines, meaning patients may be less likely to access the latest medicines when they need them and when they are available in other countries.

Medicines Australia believes that the AEUFTA provides an opportunity for the Australian Government to correct this policy instability either through:

- a commitment in the trade agreement to revert to its previous policy of not pursuing damages claims against innovator companies following the loss of patent proceedings and dismiss all existing claims for damages; or
- prior to commencing any damages claims against innovator companies, the Commonwealth commits to the introduction of an arm's length merit assessment of the completed patent proceedings. This would require an independent arbitrator or similar, prior to the Commonwealth deciding to pursue a damages claim, to assess the proceeding on its merits with respect to the reasonableness of the plaintiff taking the action in the given circumstances.

III. Regulatory Harmonisation

Closer harmonisation of regulatory systems is beneficial in promoting closer economic ties, however this should not be to the detriment of displacing investment between the two jurisdictions. Trade agreements should look to streamline regulatory approval processes for access to new medicines, including alignment with the recently implemented Medicines and Medical Devices Review reforms. An AEUFTA should also not detrimentally impact other parallel regulatory developments with international regulators for work-sharing.

Medicines Australia strongly believes that regulatory cooperation between Australia and the EU should, where practicable, include the full and genuine mutual recognition of each other's Good Manufacturing Practice (GMP) inspections and certifications as a means of reducing barriers to trade between the EU and Australia.

Medicines Australia notes the EU and Japan have recently expanded their mutual recognition agreement to include new products and active pharmaceutical ingredients. Since 2004, the EU and Japan have mutually recognised GMP inspections conducted by each other's medicines regulators, the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). The agreement also allows Japan and EU countries to waive batch testing requirements for imported drugs and allows for information sharing between EMA and PMDA on inspections and quality issues.

IV. Clinical Trials

With the right incentives, Australia can build on its already strong reputation as an international innovation and investment destination. A free trade agreement between the EU and Australia could leverage this investment and ensure that incentives to support investment in R&D are retained and strengthened.

The negotiation of the AEUFTA provides the Australian Government with an ideal opportunity to further streamline and harmonise clinical trials regulation. Benefits of such an approach include:

- increasing Australia's attractiveness as a destination for investment in clinical trials; and



- reducing unnecessary duplicative costs to trade and significantly reducing costs of market access for pharmaceutical companies. This could in-turn result in more resources for investment in the R&D of new medicines or other efficiency enhancing activities, strengthening the Australian pharmaceutical industry, and generating value for the Australian economy, all whilst improving access to new medicines for patients.

Clinical trials are important in providing Australian patients with early access to new and innovative medicines as well as providing flow on benefits that raise the health and productivity of all Australians. They also attract significant local and overseas research funding. Because of this, there is considerable competition between countries for global clinical trials. In 2015, Australia invested \$1.1bn on ongoing clinical trials, including \$930m from industry sponsors, approximately 75% of which can be attributed to international inbound investment. Innovative research partnerships between hospitals, research institutions and medicines companies currently support thousands of jobs for Australian scientists and researchers and in 2015 the clinical trials sector supported approximately 6900 largely tertiary qualified jobs.⁸

Differences in research governance systems, including ethics approvals, and inconsistencies within and between states/territories in Australia, continue to hamper Australia's potential to attract new clinical trials from key trading partners such as the EU.

It should be noted that these issues have been acknowledged previously. For example, Recommendation 6 of the Commonwealth Senate Committee inquiry into the effect of red tape on health services in 2018 states:

"The committee recommends that the Australian Government, through the Council of Australian Governments, develop a standard template and associated guidelines, including reasonable timeframes, to streamline ethics and governance approval processes for clinical trials across Australia."

Clinical Trial Notification Scheme

Today, a key driver in keeping Australia globally competitive for clinical trials is the Clinical Trial Notification Scheme (CTN). This scheme has been highly successful in providing rapid access for Australian patients and clinicians to the latest innovative medicines in development, while ensuring the safety of patients.

The Australian CTN scheme does not require sponsors to submit a Clinical Trial Application (CTA) to be assessed by the TGA. In contrast, in the EU, sponsors must submit a full CTA, covering chemistry, preclinical and clinical data to the local regulator for review which mandates timelines introduced via the EU Clinical Trial Directive. This directive saw detailed regulations across all member countries in regard to CTAs, however it was also found to slow down clinical trial start-up. Medicines Australia notes that currently, the EU is further modifying the clinical trial approval process in an effort to speed it up after recognising it has reduced clinical trial activity.

Medicines Australia seeks assurance that, whenever this is discussed or considered as part of the AEUFTA negotiations, the CTN scheme be retained as a key component of keeping Australia globally competitive as a destination for global clinical trials with innovative new medicines and devices.

⁸ MTPConnect. 2017. 'Clinical Trials in Australia: the economic profile and competitive position of the sector'



V. Workforce mobility and the labour market

Medicines Australia suggests that the exchange of talent within the pharmaceutical sector should be supported and visa approval for mid-term inter-company transfers should be simple and include the ability to fast track.

The innovative pharmaceutical industry in Australia supported approximately 22,900 full time equivalent jobs in 2016. Over 12,000 of these jobs were directly employed by the industry, many of which are highly skilled positions.⁹

A policy that supports appropriate talent exchange between Australia and the EU by reducing barriers to unimpeded flow of skilled migration would provide equal opportunity for bringing expertise to Australia that will enhance and grow local talent whilst also providing opportunities for Australians to work in the EU and bring expertise home.

VI. R&D Tax Incentive

As previously demonstrated, the innovative medicines industry is a significant investor in R&D intensive activities in Australia. The research based pharmaceutical industry is, by nature, research intensive and decisions on where and when to place R&D activities are made globally and will be influenced by a number of factors against which Australia needs to introduce and maintain a competitive edge.

As biotechnology and medical technology are global industries, Australia must compete to retain the R&D activity of local companies, as well as to attract international R&D activity into Australia. It is important to maintain a stable, supportive and consistent policy environment in Australia to encourage life sciences businesses to make strategic decisions around R&D activity and bring additional investment into Australia. The R&D Tax Incentive is a key foundation for the innovation that is the life blood of the pharmaceutical and medical technology sector in Australia.

The R&D tax incentive:

- provides support to businesses in our sector to undertake, develop and extend their R&D activities that would not be otherwise possible or that would be significantly delayed;
- plays a significant role in maintaining Australia's competitiveness as a preferred location for R&D activities, including pre-clinical testing and clinical trials;
- provides Australians with early access to early stage therapeutics, diagnostics and medical devices during clinical trials and as final products;
- contributes to building a home-grown innovation ecosystem in R&D intensive industries, ensuring Australia can deliver world-class research into treatments, cures, diagnostics devices and vaccines; and
- provides an incentive for foreign direct investment in Australian clinical trials and advanced manufacturing of pharmaceuticals that can then be exported.

Medicines Australia notes that the EU does not have a R&D tax incentive system, as this is something managed by individual member states. However, policy designed to stimulate R&D such as the R&D tax incentive should be retained, internationally competitive, and acknowledged in FTAs to ensure that investment in R&D activities in Australia is not unintentionally hampered.

⁹ PwC Analysis 2018



VII. Transparency of monitoring, strengthening and improving trade relations

A transparency chapter will establish clear mechanisms through which procedures, criteria and new regulations will be shared and commented on, adhering to a consultative approach. This consultative approach will lead to greater business and operating certainty, strengthening the confidence of companies to operate in both jurisdictions. Medicines Australia notes that inefficient regulatory burden can limit timely access to new medicines.

In the Pharmaceuticals Annex to the AUSFTA, the United States and Australia agreed on provisions for increased transparency and accountability, and enhanced consultation on the operation of the PBS. Annex 2-C of the AUSFTA establishes four basic obligations pertaining to the operation of the PBS, including agreed principles on the role of innovation, transparency, an independent review process, and establishment of a bilateral Medicines Working Group. Any future trade agreement with the EU should reflect the same principles. For example, the formation of a Medicines Working Group in the AEUFTA will be important to enable the innovative pharmaceutical sector to engage effectively in monitoring and supporting the trade relationship between Australia and the EU.

The Pharmaceuticals Annex to the EU-Korea FTA also has an article on transparency. This includes clear language around the need for transparent laws, regulations and procedures regarding any matter related to the reimbursement or regulation of pharmaceutical products. This could serve as a good model for the AEUFTA.

Transparent domestic regulatory systems are important to ensure that there is consistent application of policy and that companies are aware of their obligations in different jurisdictions. Without clear and transparent regulatory systems in both Australia and the EU, a level of increased ambiguity creates an environment that stifles innovation and will impact on timely access to new medicines. This ambiguity can be addressed through provisions in a chapter on transparency, similar to Annex 2-C of the AUSFTA.

We hope this agreement would reflect and ensure that as a minimum, the current level of transparency is maintained.