Medicines Australia | Better health through research and innovation

14 December 2021

Senate Standing Committee on Economics
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Committee Members,

Re. Medicines Australia Questions on Notice following oral evidence session

Thank you for the opportunity to give oral evidence on 8 December. We appreciate your interest and engagement in the biopharmaceutical industry. During the session, you asked us to take three questions on notice and you subsequently sent us three additional written questions. We have outlined and answered the questions below.

1. Australian patent box concessional tax rate compared to other countries

Medicines Australia welcomes the Government's decision to implement an Australian patent box scheme. The scheme, currently under consultation by the Treasury, will offer concessional tax treatment to profits derived from eligible intellectual property (IP). However, as demonstrated in the list below, the Government's proposed concessional tax rate of 17 per cent is well above global equivalents.

Please note that this list is not exhaustive of patent box regimes in other jurisdictions, but rather a selection of major countries with patent box regimes. In addition, the regimes differ in design and how the reduced tax rates are applied. For example, in some cases the patent box applies broadly to patents, software and other types of IP.

Table 1: Patent box tax rates in other countries[1]

Country	Concessional tax rate under patent box	Standard tax rate that would otherwise apply
Belgium	3.75%	25%
Luxemburg	5%	25%
Singapore	5%	17%
Netherlands	7%	20.00% - 25.00%
Ireland	6.25%	12.50%
United Kingdom	10%	19%
France	10%	32%
Spain (federal regime)	10%	25.00%
Portugal	10.5%	21.00%

As highlighted in our submission to the inquiry, since the policy aim of the Government is to "encourage companies to base their medical and biotechnology research and development (R&D) operations, and commercialise innovation, in Australia and to retain associated patent profits in

[1] See OECD (2021): https://qdd.oecd.org/data/IP_Regimes

Australia", the concessional tax rate must be viewed in a global context. For the patent box to be effective in increasing the competitiveness of the Australian tax system for globally mobile innovative companies, the proposed concessional tax rate of 17 per cent must be lowered.

In addition to a globally competitive concessional tax rate, the design of the regime must also be competitive. In the list of regimes above, the UK's patent box provides a model for Australia which is in many ways superior to the model proposed in the Australian Treasury's discussion paper. To ensure that the patent box meets its policy objectives, the Government should establish an expert working group with industry representation to support the design and implementation of the patent box.

2. Data exclusivity period: purpose and international comparison

Data exclusivity, also referred to as Regulatory Data Protection (RDP), is a form of IP provided for medicines. Data exclusivity operates in parallel to any patent term and commences at the time a new pharmaceutical product is registered with the regulator. Data exclusivity is important as it prevents other companies from using or relying on the data generated by the innovative research company's clinical development programme, without having conducted any clinical research or borne any of the risks. RDP is particularly important for products where patent protection is not available or has expired. Data exclusivity usually expires several years before the patent.

Unlike a patent, data exclusivity generally does not require lengthy complex litigation to enforce. In addition, data exclusivity does not prevent a third party from lodging their own data package during the data exclusivity period, if they have one, to register and bring to market a competitor medicine.

Data exclusivity incentivises innovative companies to invest in developing new medicinal products and generating, and making public, the extensive body of data required for the approval of innovative products. Data exclusivity is fundamental to our innovation model and strong protection also offers a positive signal of stability for long-term investment decisions. The table below details how Australia's data exclusivity period compares with other innovation driven jurisdictions with world-leading biopharmaceutical industries with whom we compete.

Table 2: Data exclusivity periods in innovation driven OECD countries

Jurisdiction	Data exclusivity period	Overall rank on U.S. Chamber International IP Index[2]
United States	Dependent on the type of product: • 7 years for orphan medicines, i.e. treatments for diseases or conditions affecting fewer than 200,000 in the U.S. • 5 years for new chemical entities, i.e. a pharmaceutical product that contains an active moiety that has not previously been approved by the FDA. • 3 years may be granted in certain circumstances, e.g. a different disease the medicines can treat is identified • For certain new antibiotics, an additional 5 additional years may be added to any other exclusivities for that medicine	1st

[2] https://www.theglobalipcenter.com/report/ipindex2021/

European Union	8 +2 + 1 years: • 8 years during which the marketing-authorisation holder benefits from the exclusive rights to the data. • +2 years during which a third company can rely on the data package to prepare its own marketing authorisation dossier. • +1 year of additional market protection may be available in a case of a new therapeutic indication which brings significant clinical benefit in comparison with existing therapies.	6 EU Member States in top 10
United Kingdom	8 + 2 + 1 years (same as the EU)	2nd
Australia	5 years	14th

As demonstrated in the table above, Australia has the opportunity to strengthen its IP regime to align with other innovative jurisdictions, particularly on data exclusivity. The Government should increase data exclusivity provisions to align with the EU.

3. The Global Talent Visa and a highly skilled workforce

The Global Talent Visa (GTV) Program is a commendable initiative that aims to bolster Australia's workforce with highly skilled professionals across target sectors including health industries. For the biopharmaceutical industry, the key limitation in the GTV Program is that it relies on identifying specific individuals as opposed to cohorts of skilled and STEM-qualified workers. These workers may not meet the eligibility criteria of the GTV program, including the requirement to meet the Fair Work high income threshold of AUD158,500. It is key to ensure that the Australian visa system enables companies and research institutes to effortlessly secure working visas for all levels of researchers and essential colleagues, including graduates who may not yet have reached their potential.

As highlighted in our submission, in addition to reviewing the visa system, Medicines Australia recommends that the Government implements the following measures to boost our future competitiveness and help create highly skilled jobs:

- Support further investment in the innovative medicines sector to continue to drive the demand for high-skill jobs
- Ensure that Australia has a suitably skilled and adaptable workforce to supply people qualified in STEM
- Reduce employment barriers through initiatives targeted (but not limited to) people of Aboriginal and Torres Strait Islander backgrounds, people with a disability, women, and people from diverse cultural backgrounds
- Work with the medicines industry and the education, training and research system to better align training with industry needs

4. How much risk do you see for Australia in its supply chains at a component level, and what role do you think the Australian Government should play in helping to support local component manufacturers, to ensure that we are protected in future pandemics?

Biopharmaceutical supply chains are global and complex. A biomedical product consists of many ingredients and components sourced from several different countries. For example, as mentioned in our submission, the Pfizer/ BioNTech vaccine contains 280 different ingredients sourced from 86 suppliers located in 19 countries. The supply chains for the Oxford/AstraZeneca, Johnsson & Johnson, and Moderna vaccines are similarly complex. As it is not possible to relocate entire supply chains in

any one country, this means that there is an element of risk for Australia in its supply chains at an ingredient and component level.

As highlighted in our submission, for Australia to build a more resilient medicines supply chain, we must be a trusted partner in a globally interconnected research-driven pharmaceutical industry. This applies to biopharmaceutical ingredients and components as well as to finished biomedical products. The Australian Government should focus its efforts to reducing trade barriers to enable the frictionless movement of pharmaceutical ingredients and components across borders.

The Government has several working groups and other initiatives to monitor and manage supply chain disruptions with industry. In addition, the Government, Medicines Australia, and the Generic Biosimilar Medicines Association (GBMA) are continuing to work together under authorisation by the Australian Competition & Consumer Commission (ACCC) to manage and minimise risks that could disrupt medicine supply to hospitals and patients.

In addition, Australian biopharmaceutical manufacturing is inextricably linked to and reliant on the wider domestic R&D ecosystem. The Government should therefore consider the whole R&D ecosystem in conjunction with domestic manufacturing capabilities, including R&D incentives, reimbursement processes, the regulatory landscape, a skilled workforce, and a strong IP regime. To improve the coordination, consistency, and collaboration across Australia on these matters, recommend that the Government establish a high-level government-industry forum for Australia's pharmaceutical and biotechnology sectors.

5. Given that over half the world is still yet to be vaccinated, how would you make the argument that we'd all somehow be better off if vaccination IP was locked up and rendered unaffordable for rapid-roll out in developing countries, thereby increasing the risk of new variants emerging?

The international IP system has enabled – not undermined – the work of the global biopharmaceutical industry which has resulted in highly effective COVID-19 vaccines. By licensing their IP to trusted partners, COVID-19 vaccine sponsor companies have enabled safe and effective scale-up of manufacturing around the world.

Medicines Australia agrees that much more must be done to vaccinate the world, however, waiving IP will not help in ensuring that developing countries have access to vaccines. This is because waiving IP will not address the real barriers that are stopping worldwide vaccine equity: sufficient know-how, ingredients, workforce, and infrastructure to manufacture COVID-19 vaccines. It will also not overcome trade restrictions, regulatory inadequacies, or healthcare system deficiencies. Instead, waiving IP will undermine current efforts to scale up the manufacture of safe vaccines by creating a greater demand for already scarce ingredients in the supply chain.

There have been intensified global calls in recent months for a temporary intellectual property waiver of COVID-19 vaccines under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – commonly referred to as the TRIPS waiver. The proposal, originally submitted by India and South Africa, gathered momentum in May after the US announced its support for the waiver. Several major countries, including the UK, Britain, Canada and Japan, continue to oppose the proposal. Most recently, the Australian government, despite its stated understanding that patents are not a barrier to vaccine availability, said it was "open to any agreed solution" on the proposal.

The TRIPS waiver could disrupt the global supply chains of the raw materials that are crucial to develop the quantities required by the world. For example, the Pfizer/BioNTech COVID-19 vaccine contains 280 different ingredients sourced from 86 suppliers in 19 different countries. The speed of

manufacturing vaccine doses is not being limited by the number of manufacturing plants but by the scarcity of raw materials for the vaccines and export restrictions of the finished products. There are currently more than 60 notified export restrictions on medical goods globally and 22 per cent of countries impose tariffs on vaccines.

All vaccine and medicine manufacturing establishments must abide by rigorous procedures and quality controls to make sure that what the patient receives in their arm is safe and of the highest quality. There is a risk that the waiver could open the door to counterfeit vaccines that are not manufactured with the right technology and without required safety and quality checks. Not only could this lead to serious side effects, but it would also boost anti-vaccination misinformation.

There are several issues which need to be addressed by governments if we are ever going to achieve a vaccinated world. To advance vaccine equity, governments need to urgently eliminate trade barriers, optimise vaccine production, support countries' readiness to vaccinate their populations, drive further innovation and create a greater willingness to share more doses with developing countries. Unlike other wealthy countries, Australia has made no vaccine sharing commitments to the COVAX program. Australia is well positioned to step up additional funding to COVAX as well as making a commitment to share vaccine doses.

In addition, waiving IP would also have long-term damaging consequences for the biopharmaceutical industry and, as a result, the health of Australians. Strong IP rights and the ability to licence and enforce such rights as appropriate are critical to biomedical innovation because they secure the financial return that makes continuing investment in R&D possible. Significant capital is required for the R&D activities leading to biomedical innovations, and indeed the capacity of industry to respond to the COVID-19 pandemic in the way that it has is derived from the commercial incentive provided by patent protection to invest in skills, knowledge, and technology. The availability of patent protection for biomedical innovations is essential for ensuring investment in discovery science, early-stage development, clinical trials and all the way through to the final regulatory approval process. The loss of ownership of core IP in effect, remove the commercial viability for companies and undermining IP within the sector more generally will have a chilling effect on innovation. It is therefore important for the pipeline of future biomedical innovations, not to mention national and global economic growth, that companies are recognised for their innovation.

6. Could you expand a bit on your proposal to expand the patent box to offshore activity that includes a significant proportion of domestic input. Would you propose specific value thresholds on the level of domestic R&D?

The development of new biopharmaceutical products is long and complex. As such, there are often instances where a part of the R&D needs to be conducted overseas. For example, phase 3 clinical trials require large number of participants who must meet specific eligibility criteria to take part in the trials. Oftentimes there is not enough sufficient eligible Australian participants, and as a result, phase 3 clinical trials are conducted in several countries simultaneously to ensure that the required recruitment can be met in a timely way. In addition, in other instances, the R&D service needed may not available domestically due to a lack of capability or capacity. For example, pre-clinical toxicology studies (which are vital to demonstrate the safety of a new medicine before it is tested humans) are often unavailable in Australia. In both these cases, where the product is being developed by an Australian company, the R&D expenditure will be incurred by the company.

If eligible R&D is solely limited to the proportion of associated R&D that was conducted in Australia by the company, it would drastically diminish access to the patent box, through no fault of the company. By extension, it would also undermine the policy objective of the patent box. Given that the Australian

R&D landscape makes it difficult or at times impossible to conduct all biomedical R&D domestically, the Government should apply an arrangement that will allow for R&D to be conducted overseas under the patent box regime. To ensure that this arrangement is designed well, the Government should establish an expert working group with industry representation to support the design and implementation of the patent box.

To discuss these issues further, please contact Jamie Snashall (Head of Government Relations, [redacted]).

Yours sincerely,

[redacted]

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