Public Health Association of Australia
submission to the inquiry into the implications of the COVID-19 pandemic for Australia’s foreign affairs, defence and trade

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The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public’s health in Australia. The PHAA works to ensure that the public’s health is improved through sustained and determined efforts of our Board, National Office, State and Territory Branches, Special Interest Groups and members.

We believe that health is a human right, a vital resource for everyday life, and a key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people’s health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

Our mission as the leading national organisation for public health representation, policy and advocacy, is to promote better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health. Members of the Association are committed to better health outcomes based on these principles.

Our vision is for a healthy population, a healthy nation and a healthy world, with all people living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health and wellbeing for all.

The reduction of social and health inequities should be an over-arching goal of national policy, and should be recognised as a key measure of our progress as a society. Public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.
PHAA submission on inquiry into the implications of the COVID-19 pandemic for Australia’s foreign affairs, defence and trade

Introduction

PHAA welcomes the opportunity to provide input to an inquiry into the implications of the COVID-19 pandemic for Australia’s foreign affairs, defence and trade.

This submission addresses issues related to trade policy that affect access to health-related products such as medicines, vaccines, diagnostic tests and medical devices during the COVID-19 pandemic. It addresses primarily the following term of reference:

Supply chain integrity/assurance to critical enablers of Australian security (such as health, economic and transport systems, and defence)

PHAA Response to the Inquiry Terms of Reference

Supply chain integrity / assurance to critical enablers of Australian security (such as health, economic and transport systems, and defence)

Access to medicines, vaccines, tests and medical devices – trade and intellectual property issues

Patents and other intellectual property protections can present barriers to procuring medicines, vaccines, diagnostic tests and medical devices. In a public health emergency like COVID-19, these barriers can lead to shortages of life-saving products.

We have already seen examples where patents have created obstacles to access. Hundreds of patents on N95 face masks held by a US company have resulted in critical shortages of this vital personal protective equipment needed by health workers.¹ One hundred and fifty civil society organisations including Médecins Sans Frontières recently called on Gilead Sciences, maker of the potential COVID-19 treatment remdesivir, to release the patents it holds on the drug in more than 70 countries.² This action by Gilead seems unlikely, since the company had applied for an extra period of exclusivity from the US Food and Drug Administration, and only dropped its application after a public outcry. Gilead has negotiated voluntary licenses with pharmaceutical companies in India, Pakistan and Egypt to produce the drug, but only for distribution to 127 mainly low-income countries.³ More than 70 countries, including some large middle-income countries which are badly afflicted by COVID-19, such as Brazil and Mexico, are excluded from the deal, meaning that Gilead may set a price that is out of reach for large parts of these populations, and production may not be able to be scaled up quickly enough to meet the health need.

Utilise safeguards in Australia’s Patents Act to address pharmaceutical shortages

The Commonwealth Patents Act 1990⁴ includes some important safeguards that enable patented inventions to be exploited without the consent of the patent owner. These are its compulsory licensing and Crown use provisions. Use of these provisions is permitted under the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁵ and Australia should prepare to use them to prevent shortages of medical supplies.
Under the Act, the Federal Court can order that a compulsory license be granted for a patented invention under certain conditions, meaning that a third party (e.g. generic medicines manufacturer) can produce copies of the patented invention without the permission of the patent owner. However, one of the conditions for issuing a compulsory license is that “the applicant has tried for a reasonable period, but without success, to obtain authority from the patentee to exploit the original invention on reasonable terms and conditions” (Section 133, Para 3(c)). This condition may slow down the process if negotiations with the patent owner take a long time. Canada has passed emergency legislation to remove its requirement that negotiations with the patent owner take place before a license is issued during the COVID-19 pandemic. Australia should consider doing the same.

The Patent Act’s Crown use provisions provide another mechanism allowing Federal, State and Territory governments, or a party authorised by a government to over-ride a patent in an emergency in order to provide a service primarily provided or funded by the Commonwealth or a State or Territory. These provisions may be faster and easier to use since they only require ministerial approval rather than an application to the Federal Court.

**Ensure Australia can import pharmaceuticals manufactured under compulsory license**

In addition to preparing to use the provisions in the Patents Act, the Australian Government should also ensure that we can import drugs manufactured under compulsory license in other countries, in cases where there is insufficient manufacturing capacity in Australia to produce them locally. To do this, Australia will need to revoke an earlier decision at the World Trade Organization to declare itself an “ineligible importing member”.

**Engage in international initiatives to share intellectual property, knowledge and data**

To ensure equitable access to COVID-19 medicines, vaccines and tests at a global level, and in line with the World Health Assembly COVID-19 Response resolution, the Australian Government should commit to ensuring the open sharing of intellectual property, knowledge and data that will enable timely and affordable access for people of all countries to medical products to combat COVID-19.

Specifically, Australia should join 39 other countries in endorsing the World Health Organization’s COVID-19 Technology Access Pool (C-TAP), and should use enforceable provisions in funding agreements to ensure that publicly-funded research outcomes are affordable and accessible to all on a global scale.

**Reconsider the types of provisions included in trade agreements that can compromise access to medical products**

Finally, the COVID-19 pandemic necessitates a fundamental re-think of the types of rules that are negotiated in trade agreements, including those that can encourage monopolies and reduce affordable access to all forms of medical supplies, and put at risk the lives of people in every country of the world.
Conclusion and recommendations

The COVID-19 pandemic has highlighted risks and weaknesses in the current global trade environment. At a time when there is an urgent global need for access to medicines, a potential vaccine, tests and medical equipment, there is a real risk that rather than science or supply chains, trade barriers block access.

PHAA recommends that the Australian Government should:

- prepare to use the compulsory licensing and/or Crown use provisions in the Commonwealth Patents Act to over-ride patents where this is necessary to prevent shortages of critical products during COVID-19
- amend the compulsory licensing provisions in the Patents Act to remove (or suspend for the duration of the pandemic) the requirement to negotiate with the patent owner prior to issuance of a compulsory license
- revoke an earlier decision at the World Trade Organization to declare itself an “ineligible importing member” of drugs produced under compulsory license in other countries.
- commit to ensuring the open sharing of intellectual property, knowledge and data that will enable timely and affordable access for people of all countries to medical products to combat COVID-19 and endorse the World Health Organization's COVID-19 Technology Access Pool
- use enforceable provisions in funding agreements to ensure that publicly-funded research outcomes are affordable and accessible to all on a global scale
- reconsider the rules negotiated in trade agreements which can encourage monopolies and reduce affordable access to medical supplies

The PHAA appreciates the opportunity to make this submission. Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.

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30 June 2020
References


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8. World Health Organization. Seventy-third World Health Assembly COVID-19 Response: Draft resolution A73/CONF./1 Rev. 1. [https://apps.who.int/gb/e/e_wha73.html#resolutions](https://apps.who.int/gb/e/e_wha73.html#resolutions); WHO; 2020.