Public Health Association
AUSTRALIA

Public Health Association of Australia submission on the Australian-European Union Free Trade Agreement

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Introduction

The Public Health Association of Australia

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the role of the Public Health Association of Australia (PHAA).

PHAA is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

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Health Equity

As outlined in the Public Health association of Australia's objectives:

> *Health is a human right, a vital resource for everyday life, and 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, political, and 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.*

The PHAA notes that:

- Health inequity differs from health inequality. A health inequality arises when two or more groups are compared on some aspect of health and found to differ. Whether this inequality (disparity) is inequitable refers to measurable differences between (or among, or within) groups.
- Health inequity occurs as a result of unfair, unjust social treatment – by governments, organisations and people, resulting in macro politico-economic structures and policies that crate living and working conditions that are harmful to health, distribute essential health and other public services unequally and unfairly, preventing some communities and people from participating fully in the cultural, social or community life of society.

Preamble

PHAA welcomes the opportunity to provide input to the potential opportunities and impacts of a possible Australian-European Union Free Trade Agreement (Australia-EU FTA) to the Department of Foreign Affairs and Trade (DFAT), particularly in light of the growing number of bilateral and multilateral trade agreements. PHAA firmly advocates for the reduction of social and health inequities as an over-arching goal of national policy and recognised as a key measure of our progress as a society. The Australian Government should take this into account in the negotiation of all international treaties. Treaties, along with all public health activities and related government policy should be directed towards reducing social and health inequity nationally as well as internationally.

Response to the Proposed Australian-European Union Free Trade Agreement

Public Health Association of Australia policy on trade agreements and public health

PHAA has a policy on trade agreement and health which can be found here: http://www.phaa.net.au/advocacy-policy/policies-position-statements#Intnerational%20Health

The policy states that:

1. Trade agreements should not limit or override a Government's ability to legislate and regulate systems and infrastructure that contribute to the health and well-being of its citizens.
2. The ability of governments to develop and implement policy that protects public health needs to be preserved in trade agreements.
3. PHAA advocates a trade regime that ensures ecological sustainability and equity in population health as well as economic development.

The policy also commits to advocating at the national and international levels to promote and protect public health within international trade agreements and limit adverse impacts of trade agreements on human and planetary health in Australia and internationally.

Potential impact of the Australian-EU FTA on public health

Trade agreements are a significant determinant of health. They can affect many aspects of health care and public health:[1] [2]

- Access to affordable medicines;
- the equitable provision and quality of health care services;
- the ability of governments to regulate health damaging products such as tobacco, alcohol and processed foods;
- the nutritional status of populations; and
- access to many of the social determinants of health such as employment and income.

PHAA is particularly concerned about the emerging trend of trade agreements that aim to extend into areas that have previously been matters for domestic policy making. This includes agreements such as the Trans Pacific Partnership Agreement (TPPA) to which Australia is a party.

PHAA is concerned that proposals under previous trade agreements impact the rights of governments to regulate health, environmental or other public interest objects. Some of these proposals have included:

- expanded intellectual property rights and constraints on operation of the Pharmaceutical Benefits Scheme that would increase medicine costs for both Government and the Australian community;
- investor-state dispute settlement mechanisms enabling foreign corporations to sue governments over their health related policies and laws;
- provisions that would provide greater rights to industry to participate in policy making processes.

Investor-state Dispute Settlement

Investor-state dispute settlement (ISDS) is a legal mechanism included in some trade agreements and investment treaties. ISDS provides a legal mechanism for foreign investors to contest decisions by national governments that they believe impinge on their investments.

ISDS was originally included in these agreements to provide recourse for developed country corporations investing in developing countries without strong legal systems[3]. But now ISDS cases are frequently launched against developed countries as well. Many ISDS cases involve environmental and public health policies and large amounts of money and there is widespread concern around the world about the effects on the capacity of governments to regulate to protect the environment and public health.

Including ISDS clauses in Australia's trade agreements may impact Australia's ability to implement new policies that support public health. These include innovative policies in the areas of alcohol and food policy and tobacco control (although the PHAA notes the complete exemption of Australia's tobacco control measures from ISDS in the TPPA). The costs to the health system from the health effects of tobacco, alcohol and obesity are estimated at $6 billion per year, with lost productivity as a result of these factors estimated at almost $13 billion per year[4]. But ISDS provides an avenue for corporations to seek compensation from governments for introducing policies and laws to regulate the health-damaging products that contribute to rising rates of chronic disease, if they believe these policies and laws harm their investments.

From a public health perspective, there are no arguments in favour of including ISDS in trade and investment agreements. But there are many arguments against providing this mechanism in Australia's trade and investment agreements.

Many investor-state cases concern public health and environmental issues

Over the last decade there has been a large increase in investment arbitration cases. By 2011 there were 450 known ISDS cases[5]. Key examples relevant to public health include Philip Morris Asia's case against Australia under the Hong Kong-Australia Bilateral Investment Treaty, over the introduction of tobacco plain packaging. Eli Lilly, a Canadian pharmaceutical company, is also suing the Canadian Government for $500 million over court decisions to revoke patents for two drugs that were found not to deliver the promised benefits. There have been many cases involving corporations challenging decisions to protect the environment; decisions which are often made for public health reasons as well as environmental reasons.

Flaws in the investor-state dispute settlement process

Investor-state dispute settlement is a fundamentally flawed and pro-investor system.

The costs of arbitration can be very high. It can cost millions for countries to fight legal claims under ISDS, even if they successfully defend them. The Organisation for Economic Co-operation and Development (OECD) has estimated the costs average more than $8 million per case[6].

The awards involved in ISDS cases are also often very high. The Czech Republic, for example, had to pay more than $350 million USD in an ISDS case, which is reported to have almost doubled its public sector deficit[7]. El Salvador has been sued for over $300 million USD by Pacific Rim, a Canadian gold mining company over its refusal to grant permits for cyanide-based gold mining[8]. In some cases awards have amounted to over a billion dollars.

The ISDS process lacks the safeguards of domestic legal processes. Arbitrators can have conflicts of interest, there are no appeals, and decisions are ad hoc as arbitrators do not have to take precedents into account[9].

A report by Corporate Europe Observatory and the Transnational Institute[10] describes how the boom in investment arbitration cases over the last couple of decades has given rise to an elite investment arbitration industry dominated by a small number of investment law firms and arbitrators. According to this study, investment arbitration lawyers have encouraged governments to sign treaties with poorly worded ISDS clauses that expose them to legal cases, have encouraged corporations to use lawsuits and have actively prevented changes to the investment arbitration system.

The Investment Court System proposed by the EU for its trade agreement with the US, the Trans-Atlantic Trade and Investment Partnership (TTIP), does not appear to be a viable alternative. This model repeats some of the same flaws as the ISDS mechanisms it is meant to replace, including the potential for high arbitration costs and conflicts of interests[11].

Regulatory chill

The threat of legal action, or even the existence of an ISDS mechanism, can deter governments from implementing public health policies and laws. Corporations can also delay the uptake of innovative public health policies and laws in other countries by launching ISDS claims against 'first movers' (the first country to introduce a new approach).

'Safeguards' and exceptions may not be effective in preventing cases

Recently signed trade agreements such as the agreement between South Korea and Australia FTA (KAFTA) and the TPPA include some legal safeguards which are intended to protect public health and the environment. However experts have cautioned that these legal safeguards are insufficient to prevent corporations from bringing ISDS claims over legitimate health and environmental policies (with the exception of ISDS claims over tobacco control measures in the case of the TPPA)[12] [13] [14].

Intellectual Property and extension of monopolies on medicines

PHAA is concerned over the potential for extending impact of intellectual property measures in this trade agreement that may go beyond those required under the Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) and the domestic IP laws of Australia. PHAA would oppose any proposals in which the Australian-EU FTA would:

- expand the scope of patentability;
- mandate patent term extensions;
- extend the protection of clinical trial data; and

- strengthen enforcement of intellectual property rights (particularly any provisions which would facilitate the seizure of medicines in transit from one country to another).

If included, these types of provisions would delay the entry of generic medicines in Australia and signatory countries, increasing the costs of medicine subsidies to Australian taxpayers and significantly reduce access to affordable medicines. PHAA also notes that the Productivity Commission recommended that the Government not generally seek to include IP provisions in bilateral and regional trade agreements – and that any IP provisions proposed should only be included after an economic assessment of the impacts on patients and partner countries. Furthermore, any IP provisions that reduce future policy flexibility should be avoided.

Australia should oppose provisions to expand the scope of patentability.

Provisions to expand scope of patentability to new forms and new uses of known substances weaken pharmaceutical patents laws and facilitate the practice of pharmaceutical evergreening - in which patent owners extend monopolies by securing additional patents through modifications to existing drugs. Evergreening further delays the entry of generic medicines. A 2013 study of the 15 costliest drugs in Australia found a mean of 49 patents associated with each drug[15]. The Australian Generic Medicines Industry Association has found that delays in the entry of generic competition for 39 PBS listed medicines due to secondary patenting cost taxpayers $37.8 - $48.4 million over a 12 month period (Nov 2011-Nov 2012)[16] [17]. Specifically, researchers have shown that delays to generic entry for the antidepressant venlafaxine (Efexor) due to secondary patenting on modified forms of the drug cost the Australian government $209 million[18]. Similarly, researchers in the US found that secondary patenting on HIV medicines ritonavir and lopinavir/ritonavir could delay generic entry for an additional 19 years beyond the original patent term[19] [20].

While Australian practice currently allows patents for new uses and new methods of a known product, the government should avoid agreeing to this provision in future trade agreements as this would constrain future patent reform in Australia[21].

Australia should reject proposals to extend data protection in trade agreements

Data protection measures would also delay the entry of cheaper generic medicines. While industry claims that data protection is necessary for further R&D investment, the Pharmaceutical Patent Review (PPR) found that 'data protection appears to have little impact on the levels of pharmaceutical investment in a country'[22]. There is no evidence that current levels of protection in Australia provide insufficient incentives for investment and the PPR recommended against extending data protection for biologics[23]. Studies of data protection measures introduced in Jordan through FTAs showed that in the period 02-06, data protection delayed the introduction of generic medicines for 79 per cent of new medicines[24]. Similarly, assessments of data protection provisions in Guatemala have shown prices for medicines with data protection to be substantially higher[25]. In Thailand, extending market exclusivity for five years was found to increase medicine outlays between 9 and 45 per cent (based on 2002 data)[26].

Data protection has the effect of delaying generic entry and increasing medicine prices. In addition, researchers have pointed out that data protection presents a potential impediment to compulsory licensing – a safeguard within TRIPS that must be protected in FTAs[27]. Delays in generic market entry for PBS listed medicines delay statutory price reductions, costing taxpayers millions of dollars each year[28].

Australia should reject provisions for patent term extensions in trade agreements

While Australia currently allows for patent term extensions, which are based on the oft-cited industry claim that they are required to recoup money for research and development (R&D), the independent PPR found that there is no evidence that the costs of extension terms had led to a commensurate increase in R&D[29]. The cost of extensions for PBS drugs during 2012-13 was estimated to cost the public $240 million in the medium term and $480 million over the long term[30] [31]. The PPR concluded that Australia should work to reduce the length of patent term extensions. In addition, researchers have pointed out that the regulatory approval process for the Therapeutic Goods Administration (TGA) is subject to statutory time limits and deduction in fees in case of delays – meaning the granting of extensions for rare delays 'makes little sense'[32].

Australia should oppose strong enforcement measures including the seizure of suspected Intellectual Property Rights (IPR) infringing medicines in-transit

The seizure of suspected IPR infringing medicines in-transit would be disastrous for access to medicines, in particular in low and middle income countries. There have already been documented cases in which legitimate medicines have been seized in-transit by customs authorities, delaying access to medicines[33]. Australia should reject any proposal for border measures for IP enforcement in the Australian-EU FTA.

Transparency and independent analysis of trade agreements

The PHAA has engaged in many discussions with the Department of Foreign Affairs and Trade and has written many letters and submissions over recent years to highlight the potentially health-damaging effects of trade negotiations. We have also repeatedly expressed concern about the treaty-making process and in particular the lack of transparency in the negotiations.

At present it is extremely difficult to access information about the specifics of the issues being discussed in trade negotiations. While we appreciate the efforts of Australia's trade negotiators (within the constraints of their mandate) to share general information about the status of negotiations and Australia's positions on key issues of interest to us, we continue to be frustrated by the lack of detail provided and our lack of access to negotiating text. This severely limits the ability of our Association and its expert members to assess the implications of trade treaties.

It is inevitable that tensions arise between the interests of large transnational corporations and the broader national polity, the public interest. It is unfortunate but also true that corporate lobbyists in the United States have privileged access to and disproportionate influence over political parties and leaders. Many of the most powerful lobbyists are representing overseas owned transnationals whose ultimate obligation is to their overseas shareholders. In these circumstances the secrecy and lack of transparency of trade negotiations represents a serious threat to the public interest.

We have been assured many times that the Australian Government pursues the interests of Australians in trade negotiations and will not accept provisions that will compromise the health system or access to generic medicines. However, there are several issues that make us wary of these general reassurances.

Our members are very well aware that when it comes to legal treaty text, "the devil is in the detail". The exact wording is critically important. Because we cannot see the proposed wording during the negotiations, our expert members cannot make an independent assessment of the potential consequences on the health of Australians.

Trade negotiations involve bargaining, and health sector interests can often be traded off in exchange for wins in other areas. Our previous Prime Minister Tony Abbott has referred to the "horse trading" that inevitably takes place in the negotiating context.

The current process for public and stakeholder consultation is very ad hoc. There should be requirements for trade negotiators to systematically consult with stakeholders. Position papers and composite drafts of treaty texts should be released at key points during the negotiations.

PHAA also recommends, given the significant impact that trade agreements can have on many aspects of health, that it is essential that health impact assessment of all treaties be undertaken during negotiation, after final agreement is reached and after implementation.

Conclusion

The PHAA appreciates the opportunity to make this submission and would be happy to elaborate on the views expressed at a future public hearing.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

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