Public Health Association
AUSTRALIA

Public Health Association of Australia

Submission to the Department of Foreign Affairs and Trade on the Regional Comprehensive Economic Cooperation Agreement (RCEP)

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Contents

Executive Summary **3**

Public Health Association of Australia **4**

1) Australia's response to Japan's RCEP IP proposal **5**

1.1) Australia should oppose provisions to expand scope of patentability. 5

1.2) Australia should reject provisions for patent term extensions in RCEP 6

1.3) Australia should reject proposals to extend data protection in RCEP 6

1.4) Australia should oppose measures for the seizure of suspected IPR infringing medicines in-transit 7

2) Australia's approach to the RCEP negotiations: protecting public health **7**

2.1) Reject investor state dispute mechanisms in RCEP 7

2.2) Do not include intellectual property in the definition of investment 8

2.3) Avoid provisions that would increase pharmaceutical expenditure in Australia 8

2.4) Ensure that the RCEP does not introduce 'TRIPS Plus' intellectual property privileges in developing countries 8

2.5) Preserve and affirm countries' ability to use flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and public health 8

2.6) Do not propose or support enforcement measures in RCEP that go beyond TRIPS 9

2.7) Commit to transparency and civil society input 9

2.8) Ensure aid effectiveness and regional responsibility 10

Conclusion **10**

Acknowledgements **11**

References **12**

Executive Summary

The Public Health Association of Australia (PHAA) welcomes the opportunity to provide this submission on the Regional Comprehensive Economic Cooperation agreement (RCEP) to the Department of Foreign Affairs and Trade. We note that the aims of RCEP include to 'boost economic growth and equitable economic development' in the region.[1] However, it is essential that efforts to achieve these aims do not inadvertently compromise public health in the region.

We were alarmed in February 2015 to see a leaked proposal by Japan for strong intellectual property protections in RCEP. We realise that, as a proposal by only one country it is unlikely to reflect either the totality of views among negotiating countries, or the Australian government position. However, this has alerted us to some of the issues under discussion and the potential risks for public health.

This submission raises public health concerns in the areas of intellectual property protection and enforcement and investor state dispute settlement mechanisms (ISDS). In the absence of access to negotiating text, our concerns draw on leaked Japanese IP negotiating text for RCEP, observations from Australia's involvement in the Trans Pacific Partnership Agreement, ASEAN-AUSTRALIA-NEW ZEALAND FTA and the Anti-Counterfeiting Trade Agreement, and research on the effects of stringent IP measures and ISDS in Australia and other countries.

In our view, Australia has an obligation to developing countries in our region not to support proposals that would compromise public health and access to affordable medicines. PHAA calls on the Australian Government to reject any proposals that would expand intellectual property protections in any of the RCEP countries. These include, but are not limited to:

- provisions to expand the scope of patentability (e.g. to include new forms and new uses of known substances);
- provisions for extension to patent terms;
- proposals to extend protection of clinical trial data; and
- enforcement measures beyond TRIPS, particularly measures for the seizure of suspected IPR infringing medicines in-transit.

We strongly urge the Government to oppose the inclusion of Investor State Dispute Settlement provisions in RCEP as they are antithetical to public health.

We also call on the Government to oppose the inclusion of intellectual property in the definition of investment and to oppose enforcement measures that go beyond TRIPS.

Australia must avoid provisions that would add to pharmaceutical expenditure. In addition, the Government should work to ensure that the RCEP does not impose 'TRIPS Plus' intellectual property standards on developing countries. RCEP must preserve and affirm countries' ability to use legal flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and public health.

We believe that given the significant public interest issues at stake there is a need for greater transparency in trade negotiations. As we argued in our recent submission to the Senate inquiry into the Commonwealth's treaty-making process, we call for:

- The release of treaty texts before endorsement by the Cabinet, in sufficient time for independent assessments of their implications before finalisation.
- Mandatory health impact assessments during negotiation, after release of the final agreements and following implementation.
- Processes for systematic consultation and for release of position papers and composite drafts of treaty texts at key points during the negotiating processes.
- Treaty texts to explicitly prioritise health in any areas where health may conflict with trade or other goals.

We note that Australia spends hundreds of millions of dollars in health aid in the region and that to ensure aid effectiveness, the Government must support low and middle income countries to resist IP and ISDS measures that pose a risk to public health.

Public Health Association of Australia

The 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. The PHAA has a vision for a healthy region, a healthy nation and healthy people living in a healthy society and a sustaining environment while improving and promoting health for all.

PHAA has a policy on trade agreements and health which states that:

1. Trade agreements should not limit or override a nation's ability to foster and maintain systems and infrastructure that contribute to the health and well-being of its citizens by detracting from a nation's ability to legislate and regulate in the national interest;

2. Policy space needs to be preserved in trade agreements for national governments to regulate to protect public health; and

3. PHAA advocates a fairer regime of trade regulation that addresses sustainability issues as well as economic development and which prioritises equity within and between countries as a necessary condition for global population health improvement.

The policy also commits the association to 'advocate at the national and international levels to promote and protect public health within international trade agreements and limit adverse impacts of trade agreements on health and well-being, both within Australia and in other countries.' [2]

1) Australia's response to Japan's RCEP IP proposal

Japan's RCEP intellectual property proposal, dated October 4 2014 and leaked in February 2015,[3] proposes a number of stringent IP measures that go beyond those required under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the domestic IP laws of most of the negotiating countries, including Australia. According to this text, Japan is asking Australia and the negotiating countries to:

- Expand the scope of patentability to include new forms and new uses of known substances, even where there is no enhanced efficacy;
- Mandate patent term extensions to compensate for delays in marketing approval processes;
- Provide at least six years of protection for clinical trial data; and
- Introduce stringent enforcement of intellectual property rights, including the seizure of medicines in-transit from one country to another which are *suspected* of infringing these rights in the transit country.

These proposals, if adopted, would delay the entry of generic medicines in Australia and the RCEP signatory countries, thus increasing the costs of medicine subsidies to Australian taxpayers and significantly reducing access to affordable medicines in many of the RCEP countries. We note that in Australia, 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.[4]

1.1) Australia should oppose provisions to expand 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.[5] 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).[6,7] 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.[8] 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.[9,7]

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 RCEP because this would constrain future patent reform in Australia.[7] It is particularly important for developing countries to be able to limit the scope of patentability and apply strict criteria for patent eligibility. India's domestic patent law currently applies strict criteria, excluding 'the mere discovery of a new form of a known substance which does not result in the enhancement of [the] known efficacy… or any new property or new use for a known substance' from eligibility for a patent (Section 3d).[10] This law has been used to prevent pharmaceutical evergreening on much needed cancer drugs – enabling the entry of generics and subsequently more affordable prices. China has also begun to apply tests of novelty and has rejected attempts to evergreen a key HIV/AIDS and hepatitis B drug.[11] India and China are the main source of generic medicines for many low and middle income countries and need to maintain strict criteria for patent eligibility not only for their populations, but for many of the world's poor.

1.2) Australia should reject provisions for patent term extensions in RCEP

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 Pharmaceutical Patent Review (PPR) found that there is no evidence that the costs of extension terms had led to an commensurate increase in R&D.[12] The cost of extensions for PBS drugs during 12-13 was estimated to cost the public $240 million in the medium term and $480 million over the long term.[12,7] 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'.[7] It is particularly important that low and middle income countries resist extending patent terms because the costs associated with these (as identified above) would likely make them prohibitively expensive, with life or death consequences.

1.3) Australia should reject proposals to extend data protection in RCEP

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 found that 'data protection appears to have little impact on the levels of pharmaceutical investment in a country'.[13] 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.[7] 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.[14] Similarly, assessments of data protection provisions in Guatemala have shown prices for medicines with data protection to be substantially higher.[15] In Thailand, extending market exclusivity for five years was found to increase medicine outlays between 9 and 45 per cent (based on 2002 data).[16]

Data protection has the effect of delaying generic entry and increasing medicine prices – a feature that low and middle income countries must avoid in order to meet public health objectives. 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.[17] Along with the need to support low income countries in the region, Australia should also reject these provisions as a matter of national interest. Delays in generic market entry for PBS listed medicines delay statutory price reductions, costing taxpayers millions of dollars each year.[18]

1.4) Australia should oppose measures for the seizure of suspected 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.[19] Australia should reject Japan's proposal for border measures for IP enforcement in RCEP.

2) Australia's approach to the RCEP negotiations: protecting public health

This section of the submission outlines general principles that we believe should be pursued by the Australian Government in the RCEP negotiations in order to protect and preserve public health, including access to affordable medicines.

2.1) Reject investor state dispute mechanisms in RCEP

The ASEAN-AUSTRALIA-NEW ZEALAND FTA (AANZFTA) includes an ISDS mechanism for international arbitration for investors; we are therefore concerned about the prospect of Australia supporting its inclusion in RCEP.[20,21] Public health advocates have drawn attention to the serious concerns over ISDS clauses in trade agreements. A notable case is that of Philip Morris Asia – which is suing Australia for tobacco plain packaging laws through an ISD mechanism in an investment agreement between Hong Kong and Australia. ISDS measures enable companies to sue governments if they enact laws that affect their profits. Health advocates have pointed out that ISDS processes do not have many of the safeguards and transparency of domestic legal systems and the threat of legal action can have a powerful effect on governments considering new laws for public health.[22,23]

2.2) Do not include intellectual property in the definition of investment

Intellectual property has been at the heart of several ISDS cases over health-related matters, including the claim by Philip Morris against Australia and by Eli Lilly and Company against Canada. There is a strong rationale for restricting the definition of investment under RCEP to effectively carve out intellectual property rights.

2.3) Avoid provisions that would increase pharmaceutical expenditure in Australia

Medicines already represent a substantial proportion of the health budget in Australia, and concerns have been repeatedly raised concerning the sustainability of the Pharmaceutical Benefits Scheme. Empirical research indicates that disadvantaged people are more vulnerable to rising medicine costs and that increasing out of pocket costs impede access and undermine medication adherence. Research has shown that when co-payments rise, use of prescription medicines falls and disadvantaged groups such as the poor and elderly are those most affected.[24,25]

2.4) Ensure that the RCEP does not introduce 'TRIPS Plus' intellectual property privileges in developing countries

It is highly inappropriate for developed countries to require TRIPS+ provisions of developing countries, or to support the efforts of other countries to do so. The 2009 Report of the UN Special Rapporteur on the Right to Health stated that 'Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.'[26] It is also important to note that Australia has never before required developing countries to agree to 'TRIPS Plus' intellectual property provisions in its trade agreements. Furthermore, such requirements would be inconsistent with Australia's commitments as a signatory to the UN Political Declaration of the High Level Meeting on Prevention and Control of Non-communicable Diseases[27] and the UN Political Declaration on HIV. [28]

2.5) Preserve and affirm countries' ability to use flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and public health

TRIPS included some important flexibilities to enable countries to protect public health, which were re-affirmed in the 2001 Doha Declaration. These include permitting compulsory licensing and parallel importation, [29] exclusions to patentability, flexibility in applying high patentability standards and safeguards such as pre-grant opposition. These flexibilities must be preserved under RCEP.

2.6) Do not propose or support enforcement measures in RCEP that go beyond TRIPS

The Australian Parliamentary Joint Standing Committee on Treaties made several reservations with respect to enforcement measures in the Anti-Counterfeiting Trade Agreement (ACTA) and recommended that patents be excluded from the application of civil enforcement and border measures.[30] Australian IP academics have called on Australia to reject stringent enforcement measures in trade agreements, such as the inclusion of presumption of patentability in enforcement proceedings.[31] Other 'TRIPS PLUS' measures that Australia should reject include any measures for rights-holder determined value in determining damages and statutory damages.[31]

While Australian law currently has many 'TRIPS PLUS' measures on IP enforcement, the inclusion of these measures in a regional treaty like RCEP would restrict future changes to domestic law and should be avoided.

Australia has signed on to stringent enforcement measures beyond those in TRIPS including 'obligations to provide for an account of profits as a remedy for IP infringement, to provide statutory or at least additional damages, and legal costs, obligations on an alleged infringer to provide information about the origin and distribution network of the infringing goods, and powers for customs authorities to provide right holders with information on goods seized at the border' in the Anti-Counterfeiting Trade Agreement (ACTA).[32] These types of provisions should not be included in RCEP.

2.7) Commit to transparency and civil society input

We ask that the Government commits to the utmost transparency in the RCEP negotiations, and to consulting as fully as possible with civil society organisations.

We believe that there is a need for greater transparency in trade negotiations due to the number of public interest issues at stake. As we argued in our recent submission to the Senate inquiry into the Commonwealth's treaty-making process, we call for:

- The release of treaty text before it is signed by the Cabinet, in sufficient time for independent assessment of the implications before it is finalised.
- Mandatory health impact assessments during negotiation, after release of the final agreement and after implementation.
- Processes for systematic consultation and for release of position papers and composite drafts of treaty texts at key points during the negotiating process.
- Treaty text to explicitly prioritise health in any areas where health may conflict with trade goals.

2.8) Ensure aid effectiveness and regional responsibility

Australia should ensure aid effectiveness by supporting low and middle income countries in RCEP. We note that Australia is currently providing hundreds of millions of dollars in health assistance to Burma, Cambodia and Indonesia.[33] Australia is reimbursing essential health care costs for the poor in Cambodia[34] and is supporting HIV, TB and infectious disease programs in Indonesia.[35] Over one hundred million dollars has been spent on HIV in Indonesia since 2008. We have shown that the adoption of stringent IP protection in RCEP would delay the availability of generic medicines, thus potentially reducing Australia's aid effectiveness in the region. For example, public health researchers have shown that if Vietnam were to agree to IP measures proposed by the US in the TPPA, more than half of the HIV population currently receiving antiretroviral treatment (already only 68% of people living with HIV who are eligible under WHO guidelines) would no longer have access.[36]

Conclusion

The PHAA is alarmed by leaked IP proposals to RCEP and other risks to public health that have arisen in other recent bilateral and regional trade agreements, including the Trans Pacific Partnership Agreement and Anti-Counterfeiting trade agreement.

This submission has raised serious public health concerns in the areas of intellectual property protection and enforcement and investor state dispute settlement mechanisms (ISDS).

Australia has an obligation to developing countries in our region not to support proposals that would compromise public health and access to affordable medicines. PHAA calls on the Australian Government to reject any proposals that would expand intellectual property protections in any of the RCEP countries, including but not limited to:

- provisions to expand the scope of patentability (e.g. to include new forms and new uses of known substances);
- provisions for extension to patent terms;
- proposals to extend protection of clinical trial data; and
- enforcement measures beyond TRIPS, particularly measures for the seizure of suspected IPR infringing medicines in-transit.

We strongly urge the Government to oppose the inclusion of Investor State Dispute Settlement provisions in RCEP as they are antithetical to public health. To ensure aid effectiveness, the Government should oppose the inclusion of stringent IP measures and ISDS in RCEP.

We also call on the Government to;

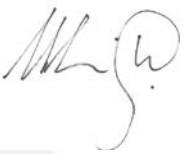
- oppose the inclusion of intellectual property in the definition of investment
- avoid provisions that would add to pharmaceutical expenditure in Australia
- work to ensure that the RCEP does not introduce 'TRIPS Plus' intellectual property privileges in developing countries
- preserve and affirm countries' ability to use legal flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and public health
- oppose enforcement measures in RCEP that go beyond TRIPS

We call for:

- The release of treaty text before it is endorsed by Cabinet, in sufficient time for independent assessment of its implications before finalisation.
- Mandatory health impact assessments during negotiation, after release of the final agreement and after implementation.
- Processes for systematic consultation and for release of position papers and composite drafts of treaty texts at key points during the negotiating process.
- Treaty text to explicitly prioritise health in any areas where health may conflict with trade or other goals.

The PHAA appreciates the opportunity to make this submission.

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



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