

Draft Letter from PHAA to Australian ministers for Health, Trade and the Prime Minister

Re Proposal from India and South Africa for a Waiver of certain provisions of the TRIPS Agreement for the duration of the Covid-19 Pandemic

Dear Minister,

The Public Health Association of Australia urges the Australian Government to support the proposed waiver when it returns to the TRIPS Council later this month.

We ask that, in determining its position, the Government gives full consideration to the following facts and arguments.

Many developing countries are facing the prospect of delays and significant cost barriers in accessing vaccines, medicines and diagnostics to control the pandemic (see below '1. Delays and Barriers'). Such delays and cost barriers are likely to be the cause of avoidable deaths. Such delays and cost barriers will perpetuate a heightened risk of international transmission including a prolonged threat to Australia's pandemic control.

In the face of the prospect of delays and cost barriers, the rapid scaling up of local production (where feasible) could make a big difference to pandemic control in developing countries. Scaling up local production calls for collaborative capacity building including organised technology transfer partnerships. Scaling up of local production would be greatly facilitated by waiving compliance with Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement (dealing with copyright, industrial designs, patents, and the protection of undisclosed information) in relation to Covid and for the duration of the pandemic.

Three main arguments were brought forward by countries opposing the waiver when it was first considered by the TRIPS Council: (i) that intellectual property protection is not a barrier to wider access to COVID-19 health products; (ii) that the flexibilities already provided for in the TRIPS Agreement are adequate; and (iii) that IP is necessary to fund innovation.

In fact, the protection of intellectual property is a very real barrier to scaling up local production, albeit not the only challenge (see below '2. IP is a real barrier to local production and availability');

In fact, the flexibilities already provided for in the TRIPS Agreement are not well suited to the task of scaling up across a range of health products and involving collaborating groups of countries (see below '3. Existing TRIPS flexibilities are not the answer');

In fact, the proposed waiver would only apply to Covid-19 products; would only apply for the duration of the pandemic; and would only apply to those countries who chose to make use of it. In view of the very significant funding mobilised internationally to support research and development for Covid-19 health products, it is most unlikely that allowing the limited waiver proposed would materially affect commercial incentives to invest in innovation for Covid-19 products during the pandemic;

The proposed waiver would only apply to countries who choose to make use of it. Intellectual property rights would remain untouched in countries who chose not to make use of the waiver (see below, '4. Adopting the waiver would be voluntary'). However, countries whose access to Covid products is secure should not stand in the way of those countries who need the policy space to scale up local production in the face of the very real threat of delays and cost barriers and the consequential morbidity and mortality.

It would be an act of international solidarity if Australia were willing to actively participate in an organised approach to capacity building and technology transfer in our region. Such technology transfer could be greatly facilitated by the suspension of IP protections under the proposed waiver.

PHAA strongly urges the Australian Government to support the proposed waiver in the TRIPS Council.

Further detail

1. Delays and barriers

The ACT Accelerator looks set to be underfunded and likely to face supply limitations consequent upon large scale advanced purchase agreements by countries and regional blocs.

The Covax facility excludes upper middle income countries and only provides vaccine doses for the priority population fraction, at maximum 20% of the population.

Widespread and large scale advance purchasing will greatly limit supplies for direct purchasing by developing countries and push up prices because of the competition.

Monoclonal antibodies (mAbs) look set to be one of the more promising therapeutics. However, the production of mAbs is slow and complex and the end products are notoriously expensive.

There are several promising rapid diagnostic tests (RDTs) in the pipeline and as they become available they will be critical for the control of pandemic surges (such as currently taking place in Europe and the US). The advantage of RDTs in an epidemic surge is the scope for widespread and frequent testing. For these reasons the RDTs are likely to be in short supply for quite a while and probably quite expensive (in the face of Northern demand).

Delays and barriers in accessing vaccines, medicines and tests carry a real threat of avoidable [morbidity and mortality](#).

2. Intellectual property protection is a real barrier to scaling up local production and availability

It is true that there are a range of barriers to be overcome in the development of diagnostics, treatments and vaccines, not all of which are related to IP. However, there are several examples that demonstrate that exclusive IP rights can be a significant barrier.

It is also true that IP disputes have created barriers to scaling up vaccine production in the US and that the voluntary licenses imposed by AstraZeneca on the Serum Institute of India include arbitrary restrictions on countries to whom vaccines can be sold.

3. Existing TRIPS flexibilities are not the answer

While the TRIPS Agreement contains flexibilities that can promote access, many WTO Members may face challenges in using them promptly and effectively. For instance, compulsory license offers a “product by product”, and “country by country” approach with variations in national laws, whereas the pandemic requires collective global action to tackle IP barriers associated with various platform technologies as well as specific products.

Where the IP barrier lies beyond patents – design, copyright or trade secrets - national laws may not provide for sufficient flexibilities. Further, Article 31bis, a mechanism to enable compulsory licenses

for export to without manufacturing capacity, does not provide an expedited solution and many countries have also opted out of using the mechanism.

4. Adopting the waiver would be voluntary

The waiver would suspend the protections provided under TRIPS for copyright, industrial designs, patents and technical knowledge.

One of these protections is the requirement for countries to legislate to enable national judiciaries to issue permanent and preliminary injunctions under Articles 44 and 50 of the TRIPS Agreement. In the present circumstances if countries do not injunct domestic manufacturers who breach IPRs deriving from sections 1,4 ,5 & 7 they would be exposed to the risk of country to country disputes and consequent sanctions. However, if the waiver proposal were adopted and a country chose to take advantage of it the provisions of Section 2 would not apply. Countries would not be obligated to enforce.

The IP protections provided for under TRIPS ultimately depend on state to state dispute settlement. Deployment of protected vaccine technologies might still be illegal under domestic law but under a waiver, government would not be obligated to issue injunctions. Where TRIPS flexibilities have been incorporated into domestic law, access to such technologies could still be facilitated through compulsory licensing, parallel importing or other mechanisms. However, the waiver would also be useful here having regard to the difficulties of using Article 31bis and the 'product by product' character of compulsory licensing.

PHAA stands ready to provide further information if such would be helpful.

Yours sincerely