

CSO Open Letter to Thailand's Prime Minister and the Chairperson of the Special Committee on the Study of the CPTPP's Impact Concerning Thailand's Position to Join the CPTPP

5 August 2020

Your Excellency,

We write this open letter to you on behalf as global community groups and civil society organizations that have been advocating to address inaccessibility of essential medicines at affordable prices due to intellectual property (IP) barriers and free trade agreements that introduce trade rules more stringent than the World Trade Organization's (WTO's) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Civil society groups and non-government organizations in Thailand have, since March 2020, been expressing their grave concerns over the adverse impact of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) on access to lifesaving medicines.

We strongly support these concerns being raised by the social movement in Thailand calling on their government not to join the CPTPP that was concluded and signed by 11 countries. We note that only 7 of the original 11 signing countries have ratified the CPTPP; Chile, Peru, Malaysia and Brunei are yet to even ratify the CPTPP.¹ Despite the fact that some critical provisions harshly undermining access to medicines have been suspended after the United States decided to withdraw from the CPTPP negotiations in 2016, serious concerns over access to medicines remain in the agreed CPTPP text.

Thailand is a globally recognized leader in the provision of universal healthcare and provides healthcare services for over 48 million people at no cost under the universal health coverage (UHC) scheme. Owing to the government's remarkable policy of issuing compulsory licenses (CLs) in 2006-2007, the UHC scheme has been able to provide life-saving drugs required for the treatment of HIV, heart disease and cancer for millions of patients by importing and producing affordable generic drugs at 82% - 97% lower costs than the patented drugs' prices. However, several provisions in the CPTPP could threaten Thailand's ability to produce and import affordable generic medicines.

Moreover, the CPTPP may also impact on the ability and capacity of Thailand's Government Pharmaceutical Organisation (GPO) to produce medicines and

¹ <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/Pages/comprehensive-and-progressive-agreement-for-trans-pacific-partnership>

vaccines. At the beginning of the AIDS pandemic it was GPO that provided the pathway for access to affordable generic anti-retrovirals and will also play an important role in addressing the COVID-19 pandemic. If the CPTPP limits the ability of the GPO in this regard, this will have an adverse impact not just in Thailand but in the region as well.

Among the serious concerns we have over the existing provisions of the CPTPP are:

1. Potential limitations and challenges to compulsory licensing

The CPTPP provisions in the Intellectual Property Chapter are linked to the Investment and the Dispute Settlement Chapters; for countries joining the CPTPP this creates a risk of being prosecuted in an arbitration for remedies that may require countries not to pursue CL policies and/or large amounts of compensation or damages when a country enforces its legitimate rights to issue CLs to address public health challenges.

While the CPTPP investment chapter includes some exceptions on compulsory licenses these may not be sufficient for protecting government action. While the provisions of Articles 9.8.5, 18.6 and 18.41 appear to support the ability of CPTPP's member countries to issue CLs, governments joining the CPTPP remain vulnerable to being sued by foreign investors in an arbitration.

Firstly, in the investment chapter, the CPTPP text states that the expropriation provisions of the chapter would not apply to compulsory licenses. However, this exception needs a much closer examination. Article 9.8.5 of the Investment chapter states that Article 9.8 on expropriation, “*shall not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation or creation of intellectual property rights, to the extent that the issuance, revocation, limitation or creation is consistent with Chapter 18 (Intellectual Property) and the TRIPS Agreement.*” This exception leaves it open to the multinational pharmaceutical industry to challenge any compulsory license issued by Thailand claiming that it is not in accordance with the TRIPS Agreement or the IP chapter of the CPTPP.

It may also be noted that the exception covers revocation and cancellation of patents but again these can be challenged with the claim that they are not in accordance with the TRIPS Agreement or the IP chapter of the CPTPP. This can create significant pressure on the use of patent oppositions by Thai health groups that have been used to successfully challenge evergreening patents.

It may also be noted that whether or not these arbitrations are successful, it would still cost the Thai government millions of US dollars just to defend itself in even one single arbitration case. Moreover, determination of TRIPS compliance should be done only at the WTO and not through other arbitration panels outside of the WTO.

Secondly, sub-article 3(b) under Annex 9-B of the Investment Chapter states that “*Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations, **except in rare circumstances**.*”. Intellectual property (IP) is considered a type of investment in the CPTPP. Therefore, infringement of the foreign investors’ IP, including through issuance of a CL, may be interpreted as “indirect expropriations” and/or “rare circumstances” that could be used as grounds for litigation in accordance with the investment chapter or even the Dispute Settlement Chapter.

To respond to the COVID-19 pandemic, several developed and developing countries have already taken action in relation to compulsory licensing. Israel has already issued a compulsory license for the anti-retroviral lopinavir/ritonavir while Chile, Ecuador and developed countries like Germany, France and Canada have amended their IP laws allowing for the easier and timely implementation of CLs. In Argentina and India, health groups are already challenging patent applications on remdesivir and on other COVID-19 health products.²

On the other hand, the cross-over-chapter conditions in the CPTPP make the situation more difficult for CPTPP governments to make similar decisions on issuing CLs. We are concerned that by joining the CPTPP, the Thai government may be taking on restrictions and limitations on their ability to issue CLs and use other TRIPS flexibilities to ensure production and supply of generic medicines as well as other health products. The threat of being prosecuted in an international arbitration for a vast amount of compensation or damages that the government cannot afford can create a powerful barrier to the use of these legitimate public health rights of the government.

Thirdly, the COVID-19 pandemic may require governments to remove intellectual property barriers not just for medicines but also for personal protective equipment (PPE) like masks, for diagnostic kits, for vaccines and for medical equipment like ventilators. We also note that the COVID-19 pandemic has thrown up multiple challenges to local and regional production of medicines, diagnostics, vaccines and PPE. Governments may have to consider not just whether patents are barriers to access to COVID-19 medicines and vaccines but also other forms of intellectual property. For

² <https://www.knowledgeportalia.org/covid-19>

instance, there may be barriers in the form of trade secrets on techniques, methods, compilations, processes and software applied in medical devices such as ventilators and diagnostic tests or in vaccine or medicine production.³ This can include manufacturing processes, test data, medical formulas, cell lines and other biological resources, chemical formulas, processes for manufacturing and for vaccines and biologic medicines, it can cover cell lines, genomic information, and other biological material.⁴

This is not a theoretical concern as reports have emerged that attempts to manufacture ventilator parts through 3-d printing were met with legal notices from IP owners.⁵ Thus, should the Thai government need take action on other forms of intellectual property on medicines, vaccines, diagnostics and medical equipment, these would not be protected or excluded by the language of the CPTPP. Other provisions of the CPTPP investment chapter such as those on prohibiting performance requirements may also affect Thailand's ability to require technology transfer for critical COVID-19 health products and the impact of these provisions also needs to be taken into account.

2. Creating barriers in the registration of generic drugs through patent linkage

Patent linkage, that is a TRIPS-plus provision, is also included in the CPTPP, in Article 18.53. The current practice in Thailand, as in many developing countries, keeps a drug's patent status and its registration status—its approval to market the drug—separate. Each of these issues is handled by separate government agencies with specific areas of competency. The patent office assesses whether a drug is innovative and novel enough to be patented, and the national drug regulatory authority assesses whether a drug is of a high quality—safe and effective enough to be registered for use by the population they are responsible for.

The CPTPP's patent linkage requirements create serious limitations on the ability of the national drug regulatory authority to register generic medicines. Under the provisions of the CPTPP, the national drug regulatory authorities are not permitted to approve registration filed for a generic drug if it potentially infringes existing patents, unless it is consented to by the patent holders. Or, drug regulators are required to notify the patent holders, prior to marketing of generic drugs, that others are seeking marketing approval and allow the patent holders to have enough time and opportunity to seek legal remedies from allegedly infringing drugs. In many cases, it can take 5-

³ https://www.southcentre.int/wp-content/uploads/2020/04/PB73_The-COVID-19-Pandemic-RD-and-Intellectual-Property-Management-for-Access-to-Diagnostics-Medicines-and-Vaccines_EN-1.pdf

⁴ <http://infojustice.org/archives/42493>

⁵ <https://www.medicaldevice-network.com/news/3d-printed-valves-covid-19-italy/>

10 years before disputes on drug patent infringement between patent holders and generic drug firms are settled. In the case of Thailand, this can also put the Thai GPO under tremendous pressure from legal notices and proceedings for the registration of generic medicines.

Patent linkage provisions delay the market entry of generic medications. By requiring drug regulatory authorities to take on the responsibility of policing patents, this aggressive TRIPS-plus provision hinders generic drug registration while circumventing patent dispute processes between the patent holder and the patent authorities.

3. Restrictions on government procurement and impact on GPO

The CPTPP also includes provisions in the Government Procurement Chapter that may require the Thai government to revoke privileges provided to the Government Pharmaceutical Organization (GPO), which is a state-owned enterprise producing and supplying essential medicines to the hospitals throughout the country at affordable prices and having 3.4 % of the market share. The very real impact of the Government Procurement chapter on the ability of Thailand to protect and promote its local pharmaceutical industry can be seen from how the developed countries in the CPTPP have analysed the provisions of the Government Procurement Chapter.

Canada has informed its companies that the “CPTPP expands Canada’s government procurement commitments with its existing free trade partners... provides Canadian suppliers with secure access to new government procurement opportunities in Australia, Brunei, Malaysia and Vietnam. Canadian businesses will now be on a level playing field with suppliers from other countries that already have government procurement commitments with these parties...With the CPTPP, Malaysia and Vietnam have taken on government procurement commitments for the first time. Canadian suppliers will benefit from this as both countries must carry out their procurement in a manner that is consistent with the CPTPP’s robust procedural rules. Any current or future domestic policy that CPTPP members adopt must be implemented in a manner that is consistent with their obligations under the CPTPP (i.e. treating goods, services and suppliers from other CPTPP countries no less favourably than domestic goods, services and suppliers).”⁶

Australia states that the, “The CPTPP supports the expansion of Australian health exports across the Asia-Pacific.” This includes, “commitments from all CPTPP Parties that allow Australian suppliers to bid for pharmaceutical and medical equipment government procurement contracts; and

⁶ https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptppg/sectors-secteurs/government_procurement-marches_publics.aspx?lang=eng

Commitments from all CPTPP Parties in relation to government purchasing by the health department or ministry, including the purchasing undertaken by all public hospitals in Malaysia and 34 hospitals operating as SOEs in Vietnam.”⁷

It is important to also note the possible impact of other CPTPP provisions on the GPO and the government’s ability to support domestic manufacturing more generally. For instance, legal experts have pointed out that the chapter on state-owned enterprises and monopolies requires government companies to act on the basis of commercial considerations (i.e., like a private business) when it comes to the purchase or sale of goods and services and even restricts preferential procurement from local producers by State Owned Enterprises. The chapter also prevents CPTPP Parties from providing non-commercial assistance to state-owned enterprises if this adversely affects another Party. This non-commercial assistance can include financial assistance (e.g. transfers of funds, grants, debt forgiveness and loans) or other forms of favorable treatment, such as shared distribution networks or R&D support.⁸ This can also impact any policies to support other local manufacturers in Thailand.

4. Threat of revival of suspended provisions if the US re-enters the CPTPP

There are several provisions relating to intellectual property that can have a devastating impact on public health and access to medicines that have been suspended from the CPTPP after the withdrawal of the US from the treaty. However, these provisions only remain suspended. Should the US re-join the CPTPP, there are serious concerns that they will create pressure for these provisions to be revived. These suspended provisions include requirements for granting new use/process patents, market exclusivity, patent term extensions.

5. Broader concerns of impact of CPTPP on COVID-19 pandemic responses

We are also greatly concerned about the broader impact that the CPTPP may have on the Thai government’s ability and flexibility to deal with the COVID-19 pandemic as it evolves. At present Thailand is clearly an early success story in having controlled initial infections. Should Thailand decide to open up to travel and tourism again, new infections are bound to emerge and various public health responses may be required. Moreover, it is evident that like many other countries Thailand too will have to respond to the economic consequences of COVID-19 restrictions. The CPTPP may create restrictions and limitations in this respect. For instance, researchers are

⁷ <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-health>

⁸ <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-019-0518-2#main-content>

alerting the international community that health and security exceptions in trade agreements like the CPTPP are not sufficient to protect government responses to COVID-19 from investment disputes and legal challenges.⁹

There are growing concerns that the range of government actions taken in the context of COVID-19 that could be challenged could include “restricting and closing business activities to limit the spread of the virus and protect workers, securing resources for health systems by requisitioning use of private hospital facilities, putting private healthcare providers under public control, or requiring manufacturers to produce ventilators, mandating relief from mortgage payments or rent for households and businesses, preventing foreign takeovers of strategic businesses stricken by the crisis, ensuring access to clean water for hand-washing and sanitation by freezing utility bills and suspending disconnections, ensuring medicines, tests and vaccines are affordable and even debt restructuring.”¹⁰ It is of extreme concern that international law firms are already advising multinational companies in this regard.¹¹ This has led to urgent growing calls from experts for a moratorium on investment disputes related to COVID-19 noting that “governments have the duty to protect their citizens and to stop the pandemic without fear of lawsuits by foreign-owned businesses or foreign shareholders.”¹²

6. Importance of GPO for regional and international access to COVID-19 medicines and vaccines

Thailand’s Government Pharmaceutical Organisation (GPO) is globally recognized for synthesizing generic anti-retroviral medicines in the 1990s paving the way for generic production of HIV treatment in Thailand and in many other developing countries. The importance of local producers is already evident in the COVID-19 pandemic. While other countries are being forced to wait in line for masks, Thailand’s GPO manufactures and supplies them locally, crucially to all the hospitals in Thailand. Similarly, GPO is already manufacturing and stockpiling potential COVID-19 medicines like favipiravir while other countries are having to rely on imports at high costs and with long waiting periods. GPO’s affordable production and technical expertise are crucial not just for Thailand but also for the Asia-Pacific region, particularly at this time when the world is facing the deadly COVID-19 pandemic and there is a critical need for independent local and regional production centres for medicines and vaccines.

⁹ <https://www.iisd.org/sites/default/files/publications/investor-state-claims-covid-19.pdf>

¹⁰ <http://s2bnetwork.org/sign-the-pen-letter-to-governments-on-isds-and-covid-19/>

¹¹ <https://corporateeurope.org/en/2020/05/cashing-pandemic-how-lawyers-are-preparing-sue-states-over-covid-19-response-measures>

¹² <http://ccsi.columbia.edu/2020/05/05/isds-moratorium-during-covid-19/>

For instance, GPO's recently commissioned vaccine production facility is reportedly working on local COVID-19 vaccines. If these are successful or even if the GPO produces other successful vaccine candidates, this would be very important not just in Thailand but also for the Asia-Pacific region that could look to GPO for vaccine supply. This is absolutely critical in the current scenario where it is clear that developed countries do not plan to share their vaccine supplies till their own populations are inoculated. With the growing impact of COVID-19 on the health budgets of all countries, GPO's manufacture of other critical medicines at affordable prices is also critical both to the Thai UHC programme and possibly even to health programmes in neighbouring countries. However, CPTPP requirements will likely impact the ability of the Thai government to continue procuring from the GPO, delay the registration of GPO generic products and open up GPO to lengthy and expensive legal proceedings from foreign companies.

The impact of the CPTPP can be multiple and varied on Thailand and on the region if Thailand's local production capacity is impacted. In financial terms, according to a study on "Impact of the CPTPP on Access to Medicines" presented at the meeting of an extraordinary sub-committee at the Parliament on the 14th of July 2020, the primary results indicate that if Thailand joins the CPTPP with patent linkage provisions and restrictions in Government Procurement Chapter will result in an increase in the annual pharmaceutical expenditure from 1.2% of its GDP in 2019 to 3-4% in the next three decades in Thailand. The pharmaceutical import dependency ratio will increase from 71% in 2019 to 89% in the next 30 years. The scenario of severe impact and high market competition, especially from drug importation showed that in the next three decades the domestic pharmaceutical market value of Thailand may be reduced by over USD 3.3 billion, and the GPO's market value may be reduced by over USD 33 million.

Thailand has been an important leader in the international community in promoting and protecting the use of TRIPS flexibilities by developing countries to ensure access to affordable medicines. In particular, Thailand strongly supported the UN Secretary General's High Level Panel on Access to Medicines and its 2016 Report. In this report, the High Level Panel has clearly stated that: "Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health."¹³

If it joins the CPTPP, Thailand will limit the competency and flexibility of its government to pursue its policy on public health safeguards and its local pharmaceutical capacity will be severely undermined. That will create a serious risk of high prices and an increased burden of medicine expenses. The universal health coverage scheme will be inevitably destabilized due to the high costs of medicines, and people may be forced to pay out of their pockets for expensive

¹³ <http://www.unsgaccessmeds.org/final-report>

medicines or may be denied access to treatment. That will be disastrous to Thailand's public health system. For the region, any limitation on the ability of the Thai GPO to manufacture, register and export generic medicines will have a much wider impact.

The COVID-19 pandemic has shown that countries with strong universal healthcare systems and independent local production capacities for diagnostics, medicines and vaccines have been the most successful in addressing the pandemic. We strongly urge the government of Thailand that is an international leader in both these areas to maintain its priority on good public health policies. Joining the CPTPP will threaten the careful balance that Thailand has so far maintained between trade and health and prioritise the profit making interests of the multinational pharmaceutical and health industry.

We respectfully urge the government of Thailand not to join the CPTPP.

Signatories:

#	Organization name	Country
1	100% Life	Ukraine
2	Action against AIDS	Germany
3	AIDS Access Foundation	Thailand
4	AIDS and Rights Alliance for Southern Africa (ARASA)	Namibia
5	AGEP'C Public Foundation	Kazakhstan
6	Allende Program in Social Medicine	USA
7	Alternative Agriculture Network	Thailand
8	Asia Pacific Network of People Living with HIV (APN+)	Thailand
9	Associação Brasileira Interdisciplinar de AIDS (ABIA)	Brazil
10	Consumers Association of Penang	Malaysia
11	Delhi Network of Positive People	India
12	Drug Study Group	Thailand
13	Drug System Monitoring & Development Center	Thailand
14	Fundacion Grupo Efecto Positivo (FGEP)	Argentina

15	Foundation for AIDS Rights	Thailand
16	Foundation for Consumers	Thailand
17	Foundation for Integrative AIDS Research (FIAR)	USA
18	FTA Watch	Thailand
19	Grupo de Trabalho sobre Propriedade Intelectual (GTPI)	Brazil
20	Health & Development Foundation	Thailand
21	Health Global Access Project (Health GAP)	USA
22	IFARMA Foundation	Colombia
23	International Treatment Preparedness Coalition	South Africa
24	Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru)	Russian Federation
25	International Treatment Preparedness Coalition Latin American and Caribbean (ITPC-LATCA)	Guatemala
26	International Treatment Preparedness Coalition in Middle East & North Africa (MENA)	Morocco
27	Indonesia AIDS Coalition	Indonesia
28	Lawyers Collective	India
29	NGO Answer	Kazakhstan
30	Open Society Georgia Foundation	Georgia
31	Partnership Network (Association)	Kyrgyzstan
32	People's Health Institute	South Korea
33	People's Health Movement (PHM) Korea	South Korea
34	People's Health Movement, South-East Asia and Pacific (PHM SEAP)	South-East Asia & Pacific Region
35	People's Health System Movement	Thailand
36	People PLUS	Belarus
37	Positive Initiative	Moldova

38	Positive Movement	Belarus
39	Positive People Armenian Network	Armenia
40	Sahabat Alam Malaysia (Friends of the Earth Malaysia)	Malaysia
41	Sukaar Welfare Organization	Pakistan
42	Thai Holistic Health Foundation	Thailand
43	Thai Network of People Living with HIV/AIDS (TNP+)	Thailand
44	Third World Network.	Malaysia
45	Treatment Action Group (TAG)	USA
46	Vietnam Network of People living with HIV (VNP+)	Vietnam

Individuals:

#	Name	Country
1	Anand Grover, Former UN Special Rapporteur on the Right to Health (2008-2014), Senior Advocate, Supreme Court of India	India
2	Professor Brook K. Baker, Northeastern U. School of Law	USA
3	Bruce Tushabe	Uganda
4	Claudio Schuftan	
5	Howard Waitzkin, MD, PhD, FACP Distinguished Professor Emeritus, University of New Mexico	USA
6	Sharad Onta	Nepal
7	Dr. Mira Shiva for Initiative for Health & Equity in Society	India
8	Peter Wiessner	Germany
9	Saludy Farmacos	USA