Doctors Without Borders/ Médecins Sans Frontières (MSF) Written Submission to the Australian Senate Foreign Affairs, Defence and Trade References Committee inquiry into the Proposed Trans-Pacific Partnership Agreement (the TPP).

October 2016

Summary:

Doctors Without Borders/Médecins Sans Frontières (MSF) provides the following written submission in supplementing our previous submission in March 2016, regarding the negative impact that the Trans-Pacific Partnership Agreement (TPP) will have on access to affordable medicines and biomedical innovation.

MSF is an international independent humanitarian organization that provides medical assistance in over 60 countries, in need of both affordable access to and innovation for medical technologies.

Competition has a proven record as a critical tool to lower drug prices and help deliver effective medical care. Intellectual property trade obligations and other protections for pharmaceutical companies that limit price-lowering generic competition are driving up drug prices.

The TPP puts in place far-reaching new government obligations that lengthen, strengthen and broaden patents and other pharmaceutical monopolies. The effect will be to further delay access to generic medicines beyond current requirements of international trade law. The provisions also undermine public health safeguards that governments and others have to promote access to medicines and limit abuse. The TPP represent a departure from previous Australian global health commitments towards developing countries.

Unless is modified, the TPP will exacerbate the global crisis of high drug prices. For example, the TPP will not allow national regulatory authorities to use existing clinical data demonstrating a pharmaceutical product's safety and efficacy to authorize the sale of competitor products, even in the absence of patents. The additional monopoly protection provided for biologic drugs and vaccines will keep already very expensive products out of the hands of millions. The TPP would also force governments to extend existing patent monopolies beyond current 20-year terms at the request of pharmaceutical companies, and to redefine what type of medicine deserves a patent, including mandating the granting of new patents for modifications of existing medicines.

The TPP also fails to address the urgent need for reform in the biomedical innovation system. The sole reliance on high medicine prices, backed by exclusivities and monopolies, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases

where patients have limited purchasing power like neglected tropical diseases or where drugs have to be used sparsely like antibiotics.

The negative impact of the TPP on public health will be felt for years to come, and will not be limited to the 800 million people in the current 12 TPP countries. It is a dangerous blueprint for future agreements and aims at being a standard-setting agreement and to create new global trade norms. Instead of doubling down on a broken model, the Australian Government should collaborate with other governments to introduce new approaches that promote both innovation and access.

It is not too late to prevent the further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the Australian government to protect the right to health of millions of people that will be negatively impacted if the TPP is approved in its current form. The TPP should be modified or rejected.

For more information on MSF's concerns with the TPP, please read our 2016 issue brief on TPP and Health: https://www.msfaccess.org/content/issue-brief-trading-away-health-trans-pacific-partnership-agreement-tpp-2016

Introduction

Doctors Without Borders/Médecins Sans Frontières (MSF) would like to provide the following written submission regarding the impact that the Trans-Pacific Partnership (TPP) trade agreement will have on access to affordable medicines and biomedical innovation for consideration by the Foreign Affairs, Defence and Trade References Committee inquiry into the Proposed Trans-Pacific Partnership Agreement (the TPP).

MSF is an international humanitarian organization that provides impartial medical assistance in more than 60 countries. In 2014 we performed more than eight million outpatient consultations, treated more than two million malaria cases, vaccinated more than 1.5 million in measles outbreaks, supported HIV/AIDS and drug-resistant tuberculosis treatment programs, and responded to other medical emergencies ranging from Ebola outbreaks in West Africa, to the refugee crisis in Europe, to armed conflicts in Syria, Yemen and Afghanistan. A more detailed description of our operational activities in 2014 is available in our annual activity report.[1]

As a medical treatment provider that needs both affordable access to and innovation for medical technologies, MSF is able to speak about the relationship between trade, intellectual property and health, and about the role competition has played in enabling access to medical care for millions.

Intellectual property trade obligations and other protections for pharmaceutical companies that limit competition are driving up drug prices worldwide. Unless modified, the TPP will exacerbate the global crisis of high drug prices. Provisions in the TPP will lengthen, strengthen and broaden monopolies for pharmaceutical companies, delaying access to affordable medicines for millions beyond current requirements of international trade law. The TPP will also fail to address the urgent need for reform in the biomedical innovation system.

MSF urges the Foreign Affairs, Defense and Trade Committee and the Australian government to seriously consider the negative impact the TPP will have on the health of millions of people before ratifying, implementing and encouraging additional countries to adopt to the TPP's restrictive provisions for pharmaceuticals.

Importance of competition for access to affordable medicines

MSF's medical operations have been challenged by the high price of medicines for many years. In 2001, high prices left MSF unable to save the lives of our patients. Pharmaceutical companies charged MSF and others an astronomical US $10,000 per person, per year for HIV medicines. This meant that MSF and governments, in the face of thousands of people dying daily from AIDS-related illnesses, could only provide treatment to a very limited number of people. In response, affected governments applied legal safeguards to remove patent barriers and foster generic competition and HIV treatment costs fell, virtually overnight, to one US dollar a day per person.[2]

With competition, prices for first-line HIV medicines have continued to fall and today almost 16 million people receive treatment,[3] including through Australian government-funded programs such as the Global Fund for AIDS, Tuberculosis and Malaria (Global Fund). In 2012, generics accounted for 96% of all treatments purchased by donor-funded programs like the Global Fund.[4] The reliance on generic competition by MSF and by government-funded donor programs provides important savings that stretches investments in global health further, saving millions of lives. For Australia, this investment includes the more than half a billion dollars pledged the Global Fund since 2004[5].

Price-lowering generic competition remains critical to the ability to deliver effective care. We need generic competition for new HIV medicines that sustain the lives of patients on treatment and provide better medical outcomes. Currently patented HIV medicines can be 20 times more expensive.[6]
We also need access to affordable treatment for many other diseases. New medicines to treat hepatitis C, which chronically affects up to 150 million people worldwide[7] and close to a quarter of a million people in Australia alone,[8] provide a critical illustration. These medicines, including Gilead's sofosbuvir and combination products, offer the potential for a cure. However, patents and other monopolistic protections have allowed pharmaceutical companies like Gilead to charge exorbitant prices.

Australia has laudably committed to making these medicines available to all Australians living with hepatitis C, a move "that could all but eradicate the deadly and debilitating disease within a generation." However, subsidising access to four treatments that cost patients up to $100,000 per person will cost the Australian government a billion dollars over the next five years.[9] Given that it only costs an estimated $101 per person (or slightly more than one dollar per pill) to produce a key treatment, sofosbuvir, responsible for much of these costs,[10] these high prices paid by patients and governments like Australia are clear evidence of Gilead's monopoly abuse.

While new hepatitis C medicines are less expensive in other countries, they are still unaffordable, especially in developing countries considered 'middle-income' economies where most people with hepatitis C reside. As generic treatments are starting to enter the market, prices are falling[11] in some countries that have safeguards that curb industry abuse and promote competition.[12] However, if the TPP is implemented in its current form, countries will have to change their legal regimes and be in the same position as the Australia, facing billion-dollar budget commitments in order to respond to the public health needs of their populations. Many of those countries are still low or middle income countries with insufficient domestic resources to pay for expanded health care, and are also facing reduced donor assistance for health at the same time that the TPP would mandate significantly increased expenditures for new medicines and vaccines.

As illustrated in the 2013 Pharmaceutical Patents Review and relevant submissions, "pharmaceutical monopoly protections already cost Australian taxpayers hundreds of millions of dollars each year."[13] For example, in Australia, the result of the introduction of patent term extensions, a rule that will be exported to developing countries under the TPP, was an estimated increase in "annual cost to the Pharmaceutical Benefit Scheme (PBS) from $6 million in 2001- 02 to $160 million in 2005-06," due to a delayed entry to the PBS of cheaper generic drugs.[14]

The TPP will exacerbate the global crisis of rising medicine prices

Intellectual property global trade obligations for pharmaceuticals, now nearly fully implemented worldwide through the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) are already driving up drug prices by delaying competition. The TPP will exacerbate these challenges by unnecessarily strengthening pharmaceutical companies' monopolies and market power.

While the text has improved over initial proposals from the United States, mostly due to the widespread opposition of the rest of the TPP countries, the TPP will still go down in history as the worst-ever trade agreement for access to medicines.

Our analysis of the now publicly released text shows that the TPP puts in place far-reaching new obligations for governments that lengthen, strengthen and broaden patents and other pharmaceutical monopolies beyond international trade rules established by the TRIPS Agreement and restrict access to price-lowering generic competition. The provisions also undermine public health safeguards that

governments and others have to limit abuse, affirmed by the 2001 WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA 61.21).

Developing countries currently part of the TPP negotiation, namely Vietnam, Malaysia, Mexico and Peru, will be forced to change their laws to incorporate abusive new monopoly protections for pharmaceutical companies that will limit access to price-lowering generic competition.

Examples of these new obligations are summarized in an annex to this submission. For a more detailed analysis, please refer to MSF's issue briefs and analysis, available online.[15]

The TPP's overall negative impact on health and access to medicines

The overall negative public health impact of the TPP has been recognized by many others, including but not limited to the World Health Organization,[16] UNITAID,[17] the Holy See[18] and the World Medical Association.[19]

The negative impact of TRIPS-plus provisions that expand protections for pharmaceutical companies at the expense of affordable access to medicines, beyond what is currently required by international trade rules through the WTO's TRIPS Agreement has been well documented.[20] For example, a 2009 study evaluating the impact that just two TRIPS-plus provisions like those included in the TPP would have on Peru if implemented in a different trade agreement estimated that they "would lead to an increase of 459 million USD in Peru's total pharmaceutical expenditure in 2025 and a cumulative increase in expenditure of 1267 million dollars (at present value, PV) for the same year."[21]

One analysis of the TPP's overall potential impact on the cost of health care found that in Vietnam HIV treatment access would be significantly affected. The results indicated that "82% of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30% of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPP proposals" as identified in leaked versions of TPP negotiating texts. That is less than half of the HIV-treatment eligible population receiving treatment in Vietnam as of November 2014, according to the study. As the study also highlighted, "similar price impacts can be expected for other countries participating in the TPP."[22]

Below we highlight some of the specific provisions included in the TPP and their effects on access to medicines.

The TPP lowers standards of patentability

Under the WTO's TRIPS Agreement governing global intellectual property obligations, governments have to grant 20-year patents on pharmaceutical products but also have important flexibility to define what does and does not deserve a patent in a way that addresses the needs of their own citizens and innovation system and prevents abuse of the patent system, as long as they abide by the patentability criteria and patentable subject matter agreed as international norms.

It is in the public interest for governments to retain these flexibilities, including the ability to strengthen patentability criteria and limit industry patent evergreening and other abusive practices. Allowing for stricter patentability curtails the worst excesses of the patent system, ensuring that innovators focus their energies on truly useful and new drugs and other medical technologies, rather than business strategies that extend existing patent monopolies with low or no inventive and societal contribution. Australia recognized this with its own legislative amendments in 2012 under the 'Raising the Bar Act,' which was "intended to moderate the problem [of evergreening] somewhat…"[23]

Governments should continue to make adjustments to its patent system to achieve a better balance between rewarding innovation and providing for health and other public needs. The TPP should not prohibit signatory countries from doing the same. However, the current text of the TPP mandates the granting of secondary patents on modifications of existing drugs. The relevant section is Article 18.37 Patentable Subject Matter of Chapter 18 (Intellectual Property) that reads as following:

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.

The obligation to grant new patents on modifications of known products is not required under international trade law, and it threatens to restrict or delay access to price-lowering generic competition by extending patent monopolies beyond the 20-year original patent term. It is difficult to completely estimate how long monopolies will be extended, and most likely the effects will differ drug by drug and country by country, but a recent study found that granting secondary pharmaceutical patents extends the life of monopoly protections by an average of more than six years in the US.[24]

The TPP mandates additional data regulatory protection

The TPP mandates that clinical test data be protected with a period of exclusivity, including for the first time in a US-lead trade agreement a specially-extended period of protection for biologic products, independent and additional from patent protection.

Biologics are a class of medical product that include many drugs and vaccines[25] that are already very expensive and in too many instances unavailable as a prevention and treatment option in many of the countries where MSF works due to high prices and reduced competition. Example of biologics products include medicines for the treatment of cancer, arthritis, and diabetes and vaccines like PCV for the prevention of pneumonia. MSF currently has an ongoing public campaign to reduce the price of pneumonia vaccines to increase access for children living in developing countries: http://www.afairshot.org/

This regulatory exclusivity prevents drug safety authorities from using existing clinical data to give market approval to generic or biosimilar medicines, delaying price-lowering competition and keeping medicines prices high for longer.

Protection of data with exclusivity for any class of drugs is not required by the TRIPS Agreement or any other international law and the United Nations recommends against implementation of data exclusivity, especially in developing countries. An evaluation of the impact of ten years of implementation of data exclusivity rules in Colombia from 2003-2011 found that they resulted in an increase of more than US $396 million in additional expenses for the public health system.[26] Another study found once Guatemala enacted data exclusivity due to DR-CAFTA obligations, some medicine prices rose as much as 846 percent.[27] In Jordan data exclusivity enacted due to the US-Jordan trade agreement, delayed the introduction of cheaper generic versions of 79% of medicines between 2002 and 2006. Prices of medicines under data exclusivity in Jordan were up to 800% higher than in neighbouring Egypt.[28]

An assessment by the US Federal Trade Commission found that additional exclusivity for biologics is not warranted to promote innovation, and it imperils the public health and budgetary benefits to accelerate the entry of follow-on biologics.[29] In the United States, the Obama Administration estimates that reducing

data exclusivity for biologics by five years would result in savings of nearly US $7 billion over ten years.[30]

In Australia, according to a submission made by Gleeson, Lopert and Moir to the Department of Foreign Affairs and Trade, "if biosimilars had entered the market prior to July 2013 for each of the ten biologics accounting for the highest government expenditure, this would have resulted in over $205 million in savings through public subsidies alone in the year 2013-14."[31]

We welcome the leadership of Australia and other countries during the TPP negotiation to limit the public health negative impact of the initial US government demands on biologics but we read with concern reports that Australian trade envoy has reassured pharmaceutical companies that the TPP will provide "at least eight years of market protection" for biologic drugs, and "potentially as long as 12 to 17 years"[32] and we reiterated the need for Australia not to trade away health in this important area.

Additional provisions of concern for access to medicines

MSF is also concerned about other provisions included in the TPP, including provisions in the "Transparency and Procedural Fairness Chapter" that could restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs and provisions in the "Investment Chapter" that give pharmaceutical companies the right to sue governments for regulations and decisions that reduce their expected profits in private, supra-national investor-state dispute settlement (ISDS) tribunals, the decisions of which can usually not be appealed.

As MSF highlighted in a 2014 submission to the Senate Foreign Affairs, Defence, and Trade Legislation Committee, "the impact and potential impact of ISDS clauses on public health as assessed by MSF pose an unnecessary risk to public health objectives – which includes the serious concern that these clauses' affect the ability of governments to ensure access to affordable medicines."[33] For example, pharmaceutical company Eli Lilly is currently suing the Government of Canada for $500 million (CAD) over Canada's patent policies that resulted in the rejection of two of Eli Lilly's patent applications under similar provisions in the North American Free Trade Agreement (NAFTA).

As demonstrated in the Eli Lilly case, ISDS allows companies to challenge the legitimate exercise of a national law for pharmaceutical patenting. In addition to undermining the use of the law, it could also have a chilling effect on the further applications or adoption of national laws that uphold international obligations and also make use of existing public health safeguards to better balance the obligation to grant monopoly pharmaceutical protections with a country's public health policy needs.

The TPP is bad for biomedical innovation

MSF recognizes the need to reward innovation and finance research and development (R&D). We are a humanitarian medical organization that welcomes innovations that improve medical outcomes. However, the TPP will also fail to address the urgent need for reform in the biomedical innovation system. The sole reliance on high medicine prices, backed by monopolies expanded and further entrenched by the TPP, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases disproportionately affecting developing countries, where patients have limited purchasing power.

In fact, the current innovation model is failing patients in all countries. For example, in Australia, a review of 59 new drugs approved between 2005 and 2007 found only seven (<12%) were rated "important innovations,"[34] due in large part to the fact that the current innovation model incentivizes development of new products that do not represent increased therapeutic benefit to patients. In contrast to

the development of new treatments that do not represent a therapeutic advance for patients, despite the need for new antibiotics that must be affordable and used sparingly, pharmaceutical companies, including Pfizer, the world's largest, have abandoned antibiotic drug development altogether. We are now also facing a crisis of growing antibiotic resistance that outpaces the development of new antibiotics. Governments are already funding innovation and providing drug companies with tax incentives and subsidies to promote innovation while paying record prices. In some cases, governments are paying twice – first by paying a significant percentage of the R&D costs and second by paying high prices. The Human Papillomavirus (HPV) vaccines for the prevention of cervical cancer is an example, originally developed by Australian researchers from University of Queensland and reportedly priced at $450 per person for non-government purchases in Australia.[35]

Seeking longer and stronger monopoly protection for pharmaceutical companies not only does little for innovation, but it perpetuates a failed innovation business model that is hurting Australian patients as well as patients abroad. We believe new approaches to promote medical innovation, including approaches that MSF and others have supported, are demonstrating that significant medical breakthroughs with access are possible – in particular, when incentives break the link between the cost of R&D and the price of the end product.[36] Instead of doubling down on a broken model, the Australian government should collaborate with other governments to introduce new approaches that promote both innovation and access. In this sense, TPP is a missed opportunity to promote public health driven biomedical innovation.

MSF has recently published a report on biomedical innovation, "Lives in the Edge," that provides an overview of some the challenges with the current innovation system and our proposals on steps governments need to take to amend it. The full report is available here: http://www.msfaccess.org/content/report-lives-edge-time-align-medical-research-and-development-people%E2%80%99s-health-needs

Harmful provisions for health in other trade agreements are a worrying trend: RCEP

At the same time Australia is considering ratification and adoption of the TPP, Australia's trade negotiators are actively pursuing another regional trade agreement with similarly concerning provisions for access to medicines, health and biomedical innovation. The Regional Comprehensive Economic Partnership (RCEP) is a trade agreement that has been under negotiation since 2012 between Australia, the ten Association of South East Asian (ASEAN) members, India, New Zealand, China, Japan and the Republic of Korea.

According to leaked texts, countries are being asked to consider similarly damaging provisions for access to medicines and pro-patient innovation, including mandatory data exclusivity, patent term extensions and broadening and strengthening of IP enforcement. Given that RCEP includes ten developing countries, including several UN-classified "Least Developed Countries" (LDCs), and India, a country whose role in providing access to affordable generic medicines has been so significant it is known as the "pharmacy of the developing world," these harmful proposed rules are all the more concerning. We urge Australia and all RCEP negotiators to refuse these harmful provisions and to ensure they do not make it into a final agreement.

This RCEP issue brief contains more information on MSF concerns on impact on health and innovation: http://www.msfaccess.org/sites/default/files/ACCESS_Brief_RCEPTradingAwayHealth_ENG_2016.pdf

Conclusion: the TPP is a bad deal for medicine

The TPP is a bad deal for medicine; it's bad for humanitarian medical treatment providers such as MSF, and it's bad for people who need access to affordable medicines around the world, including in Australia. We urge the Australian government to reject TPP and play an active role in rejecting harmful proposals in the current RCEP negotiation, taking full consideration of the health impact and promoting policies that ensure both innovation and access to affordable medicines for all.

MSF has for years raised the alarm about the challenges of high prices and lack of needs-driven incentives to promote innovation for our medical operations. Governments around the world are under increasing pressure from patients, payers and medical providers in their own countries to address exorbitant drug pricing as barriers to effective medical care and sustainability of health programs and the emergency of antibiotic resistance with a nearly dry pipeline for new drugs. It is incomprehensible that at the same time the TPP terms will lock in high prices and monopolies as the dominating incentive mechanism for biomedical innovation and keep price-lowering generic competition off the market for years to come.

At a time when the high price of life-saving medical tools, including hepatitis drugs, biologics and vaccines is becoming a barrier to effective medical care worldwide and access to medicines are being rationed because of high prices, it very concerning to see governments considering locking in rules that will keep prices high for longer and will do little to advance the fundamental changes that are needed in the biomedical innovation system. Instead countries should tune in to the growing recognition that high prices are a global and unsustainable challenge and consider alternative ways to incentivize innovation which do not require a trade-off between tomorrow's innovations and the lifesaving medicines we need today.
There are ongoing efforts in international fora about how this could be achieved, including in the commitments made by Australia and all UN Member States on new models for biomedical innovation that de-link research and development costs from prices and sales to ensure both affordability and stewardship at the UN Political Declaration on Antimicrobial Resistance.

In the same direction, the recently released report of the UN Secretary General Ban Ki-moon's High Level Panel on Access to Medicines acknowledges the failings of today's system of monopoly protections and high prices both for access and innovation and made a variety of recommendations[37] including increase transparency, accelerating competition, reforming incentives for innovation and preserving rules that help governments bring prices down. The Report also alerts against the negative public health impact of provisions included in the TPP and recommends a full public health assessment.

Every country has the right and the obligation to take steps to increase access to medicines and implement a patent and regulatory system in line with its public health needs; the TPP will take away key components of that flexibility and limit the tools that governments and civil society have to try to ensure access to affordable medicines.

The negative impact of the TPP on public health will be enormous, be felt for years to come, and will not be limited to the 800 million people living in the current 12 TPP countries. It is a dangerous blueprint for future agreements and aims at being a standard-setting agreement and to create new global trade norms.
Pharmaceutical companies already enjoy some of the highest profit margins and strongest monopoly protections of any industry. Granting them extended and additional market exclusivity and power is unnecessary to promote innovation and it will cause needless death and suffering. We urge the Australian government to uphold its obligations to protect public health and fight back against unjust profiteering.

It is not too late to prevent further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the Australian government to protect the right to health of millions of people

that will be negatively impacted if the TPP is approved in its current form. The TPP should be modified or rejected.

Annex

Examples of new TPP intellectual property obligations that will keep medicines prices high

TRIPS-Plus Provision	Description and Impact
Lowering the standards for patentability – creating new patent monopolies for existing medicines.	The TPP requires countries to grant secondary patents on modifications of existing medicines for at least one of the following: new uses, methods of use or new processes of a known product. This provision is designed to prevent countries from using public health safeguards in their national patent laws and judicial decisions that limit abusive patent evergreening. The effect will keep medicine prices high by delaying the availability of price-lowering generics.
Creating data/market exclusivity – preventing drug regulatory authority (DRA) from approving any generic or biosimilar drug formulation during the period of exclusivity.	The TPP requires countries to protect clinical test data with a period of market exclusivity for at least 5 years for small molecules and at least 3 years for modifications on existing medicines, or 5 years for combinations, which facilitates abusive data evergreening. Furthermore, the TPP contains, for the first time in a US trade agreement, a data protection obligation for a class of products called biologics, already expensive products which are used to treat and prevent cancer, diabetes and many other conditions. The protection for biologics is for at least 8 years of market exclusivity or 5 years with other measures that provide a comparable outcome. These data obligations grant a distinct monopoly protection to medicines, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delaying competition.
Mandating patent term extensions – extending 20-year patent terms.	The TPP requires countries to create two mechanisms to extend patent terms. At present, patents on drugs in most countries last for 20 years from the date of filing. The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from competition.
Requiring new forms of intellectual property enforcement – granting customs officials new powers to detain trade of medicines, requiring mandatory injunctions for alleged IP infringements; raising damages amounts.	The TPP contains a variety of obligations that increase the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines, and limits countries' judicial systems' capacity to balance commercial interests and public health interests in intellectual property disputes. These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law.

MSF is also concerned about other provisions in the TPP, including:

- Provisions in the Transparency and Procedural Fairness Chapter that could restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs.
- Provisions in the Investment Chapter that give pharmaceutical companies the right to sue governments for regulations and decisions that reduce their expected profits in private, supranational investor-state dispute settlement (ISDS) tribunals whose decisions are usually un-appealable.
- Provisions in the Technical Barriers to Trade Chapter that prohibit governments from requiring pharmaceutical companies to disclose "sale or related financial data concerning the marketing of the product" or "pricing data" as part of approval for marketing determinations.

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