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The Hon Kevin Rudd MP
Prime Minister of Australia
Parliament House
CANBERRA ACT 2600
AUSTRALIA

Geneva, 15 July 2013

Dear Prime Minister,

We are writing to express serious concern over provisions under negotiation in the Trans-Pacific Partnership Agreement (TPP) that threaten to restrict access to affordable medicines for millions of people, especially in low- and middle-income countries. Unless certain damaging provisions are removed, the TPP has the potential to become the most harmful trade pact ever for access to medicines.

Médecins Sans Frontières/Doctors Without Borders (MSF) is an independent international medical humanitarian organization that delivers medical care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries. In order to fulfill its mission, MSF requires access to affordable medicines.

Generic competition has proven to be the best way to reduce drug prices and improve access to treatment. MSF began providing antiretroviral (ARV) treatment for HIV/AIDS in 2000 when the cost of treatment was more than 10,000 USD per patient per year. MSF now treats 285,000 people in HIV/AIDS projects in 21 countries, mostly with generic drugs produced in Asia. These generics have reduced the cost of treatment by nearly 99% to less than 140 USD per patient per year. Ministries of health, humanitarian medical treatment providers like MSF, and donors routinely rely on affordable quality generic medicines to treat a variety of health needs.

The TPP is being negotiated without opportunity for meaningful public input. Leaked texts, however, indicate that stringent intellectual property (IP) provisions proposed by the United States go well beyond rules established by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These demands, summarized in an annex to this letter, will roll back public health safeguards and flexibilities enshrined in international law, and put in place far-reaching monopoly protections that will restrict generic competition and keep medicine prices unaffordable.

We believe this presents a direct threat to the future availability of affordable medicines for MSF's patients and for millions of others around the Asia-Pacific region. We are also concerned that the TPP, billed as a '21st century model trade agreement', could become a global standard, with worldwide damaging repercussions for access to treatment.

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Negotiating countries should reject provisions that will harm access to medicines and ensure that the final text is aligned with relevant global public health commitments. Such commitments include the 2001 WTO Doha Declaration on TRIPS and Public Health and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property.

The medical research and development (R&D) system as it stands today does not deliver innovation for neglected populations and it results in unaffordable medicine prices for patients worldwide. Stricter IP rules reinforce, instead of reform, this broken system. There is a pressing need for a paradigm shift in the way pharmaceuticals are researched and developed, and how intellectual property is applied to medicines as global public goods. Governments should introduce global norms which delink drug development and price. MSF believes this is essential to closing the gap in access to medicines for millions of people around the world by promoting both innovation and access.

We thank you for your attention and are available for further discussions and information.

Sincerely,

Dr. Unni Karunakara,
International President
Médecins Sans Frontières

Dr. Manica Balasegaram
Executive Director, Access Campaign
Médecins Sans Frontières

Paul McPhun
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C.C.:
Tanya Plibersek, Minister for Health and Medical Research
Chris De Cure, Australia TPP Lead Negotiator

MEDECINS SANS FRONTIERES

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ANNEX

Certain provisions are critical to maintaining legal and regulatory flexibility for the protection of public health and access to medicines. MSF urges TPP negotiating countries to:

1. **Retain flexibility in determining patentability criteria and subject matter.** The TPP proposal requires new patents be granted for existing drug modifications, even in the absence of improved therapeutic efficacy, facilitating abusive patent evergreening practices that extend monopolies. The TPP also requires the patenting of diagnostic, therapeutic, and surgical methods, potentially exposing doctors to liability for performing patented procedures.

2. **Allow pre-grant opposition.** Pre-grant opposition is an important tool to combat weak patents that allows both public oversight and technical support to national patenting authorities. The TPP proposes to prohibit this legal safeguard, making challenging undeserved patents more expensive and cumbersome.

3. **Not mandate data exclusivity.** Data exclusivity is not required by international law and represents a way for pharmaceutical companies to delay generic competition, even in the absence of a patent barrier. If data exclusivity is imposed, generic companies face the choice of unethically repeating costly clinical trials on drugs, or waiting out the term of data exclusivity before registering a product. The TPP proposal mandates data exclusivity, and proposes to extend its coverage for biological products.

4. **Not mandate patent linkage.** The processes of patenting a drug and obtaining regulatory approval are usually independent. The TPP proposal, however, requires countries to link these two processes and prohibits national drug regulatory authorities, charged with evaluating drug safety and efficacy, from approving generic medicines until patents have expired. This link delays generic competition and brings the responsibility of evaluating drugs' patents under the purview of drug regulators.

5. **Not mandate patent term extensions.** International law requires patents for pharmaceutical products to be granted for 20 years, but the TPP proposal requires countries to grant patent term extensions, prolonging high-priced monopolies and further delaying generic competition.

6. **Not expand IP enforcement requirements.** Expanding enforcement to include higher damages thresholds, mandatory injunctions and increased authority for seizures by customs officials on the mere suspicion of an infringement. This interferes with a country's ability to balance public health interests in enforcement disputes and leads to delays in the trade for pharmaceuticals.

7. **Remove intellectual property from the Investment Chapter.** The TPP proposal gives pharmaceutical companies the right to sue governments that have regulations which reduce the companies' expected profits. This action will take place in a private, supra-national tribunal. This restricts a country's ability to structure legal and regulatory systems to best suit the public health needs of their population.