

Trans-Pacific trade pact triggers fears over drug prices

A new trade agreement being negotiated between 12 countries has come under fire from health campaigners who say it will push up drug prices and weaken health services. Chris McCall reports.

Marh Mansor is HIV positive and lives in the outskirts of Malaysia's capital, Kuala Lumpur. For him, a new Pacific trade deal is a personal threat. He fears that, if it goes ahead, it might mean his life-saving antiretroviral treatment will be just too expensive to get.

49-year-old Mansor is a former intravenous drug user who learned he was infected with HIV in 2004. At one stage, he started to develop AIDS, and needed treatment for tuberculosis. But for the past 5 years, he has been stable on generic antiretroviral drugs paid for by the Malaysian Government. He also has hepatitis C but cannot afford treatment for that. It is too expensive.

If his first-line therapy eventually starts to fail, he will need second-line drugs, which the Malaysian Government does not currently pay for. The cost would be around 1000 ringgit per month, roughly US\$265. If the new Trans-Pacific Partnership (TPP) goes ahead, he fears drug prices will increase and treatment could become unaffordable, for either him or his government. Around 86 000 people are living with HIV in Malaysia, according to official statistics. "We survive because of the generics", Mansor told *The Lancet*.

The word partnership has a homely ring but the talks have taken more than a decade. 12 governments, including Malaysia's, are stressing the potential benefits of cheaper goods and services. Free trade sounds good, but this agreement has been criticised in virtually every country about to sign up to it, particularly over health, especially pharmaceuticals. Doctors in Japan, people with HIV/AIDS in Malaysia and Vietnam, consumer rights watchdogs in Australia, even experts on intellectual property rights in the USA, have condemned it as likely to push up prices, weaken health services, and deprive some people of life-saving treatments.

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The drive to global free trade has produced some anomalies in health. These include babies who cannot get vitamin injections because beauty clinics in other countries pay more, and rich multinationals suing governments over health laws passed to protect their citizens.

Médecins Sans Frontières (MSF) sees in TPP a covert bid by US-based conglomerates to extend, potentially indefinitely, the life of patents on drugs they develop—so-called patent evergreening. Legal policy adviser Judit Rius Sanjuan says the losers are likely to be people with HIV/AIDS, hepatitis C, and other hard-to-treat illnesses who find life-saving drugs denied to them due to cost.

Generic antiretroviral drugs have brought the price of HIV/AIDS treatment down 99%, she says, allowing MSF to set up programmes to

tackle the disease in Africa and poorer parts of Asia. The price of antiretroviral treatment was once \$10 000 per year per patient. Now it is around \$120 per year per patient. This "game changer", Sanjuan says, would not have happened with provisions like those in the TPP.

TPP "is about creating a low quality patent system. This is pure greed and trying to delay generic competition. This is basically hyper regulation to promote the interests of pharmaceutical companies", she told *The Lancet*.

Secretive talks

Few areas of the world these days are not covered by a free trade agreement. It is a field of confusing acronyms, whose precise meanings are constantly shifting. Any deal's effects are only seen by the general public once it is implemented, and hard to revoke. The TPP is wide ranging, and pharmaceuticals are a small part. It is an unusual deal—a free trade agreement within a free trade agreement. Its 12 members all belong to the wider Asia-Pacific Economic Cooperation forum (APEC). They include two of the world's largest economies and pharmaceutical markets, the USA and Japan. Other countries expected to sign up include Australia, Canada, Malaysia, Mexico, Peru, and Vietnam. Another Asian economic powerhouse, South Korea, is also interested. India, the source of much of the world's generic medicines, might be too. The deal could become a model for a free trade region, including all of APEC, together representing around half of the world's population.

Yet the talks have been secretive. National parliaments will get little more than the chance to say yes or no to a done deal. Even among those following it closely, few are sure what is in it. The only drafts circulating publicly



The price of antiretroviral drugs could increase under the TPP agreement

were leaked by WikiLeaks. People following the deal say, as far as they can tell, these leaks are genuine. Their contents worry many.

The intellectual property chapter is the part of the TPP that has drawn the most criticism, particularly its provisions on patents. Public Knowledge, an advocacy group based in Washington, DC, with an interest in intellectual property law, says fears of patent evergreening are realistic. Lawyer Sherwin Siy cites his own impression of US negotiators' priorities. "If you talk to the people who are doing the trade negotiations they perceive their mandate as to get the best possible deal for US companies and US industry", said Siy.

Free trade negotiations are unlike other trade negotiations, Siy told *The Lancet*. They require other countries to change their domestic laws. Already some governments have found free trade agreements exploited by multinational companies to challenge their laws, using clauses originally designed to prevent expropriation of property by foreign nations, for example through nationalisation.

The leaked proposals would require signatories to extend patents in line with the laws of other signatories. The current global standard patent length is 20 years, extended in the 1990s as a result of earlier free trade talks under the World Trade Organization. However, there are still variations between countries. Australian pharmaceutical patents can last 25 years. If patents based on new uses of existing medicines are recognised in one TPP country, pharmaceutical firms might be able to enforce that in others.

Pharmaceutical companies can patent various uses of a drug. They can seek data exclusivity, meaning the data on which the patent is based, normally released as part of the patenting process, remains proprietary for a certain period, typically 5 years in the USA. For biologics—medications manufactured in living systems, often using recombinant DNA techniques—

this can be 12 years. This alone can delay the marketing of generic medications, as generic manufacturers may have to run all their own tests to market the drug.

Drug development

Perhaps not surprisingly, the US drug industry says the fears are over stated. A 2014 study by Tufts University in Boston put the typical cost of developing and marketing a new drug at \$2.6 billion. To find this level of funding, the pharmaceutical industry says it needs these protections. "These are things that we believe will encourage more development, particularly into very hard to research diseases", said Mark Grayson, a spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA), which supports the TPP. Not every drug is a success, he said, and research and development also had to cover the cost of the failures.

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Luc Besançon, chief executive officer of the International Pharmaceutical Federation, said experience has proved that free trade principles can create gaps in services when applied to health. He cites the experience of the European Union, arguably now the most developed free trade area in the world. Unlike other products, the end users of medicines often receive them via subsidies of some kind, from government benefit schemes, aid agencies, or other organisations. They often do not pay for them directly.

Prices of medicines are determined at a national level, he said, and pharmaceutical firms tend to buy where prices are low and sell where they are high. When stocks are limited, medicines tend to be channelled to where the market is most profitable. In the past, stocks of vitamin

injections produced in Greece have been sent to cosmetic clinics in richer EU countries, leaving Greek hospitals short of stocks for newborn babies. "Of course, the cosmetic clinics are likely going to be paying a higher price than hospitals", Besançon said. "You are transferring the problem to another country because of the free trade agreement. Nothing prevents one country in shortage having a vacuum effect." However, the TPP could have positive aspects, he said, in speeding up approvals for drugs or improving quality.

No turning back?

Disputes under TPP will be settled by an Investor State Dispute Settlement system, which sits above national law. Australian consumer rights organisation Choice says similar provisions are currently being used by tobacco giant Philip Morris to sue the Australian Government over laws requiring cigarettes to have plain packaging.

Choice policy adviser Sarah Agar says these tribunals do not follow normal procedures of a national court. Someone can issue a ruling one day, and a few weeks later they might have been recruited to act as an advocate on behalf of a client. "They tend to be very secretive. There is very clearly a conflict of interest. There are generally no appeals", she said.

Choice says independent research has shown TPP would not benefit Australian consumers. That has not convinced Australia's Government, which is pressing ahead to sign up. Agar believes there will most likely be a finalised agreement within weeks, and little chance of turning back. "Once the agreement has been signed it is quite difficult to slow down the implementation process. It would take something very significant for the Australian Parliament to refuse to ratify the agreement once it has been signed."

Chris McCall