

## TPP: trade-offs for health behind closed doors

A dozen countries have signed the Trans-Pacific Partnership, a major trade agreement that has complex implications for global health. Ted Alcorn reports from New York.

On Feb 4, 2016, after 7 years of negotiations, representatives from the USA, Japan, and ten other countries signed one of the largest trade and investment agreements in years, the Trans-Pacific Partnership (TPP). The negotiations were closed to the public, who only glimpsed drafts of the agreement when they were occasionally leaked. The participants were heavily lobbied by major industries. And the final language has complex implications for domestic policies in the participant countries, including for public health. As legislators consider ratifying the agreement, close observers question how future negotiations could be made to yield a more representative, more legitimate outcome.

### Striking a balance on drugs

In the popular imagination, trade agreements reduce tariffs and eliminate quotas, but trade between signatories to the TPP is already relatively free of these factors. So in important respects, the agreement seeks to ease commerce by offering greater certainty about other, deeper aspects of trade, such as reducing the risk a recipient country will steal an importer's intellectual property. This, in turn, has important implications for affordable access to life-saving medicines.

The crux of this issue is that developing new drugs requires costly upfront investments in research. Governments encourage companies to make those investments by offering them, for a period of time, exclusive rights to sell their new product as a monopoly—and thus at higher prices than in a competitive market. In theory, profits earned during this period incentivise future research and allow drug developers to recoup their earlier investments. But they do

so by demanding higher prices from consumers, and when those consumers are poor and in acute need of medicine, this can stop ill people from receiving life-saving care.

The TPP requires signatory countries to lengthen this period of monopoly by a variety of means. Manufacturers of new biological drugs—the large and growing group of medicines manufactured in or extracted from biological sources rather than synthesised chemically—will have between 5 and 8 years before their

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safety and efficacy data are made available, opening the door to generic competition. The TPP also includes measures that allow drug makers to extend their monopolies, for example by withholding regulatory approval for competitive drugs until the producers have demonstrated they do not violate active patents. Whereas some of the signatory countries already had these protections in place, those with weaker laws will have to strengthen them.

This final language required an accommodation by the USA, which had advocated for 12 years of data exclusivity and other measures, only acceding to changes in the final negotiation. But Judit Rius, US manager and legal policy adviser for Médecins Sans Frontières (MSF) Access Campaign did not see the final terms as

a compromise. They were an improvement, she said, but the original position of the USA was so extreme that the final terms remained “completely disproportionate”. Apart from the duration of exclusivity, she objected to the concept of exclusivity itself: “They are perpetuating an innovation system that is not working.” In its place, MSF has called for an entirely new system for financing and incentivising innovation that doesn't require patients and treatment providers to pay higher prices for new drugs.

Generic drug manufacturers were more circumspect. Nawel Rojkjaer, senior director of international affairs at the world's second largest generic drug manufacturer Mylan, said their company weighs the entire global market in its decisions to develop new “biosimilar” copies of biological drugs. So lack of access to any individual country or group of countries might not deter them from investing. But she said the USA did not pursue the public interest in the negotiations: “The US Trade Representative's goal when it comes to pharmaceuticals is not to promote balance; it is to promote longer patent protections



Ministers from 12 countries signed the Trans-Pacific Partnership in February, 2016

and longer exclusivity periods that benefit the pharmaceutical industry.”

Tom Bollyky, a senior fellow at the Council on Foreign Relations who previously worked both as a US trade official and to improve access to HIV treatment in South Africa, says that a trade negotiation is poor footing for achieving a wholesale transformation of drug research and development. “These agreements are geared for what the world looks like today. And people want them to be a vehicle to getting to a different place, whether its on research and development of drugs or on revitalising US manufacturing. And they are not really structured that way.”

The practical impact of the agreement is difficult to gauge because there is little experience by which to judge; the first biosimilar drug was released only last year. But if the magnitude of the effect is up for debate, its direction is not—drug developers will face less competition, and will charge higher prices.

### Carving out tobacco

Public health advocates had more to cheer about in a separate section of the agreement, which strengthened countries’ abilities to implement strong tobacco-control measures.

For decades, companies have been empowered to resolve claims that foreign countries are discriminating against their products through what is known as an investor-state dispute settlement (ISDS). But in recent years, Philip Morris International has used ISDS to sue some countries that attempted or considered implementing tobacco control regulations, even when consistent with public health practice and international law, in what looks like a tactical attempt to block countries’ efforts to reduce tobacco use.

In 2011, the company launched a dispute against Australia for requiring plain packaging of cigarettes, arguing that it was a detriment to foreign investors. Although a court threw

out the suit in December, 2015, the country spent US\$35 million defending itself, and New Zealand held up a similar policy pending the result.

Nor does a judicial defeat necessarily mean that there are no positives for the tobacco company, comments Gregg Haifley, the director of federal relations at the American Cancer Society Cancer Action Network. “For them, win or lose in the litigation, every day of delay is another day of potential newly addicted tobacco users who are going to use their product, in many cases for the rest of their lives.”

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To the surprise of many, the final language of the TPP explicitly exempts tobacco products from ISDS. Chris Bostic, the deputy director for policy at the advocacy organisation Action on Smoking and Health, says this was particularly notable because earlier in the negotiations the USA had signalled a willingness to move to an even weaker position. But a consortium of organisations built support in Congress, engaged the Department of Health and Human Services to push back, and organised other signatory countries to take strong positions that ultimately caused a change of heart. “I think in the end it was a political decision in the USA that [the TPP] is more likely to pass the US Congress with a tobacco carve-out than without it”, says Bostic.

### Towards greater transparency

Trade negotiations are moments of opportunity. They create a space in which decisions of domestic policy that would normally be subject to lengthy debate by legislators are decided with finality, on a multinational scale, behind closed

doors. And the vast wealth exchanged by the participating countries intersects, putting immense pressure on them to come to an agreement.

This is why public health advocates must engage in this arena, says Matthew Myers, president of the Campaign for Tobacco-Free Kids, who led efforts that resulted in the exemption for tobacco. But they begin at a grave disadvantage. “One of the problems with trade agreements is that the industry that will benefit is heavily engaged from day one. The public and non-profit organisations often don’t play at all, and if they do, don’t play at the same level.” Through positions as “cleared advisors”, industry representatives can view and comment on drafts before they are made public. The meetings themselves took place in half a dozen countries over as many years and so participation requires enormous investment—the kind that only a focused, well-resourced industry has historically been able to bring to bear.

At the very least, the process can be made more transparent. Mark Wu, an assistant professor at Harvard University Law School who led US negotiations on intellectual property for several previous trade agreements, says: “There’s a concern by certain members of the public that their views aren’t being heard by the negotiators, but also a concern that they don’t have the necessary information to make informed choices about the trade-offs that affect American interests.” He suggests that the USA publicly releases more details about its negotiating objectives for each section, similar to the European Union; releases information about proposals under consideration as long as its negotiating partners agree; and provides more details about the economic models they review in their decision making. Otherwise negotiators risk sending the signal they have something to hide, even when they don’t.

*Ted Alcorn*