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A matter of life and death

By Martin Khor

Of all the issues currently being negotiated on the Trans Pacific Partnership Agreement, none are more important than the ability of patients to get life-saving medicines at affordable prices, which many fear may be a victim of the agreement.

If you or some family members or friends suffer from cancer, hepatitis, AIDs, asthma or other serious ailments, it's worth your while to follow the Trans Pacific Partnership Agreement (TPPA) negotiations, now going on in Singapore.

It's really a matter of life and death. For the TPPA can cut off the potential supply of cheaper generic medicines that can save lives, especially when the original branded products are priced so sky-high that very few can afford them.

The fight for cheaper medicines has moved to cancer and other deadly diseases, when once the controversy was over AIDS medicines.

Recently, a cancer specialist in New Zealand (one of the TPPA counties) warned that the TPPA would prolong the high cost of treating breast cancer because of new rules to protect biotechnology-based cancer drugs from competition from generics. And this will affect the lives of cancer patients.

Some cancer medicines can cost a patient over US\$100,000 for a year's treatment, way above what an ordinary family can afford. But generic versions could be produced for a fraction, making it possible for patients to hope for a cure and a reprieve from death.

In India, local companies are leading the fight to make medicines more affordable to thousands of patients suffering from breast, kidney, liver and gastro-intestinal cancer and chronic leukaemia.

For example, an Indian company produced a generic drug for kidney and liver cancer 30 times cheaper than the branded product (US\$140 versus US\$4,580 for a month's treatment) after it was given a compulsory license.

India has a patent law that disallows patents for a newer form of drugs or known substances unless it improves the medicine's efficacy or effectiveness. Under WTO rules, countries are free to set their own standards for novelty, or whether a product is novel enough to be eligible for a patent.

Also, in many countries, including Malaysia, the patent law allows for companies to obtain compulsory licenses to import or make generic versions of original medicines. Governments grant such licenses if the branded products are too expensive and the original companies do not offer attractive terms for a voluntary license to other firms.

Multinational companies have strongly opposed compulsory licenses or the Indian-type laws that allow for patents only for genuine innovations.

This is where the TPPA comes in. Mainly at the insistence of the United States, countries are being asked to accept "TRIPS-plus" standards of intellectual property, that go beyond the rules of the WTO's agreement on IP.

Especially noteworthy is the US insistence that the TPPA countries agree to give a type of intellectual property known as "data exclusivity" for 5 years to companies producing original medicines.

This is extended to 8 or 12 years for "biologics", or medicines made with biotechnology. Many of the new medicines for treating cancers are biologics.

This will cause immense problems for patients waiting for cheaper medicines because "data exclusivity" prevents generic companies from relying on the safety and clinical trial data of the original company to get safety clearance for their generic products.

Thus, even if a generic company can prove that its medicine is bio-equivalent to the original medicine that has already passed the safety standard required by the health regulatory authorities, it will not be allowed to sell its medicine unless it comes up with its own safety and clinical trial data.

This goes against current practice of generic medicines and safety standards. But the US is insisting on this in the TPPA.

Few generic companies have the funds or technical ability to do their own clinical trials, and thus generic medicines could well be prevented from being used in TPPA countries for five to 12 years – even if the medicines are not patented.

Being deprived of affordable medicines is a matter of life and death, and will cost many lives. That is the most outrightly significant aspect of the TPPA, and this is why so many groups of patients, health organisations and independent medical experts have been outraged and outspoken in their opposition to the TPPA.

George Laking, a cancer specialist in New Zealand, last week raised the alarm that the TPPA could make cancer treatment unaffordable because the data exclusivity clause would lock in the extraordinary high prices of cancer drugs.

In an article he co-authored in the New Zealand Herald, Laking uses the example of Herceptin, an anti-cancer medicine which costs US\$100,000 for a year's treatment.

Once Herceptin comes off patent, it will become cheaper because generic forms can be made, he says. Also, new medicines that have fewer side effects and greater efficacy are being developed all the time.

That means more people will get through the treatment with less pain and distress. But the cost of new "generic" versions of Herceptin and other such pharmaceuticals looks likely to become a casualty of the TPPA, said Laking.

"The new drugs will stay expensive for longer, because access to generic versions will be delayed between eight and 12 years, because of the new data exclusivity rules in the TPPA," he remarked.

"These extended monopoly rights go far beyond existing international norms... This would be the first time in the history of such agreements that exclusive long-term monopoly rights over these "biologic" medicines will have been guaranteed....

"Each additional year of exclusivity will cost consumers and taxpayers many millions of dollars. This will be profitable for the pharmaceutical industry, but not so good for cancer patients and their families."

According to Jamie Love of Knowledge Ecology International, an expert on drugs and patents, the average cost of 8 biologic cancer drugs registered with the US drug authorities in 2011-2013 is \$128,000 (for a year's treatment), with the most expensive being over \$390,000. At such prices, hardly anyone in developing countries can afford these medicines.

Recently, eight prominent organisations including Medicins Sans Frontieres, Oxfam, Public Citizen, Health Gap and Knowledge Ecology International, issued a strong statement on their deep concern about the public health implications that the TPPA's measures will have for millions of patients in need of access to affordable medicines around the whole Asia-Pacific region.

The new US approach "not only preserves the life-threatening and access-restricting proposals that the US has been pushing since 2011, but also fails to provide adequate recognition of the urgent access to medicines needs of patients living in developing countries."

Said the groups: "The negotiations must take into account the health needs of all patients living in TPP countries, and the US must halt its efforts to limit countries' freedom and flexibilities, otherwise the TPPA will jeopardize many, if not millions, of lives".

Developments in India, which is not a TPPA country, show the patient-friendly policies that can emerge when public health concerns are given priority.

Two generic companies are producing generic versions of the drug Sorafenib which treats kidney and liver cancers. The original product, named nexavar, cost US\$4,600 per patient per month. A compulsory license was granted to a local firm to produce a generic version of sorafenib for US\$140 a month, or 30 times cheaper.

Another Indian company is producing a generic version of the drug Gleevac, which is used to treat a chronic form of leukaemia as well as gastrointestinal cancer, bringing the cost of treatment down from US\$70,000 a year (in the USA) to US\$2,500 a year in India.

This was possible because the Indian government denied the original company a patent on Gleevac because it was not judged to be novel enough, and an objection to that decision was rejected by the Indian Supreme Court.

India also rejected a patent application on tenofovir, a drug to treat AIDS, after opposition to its application was filed by several organisations. Cheaper generic versions are now available.

The Indian company Cipla has also produced a generic version of the kidney cancer drug nexavar (although it has been sued for doing so) and a lung cancer drug tarceva.

Another Indian company Biocon has produced a generic version of the breast cancer drug Herceptin. Due to a challenge by the originator company, its production has been stalled.

There is a citizens' campaign on affordable trastuzumab (which is the non-proprietary name for the breast cancer drug) to make the drug available cheaply.

Countries that join the TPPA will find it very difficult or impossible to undertake policies and practices similar to India's, should the US proposals in the intellectual property chapter be accepted.

Moreover, countries like Malaysia that don't produce the generic drugs have the option to import them from India. But if the TPPA imposes data exclusivity rules of the type desired by the US, it would be difficult or impossible to sell them here.

Malaysians would be deprived of the much cheaper generic medicines not only for treating cancer, hepatitis, AIDS, and many other diseases, at least for many years. How many lives would be affected?

Some countries are however opposed to some of the US proposals. According to a briefing on the TPPA by the Malaysian Ministry of Trade and Industry on 20 February, the IP chapter remains the most problematic, with many differing views.

The views and positions that defend public health must prevail, for after all, it is a matter of life and death.

Author: Martin Khor is the Executive Director of the South Centre. Contact: director@southcentre.int.

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For more information, please contact Vicente Paolo Yu of the South Centre: Email yu@southcentre.int, or telephone +41 22 791 80 50.