A Matter of Life and Death

By Martin Khor
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Martin Khor, executive director of the South Centre, warns that negotiations on the Trans Pacific Partnership Agreement are a matter of life and death.

GENEVA, Mar 9 2014 (IPS) - 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 negotiations on the Trans Pacific Partnership Agreement and other similar bilateral trade agreements.

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.

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 100,000 dollars for a year's treatment. 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 gastrointestinal cancer and chronic leukemia.

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

India has a law that disallows patents for a newer form of drugs or known substances unless it improves the medicine's efficacy or effectiveness. Under the World Trade Organisation (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, 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 standards of intellectual property, that go beyond the rules of the WTO's.

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

This is extended to eight 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 the current practice of generic medicines and safety standards. But the U.S. 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.

That is the most significant pubic health-related 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 agreement.

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

In mid-February, 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.

Said the groups: “The negotiations must take into account the health needs of all patients living in TPPA countries, and the U.S. 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.

For instance, an Indian company is producing a generic version of the drug Gleevac, which is used to treat a chronic form of leukemia as well as gastrointestinal cancer, bringing the cost of treatment down from 70,000 dollars a year (in the U.S.) to 2,500 dollars a year in India.

This price 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.

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

Moreover, countries that don't produce the generic drugs have the option to import them from India and other generics-producing countries. But if the TPPA imposes data exclusivity rules of the type desired by the U.S., it would be difficult to import and sell them.

Some countries are opposed to some of the U.S. proposals. The views and positions that defend public health must prevail, for after all, it is a matter of life and death.