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Don't Swallow This Pill

India needs to resist the European trade agenda on medicines

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Are the European Union and its multinational pharmaceutical companies now pressuring the Indian prime minister's office? In recent months, as negotiators from India and Europe have been thrashing out the details of a free trade agreement to be signed within months, people living with HIV have been hitting the streets. From New Delhi to Nairobi and Brussels to Bangkok, they have been protesting against the very real threat posed to India's ability to supply life-saving generic medicines to people across the developing world.

Publicly, both sides have assured that the trade deal will not harm access to the affordable generic medicines, and reiterate, as if by rote, the primacy of people's health over economic interests. But the Indian press now reports that the PMO, under pressure to conclude the deal, has asked the concerned government department to reconsider intellectual property (IP) provisions it had earlier rejected.

What is at stake? India became the 'pharmacy of the developing world' because its generic manufacturers are able to produce medicines that are patented elsewhere. This has made it a safe haven for affordable medicines. Médecins Sans Frontières now purchases more than 80% of the medicines it uses to treat 1,60,000 people living with HIV/AIDS around the world from producers in India. But this safe haven has been under constant attack.

Six years ago, the first attack came when India was obliged under international trade rules to introduce patents on medicines. Already, patents have been granted on cancer, AIDS and hepatitis medicines. But crucially, India's parliamentarians sought to balance patents with public health, and designed a strict patent law that would stand up to trade rules and protect access to affordable generic medicines.

One core provision of the law stops pharmaceutical companies from abusing the patents system. Section 3d says no patent shall be granted for a minor change to an existing medicine, if it shows no significant therapeutic efficacy over one which already exists. This prevents "evergreening", when companies seek monopolies to block out generic competition for as long as possible, simply by making minor changes to a drug.

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This has irked multinational pharmaceutical companies, which launched a second attack on the pharmacy of the developing world. As patent applications for several big-ticket drugs – oseltamivir for avian and swine flu, imatinib for leukaemia and, very recently, lopinavir/ritonavir and atazanavir for AIDS – failed to pass the patentability test in India, companies sought to overturn the law, or empty it of any substance. Novartis notoriously took the government of India to court in 2006, but lost. Other companies like Bayer have taken a stab, but have yet to succeed.

Say no to monopoly protection

Enter the free trade agreement negotiations, as the European trade agenda becomes the latest mouthpiece for the multinational pharmaceutical companies. Until now, much of the debate on generic production in India has focussed on patents. Now, the EU has changed track and is pushing hard for India to sign up to another means of blocking off generic production: data exclusivity.

With data exclusivity, India would be agreeing to grant a period of exclusivity over the clinical trial data submitted by a pharmaceutical company. This in turn would prevent the Drugs Controller General of India – the body responsible for approving medicines for market – from registering a generic medicine until that time was over. The multinational pharmaceutical industry has asked for that time to be 10 years.

Data exclusivity is a backdoor to monopoly protection. It also sweeps away the attempts by India's parliamentarians to balance health and profits. It makes a mockery of India's patent offices' work to apply rigorous standards and ensure only innovative medicines are granted a monopoly. Now, a pharmaceutical company would merely have to submit clinical trial data to obtain several years of monopoly, whether the drug was patented or not, whether it was old or new, whether it showed inventive step or not, or gave added therapeutic benefits or not.

The effect on access to affordable medicines is clear. India can learn from the countries that have preceded it down this path. Jordan brought in data exclusivity as part of a trade deal with the US. A study by Oxfam found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data exclusivity. The study also found that prices of these medicines under data exclusivity were up to 800% higher than in neighbouring Egypt.

India should not repeat others' mistakes, or the effect would be felt far beyond India's borders. The country is the source of the vast majority of drugs used to treat AIDS in developing countries. Affordable medicines produced in India have played a major part in reaching the more than five million people receiving HIV/AIDS treatment across the developing world today.

In 2000, treating one HIV positive person for a year cost more than Rs 4,00,000. Thanks to competition among generics from India, this same treatment today costs Rs 3,000. Any measure in the free trade agreement that would have the effect of blocking competition would effectively be turning the clock back on access to medicines. India needs to stand strong and resist European demands.

The writer is international president, Médecins Sans Frontières.