

India's global pharmacy role threatened by EU pact

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A pharmacist near a tablet counting machine at a Cipla manufacturing unit on the outskirts of Mumbai, India, Thursday, Feb 9, 2012. Efforts by India and the European Union to strengthen trade are threatening India's ability to deliver life-saving medicines to the world's poorest, analysts say as the two sides resume protracted negotiations on a free-trade pact. Health industry workers and activists worry that India may bow to EU demands for strict intellectual property protections and investor guarantees, which could result in the slow poisoning of its own generic pharmaceutical industry. India's \$26 billion drug industry has become an immense profit engine, growing at 15-25 percent a year _ but also a lifeline for millions of patients in poor countries, many in Africa, unable to pay sky-high Western prices to treat illnesses that include HIV, malaria, asthma and cancer. (AP Photo/Rafiq Maqbool)

(AP) -- Efforts by India and the European Union to strengthen trade are threatening India's ability to deliver lifesaving medicines to the world's poorest, analysts say as the two sides push through protracted

negotiations on a free-trade pact.

India's prime minister and top EU officials are hoping their summit Friday in New Delhi helps move beyond disagreements over issues like European labor market limits and Indian duties on cars.

But [health industry](#) workers and activists worry that India may bow to EU demands for strict intellectual property protections and investor guarantees, which could close down the world's generic drug supply.

India's \$26 billion drug industry has become an immense profit engine, growing at 15-25 percent a year - but also a lifeline for millions of patients in [poor countries](#), many in Africa, unable to pay sky-high Western prices to treat illnesses that include HIV, [malaria](#), asthma and cancer. For HIV alone, India makes more than 80 percent of the world's medicines.

The EU says it has suggested a clause in the free-trade pact "to ensure that nothing in the proposed agreement would limit India's freedom to produce and export lifesaving medicines."

Despite the EU assurance, Indian drug makers and [health workers](#) say two broad provisions in the agreement - one on intellectual property rights, and the other on investor lawsuits - would make it much easier for international pharmaceutical giants to sue the [Indian government](#), [drug manufacturers](#) and distributors.

That, they argue, would dramatically curtail Indian production of many lifesaving drugs, or cause prices to rise to levels many cannot afford.

"The EU has changed strategy and has now focused on enforcement," trying to create an [intellectual property](#) rights regime "that will intimidate even legitimate [generic manufacturers](#) and thereby impact

access and availability," said Dilip G. Shah, a former [Pfizer](#) executive who now heads both the Indian Pharmaceutical Alliance and the industry's Vision Consulting Group.

Activists have unleashed a global campaign to call the EU out on the policies. Analysts and drug makers say they have a point. While India's pharmaceutical companies would likely survive under a regime limiting generics, millions of the world's neediest patients, including within India, may not.

"The industry will be OK. They can produce anything" including drugs for Western multinationals, pharmaceutical analyst Bino Pathiparampil of IIFL Capital said. They may also gain from easier access to European markets.

"But there would be a serious impact on society, as many of the poor would be cut off from treatments," he said.

Since the talks began in 2007, Indian negotiators have refused to hamper the country's [generic drug](#) industry by undermining the low-cost production, high-quality professionalism or permissive licensing regime that has helped the industry grow.

But India and the EU both face different pressures today than when they started five years ago. Following a year of economic turmoil, Europe is eager to reach India's young and upwardly mobile market of 1.2 billion people, while India wants to prove its place among the world's economic powerhouses.

Now would also be an ideal time for India's government to show progress on a pact that can distract from a year of embarrassing corruption scandals.

The EU is India's biggest trading partner, accounting last year for \$92 billion in bilateral sales. The trade pact, they say, would lift that to an annual \$237 billion by 2015.

With the talks held behind closed doors and without participation by health ministers, analysts say there are few voices to prevent the final draft from giving multinational pharmaceuticals enough power to shut generics down.

On Friday, hundreds of people living with HIV protested in New Delhi to press Indian officials to reject any rules that might limit world supplies of anti-retroviral treatments.

"Whether we get to live or die should not be up to trade negotiators," Mundrika Gahlot of the Delhi Network of Positive People said in a statement.

Half of the generics India produces are used domestically, as India grapples with its own health care crisis and many impoverished patients are left to pay for care themselves.

The European Union has suggested it could drop two demands that would have affected the generics industry, specifically on patent extensions and on allowing companies to keep scientific data and clinical studies under wraps.

But experts say there are even more worrying provisions in the draft, which has been leaked during the talks and discussed by Indian negotiators with health care workers.

Measures to strengthen [intellectual property rights](#), for example, would require courts to impose injunctions on drug production whenever a complaint is filed, whereas courts today often allow production of

lifesaving drugs to continue while cases are pending.

There are also measures for widening lawsuits so patent holders can sue not just pharmaceuticals producing generics, but also those who supply materials as mundane as plastic bottles, nonprofit groups and foreign governments who purchase the drugs, and hypothetically even those who use them - the patients.

Another measure would let investors sue the Indian government if they feel their investment is being undermined, for example, by a license that allows a generic to be produced.

"Who do these measures serve? Not the European people, not the Indian people, not even the governments," said Indian lawyer Anand Grover, who since 2006 has served as a U.N. Special Rapporteur on human rights to health. "In fact, this is for a very small, profit-taking group of people."

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