

HEALTH:

Goodbye to Cheap Indian AIDS Drugs?

Ranjit Devraj

NEW DELHI, Nov 26 (IPS) - As India moves to meet a New Year's Day deadline to comply with the Trade Related Aspects of Intellectual Property Rights (TRIPS) regime of the World Trade Organisation (WTO) the cheap, generic anti-AIDS drugs that this country is famed for could be a thing of the past.

On Nov.19, the World Health Organisation (WHO) announced that the Hyderabad-based pharmaceutical Hetero Drugs Limited, had voluntarily withdrawn all six of its generic antiretroviral (ARV) drugs from the world body's list of approved drugs following concerns about their laboratory tests.

ARVs are substances used to kill or inhibit the multiplication of retroviruses such as HIV.

It was the third time since June that an Indian company has removed anti-AIDS drugs following WHO inspections which claimed that bioequivalence tests -- meant to show the drugs have the same effect as the original patented brands - were faulty. And this has deeply upset those involved in fighting the global HIV/AIDS epidemic.

Earlier this month Indian pharmaceutical giant Ranbaxy pulled its AIDS drugs off the WHO's list after the global body also claimed there were discrepancies in the equivalency tests. It followed the removal by India's Cipla of two HIV/AIDS drugs in June for similar problems..

Cipla is the Indian company credited with introducing the 'dollar-a-day' treatment that dramatically transformed drug access for HIV-infected people around the world.

But the fact of the matter remains.

Both Ranbaxy and Cipla were able to prove to WHO, before the voluntary pull-off, that their ARVs met the global body's bioequivalence standards -- though not before their world business had taken a knock that benefited the manufacturers of costlier patented drugs.

That initially led to charges from non-governmental organisations (NGOs) that the world health body was acting at the behest of western pharmaceutical giants.

However, things, now, have become more complicated.

Why did the two Indian pharmaceutical companies pull their ARVs from the market, if they had insisted all along that their drugs met WHO pre-qualification standards?

"We are concerned over the withdrawals. Earlier it was WHO which dropped the drugs. This time the companies are doing it on their own. We may ask the Drugs Controller of India (DCGI) to look into the issue," a senior health official told IPS.

WHO's pre-qualification list was created to guide procurement by aid agencies and donors interested in fighting the global HIV/AIDS epidemic and includes more than 60 ARVs made by both patented and generic drug manufacturers.

According to the internationally-known drug policy expert, Mira Shiva, the actual culprit in the whole debacle involving Hetero, Ranbaxy and Cipla was actually the WTO and not WHO.

Shiva who is attached to the Voluntary Health Association of India (VHAI), a leading health NGO, said Indian pharmaceutical companies that specialise in cheap generics drugs could face legal action, initiated by the WTO, if they continued to manufacture and sell them after Jan. 1, 2005.

"The TRIPS regime (in the WTO structure) has been identified as one of the worst international trade regimes and resistance to it in developing countries has come from farmers, public interest and human rights minded social action groups, as well as drug and health activists," Shiva told IPS.

TRIPS agreement, introduced in the late 1990s, defines how products can be protected from piracy. A major criticism has been that in its current form, intellectual property rights regimes (IPR) -- like TRIPS -- serve to stifle competition. For poor nations it makes developing their own industries independently more costly, if at all possible.

"Excessively high levels of intellectual property protection required by TRIPS have shifted the balance away from the public interest, towards the monopolistic privileges of IPR holders," said Martin Khor of the Malaysia-based Third World Network. "This undermines sustainable development objectives, including eradicating poverty, meeting public health needs, conserving biodiversity, protecting the environment and the realisation of economic, social and cultural rights."

Shiva pointed out that a TRIPS review was due in 2000 but was never carried out although the WHO was both aware and concerned about the effect the regime would cause to drug prices and access especially in the developing countries.

So far, India's pharmaceutical business has followed the fiercely nationalistic India Patents Act of 1970 that fostered the phenomenal growth of the industry that came to be hailed by the United Nations Council for Trade and Development (UNCTAD) as a model for developing countries.

According to a World Bank study in the mid-1990's prices for four typical drugs were ten times more expensive in neighbouring Pakistan, 17 times more expensive in Britain and

37 times more expensive in the United States than in India.

The Indian law has safeguards for both inventors as well as users but recognizes process patents as against the product patents regime required by TRIPS/WTO.

An amendment to the Act, designed to meet the WHO deadline is slated to be tabled by the government during the winter session of the Indian Parliament next month. If the government fails to get a consensus, it is expected to resort to an ordinance.

India signed the relevant WTO agreement on the issue in 1995 as part of its economic liberalisation under a Congress government but the party lost the elections in the following year because of widespread public perception that globalisation had benefited only a small elite.

The Congress party had to wait eight years before it could return to power in May on a promise to pursue liberalisation "with a human face." But Kamal Nath its current minister for commerce and industry said the country could not avoid taking at least "credible steps" to fulfill its multi-lateral obligations.

Political opposition to the bill that would amend the Indian Patents Act has come from the major communist parties united as the Left Front, which provides critical support to the Congress-led coalition government.

"The Jan. 1 deadline should not be used as a plea to rush through legislation for which the country may have to pay a heavy price later," said D. Raja, National Secretary of the Communist Party of India (CPI).

In the meanwhile Poornima Mane, director for social mobilisation and communication at UNAIDS, the U.N. body charged with fighting HIV/AIDS said patients should continue using Ranbaxy and CIPLA drugs that are available in the market.

"We want to clarify this so that patients do not panic. This (the voluntary withdrawals) does not mean that the drugs are not good. The worst thing will be if people stop using these drugs and develop resistance," she said.

But Mane said both UNAIDS and WHO were monitoring the situation in India "since this country will have to follow the WTO restrictions coming up next year and also because it is the biggest producer of generic drugs."

India itself has 5.1 million people afflicted with HIV according to the 'AIDS Epidemic Update', an annual report prepared by UNAIDS and WHO and released here this week. Globally, the number of the HIV-afflicted people has reached 39.4 million up from the 36.6 million estimated in 2002. (END/2004)