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Asian countries act to get cheap drugs

Starting with Malaysia in 2003, many Asian countries are now taking actions to promote cheaper medicines through compulsory licensing, with Indonesia being the latest case.

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By Martin Khor

Recent government actions by Indonesia and India to issue compulsory licenses are extending the trend in Asia to increase access to cheaper medicines to treat serious ailments, especially HIV/AIDS, cancer and hepatitis B.

The supply of generic medicines, either through import or local production, has been the major method of reducing prices and making the drugs affordable to more people.

When the required medicines are patented, which usually results in high prices, governments are allowed by the WTO rules to issue a compulsory license to enable themselves or private companies to import or produce generic versions, which usually cost much less.

In 2003, Malaysia became the first developing country to issue a compulsory license to a local firm to import drugs to treat HIV-AIDS from India. The cheaper generic drugs enabled the government to treat many more patients within the same budget.

Following this, Indonesia in 2004 issued a Presidential decree enabling the production of a some HIV-AIDS drugs while Thailand in 2007 issued compulsory licenses for several HIV-AIDS and cancer drugs.

In March this year, India approved its first compulsory license enabling a local company to produce a generic version of an anti-cancer drug, which could reduce the price of treating kidney and liver cancer from US\$5,200 a month (the price of the branded product) to \$160 a month (the price of the generic product).

The latest measure was taken on 3 September by Indonesian President Dr. Susilo Bambang Yudhoyono who issued a decree which has the effect of a compulsory license. It enables local manufacturers to make, import and sell generic versions of seven patented drugs used for treating HIV-AIDS and hepatitis B.

The decree said that in line with the urgent need to control HIV/AIDS and Hepatitis B in Indonesia, "it is necessary to continue and expand the access policies to provide access to antiviral and anti-retroviral medicines still protected by patent."

This is the third time Indonesia has issued a set of compulsory licenses. The latest decree stated that the 2004 and 2007 decrees were no longer sufficient to implement the policies.

The compulsory license is aimed at significantly reducing the prices of these life-saving medicines and making them accessible to thousands more Indonesian patients.

"We will ensure the availability of good-quality, safe and effective generic versions of anti-retroviral and anti-viral drugs," said HM Subuh, infectious disease control director at the Indonesian Health Ministry, as quoted in the Jakarta Post of 19 October.

According to the decree, the generic companies would have to pay a royalty of 0.5% of the net sales value of the generic drugs to the companies that own the patents, such as Merck, Glaxo SmithKline, Bristol Myers Squibb, Abbott and Gilead.

The first decree in 2004 enabled cheaper generic medicines that provided HIV-infected patients with first-line anti-retroviral therapy. However, these have become ineffective or less effective because of increasing resistance or the lower safety of the drugs.

The latest decree enables the supply of generic anti-retroviral products for not only better first but also second-line anti-retroviral therapy.

"With the 2012 regulation, we obviously can improve access to quality but affordable drugs," Maura Linda Sitanggang, the Health Ministry's Director General for Pharmaceuticals and Medical Equipment, told The Jakarta Post. "We're using this mechanism concerning public interest on the production of quality but affordable medicines to treat HIV and HBV."

The seven medicines which are the subject of the compulsory license (known in this case as for "government use") are efavirenz, abacavir, didanosin, lopinavir + ritonavir combination, tenofovir, tenofovir + emtricitabine, and tenofovir + emtricitabine + efavirenz.

All the drugs are used to treat HIV-AIDS. The drug tenofovir (brand name Viread produced by patent holder Gilead) is also used to treat hepatitis B, which affects 13 million people in Indonesia. It had been approved in the United States for treating HIV-AIDS in 2001 and for treating chronic Hepatitis B in 2008.

The combination drug tenofovir + emtricitabine (brand name Truvada, produced by Abbot) is taken in a single dose once a day. It has been used to treat HIV-AIDS and in July 2012 it also became the first drug approved by the US Food and Drug Administration for use as a preventive measure, to reduce the risk of HIV infection to people at high risk of infection including those who may engage in sex with HIV infected patients.

The Indonesian decree was the second compulsory license in Asia this year.

In India, the Patent Office in March approved the country's first compulsory license to a local firm Natco Pharma to make a generic version of the cancer drug sorafenib tosylate (brand name Nexavar, produced by Bayer).

It was argued that at the high price of 2.8 lakh rupees (US\$5,200) for a month's dosage of Nexavar, only 200 patients were treated in India in a year. Natco said that 8,000 people would need the drug, and it could supply a generic version at 8,800 rupees (US\$160) for a month's treatment.

The drug is used to treat advanced kidney and liver cancer. According to the terms of the license, Natco would pay Bayer royalties of 6% of its net sales.

Bayer challenged the compulsory license and on 16 September the Intellectual Property Appellate Board rejected its petition, ruling that "If a stay is granted it will jeopardise the interests of the public who are in need of the drug."

Other developing regions have also been making use of the compulsory license option in the WTO's intellectual property treaty known as TRIPS. They include Brazil and Ecuador in Latin America and Kenya, Zambia and Zimbabwe in Africa.

In 2001, the WTO's Ministerial Conference in Doha adopted a TRIPS and Public Health Declaration that asserted that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

It affirmed that the Agreement should be interpreted in a manner supportive of the right to health and access to medicines for all.

The Declaration clarified: "In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Table: Active Substance Name, Name of Patent Holder, Patent Number, and Duration of Patents for Antiviral and Antiretroviral Medicines

NO.	NAME OF ACTIVE SUBSTANCES	NAME OF PATENT HOLDERS	PATENT NUMBER	DURATION OF PATENT
1.	Efavirenz	Merck & Co., INC	ID 0005812	Until the end of patent period, August 7, 2013
2.	Abacavir	Glaxo Group Limited	ID 0011367	Until the end of patent period, May 14, 2018
3.	Didanosin	Bristol - Myers Squibb Company	ID 0010163	Until the end of patent period, August 6, 2018
4.	Combination Lopinavir and Ritonavir	Abbott Laboratories	ID 0023461	Until the end of patent period, August 23, 2018
5.	Tenofovir	Gilead Sciences, Inc.	ID 0007658	Until the end of patent period, July 23, 2018
6.	Combination Tenofovir and Emtricitabine Combination Tenofovir, Emtricitabine and Efavirenz	Gilead Sciences, Inc.	ID P0029476	Until the end of patent period, 3 November 2024

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