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Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines *Precedent-Setting Government Order has Extraordinary Lifesaving Potential*

On September 3, the government of Indonesia took a quiet but exceptionally important step to expand access to medicines and help save and improve lives of people living with HIV/AIDS and hepatitis B.

President Dr. H. Susilo Bambang Yudhoyono signed a decree authorizing government use of patents for seven HIV/AIDS and hepatitis medicines. If implemented to the full, the measure would introduce widespread generic competition and generate potentially massive cost savings in the world's fourth most populous country. The decree licenses patents for a slate of HIV medicines, and may represent the broadest single use of pharmaceutical patent licensing power by a country since the World Trade Organization 1995 Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS).

Indonesia's action sets a powerful example for other countries and a critical precedent for global public health. The Presidential decree is part of an effort to greatly expand access to newer and more appropriate antiviral and antiretroviral treatments in Indonesia.

More information, including a copy of the decree (in Indonesian and a rough unofficial English translation), a table of the licensed medicines, and more on Indonesia's response to HIV and hepatitis B, is available here: <http://www.citizen.org/actions-indonesia>.

Table of licensed medicines

ACTIVE SUBSTANCE	PATENT HOLDER	PATENT NUMBER	DURATION OF PATENT
Efavirenz	Merck & Co., INC	ID 0005812	Until the end of patent period, August 7, 2013
Abacavir	Glaxo Group Limited	ID 0011367	Until the end of patent period, May 14, 2018
Didanosine	Bristol - Myers Squibb Company	ID 0010163	Until the end of patent period, August 6, 2018
Combination Lopinavir and Ritonavir	Abbott Laboratories	ID 0023461	Until the end of patent period, August 23, 2018
Tenofovir	Gilead Sciences, Inc.	ID 0007658	Until the end of patent period, July 23, 2018
Combination of Tenofovir and Emtricitabine Combination of Tenofovir, Emtricitabine and Efavirenz	Gilead Sciences, Inc.	ID P0029476	Until the end of patent period, 3 November 2024

Indonesia's Government Use Order

The order cites an urgent need to combat HIV and hepatitis B and correspondingly expand government access policy, stating that prior government use orders for patents on three older HIV medicines are "no longer sufficient." Indonesia previously made government use of patents in 2004 (lamivudine and nevirapine) and again in 2007 (efavirenz, lamivudine and nevirapine). The new order replaces the prior decrees, licenses efavirenz

Read more about the global campaign to improve access to second-line HIV/AIDS treatment at: www.citizen.org/Kaletra-campaign.

again and adds six more medicines to the protocol. The new protocol also has the potential to supplement recent licenses negotiated between Gilead Sciences and the Medicines Patent Pool, creating opportunities to procure from additional suppliers. The order grants the Minister of Health authority to appoint pharmaceutical companies to exploit patents for and on behalf of the government. The authorization will be effective until the end of the term of each patent.

Licensing authorizes the use of patented technology under enumerated conditions. Making government use of a patent does not eliminate or override that patent. It facilitates generic competition, including potentially generic imports and/or local production of medicines. Indonesia has established a 0.5% royalty for the holders of the patents.

Advancing the Treatment Revolution

Over the past 10 years, generic competition has produced a revolution in HIV/AIDS treatment, reducing prices for first-line antiretroviral medications from about USD 15,000 per year to about \$150 per year and enabling more than 8 million people worldwide to access basic treatment. But high prices and patent-based monopolies continue to limit access to needed newer treatments, and impede the goal of an AIDS-free generation. Robust generic competition is essential to advancing the treatment revolution.

For example, in Indonesia, lopinavir + ritonavir, an HIV combination treatment marketed by Abbott Laboratories under the trade names Alluvia and Kaletra, costs USD 83.30 per month or about \$1000 per person per year for public programs (the private sector price is several times more). This price is high for treatment programs and people who are infected with HIV in Indonesia, where the per capita income is \$2900. Generics manufacturers sell lopinavir + ritonavir at prices less than \$400. The cost savings from lopinavir + ritonavir and other medicines could help Indonesia dramatically scale up its HIV response, and inaugurate broad advanced treatment.

According to the World Health Organization (WHO), "availability and affordability of second-line regimens is the key to universal access to HIV treatment." Indonesia's HIV/AIDS epidemic is one of the fastest-growing in Asia. Indonesia has an HIV-positive population of 310,000 according to UNICEF estimates. About 23,000 people receive antiretroviral therapy in Indonesia today, compared with an estimated 70,000 people and growing who need it.

To date, the majority of financial support for HIV response in Indonesia comes through international sources, including the Global Fund to Fight AIDS, Tuberculosis and Malaria. But falling donor commitments are raising concerns for sustaining and scaling up treatment in Indonesia and around the world. Indonesia's financial contribution to national HIV response has increased from 27 percent in 2006 to 42 percent in 2010. But reaching its commitment to cover at least 70% of the cost by 2015 could be difficult without additional cost savings.

The government use order also aims to expand access to hepatitis B treatment. Tenofovir is a powerful antiviral used for treatment of hepatitis B, which affects about 13 million people in Indonesia.

Compulsory Licenses and Government Use of Patents Around the World

Many countries have used compulsory licenses to promote public interest objectives and to remedy anti-competitive practices in a variety of technology sectors. In recent years, a number of countries have issued licenses to improve access to medicines, including India, Thailand, Brazil, Malaysia, Zambia and Ecuador, among others. The United States is perhaps the world's most frequent user of compulsory licensing, including the government use of defense technologies, and judicially issued licenses to remedy anti-competitive practices in information technology and biotechnology, among other instances.

Government use and compulsory licensing are an integral component of patent rules. The right of countries to issue compulsory licenses is enshrined in the World Trade Organization's TRIPS Agreement of 1995 and the unanimous Doha Declaration of 2001 on intellectual property and public health. The WTO's Doha Declaration also states, "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Congratulations to Indonesia's Access Campaigners

Congratulations to Sindi Putri, Abdullah Denovan and their colleagues at ITPC Indonesia and JOTHI, among other organizations, who are helping advance access in Indonesia.