

INDONESIA GOVERNMENT GRANTED 7 COMPULSORY LICENCES TO PROMOTE ACCES TO HIV RELATED MEDICINES

“Starting with Malaysia in 2003, many Asian countries are now taking action to promote cheaper medicines through compulsory licensing, with Indonesia being the most recent case. Recent government actions by Indonesia and India to issue compulsory licenses –CL– are extending the trend in Asia to increase access to cheaper medicines for treating serious ailments, especially those related to HIV/AIDS, cancer and Hepatitis B” (1). In recent years, a number of countries have issued licenses to improve access to medicines, including, Thailand, Brazil, Malaysia, Zambia, Ecuador and India, among others.

Indonesian President Susilo Bambang Yudhoyono issued a decree on 3rd September 2012 that allows the government to use patents for seven HIV/AIDS and hepatitis B medicines. “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 on 19th October.

Under World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (WTO’s TRIPS), WTO members have the right to grant compulsory licenses, in order to promote access to vital medicines. It is not the first time that Indonesia government issued a compulsory licence (known in the Indonesia case as for “government use”) for HIV drugs, the previous decree goes to 2004 and 2007, but the present Indonesia’s decree may represent the broadest single use of CL for pharmaceuticals by a country, since the creation of WTO in 1995.

The decree renews a previous compulsory licence -CL- issued against Merck & Co (US)’s HIV anti-retroviral (ARV) Sustiva (efavirenz) in 2007, and adds six more drugs to the list. Pre-existing 2007 compulsory licenses remain against Boehringer Ingelheim (Germany)’s ARV Viramune (nevirapine) and Shire Pharmaceutical (United Kingdom)’s Hepatitis B treatment lamivudine. These drugs can be now licensed by the Ministry of Health to pharmaceutical companies to exploit patents on behalf of the government, effective until the end of term of each patent, with a 0.5% royalty paid to the patent holder. Summary of Indonesia’s compulsory licenses of 3rd September 2012:

Table 1. Licensed medicines (2).

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

Indonesia has set an important precedent, not just for the people living with HIV within its country, who have been campaigning for this, but also for other developing countries, (...) As medicines for HIV and Hepatitis B are increasingly under patent in developing countries, Indonesia has shown that countries can and should take action to enable the production of low-cost versions of essential life-saving medicines for their citizens. The next step is the full implementation of the decree. Other countries that have faced blocking on access to generic medicines should consider following Indonesia's lead", said Michelle Childs of Medecins Sans Frontieres (3).

The International Federation of Pharmaceutical Manufacturers and Associations – IFPMA-, representing global drug manufacturers, expressed concern at the wide-ranging decree. Andrew Jenner, its director of innovation, intellectual property and trade, said developing countries had a right to override patents by issuing so-called compulsory licenses in certain limited circumstances, but this should be a last resort. According to Jenner "Systematic issuance of compulsory licenses by Indonesia sets a negative precedent and can reduce the incentive to invest in the research and development of new medicines, including HIV/AIDS and hepatitis therapies (...) We believe that negotiated approaches, such as tiered pricing or voluntary licensing, are generally more effective and sustainable, both medically and economically." These views and approach of IFPM to use the negotiations, voluntary licenses and corporate social responsibility have been also recently supported and promoted by the World Health Organization -WHO (4).

According to MSF (5), the Presidential decree, if fully implemented, will allow local generic production of the medicines (which will open up competition, and could significantly reduce prices) while each of the innovator companies will be paid a royalty of half a percent. There are 310,000 people living with HIV in Indonesia.

As Brook Baker said "It is a tremendous victory for people living with HIV in Indonesia that it has issued new compulsory licenses on seven anti-retroviral medicines, allowing the government to access generic versions of those medicines – domestically or by importation – at much cheaper prices. Indonesia now stands at the head of the pack of countries that have stood up to Big Pharma's corporation power and to the trade and diplomatic pressure exerted by US and EU powers that consistently advance the IP monopoly rights of pharmaceutical multinationals" (6).

The Indonesian Presidential decree is an effort to expand access to newer and more appropriate antiretroviral treatments and as stated by Public Citizen Organization, "Indonesia's action sets a powerful example for other countries and a critical precedent for global public health."

Germán Velásquez Ph.D.

Special Adviser for Health and Development at the South Centre, Geneva
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REFERENCES

1. Khor M. Measure to make drugs affordable. Global Trends. The Star on line. 2012 Oct 22.
2. Public Citizen. Actions in Indonesia [internet]. Disponible en: <http://www.citizen.org/actions-indonesia>
3. MSF responds to Indonesia's intent to issue compulsory licenses on 7 HIV drugs. Geneva; 2012 Oct 12.
4. Beyer P. Socially responsible licensing policies in the medical sector. PTT presentation at the WTO Workshop on IP & public health. Geneva; 2012 Oct. p. 9 – 12.
5. MSF responds to Indonesia's intent to issue compulsory licenses on 7 HIV drugs. Geneva; 2012 Oct. 12.
6. Baker B. Indonesian Compulsory Licenses Show Values of Pro-Access TRIPS-Flexibility Terms in Voluntary Licenses [internet]. 2012 Oct 30. Disponible en: <http://infojustice.org/archives/27620>