

## Ecuador's Presidential Declaration on Access to Medicines and Compulsory Licensing

### – *Background* –

On October 26, 2009 Ecuador's President Rafael Correa declared access to priority medicines affecting the health of the Ecuadorean population to be a matter of public interest.<sup>i</sup> Under Andean Community law, the declaration opens the door to competition of generic medicines with patented brand-name drugs, through use of an internationally recognized legal mechanism called compulsory licensing. The declaration could lead to government policies that expand access to medicines.

Globally, competition has consistently proven the most effective method to reduce medicine prices, and ensure prices continue to fall over time. Over the last ten years, generic competition has produced a revolution in HIV/AIDS treatment, reducing prices for first-line antiretrovirals from around \$10,000 to around \$100 per year, and enabling over four million people worldwide to access treatment.

By issuing a compulsory license, a government can authorize competition with patented products, including the importation, domestic production, distribution and/or sale of generic medicines. In exchange, licensees pay reasonable royalties to the patent holder, set by the government according to the circumstances of each case. Compulsory licenses do not “eliminate” or “override” patents. Instead, they authorize the use of patented technology under enumerated conditions.<sup>ii</sup>

Countries' right to issue compulsory licenses “on grounds of their choosing” is enshrined in the World Trade Organization's TRIPS Agreement (1995) and unanimous Doha Declaration (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.”

Ecuador's Presidential declaration does not on its own issue a compulsory license. Rather, it authorizes procedures by which the government can subsequently decide, case-by-case, to issue compulsory licenses for priority medicines (as determined by the Ministry of Public Health), based in public interests such as reducing treatment costs and enabling greater access to treatment. The declaration follows public pronouncements by President Correa articulating a vision of intellectual property as “a mechanism for development for the people,” and is an important step toward access to medicines for all.

Many countries have used compulsory licenses to promote public interests and remedy anti-competitive practices in a variety of sectors. Today, the United States is perhaps the 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 others. Canada routinely issued compulsory licenses during the 1960s and 70s to develop its national pharmaceutical industry. In recent years, a number of countries have issued compulsory licenses to improve access to medicines, including Thailand, Malaysia, Eritrea, Mozambique and Indonesia, among others.

In 2007, Brazil issued a compulsory license for the HIV/AIDS medicine efavirenz. Brazil has provided treatment to hundreds of thousands of people living with HIV/AIDS and saved well over US\$1 billion through its combined medicines strategy of domestic production, importation, negotiation and compulsory licensing.

President Correa signed the declaration Friday October 23, but his office released it on the 26th. The declaration enables Ecuador's government officials to consider introducing generic competition with some of the country's expensive patented drugs, including second-line HIV/AIDS treatments that cost more than double the current competitive price, and lifesaving cancer treatments that exceed \$35,000 per person, per year, and which some hospitals cannot afford. The UNAIDS 2008 report estimated 42% of Ecuadoreans needing antiretroviral therapy received it. Resource constraints in Ecuador limit availability of treatment.

Ecuador's declaration cites Constitutional principles as well as provisions of the National Development Plan and international agreements, including the WTO TRIPS Agreement and the World Health Assembly Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The declaration charges the Intellectual Property Institute of Ecuador (IEPI) with establishing royalties and the terms of licenses, in compliance with all applicable national legislation and international rules. The Presidential declaration incorporates requirements of the WTO's TRIPS Agreement and Andean Community legislation, including excerpting some passages word-for-word. IEPI has published an administrative guide to compulsory licensing for the use of Ecuador's government agencies.

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<sup>i</sup> The declaration is available online, in Spanish, at: <http://www.sigob.gov.ec/decretos/>.

<sup>ii</sup> There are several common misunderstandings about the TRIPS Agreement's provisions and compulsory licensing for medicines. Three of the most commonly perpetuated myths are that compulsory licenses "eliminate" or "override" patents, that they can only be issued in an emergency, or that negotiations with pharmaceutical companies are always required before issuing compulsory licenses. For more information on these and other common misunderstandings, please see the World Trade Organization document "TRIPS and Health: Frequently asked questions Compulsory licensing of pharmaceuticals and TRIPS," available at [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/public_health_faq_e.htm)