

## ***Ecuador compulsory licensing updates 2009-2010***

*Peter Maybarduk  
Public Citizen / Essential Action*

*In reverse chronological order*

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### ***Ecuador creates public pharmaceutical firm Enfarma*** *Sent February 8, 2010*

Friends, an overdue Ecuador update:

On December 21, 2009, President Correa signed Decreto 181, creating the public pharmaceutical firm Enfarma. Enfarma's charter includes procurement through imports, as well as manufacturing (beginning in late 2011) and innovative research and development. Enfarma is expected to cooperate with private sector firms around the world as well as public programs in other Latin American countries. A council of high-ranking Ministers oversees Enfarma, and a program staff manages day-to-day operations. Following initial infusions of public funds, the government plans for Enfarma to become self-sustaining.

Enfarma was designed in part to help implement Ecuador's new policy on access to medicines and licensing patents. Enfarma will collaborate with IEPI, Ecuador's patent office, ensuring compliance with all applicable legislation. Its creation reflects the growing Andean regional interest in access to medicines and in pharmaceutical pricing, research and development that respond to the public health priorities of the region.

Decreto 181 is available here (in Spanish):  
<http://www.sigob.gov.ec/decretos/Decretos20092013.aspx>

Read about Ecuador's compulsory licensing policy here:  
[http://www.essentialaction.org/access/index.php?/categories/8-Country Disputes and Other Issues](http://www.essentialaction.org/access/index.php?/categories/8-Country+Disputes+and+Other+Issues)

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***South American Health Ministers Applaud Ecuador's Policy on Access to Medicines and Compulsory Licensing at UNASUR Meeting***

Sent Nov. 25, 2009

During this week's Meeting of the South American Union of Nations (UNASUR) in Guayaquil and Quito, UNASUR Health Ministers announced their strong support for Ecuador's new policy of licensing patents to improve access to medicines.

Speaking for the delegates, Peruvian Health Minister Oscar Ugarte Ubillús said Ecuador's decision is an "exercise of sovereignty, a positive act, in accordance with international rules, for which the UNASUR ministers and officers of Health offer our support."

Ministers from Argentina, Paraguay, Bolivia, Brazil, Venezuela and Chile each spoke in turn in support of Ecuador's policy.

The ministers also discussed the advantages of block negotiating for better AH1N1 vaccine access.

So far the news stories I've seen on this subject are all in Spanish. I've pasted in stories from Voice of America and El Nuevo Empresario (Guayaquil) below.

Peter Maybarduk  
Essential Action

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<http://www1.voanews.com/spanish/news/latin-america/Medicamentos-sin-patentes-Ecuador-73120057.html>

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***Ecuador's compulsory license policy: Corrections to some early media reports***

*Sent November 2, 2009*

Dear friends,

You will recall last Monday, Ecuadorean President Rafael Correa announced a new national access to medicines policy through decree no. 118, declaring access to priority medicines a matter of public interest, and establishing procedures for issuing compulsory licenses. Such licenses would authorize price-lowering competition with expensive patented drugs.

Many news articles, in Spanish, English and French, reported on the decree, as well as on subsequent comments and analyses by the patent office, national and international pharmaceutical companies, and observers. Unfortunately, several inaccuracies circled the globe through some of these reports. We would like to take the opportunity to correct a few of the most common inaccuracies now.

***First, compulsory licenses do not eliminate or break patents.*** They simply authorize use of a patented technology. Under compulsory licenses, patent holders retain their patents and a variety of related rights, including the right to be adequately compensated through

royalty payments and any rights reserved through restrictions set out in the license. For example, sometimes compulsory licenses are limited to public, non-commercial use. In this case the patent holder would retain exclusive rights in the private market (i.e., the right to be the exclusive seller to private pharmacies and insurers). Ecuador will issue compulsory licenses, which is qualitatively different from annulling patents.

***Second, Ecuador has not predetermined the number of licenses it intends to issue, nor will it license all medicines en masse.*** Ecuador's patent office (IEPI) will consider compulsory license requests on a case-by-case basis. IEPI will consult with the Ministry of Public Health and take into account the public interest that licensing a particular medicine would serve. Some news articles reported Ecuador would "license 2,214 medicines" or "eliminate over 2,000 medical patents." 2,214 is actually the total number of granted and/or requested patents for pharmaceuticals in Ecuador. Often, multiple patents apply to a single medicine. Therefore, it is not even theoretically possible for Ecuador to issue compulsory licenses for 2,214 medicines, as there are not that many patented drugs. IEPI will proceed more methodically and deliberately than reported, considering license requests for priority medicines case-by-case.

Third, much speculation has surrounded the issue of royalties. ***IEPI has not predetermined the royalty rates it will require licensees to pay to patent holders.*** IEPI will instead determine royalties according to the unique circumstances of each case. IEPI is currently studying international best practices in setting royalty rates, including models and equations used in other countries. Royalty rates established by IEPI are therefore likely to correspond to international precedent.

Finally, some reports have suggested the WTO's TRIPS Agreement requires Ecuador to negotiate with pharmaceutical companies before issuing compulsory licenses, because Ecuador has not declared a public health emergency. But under WTO rules, licenses issued for public, non-commercial use are also exempt from the prior negotiation requirement.

***Ecuador has not announced whether licenses would be issued for public use, but if so, Ecuador would not be required to negotiate first.*** In cases where negotiation is required, the government need only offer reasonable terms and conditions. If the patent holder fails to reply, or refuses reasonable conditions, the government can then proceed and issue a compulsory license. In other words, pharmaceutical companies cannot hold up the government for whatever royalty rates they want. In that case the license would no longer be compulsory at all, but voluntary, and the WTO rules would cease to make sense.

Please see below for Essential Action's Backgrounder on "Ecuador's Presidential Declaration on Access to Medicines and Compulsory Licensing." You can also download a PDF at: <http://www.essentialaction.org/access/>

President Correa's decree is available online, in Spanish, at: <http://www.sigob.gov.ec/decretos/>. We hope to make an English translation of

President Correa's declaration available in short order.

Thank you, and please feel free to contact me with any questions. - Peter Maybarduk,  
Attorney, Essential Action, [peter.maybarduk@essentialinformation.org](mailto:peter.maybarduk@essentialinformation.org)

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***Breaking news & analysis: Ecuador's Presidential Declaration on Access to Medicines and Compulsory Licensing***

*Sent October 26, 2009*

[Note: President Correa's decree is available online, in Spanish,  
at: <http://www.sigob.gov.ec/decretos/>]

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

*– Background –*

**Quito, Ecuador, October 26, 2009** – Today, Ecuador's President Rafael Correa declared access to priority medicines affecting the health of the Ecuadorean population to be a matter of public interest. 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.

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, but his office released it today. 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 Ecuadorians 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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***Ecuador's compulsory licensing plans, and alternative vision for IP***

*Sent October 5, 2009 / early version July 29, 2009*

In July of this year, Ecuador's President Rafael Correa articulated a vision of intellectual property as "a mechanism for development for the people." His speech before a live audience on the nationally televised program "[Enlace Ciudadano](#)" ("Citizen Connection") announced a new state policy of using compulsory licenses to improve access to medicines.

I've translated an excerpt below. The clip is available (in Spanish and sign language) on YouTube, here: <http://www.youtube.com/watch?v=9cnsOctJ0wc>, as well as the homepage of the Ecuadorean Intellectual Property Institute (IEPI, Ecuador's patent office), here: <http://www.iepi.gov.ec/>.

Last week, President Correa announced plans to use compulsory licenses to facilitate the domestic production of medicines. Here is the story in El Universo, courtesy of Judit Rius Sanjuan: <http://www.eluniverso.com/2009/09/26/1/1355/ecuador-eliminar-patentes-medicamentos.html?p=1355&m=861>).

Correa, an economist recently elected to a second term (with a simple majority and a twenty-three point lead over his closest competitor), has charged high-ranking officials in his administration to implement the policy.

Nevertheless, we have heard reports of multinational pharmaceutical companies organizing behind the scenes to disrupt the licensing policy before it can take effect. To realize President Correa's vision, Ecuador needs the support of the global access to medicines movement.

To show your support and find out how you can help, write:

Essential Action, [peter.maybarduk@essentialinformation.org](mailto:peter.maybarduk@essentialinformation.org) and

Health Action International Ecuador, [teranj\\_aisec@cablemodem.com.ec](mailto:teranj_aisec@cablemodem.com.ec)

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From "Enlace Ciudadano," July 16, 2009:

"Therefore, the subject of intellectual property is tremendously important. What is our vision? When something has been invented or discovered, the more people that use it, the better. For example, a medicine. We're talking about human rights. Do you think it's ethically sustainable that if a cure for cancer is invented, people could continue to die because they don't have the resources to pay? That because the medicine has a registered property right, and because I, Laboratory X, invested in its development, you have to pay me \$2,000 for each pill?

This cannot be. When making the [gestures to indicate a "single"] pill costs far less. And

it's to save lives. Especially in these situations, we have to change our conception of property; the traditional conception, the neoliberal conception. Compañeros, we are discussing all of this.

There is, in our legislation, what they call compulsory licensing. I, as President, can order that we issue a compulsory license for Brand X, so they can copy this medicine and make generics, and the people have access to this medicine, to health, to a cure for their illness. [Applause.] And this is exactly what we are going to begin to do, with respect to medicines, with respect to agrochemicals, with respect to everything possible."

. . . [Correa addresses non-profit motives that also drive innovation ("vocation" and "dedication"), and cites universities as key centers of research and innovation in the public interest.] . . .

"Intellectual property is a mechanism for development for the people. This is our vision of intellectual property. It's not a mechanism to enrich the pharmaceutical or agrochemical companies. It's a mechanism for development for the people."

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### ***Civil society organizes for access to LPV/r (Kaletra) and compulsory licenses in Latin America***

*Sent February 2, 2009*

Thursday and Friday, January 22-23, civil society groups from all over Ecuador met in Quito to sign the charter for a new national HIV/AIDS network, REDEVIDA.

Monday January 26, REDEVIDA delivered a letter to the Ministry of Public Health in Ecuador, signed by delegates from nineteen member organizations, in "unconditional and complete" support of an Essential Action proposal to reduce prices and improve access to patented HIV/AIDS treatment lopinavir/ritonavir (Abbott's Kaletra) in Ecuador through open licensing.

On Tuesday, REDEVIDA and the Ecuadorean Coalition of Persons Living with HIV/AIDS sent a letter to civil society groups in Mexico and the United States, in support of their campaigns against Abbott's unfair pricing schemes, and in Colombia, in support of their compulsory license request for Kaletra, now pending with the Colombian government.

On Wednesday, activists in Mexico (Mexico City, Tabasco and Tijuana), the United States (Chicago) and Colombia (Bogotá) demonstrated against Abbott's Kaletra prices in protests at Abbott offices and press conferences organized by the AIDS Healthcare Foundation and local groups. Kaletra prices in Mexico and Colombia range from about \$3,500 to \$6,000 per person per year (the \$1683 Colombia "public sector price" about which we've previously written seems to be very sparsely applied, perhaps only to the military).

A few photos from the demo at Abbott's Bogotá office, which focused on both price and the pending compulsory license request, are available online [here](#). If the link doesn't work, paste

in: <http://picasaweb.google.com/comunicacion.positiva/PlantonAbbottBogota#>

Special credit is due Clinton Trout and Luz Marina Umbasía for their hard work.

An archive of news stories on the Colombia compulsory license request is available [here](#) (in Spanish). Information is also available in English [here](#).

The text of the REDEVIDA letter sent to civil society groups in Mexico, Colombia and the U.S. is pasted below, first in English (translation and any errors mine), then in the original Spanish.

These actions follow international demonstrations uniting many groups against Abbott's high prices and for LPV/r compulsory licenses at the International AIDS Conference in Mexico this past August.

Civil society groups and government health advocates are poised to initiate a regional movement for access to lopinavir/ritonavir, with compulsory licensing as a primary access-promoting tool.

I can provide more information and some of the proposals, documents, letters and government responses on request.

- Peter Maybarduk for Essential Action

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LETTER IN SUPPORT OF THE COMPULSORY LICENSE REQUEST FOR THE ANTIRETROVIRAL KALETRA IN COLOMBIA AND OF THE SIMILAR PROPOSAL NOW UNDER CONSIDERATION IN ECUADOR

Dear:

- Colombian Network of People Living with HIV/AIDS (RECOLVIH) / Working Group of HIV/AIDS Organizations
- International Coalition of Treatment Activists (CIAT)
- Member groups of the Ecuadorean Network of Organizations Working in HIV/AIDS (REDEVIDA)

We send brotherly greetings from the Ecuadorean Coalition of persons living with HIV/AIDS (CEPVVS) and the Ecuadorean network of organizations and groups working in HIV/AIDS.

In common cause, we support the proposal to obtain a compulsory license for the antiretroviral HIV/AIDS medicine Kaletra, sold by Abbott in Colombia, and from a

distance we join the “Stand Against Abbott” to assist this request.

This license will permit the substantial reduction of antiretroviral treatment costs, which will in turn contribute to expanding access to ARV treatment, the cost of which is too high for people living with HIV/AIDS in Colombia.

We would like to announce that in Ecuador we are helping initiate a similar process, which we hope the public health authorities and President of the Republic of Ecuador will lead, and will decide to issue an open license on the ARV Kaletra, and thus enable the reduction of treatment costs and increase access to more people living with HIV/AIDS.

We are sure your stand will be a fundamental advance in developing public awareness about the necessity to reduce the costs of ARV medicines in Colombia, Ecuador and other countries.

From Quito, our solidarity and support!

RED ECUATORIANA DE ORGANIZACIONES Y GRUPOS QUE TRABAJAN EN VIH/SIDA REDEVIDA

COALICION ECUATORIANA DE PERSONAS QUE VIVEN CON VIH/SIDA  
CEPVVS

Lcdo. Santiago Jaramillo

SECRETARIO GENERAL COALICION ECUATORIANA DE PVVS  
SECRETARIO EJECUTIVO RED ECUATORIANA DE ORGANIZACIONES Y  
GRUPOS CON TRABAJO EN VIH/SIDA -REDEVIDA-

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CARTA DE APOYO PARA LA LICENCIA OBLIGATORIA DEL  
ANTIRRETROVIRAL KALETRA EN COLOMBIA Y PARA LAS MISMAS  
GESTIONES QUE SE HAN EMPEZADO A REALIZAR EN ECUADOR

Estimados/as:

- RED COLOMBIANA DE PERSONAS QUE VIVEN CON VIH/SIDA RECOLVIH / MESA DE ORGANIZACIONES QUE TRABAJAN EN VIH/SIDA
- COALICIÓN INTERNACIONAL DE ACTIVISTAS EN TRATAMIENTOS CIAT
- ORGANIZACIONES Y GRUPOS INTEGRANTES DE LA RED ECUATORIANA DE ORGANIZACIONES Y GRUPOS QUE TRABAJAN EN VIH/SIDA REDEVIDA

Reciban un fraternal saludo de la Coalición ecuatoriana de personas que viven con

vih/sida –CEPVVS- y la red ecuatoriana de organizaciones y grupos que trabajan en vih/sida –REDEVIDA-

Nos solidarizamos y apoyamos la propuesta para obtener la licencia obligatoria del medicamento antirretroviral kaletra para el vih/sida, de la farmacéutica Abbott en Colombia, y nos unimos desde la distancia al PLANTON CONTRA ABBOTT para apoyar dicho pedido.

Dicha licencia permitirá reducir sustancialmente los costos del tratamiento antirretroviral, lo cual contribuirá a ampliar el acceso a tratamientos ARV's, cuyos costos son demasiado altos, para las personas que viven con vih/sida el Colombia.

Queremos expresar que en el Ecuador estamos promoviendo el inicio de un proceso similar, ante lo cual esperamos que las autoridades de la salud y la Presidencia de la República del Ecuador tomen las decisiones del caso para lograr una licencia abierta del ARV kaletra y así poder reducir los costos del tratamiento y ampliar el acceso a mas PVVS.

Estamos seguros que el plantón convocado por ustedes será un avance fundamental para crear conciencia sobre la necesidad de reducir los costes de los medicamentos ARV's en Colombia, Ecuador y otros países.

¡DESDE QUITO, NUESTRA SOLIDARIDAD Y APOYO!

RED ECUATORIANA DE ORGANIZACIONES Y GRUPOS QUE TRABAJAN EN VIH/SIDA REDEVIDA

COALICION ECUATORIANA DE PERSONAS QUE VIVEN CON VIH/SIDA  
CEPVVS

Lcdo. Santiago Jaramillo

SECRETARIO GENERAL COALICION ECUATORIANA DE PVVS

SECRETARIO EJECUTIVO RED ECUATORIANA DE ORGANIZACIONES Y

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