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## Ecuador Takes One Step Forward for Health (Issues New Compulsory Licenses) and One Step Back (Signs Harmful Trade Agreement with the EU)

In July, Ecuador issued four compulsory licenses for medicines targeting cancer and arthritis treatment and immunological reception to kidney transplant.<sup>1</sup> These licenses authorize cost-cutting generic competition with patented medicines, in exchange for royalty payments to the patent holders. Compulsory licensing is a crucial tool to expand access to medicines that are prohibitively expensive or whose costs place enormous burdens on budgets for health systems.<sup>2</sup> Ecuador has again demonstrated international leadership by exercising its health rights.

The same month, however, Ecuador also signed a trade agreement with the European Union that may undermine access to medicines.<sup>3</sup> Intellectual property was among several sensitive topics in the negotiations. The text is not yet public, but Ecuador ultimately bowed to EU pressure to adopt exclusivity measures which protect pharmaceutical monopolies and keep prices high.

Notably, Ecuador's public pharmaceutical firm ENFARMA withdrew several additional compulsory license requests during the latter stages of Ecuador's negotiations with the EU. The timing of the withdrawals raises a serious question as to whether this decision was influenced by the negotiations. Ecuador's pro-health policies continue to suffer inappropriate challenges from commercial interests with influence in the government.

Ecuador established ENFARMA in 2009 with the goal of improving the well-being of Ecuadorian society through the manufacture and distribution of safe and effective medicines at affordable prices, in part through Ecuador's licensing protocol.<sup>4</sup> Ecuador announced the new compulsory licenses at a press conference that included the Ministry of Health, the Ecuadorian Institute for Intellectual Property (IEPI) and the National Secretariat for Higher Education, Science, Technology and Innovation (SENACYT).<sup>5</sup>

Ecuador's licensing protocol conforms to World Trade Organization (WTO) rules.<sup>6</sup> The new EU-sponsored exclusivity measures go beyond the data protection required by WTO rules.<sup>7</sup> Health advocates should sound the alarm. A study conducted by the Colombian foundation IFARMA identified cancer and AIDS treatments as the types of medicines most affected by data exclusivity.<sup>8</sup>

Ecuador should take steps to mitigate the harmful effects of the exclusivity rules. For example, implementing regulations should empower health agencies to exempt products from data or marketing exclusivity (and thereby facilitate generic competition) in order to protect health. More information about Ecuador's access to medicines policy is *available at*: [www.citizen.org/actions-ecuador](http://www.citizen.org/actions-ecuador).

<sup>1</sup> Invitación rueda de prensa: Resolución de dos nuevas licencias obligatorias para el país.

<http://www.propiedadintelectual.gob.ec/invitacion-rueda-de-prensa-resolucion-de-dos-nuevas-licencias-obligatorias-para-el-pais/>

<sup>2</sup> Maybarduk P. Licencias Obligatorias un derecho soberano para promover el acceso a los medicamentos Public Citizen. Abril 2014

<sup>3</sup> EU and Ecuador conclude negotiations for trade and development agreement. European Commission - IP/14/845 17/07/2014 En: [http://europa.eu/rapid/press-release\\_IP-14-845\\_en.htm](http://europa.eu/rapid/press-release_IP-14-845_en.htm)

<sup>4</sup> ENFARMA EP, <http://www.farmacos.gob.ec/enfarma/>

<sup>5</sup> Invitación rueda de prensa: Resolución de dos nuevas licencias obligatorias para el país. <http://www.propiedadintelectual.gob.ec/invitacion-rueda-de-prensa-resolucion-de-dos-nuevas-licencias-obligatorias-para-el-pais/>

<sup>6</sup> Letter to USTR from Global Access to Medicines Director, Peter Maybarduk: USTR-2010-003 (2010 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974. <http://www.citizen.org/documents/Ecuador%20USTR%20Letter.pdf>

<sup>7</sup> Correa C. Implementación de la Protección de Datos de Prueba de Productos farmacéuticos y agroquímicos en CAFTA. ICTSD. Disponible en [http://ictsd.org/downloads/2009/01/20062122documents1\\_.pdf](http://ictsd.org/downloads/2009/01/20062122documents1_.pdf)

<sup>8</sup> Impacto de diez años en la protección de datos en Colombia. Rossi, Francisco. Serie Buscando Remedio Fundación IFARMA.2012 p.75