



Access to Medicines in Ecuador

A Summary of Compulsory Licensing

On October 23, 2009, Ecuador's President, Rafael Correa, declared "access to medicines used for the treatment of diseases that affect the Ecuadorian population and are priorities for public health" a matter of public interest, and declared that "compulsory licenses may be granted for patents ... that may be necessary for treatment." Compulsory licensing authorizes cost-cutting generic competition with patented drugs. It is a key tool to advance access to medicines. On April 24, 2010, the Ecuadorean Institute of Intellectual Property (IEPI) issued Ecuador's first compulsory license for ritonavir, an essential component of Abbott's patented lopinavir+ritonavir, commercially known as Kaletra and Aluvia. As of 2014, Ecuador has issued nine compulsory licenses covering six drugs. Licenses issued in 2014 demonstrate that the government's commitment extends beyond HIV. Ecuador should encourage robust competition so that the Ecuadorean people can reap the maximum benefit of licensing.

Generic Name	Marketed Name	Patent Holder	Compulsory License Assignee	Patent Expiry	Indication	Royalty Rates* (\$/pill)	Proposed Prices (\$) Generic (Brand)
Ritonavir	Kaletra (Aluvia)	Abbott Laboratories (Pi-97-1142)	Eskegroup S.A. 4/14/2010	11/30/14	HIV/AIDS	0.041 200mg+50mg	1.15 (2.15)
Ritonavir	Kaletra (Aluvia)	Abbott Laboratories (Pi-97-1142)	Acromax Laboratorio Quimico Farmaceutico S.A. 5/11/2013	11/30/14	HIV/AIDS	0.0484	NA
ABC + 3TC	Kivexa	Glaxo Group Limited (Sp-98-2505)	Oxialfarm CIA Lmtd 2013	5/14/18	HIV/AIDS	.0771 (600 mg + 300 mg)	4.14 (10.31)
ABC + 3TC	Kivexa	Glaxo Group Limited (Sp-98-2505)	Acromax 11/12/2012	5/14/18	HIV/AIDS		NA
ABC + 3TC	Kivexa	Glaxo Group Limited (Sp-98-2505)	Ginsburg Ecuador S.A. 2013	5/14/18	HIV/AIDS	.0771 (600 mg + 300 mg)	NA
Etoricoxib	Arcoxia	Merck Frosst Canda LMT (Sp-97-2190)	Acromax 4/1/2014	7/17/17	Arthritis	.0028 (60 mg), 0.0043 (90 mg/120	NA
Mycofenolate sodium	Myfortic	Syntex (USA) Inc. (Pi-08-1913)	Ginsburg Ecuador S.A. 5/19/2014	2/16/15	Kidney Transplant	.023 (360 mg), .013 (180 mg)	2.26, 1.16 (3.24, 1.66)
Sutinib	Sutent	Sugen INC (Sp-97-1383)	ENFARMA Empresa Publica 7/17/2014	2/15/2021 (est)	Cancer Treatment	NA	NA
Certolizumab	Cimzia	UCB Pharma (Pi-2010-2027)	ENFARMA Empresa Publica 7/18/2014	5/6/2021 (est)	Rheumatoid Arthritis	NA	NA

ABC + 3TC: Abacavir + Lamivudine

*Royalties calculated at 5% of income-adjusted price of patented equivalent in the U.S.