



Health, Intellectual Property and Biodiversity Programme

SCOPE OF COMPULSORY LICENSE AND GOVERNMENT USE OF PATENTED MEDICINES

To meet public health needs governments can use **compulsory licenses** and **government use** as a tool for procurement and import of patented medicines.¹ These mechanisms are provided for in most laws worldwide. The WTO TRIPS Agreement, as reaffirmed by the Doha Declaration on TRIPS and Public Health, recognises the right of WTO members to grant compulsory licenses and their freedom to determine the grounds upon which such licenses may be granted.

The table below provides information of instances of their use.

Compulsory Licenses/ Government Use Authorization

Country	Drug	CL/GU	Year (granted /filed)	Ground	Royalty
Brazil	Efavirenz	GU	2007	Public Interest	1,50%
China	FDC of lamivudine/stavudine/ nevirapine	CL	2005	Non-availability in the country	N/A
Colombia	Dolutegravir	GU	2024	Public Interest	4%
Congo	ARVs	GU	2007	N/A	N/A
Congo	ARVs	GU	2014	N/A	N/A
Ecuador	Ritonavir	CL	2010	Public Interest	4%
Ecuador	Abacavir/lamivudine	CL	2012	Public Interest	5%
Ecuador	Ritonavir	CL	2013	Public Interest	4%
Ecuador	Abacavir/lamivudine	CL	2013	Public Interest	7%
Ecuador	Abacavir/lamivudine	CL	2013	Public Interest	7%

¹ Countries with insufficient or no pharmaceutical manufacturing capacity can also import the medicine by issuing a compulsory license, in accordance with article 31 *bis* of the TRIPS Agreement, from an exporting country that also issues a compulsory license for such purpose. However, the use of this system would require compliance with conditions which are very restrictive and cumbersome. See Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, Policy Brief 57, January 2019, South Centre, Geneva. Available from <https://www.southcentre.int/policy-brief-57-january-2019/>.

Country	Drug	CL/GU	Year (granted /filed)	Ground	Royalty
Ecuador	Etoricoxib	CL	2014	Public Interest	0.2% - 0.4%
Ecuador	Mycofenolate sodium	CL	2014	Public Interest	2%
Ecuador	Sunitinib	CL	2014	Public Interest	N/A
Ecuador	Certolizumab	CL	2014	Public Interest	N/A
Gabon	ARVs	GU	2005	N/A	N/A
Gabon	ARVs	GU	2006	N/A	N/A
Gabon	ARVs	GU	2013	N/A	N/A
Georgia	ARVs	GU	2006	N/A	N/A
Germany	Raltegravir	CL	2016	Urgent need, public interest	N/A
Ghana	ARVs	GU	2005	Health Emergency	N/A
Guatemala	ARVs	GU	2005	N/A	N/A
Guinea	ARVs	GU	2004	N/A	N/A
Honduras	ARVs	GU	2005	N/A	N/A
Honduras	ARVs	GU	2008	N/A	N/A
Honduras	ARVs	CL	2008	N/A	N/A
Hungary	Remdesivir	CL	2020	N/A	N/A
India	Sorafenib tosylate	CL	2012	Availability and Affordability	7%
Indonesia	Nevirapine, lamivudine	GU	2004	Health Emergency	0,50%
Indonesia	Abacavir, didanosine, efavirenz, lopinavir/ritonavir, tenofovir, tenofovir/emtricitabine, tenofovir/emtricitabine /efavirenz	GU	2012	Health Emergency	0,50%
Israel	Lopinavir/ritonavir	GU	2020	National security, essential services and supplies	N/A
Italy	Imipenem/cilastatin	CL	2005	Abuse of dominant position	N/A
Italy	Finasteride	CL	2007	Abuse of dominant position	0%
Ivory Coast	ARVs	GU	2004		

Country	Drug	CL/GU	Year (granted /filed)	Ground	Royalty
Ivory Coast	Lamivudine, lamivudine/zidovudine, lamivudine/zidovudine/nevirapine, lamivudine/stavudine, lamivudine/stavudine/nevirapine, didanosine, efavirenz, indinavir	GU	2007	N/A	N/A
Ivory Coast	ARVs	GU	2007	N/A	N/A
Liberia	ARVs	GU	2005	N/A	N/A
Malaysia	zidovudine, zidovudine/lamivudine	GU	2003	N/A	4%
Malaysia	sofosbuvir	GU	2017	N/A	N/A
Mongolia	ARVs	GU	2007	N/A	N/A
Mozambique	Efavirenz	GU	2005	N/A	N/A
Myanmar	ARVs	GU	2005	N/A	N/A
Pakistan	ARVs	GU	2006	N/A	N/A
Philippines	ARVs	GU	2005	N/A	N/A
Philippines	ARVs	GU	2008	N/A	N/A
Russia	Lenalidomide	CL	2018	N/A	3%
Russia	Sunitinib	CL	2019	N/A.	10%
Russia	Remdesivir	CL	2021	National security	N/A
Sudan	ARVs	GU	2008	N/A	N/A
Swaziland	Nevirapine, zidovudine	GU	2005	N/A	N/A
Sao Tome and Principe	ARVs	GU	2006	N/A	N/A
Chinese Taipei	Oseltamivir	GU	2005	N/A.	N/A
Tajikistan	Lamivudine, stavudine, zidovudine, nevirapine, efavirenz, tenofovir, didanosine, lopinavir, saquinavir, ritonavir, nelfinavir, abacavir	GU	2005	N/A	N/A
Thailand	Efavirenz	GU	2006	N/A	0,50%
Thailand	Lopinavir	GU	2007	N/A	0,50%
Thailand	Clopidogrel	GU	2007	N/A	0,50%
Thailand	Letrozole	GU	2008	N/A	N/A
Thailand	Docetaxel	GU	2008	N/A	N/A
Thailand	Erlotinib	GU	2008	N/A	N/A

Country	Drug	CL/GU	Year (granted /filed)	Ground	Royalty
Thailand	Efavirenz/emtricitabine /tenofovir, lamivudine/zidovudine/ efavirenz	GU	2008	N/A	N/A
Ukraine	ARVs	CL	2004	N/A	N/A
Zambia	Lamivudine/stavudine/ nevirapine	CL	2004	N/A	2,50%
Zimbabwe	ARVs	GU	2002	N/A	N/A
Zimbabwe	ARVs	GU	2003	N/A	N/A
Zimbabwe	ARVs	CL	2004	N/A	N/A
Zimbabwe	ARVs	GU	2005	N/A	N/A