

## SCOPE OF COMPULSORY LICENSE AND GOVERNMENT USE OF PATENTED MEDICINES IN THE CONTEXT OF THE COVID-19 PANDEMIC

To meet public health needs, such as in the current COVID-19 emergency, governments can use **compulsory licenses** and **government use** as a tool for procurement and import of patented medicines.<sup>1</sup>

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 (read our Call for Action on Intellectual Property and Trade Measures to Address the Covid-19 Crisis [here](#)).

The South Centre offers a guide for the issuance of compulsory licenses and government use, see [here](#), [aquí](#) en español.

The table below provides information of instances of their use.

### Compulsory Licenses/ Government Use Authorization: (as of 2 March 2021)

| Country | Drug                                | CL/GU | Year (granted /filed) | Ground                                             | Royalty            |
|---------|-------------------------------------|-------|-----------------------|----------------------------------------------------|--------------------|
| Ecuador | Raltegravir                         | CL    | 2021                  | Public interest                                    | .17 USD per tablet |
| Russia  | Remdesivir (for Covid-19) *         | CL    | 2021                  | National security                                  | N.A                |
| Hungary | Remdesivir (for Covid-19) *         | GU    | 2020                  | N.A.                                               | N.A                |
| Israel  | Lopinavir/ritonavir (for Covid-19)* | GU    | 2020                  | National security, essential services and supplies | N.A                |

<sup>1</sup> 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 at <https://www.southcentre.int/policy-brief-57-january-2019/>

\* WHO recommends against the use of remdesivir in COVID-19 patients

\* WHO recommends against the use of remdesivir in COVID-19 patients

\* WHO recommends against the use of lopinavir/ritonavir in COVID-19 patients

| Country     | Drug                                                                                                                        | CL/GU | Year (granted /filed) | Ground                         | Royalty     |
|-------------|-----------------------------------------------------------------------------------------------------------------------------|-------|-----------------------|--------------------------------|-------------|
| Russia      | Sunitinib                                                                                                                   | CL    | 2019                  | N.A.                           | 10%         |
| Russia      | Lenalidomide                                                                                                                | CL    | 2018                  | N.A.                           | 3%          |
| Malaysia    | Sofosbuvir                                                                                                                  | GU    | 2017                  | N.A.                           | N.A         |
| Germany     | Raltegravir                                                                                                                 | CL    | 2016                  | Urgent need, public interest   | N.A         |
| Congo       | ARVs                                                                                                                        | GU    | 2014                  | N.A.                           | N.A         |
| Ecuador     | Etoricoxib                                                                                                                  | CL    | 2014                  | Public Interest                | 0.2% - 0.4% |
| Ecuador     | Mycophenolate sodium                                                                                                        | CL    | 2014                  | Public Interest                | 2%          |
| Ecuador     | Sunitinib                                                                                                                   | CL    | 2014                  | Public Interest                | N.A         |
| Ecuador     | Certolizumab                                                                                                                | CL    | 2014                  | Public Interest                | N.A         |
| Ecuador     | Ritonavir                                                                                                                   | CL    | 2013                  | Public Interest                | 4%          |
| Ecuador     | Abacavir/lamivudine                                                                                                         | CL    | 2013                  | Public Interest                | 7%          |
| Gabon       | ARVs                                                                                                                        | GU    | 2013                  | N.A.                           | N.A         |
| India       | Sorafenib tosylate                                                                                                          | CL    | 2012                  | Availability and Affordability | 7%          |
| Indonesia   | Abacavir, didanosine, efavirenz, lopinavir/ritonavir, tenofovir, tenofovir/emtricitabine, tenofovir/emtricitabine/efavirenz | GU    | 2012                  | Health Emergency               | 0,50%       |
| Ecuador     | Ritonavir                                                                                                                   | CL    | 2010                  | Public Interest                | 4%          |
| Honduras    | ARVs                                                                                                                        | GU    | 2008                  | N.A.                           | N.A         |
| Honduras    | ARVs                                                                                                                        | CL    | 2008                  | N.A.                           | N.A         |
| Philippines | ARVs                                                                                                                        | GU    | 2008                  | N.A.                           | N.A         |
| Sudan       | ARVs                                                                                                                        | GU    | 2008                  | N.A.                           | N.A         |
| Thailand    | Letrozole                                                                                                                   | GU    | 2008                  | N.A.                           | N.A         |
| Thailand    | Docetaxel                                                                                                                   | GU    | 2008                  | N.A.                           | N.A         |
| Thailand    | Erlotinib                                                                                                                   | GU    | 2008                  | N.A.                           | N.A         |
| Thailand    | Efavirenz/emtricitabine/tenofovir, lamivudine/zidovudine/efavirenz                                                          | GU    | 2008                  | N.A.                           | N.A         |
| Brazil      | Efavirenz                                                                                                                   | GU    | 2007                  | Public Interest                | 1,50%       |
| Congo       | ARVs                                                                                                                        | GU    | 2007                  | N.A.                           | N.A         |
| Italy       | Finasteride                                                                                                                 | CL    | 2007                  | Abuse of dominant position     | 0%          |
| Ivory Coast | ARVs                                                                                                                        | GU    | 2007                  | N.A.                           | N.A         |

| Country                      | Drug                                                                                                                                                         | CL/GU | Year (granted /filed) | Ground                          | Royalty |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-----------------------|---------------------------------|---------|
| <b>Ivory Coast</b>           | Lamivudine, lamivudine/zidovudine, lamivudine/zidovudine/nevirapine, lamivudine/stavudine, lamivudine/stavudine/nevirapine, didanosine, efavirenz, indinavir | GU    | 2007                  | N.A.                            | N.A     |
| <b>Mongolia</b>              | ARVs                                                                                                                                                         | GU    | 2007                  | N.A.                            | N.A     |
| <b>Thailand</b>              | Lopinavir                                                                                                                                                    | GU    | 2007                  | N.A.                            | 0,50%   |
| <b>Thailand</b>              | Clopidogrel                                                                                                                                                  | GU    | 2007                  | N.A.                            | 0,50%   |
| <b>Gabon</b>                 | ARVs                                                                                                                                                         | GU    | 2006                  | N.A.                            | N.A     |
| <b>Georgia</b>               | ARVs                                                                                                                                                         | GU    | 2006                  | N.A.                            | N.A     |
| <b>Pakistan</b>              | ARVs                                                                                                                                                         | GU    | 2006                  | N.A.                            | N.A     |
| <b>Sao Tome and Principe</b> | ARVs                                                                                                                                                         | GU    | 2006                  | N.A.                            | N.A     |
| <b>Thailand</b>              | Efavirenz                                                                                                                                                    | GU    | 2006                  | N.A.                            | 0,50%   |
| <b>China</b>                 | FDC of lamivudine/stavudine/nevirapine                                                                                                                       | CL    | 2005                  | Non-availability in the country | N.A     |
| <b>Gabon</b>                 | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Ghana</b>                 | ARVs                                                                                                                                                         | GU    | 2005                  | Health Emergency                | N.A     |
| <b>Guatemala</b>             | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Honduras</b>              | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Italy</b>                 | Imipenem/cilastatin                                                                                                                                          | CL    | 2005                  | Abuse of dominant position      | N.A     |
| <b>Zimbabwe</b>              | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Liberia</b>               | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Mozambique</b>            | Efavirenz                                                                                                                                                    | GU    | 2005                  | N.A.                            | N.A     |
| <b>Myanmar</b>               | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Philippines</b>           | ARVs                                                                                                                                                         | GU    | 2005                  | N.A.                            | N.A     |
| <b>Swaziland</b>             | Nevirapine, zidovudine                                                                                                                                       | GU    | 2005                  | N.A.                            | N.A     |
| <b>Chinese Taipei</b>        | Oseltamivir                                                                                                                                                  | GU    | 2005                  | N.A.                            | N.A     |
| <b>Tajikistan</b>            | Lamivudine, stavudine, zidovudine, nevirapine, efavirenz, tenofovir, didanosine, lopinavir, saquinavir, ritonavir, nelfinavir, abacavir                      | GU    | 2005                  | N.A.                            | N.A     |
| <b>Guinea</b>                | ARVs                                                                                                                                                         | GU    | 2004                  | N.A.                            | N.A     |
| <b>Indonesia</b>             | Nevirapine, lamivudine                                                                                                                                       | GU    | 2004                  | Health Emergency                | 0,50%   |

| <b>Country</b>     | <b>Drug</b>                       | <b>CL/GU</b> | <b>Year<br/>(granted<br/>/filed)</b> | <b>Ground</b> | <b>Royalty</b> |
|--------------------|-----------------------------------|--------------|--------------------------------------|---------------|----------------|
| <b>Ivory Coast</b> | ARVs                              | GU           | 2004                                 |               |                |
| <b>Ukraine</b>     | ARVs                              | CL           | 2004                                 | N.A.          | N.A            |
| <b>Zambia</b>      | Lamivudine/stavudine/nevirapine   | CL           | 2004                                 | N.A.          | 2,50%          |
| <b>Zimbabwe</b>    | ARVs                              | CL           | 2004                                 | N.A.          | N.A            |
| <b>Malaysia</b>    | zidovudine, zidovudine/lamivudine | GU           | 2003                                 | N.A.          | 4%             |
| <b>Zimbabwe</b>    | ARVs                              | GU           | 2003                                 | N.A.          | N.A            |
| <b>Zimbabwe</b>    | ARVs                              | GU           | 2002                                 | N.A.          | N.A            |