



**HAI** HEALTH  
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INTERNATIONAL

# The TRIPS Flexibilities Navigator 2.0 Explainer

# INTRODUCTION

The Trade Related aspects of Intellectual Property (TRIPS) Agreement has profoundly affected the interface between intellectual property (IP) and access to health technologies. The Health Action International TRIPS Flexibilities Navigator is designed to be a living, crowd-sourced resource that can help lawmakers, policymakers, researchers, and advocates how to better use the flexibilities in the TRIPS Agreement to improve access to patented (essential) medicines and other health technologies.

**The TRIPS Flexibilities Navigator 2.0 was developed with the input of researchers, academics, developers, and advocates following a workshop held in 2023.**

This guide is intended to help anyone wishing to use the features of the Navigator to find what they need and where, and to join the wider discussion around the use of TRIPS flexibilities as legitimate policy tools to help fulfil the fundamental human right to the highest attainable level of health.

NB: The information here is currently limited to countries in Europe, and focuses on the use of Compulsory Licensing, with the geographical and topic scope widening with the tool over time.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.



# A NEW LOOK

First and foremost, the Navigator offers a 'one-stop shop' for information on TRIPS Flexibilities and compulsory licensing, their current useage\*, the legal basis for their use in Europe (per country)\*\*, and practical information on implementation.

The Navigator 2.0 has an enhanced user experience, with readily available and searchable information on products and countries.

\* Information on current use of compulsory licensing comes from the database developed and maintained by Medicines Law & Policy.

\*\* Based on information provided by the European Patent Office.



# COUNTRY INFORMATION

Country information includes the legal basis for the issuing of compulsory licences, whether there has been a compulsory licence issued, and whether the country has generic producers.

## Austria

Austria has provisions in its legislation relating to the granting of compulsory licences.

These can be found in Sections 36 and 37 of the Austrian Patent Act.

There are three grounds for application for a compulsory licence:

1. the patented invention cannot be exploited without infringing an invention patented beforehand and the invention protected by the later patent represents an important technical progress of considerable economic significance compared to the invention protected by the earlier patent
2. the patented invention is not exploited to an appropriate extent in Austria and the patent proprietor has not done everything necessary for such exploitation (unless the patent proprietor proves that the exploitation of the invention in Austria would be an undue burden);
3. the granting of a licence for a patented invention is in the public interest.

More information can be found [here](#).



# PRODUCT INFORMATION

The product page enables the user to find out where a compulsory licence has been issued, and the associated legal basis.

## RAL

RAL is manufactured by Shionogi and is used to treat HIV/AIDS.

### Compulsory licences

Compulsory licenses have been issued for RAL in the following instance:

#### Germany issued on August 01, 2016

[Germany's](#) provisions on compulsory licences can be in Section 24 Patent Act.

According to Section 24(1) PatG, it must be demonstrated that:

1. the applicant has tried, within a reasonable period of time, unsuccessfully to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions;
2. the public interest calls for the grant of a compulsory licence.

In May 2020, the German government passed a "corona crisis package". The so-called Act for protecting the Population in the Event of an Epidemic Situation of National Importance, (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite) the "Epidemic Protection Act", provides for several amendments to existing laws. One amendment provides for measures to restrict German patents, e.g. covering pharmaceuticals or medical devices. Find out more at <https://www.twobirds.com/en/insights/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents>

More information can be found [here](#).

# OTHER FEATURES

The Navigator also offers a range of other features to help guide users through the often-complicated world of TRIPS flexibilities. This includes a glossary of terms, frequently asked questions (FAQs), and other resources, research and websites with useful information. These can all be found by clicking the Menu button in the top right-hand corner of the screen.



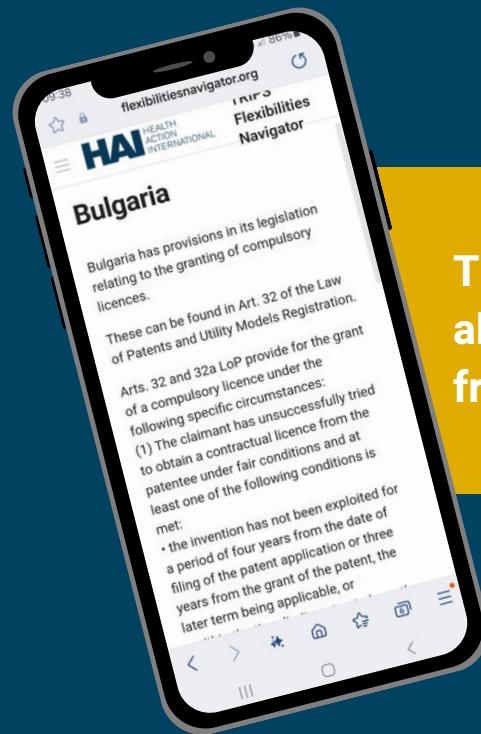
## TRIPS Flexibilities Navigator

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# WE NEED YOUR HELP!

Are we missing generic manufacturers or associations that you know about? Do you have updated resources or papers relevant to the Navigator that you are willing to share for our research page? Let us know by contacting us at [comms@haiweb.org](mailto:comms@haiweb.org) !



The Navigator's features are also available on the mobile-friendly version.

[www.haiweb.org](http://www.haiweb.org) | [www.flexibilitiesnavigator.org](http://www.flexibilitiesnavigator.org)

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