

A healthcare worker, likely a nurse or doctor, is shown in a clinical setting. She is wearing a light blue scrub top and a light blue surgical face mask. She is looking down at a tablet computer she is holding. The background is a blurred hospital hallway with a ceiling light fixture and a door.

**The TRIPS Flexibilities Navigator**  
A User Guide

# INTRODUCTION

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

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 and growing community coalescing 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.



# KEY FEATURES

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

Given that different groups will have varying needs in terms of what would be needed from the Navigator, we offer a number of pathways to follow, with tailored information for lawmakers, policymakers, advocates and researchers.

Please tell us a little about yourself

I am interested in TRIPS Flexibilities from the perspective of a...



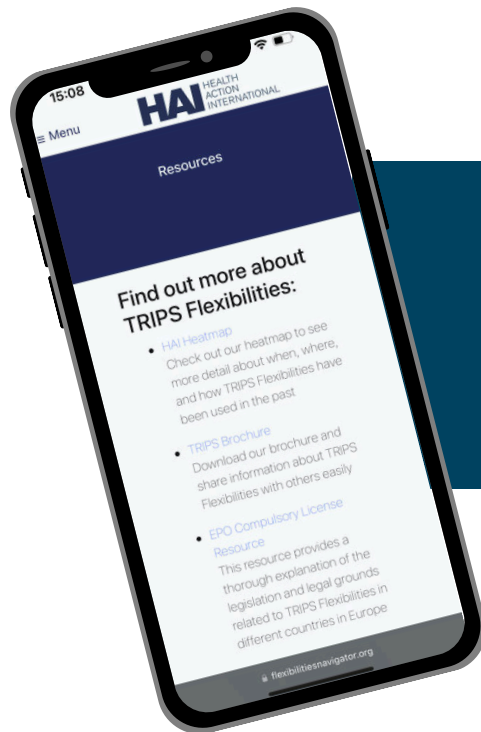
\*Information on current use of compulsory licensing comes from the database developed and maintained by Medicines Law & Policy.

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

# 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), a calendar of events, and other resources and websites with useful information. An important element if we are to mainstream the use of TRIPS flexibilities, including compulsory licensing, as legitimate tools for the achievement of policy goals and fulfillment of international commitments (such as the Sustainable Development Goals (SDGs)) is to build a supportive community of stakeholders.

Therefore, the Navigator offers several functions to help grow this community, including a new Online Discussion Forum, in which ideas can be shared and questions asked (and answered).

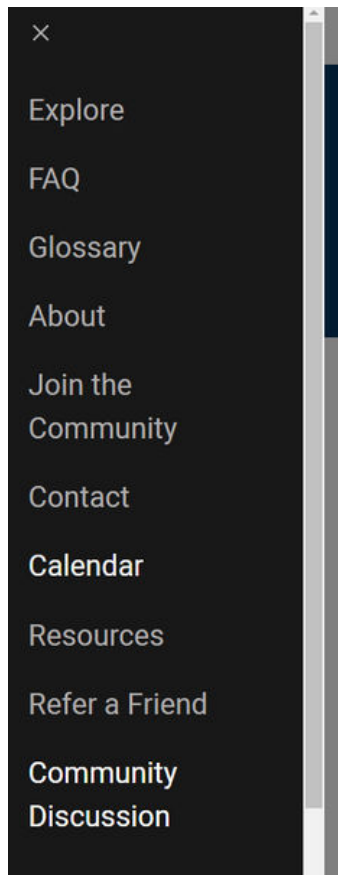


**The Navigator's features are also all available on the mobile-friendly version.**

## Community Discussion

The latest added feature is the community discussion board, on which you are encouraged to post messages with interesting news and updates about TRIPS Flexibilities, comments on ongoing processes, or general questions to experts in the field.

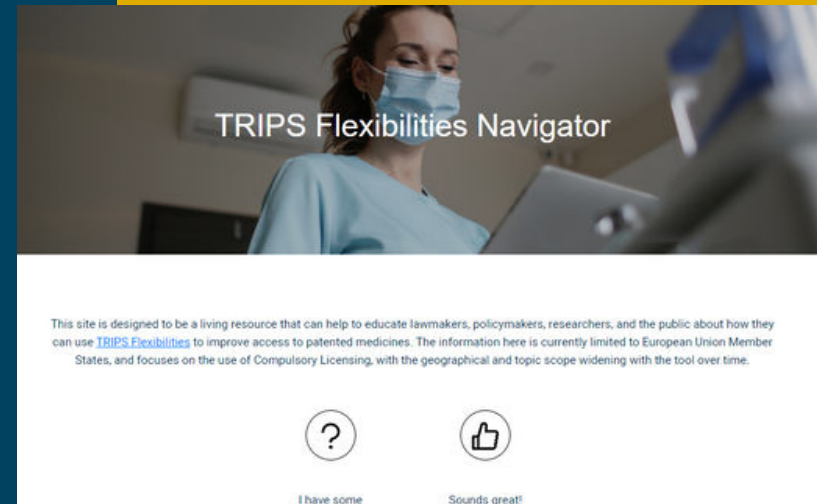
Find it by using the drop-down menu on the left of the screen.



# NAVIGATING KEY FEATURES

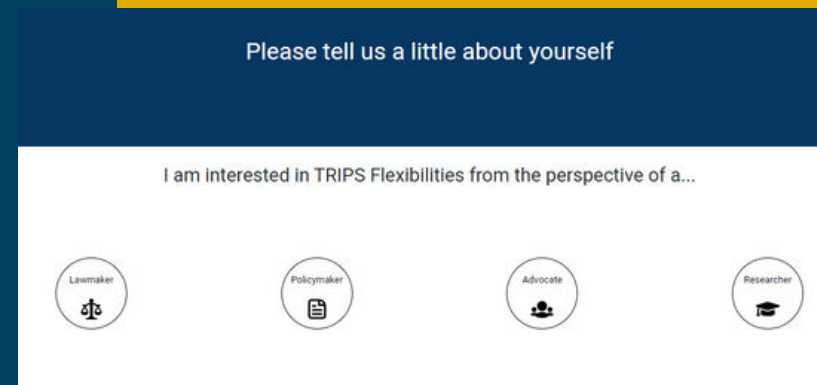
## STEP 1:

On the home page of the Navigator, you will be greeted by a brief explanation, followed by the choice to get started, or "I have some questions first", the latter being a link to FAQs about TRIPS Flexibilities. If you're ready to start with the Navigator journey, selecting "Let's get started" will lead you to choosing from which point of view you would like to continue your journey (see Step 2).



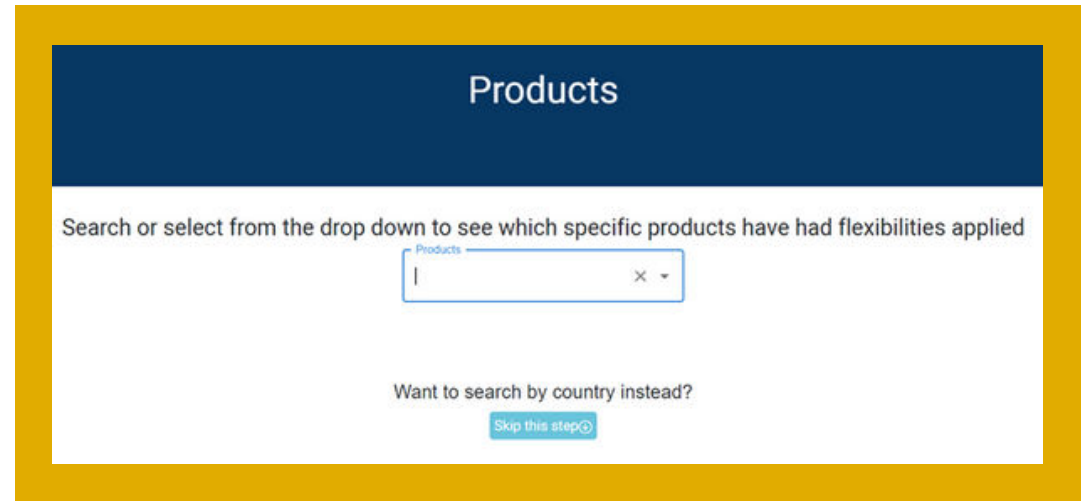
## STEP 2:

Here you can choose how you would like to move through the Navigator - as a Lawmaker, Policymaker, Advocate or Researcher. Depending on which option you choose, the Navigator journey will differ in some respects.



### STEP 3:

For the first three groups (lawmaker, policymaker, and advocate) the next step provides searchable information on current use of TRIPS flexibilities. This information is searchable by product using the drop-down menu or, by selecting "Skip this step", you can move directly to searching by country of interest (see Step 4). This may be particularly useful for national lawmakers or policymakers. See page 12 if you click "Researcher".



### STEP 4:

After having navigated through products (or skipping that step), you will come to information per country (currently limited to Europe). Here, you can select the country you are most interested in, which will pull up information on whether or not TRIPS flexibilities (specifically compulsory licensing) has ever been used in that country. If yes, details of products covered are available. In either case, information on the legal basis for the use of compulsory licensing is also given at this stage.





## Example 1:

### TRIPS Flexibilities have been used before in Germany!

The legislation that is associated with applying for a compulsory license in Germany is Section 24 Patent Act.

You can find more information about the legal basis and the grounds for applying for a license in Germany [here](#).

Know of other important legislation regarding compulsory licenses? Click [HERE](#) to tell us about them.

Trips Flexibilities Use in Germany
Disease: HIV/AIDS
Flexibility type: Art 31
Product: RAL
Generic manufacturer name: Probiosimilars
Executed: Yes

←BACK      1 / 1      NEXT→

## A Useful Tip

You can navigate back to change your profile, country, or product by scrolling with your mouse or using the navigation bar on the left-hand of the screen.

## Example 2:

### There is a legal basis for TRIPS Flexibilities in Netherlands, although compulsory licenses have not been used before.

The legislation that is associated with applying for a compulsory license in Netherlands is Patents Act of 15 December 1994 (Dutch Patent Act, hereinafter DPA), which incorporates into Dutch legislation the Trade Related Aspects of Intellectual Property (TRIPS).

You can find more information about the legal basis and the grounds for applying for a license in Netherlands [here](#).

Know of other important legislation regarding compulsory licenses? Click [HERE](#) to tell us about them.

Although compulsory licenses have not been used in Netherlands, they have been used in other nations in Europe including Albania, Germany, Italy, Romania, and Switzerland.

Click [here](#) to learn more about how and why TRIPS Flexibilities should be used.



## STEP 5:

Now you will be asked “What comes next?”. By continuing to navigate here, you will find more information on the elements required for the successful use of compulsory licensing, which in this case is access to technical expertise and certified know-how. An essential part of this links to generic manufacturers.

The table below shows the generic manufacturers we currently know about.

Manufacturer Name	Country	Link
BOGIN	Albania	<a href="https://www.bogin.nl/english">https://www.bogin.nl/english</a>
Medaxes	Belgium	<a href="https://www.medaxes.be/nl">https://www.medaxes.be/nl</a>
CAFF	Czech Republic	<a href="https://www.caff.eu/">https://www.caff.eu/</a>
IGL	Denmark	<a href="http://www.igldk.dk/?lang=en">http://www.igldk.dk/?lang=en</a>
FGA	Finland	<a href="http://www.xn--rinnakkaisliikeet-5nba">http://www.xn--rinnakkaisliikeet-5nba</a>
Gemme Biosimilaires	France	<a href="http://www.medicamentsgeneriques.i">http://www.medicamentsgeneriques.i</a>

Know of other generic manufacturers? Click [HERE](#) to tell us about them.

Are we missing generic manufacturers or associations that you know about?  
Let the community know by submitting details using the buttons provided.

### Add a Manufacturer

# NAVIGATING KEY FEATURES (CONT'D)

## STEP 6:

The final stage in the navigator process is to download your personalised action plan, which provides all the information you have searched in a single handy PDF. At this stage you can also join the wider community by adding your email address and indicating whether or not you are interested in receiving more information.



For this example, 'policymaker' was selected, as well as 'France' as a country of interest.

# RESEARCHERS

If you select a Researcher profile, your navigator journey will differ somewhat. Firstly, you will find a library of published papers, research and other resources of interest to anyone researching the use of TRIP Flexibilities. At the bottom of the library, you will then also have the choice to “Join the community” or seek other information on use of flexibilities by country or product.



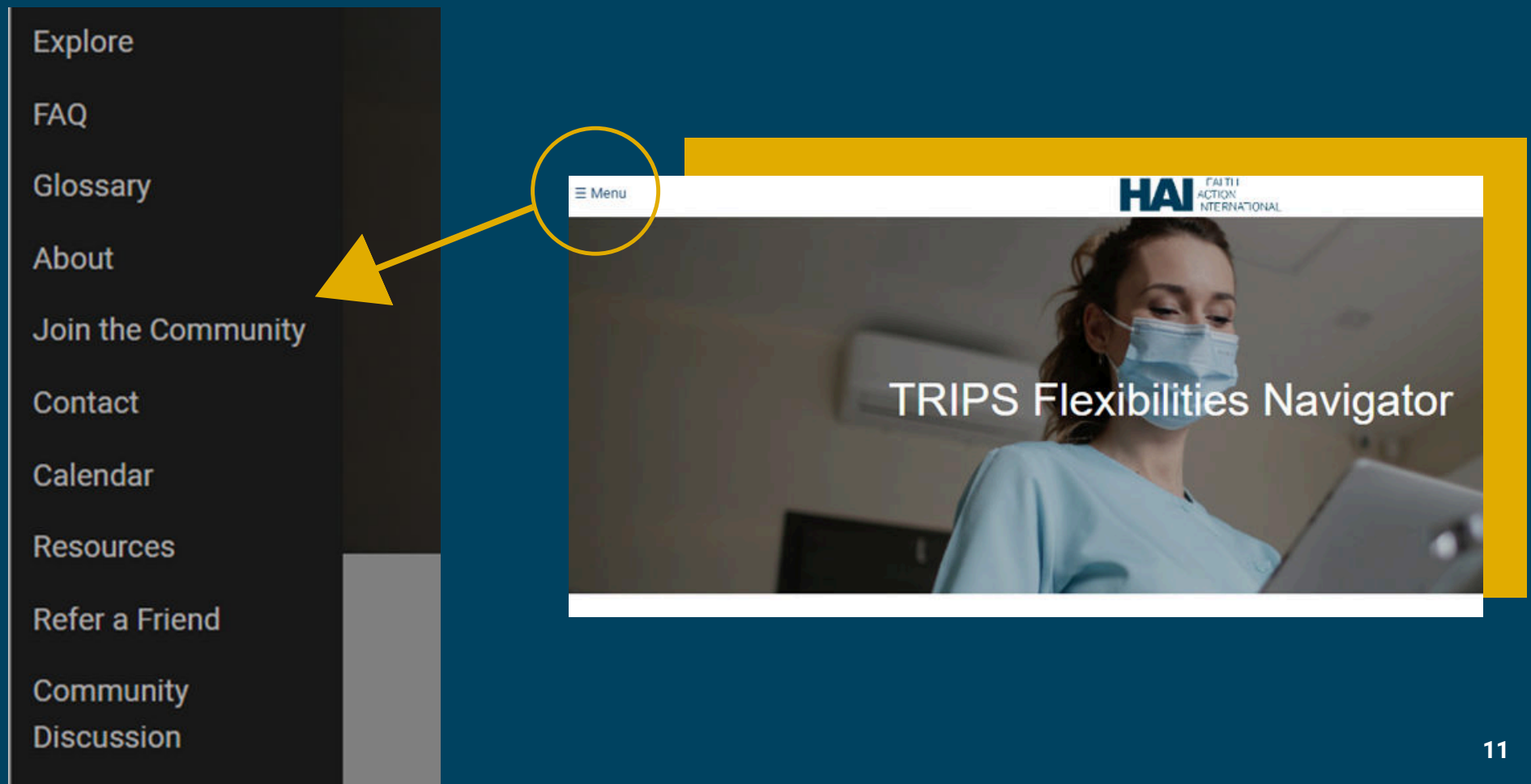
We need your help to expand the community's library of research.

Have you written a paper, or know of any other work we're missing? Then please let us know using the buttons provided.

Know of other existing research? Click [HERE](#) to tell us about it.

# FIND THE NAVIGATOR'S OTHER FEATURES

The other features offered by the Navigator, including a glossary of terms, calendar of events and FAQs, can all be found by clicking the Menu button in the top right-hand corner of the screen.






# WE NEED YOUR HELP!

The role of TRIPS flexibilities as tools to improve access to needed health technologies is clear. The Navigator can help streamline and strengthen the process of doing so but requires the input of a growing community of users to become even more useful. So please join the discussions, share your work, and spread the message (using the "Refer a Friend" button in the menu). Together we can build a community to make a difference.

If you have any feedback on this user guide, please contact us at: [comms@haiweb.org](mailto:comms@haiweb.org)

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

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