

Improving access to novel COVID-19 treatments

A briefing to Member States on how
to navigate interfaces between public
health and intellectual property



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Objective and methodology

In 2022, Unitaid, as co-lead of the ACT-A Therapeutics pillar, convened focused discussions with relevant experts and pillar members, including the World Health Organization (WHO), on the interface between access to COVID-19 therapeutics and intellectual property. An outcome of this meeting was a request for Unitaid and WHO to co-publish a briefing document for countries on pathways for countries to access more affordable therapeutic options.

This briefing document is a factual explanation of some of the legal instruments that Member States are allowed to use to promote public health and access to key therapeutics, in the framework of their multilateral trade obligations and rights and according to their national legislations and level of development.

The document is in line with WHO's mandate, included in several WHA Resolutions like the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)(WHA 61.21 and further Resolutions and Decisions on the implementation of the Plan of Action) to provide technical assistance to Member States in the application and management of intellectual property to contribute to innovation and to promote public health.

In several opportunities WHA urged Member States and WHO Secretariat to strengthen efforts on implementation of the GSPA-PHI. The GSPA-PHI represents an international consensus of priority actions to be taken to promote new thinking on needs-driven innovation and access, including through the application and management of intellectual property in a manner that maximizes public health: e.g. requesting Member States, WHO, other international organizations:

“(5.1) supporting information sharing and capacity building in the application and management of IP with respect to health-related innovation and the promotion of health in developing countries (...)

(5.2) providing as appropriate, upon request, in collaboration with other organizations, technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the TRIPS Agreement, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO Instruments related to the TRIPS Agreement, in order to promote access to pharmaceutical products: (a) consider, whenever necessary, adapting legislation in order to use to the full the flexibilities contained in the TRIPS Agreement, including those recognized by the Doha Declaration on the Trips Agreement and Public Health and the WTO Decision of 30 August 2003; (...)”

In 2022, WHA has extended the implementation plan of the GSPA-PHI until 2030 (WHA Decision WHA 75.14) and requests the WHO Director General, among other aspects:

“(1) to continue to provide technical assistance and share knowledge that could enable countries to implement actions consistent with the global strategy and plan of action on public health, innovation and intellectual property;”

Finally, during the COVID-19 pandemic, WHA Resolution on Strengthening local production of medicines and other health technologies to improve access (WHA 74.6), makes reference, among other aspects, to the use of the TRIPS flexibilities to promote equitable access and the voluntary mechanisms to promote technology transfer, including WHO C-TAP. There is a specific request to WHO Director General:

“(1) to continue to support Member States by strengthening actions related to resolutions WHA61.21 (2008), WHA66.22 (2013) and WHA67.20 (2014);

(...)

(9) to continue to provide technical support, as appropriate, upon request, in collaboration with other competent international organizations, in particular WIPO and WTO, including to policy processes and to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including the flexibilities affirmed by the Doha Declaration on the TRIPS Agreement and Public Health in order to promote access to pharmaceutical products;”

This briefing document is intended to support countries to increase access to novel COVID-19 therapeutics dealing with the challenges at the interfaces between public health and intellectual property to improve availability and/or affordability and to facilitate sourcing of therapeutics from alternative and more affordable sources where possible.

It contains background information and resources on the therapeutics landscape and WHO recommendations (**Section 2**), an overview of the Medicines Patent Pool licenses for oral antivirals and the implications for country access (**Section 3**), the WHO COVID-19 Technology Access Pool (**Section 4**), and other licenses relevant to COVID-19 therapeutics (**Section 5**), and guidance on the use of TRIPS flexibilities (**Section 6**).

Regarding the methodology, materials and information for this briefing document were sourced from publicly available sources, listed in **Annex 2**, and were selected based on relevance to the Intellectual Property of COVID-19 oral antivirals nirmatrelvir/ritonavir and molnupiravir, specifically as it relates to barriers to access in low- and middle-income countries. Documents were synthesized to align with the structure of this briefing document in order to provide a concise and logical roadmap for countries to navigate.

In addition, WTO agreements and WHO resolutions and publications such as The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA 61.21) and The joint Trilateral Study (WHO-WIPO-WTO), Second Edition, on Promoting Access to Medical Technologies and Innovation: Intersections between public health, innovation, and trade guided the development of this work.

Patent status information and licensing information for specific therapeutics was sourced from MedsPal database, WIPO PATENTSCOPE database and the WTO COVID-19 Tracker on IP measures. Information on specific manufacturers was sourced from the WHO PQ Database, WHO Technology Access Pool Database, the Medicines Patent Pool website, as well as company websites. Various legally available measures, including using TRIPS flexibilities, compulsory licensing, or exceptions for least-developed countries, are outlined for countries facing patent or other exclusivity challenges to consider pursuing, as relevant to their national context and need for specific therapeutics. A road map summarizing the options available to countries can be found below with further details on the implementation included in **Annex 1**.

Roadmap of alternatives to access COVID-19 therapeutics



NB: Detailed information on implementing the Roadmap is provided in **Annex 1**.

2

Background

New therapeutics to treat COVID-19 have become available and others in the pipeline are likely to be forthcoming. These treatments are important in fighting the pandemic in low- and middle-income countries, especially in places that continue to face vaccine access and uptake challenges, and may be increasingly important given the possibility of a potential surge and potential new variants with increased severity.

This raises the important consideration of what countries can do to ensure their citizens have access to these therapeutics once they have regulatory approval.

The World Health Organization (WHO) has a set of [living guidelines](#) that provide recommendations for or against the use of various therapeutics for COVID-19. WHO has additionally published a [tool](#) to help make decisions on which therapeutics, if any, are helpful to different populations. WHO makes recommendations on these therapeutics based on patient populations ranged by the severity of disease: ‘critical’ (in need of life-sustaining therapies such as ventilation, showing signs of sepsis or acute respiratory distress); ‘severe’ (oxygen saturation of less than 90% and signs of pneumonia and/or respiratory distress), and ‘non-severe’ (absence of the above criteria).

Table 1, on page 10, includes the therapeutics with a [WHO recommendation](#) as of December 2022 that have one or various patents in force or pending. Dexamethasone (together with other corticoids) was the first therapeutic to receive a WHO recommendation for COVID-19 treatment, however, it does not have any patents in force and is widely available.

As such, it is not addressed in this briefing. The vast majority of the other recommended therapies, however, [have been subject to patent application filings](#), therefore making IP an important element to consider for equitable access.

For products in the pipeline, full patent status information may not yet be available but forthcoming patents could pose barriers to access. Additionally, several patents on medicinal compounds or the process for making them have been granted in key producing countries, such as India, which may hamper access to affordable generics in many countries.

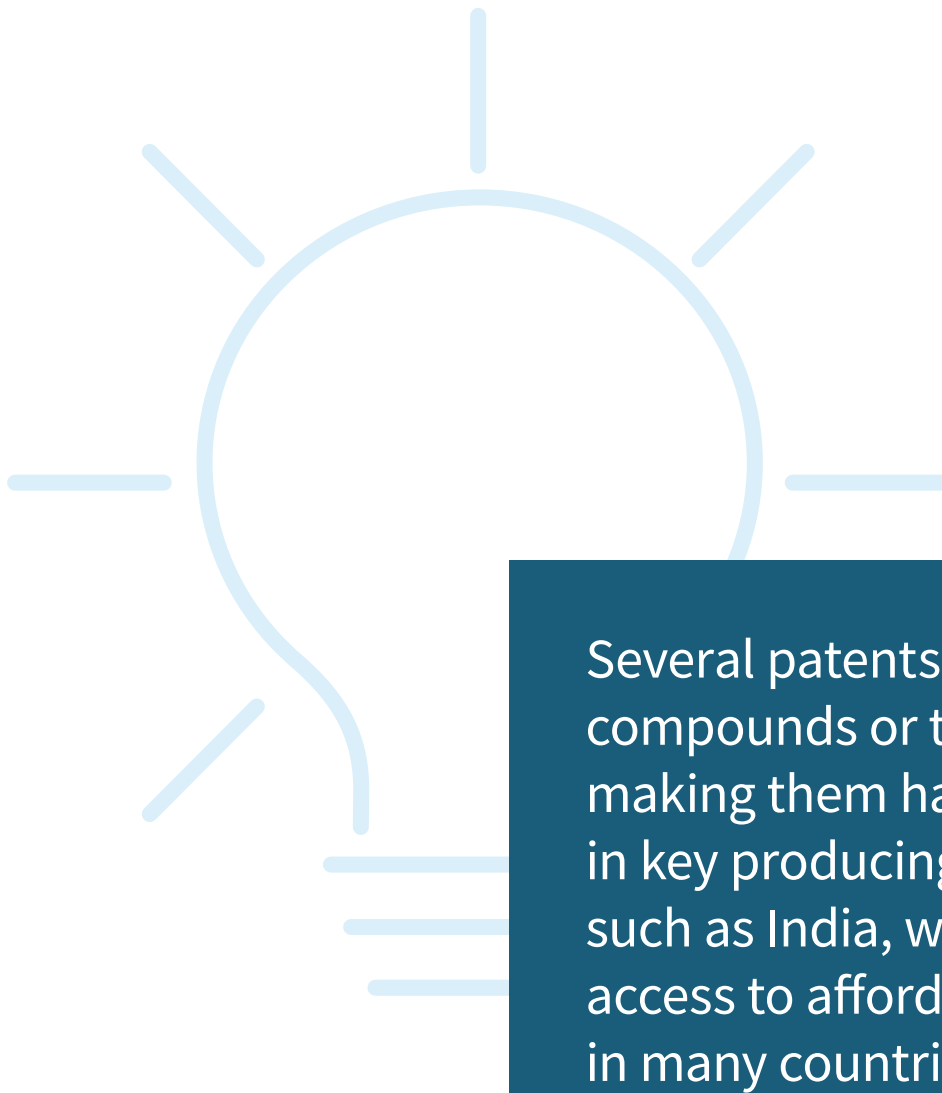
For information on the patent status of COVID-19 therapeutics, see the Medicines Patent Pool’s database on the IP status of WHO Model List of Essential Medicines and other recommended medicines, MedsPal. For the latest information on recommended therapeutics, please see the WHO’s living guidelines.

Table 1: Products included in WHO recommendations as of December 2022¹ that have one or more patents in force.

Medicine	Patent holder	Existing licenses
Baricitinib	Eli Lilly	<p>Bilateral voluntary licenses were signed with 7 manufacturers in India to supply the domestic market</p> <p>https://www.pharmaceutical-technology.com/analysis/lillys-indian-drugmakers-baricitinib-covid-19/, https://www.thehindu.com/business/natco-pharma-signs-pact-with-eli-lilly-for-baricitinib/article34582342.ece</p>
Molnupiravir	Merck, Sharpe and Dohme	<p>Medicines Patent Pool voluntary license signed covering 106 countries</p> <p>https://medicinespatentpool.org/licence-post/molnupiravir-mol</p>
Nirmatrelvir/ Ritonavir	Pfizer	<p>Medicines Patent Pool voluntary license signed covering 95 countries</p> <p>https://medicinespatentpool.org/licence-post/pf-07321332</p> <p>Additionally, there are pending compulsory licenses in Chile, Colombia, the Dominican Republic, and Peru².</p>
Remdesivir	Gilead	<p>Bilateral voluntary licences were signed with 9 generic manufacturers for supply in 127 countries</p> <p>https://www.gilead.com/-/media/files/pdfs/other/original-covid-19-voluntary-license-agreement.pdf?la=en&hash=8D1AFC9E89B3D9238809843A26F0318C ; https://www.gilead.com/purpose/medication-access/global-access/access-partnerships.</p> <p>Compulsory licenses have been granted in Hungary, Indonesia, and Russia.</p>
Sarilumab	Regeneron Pharmaceuticals and Sanofi	None
Tocilizumab	Roche and Chugai	<p>Roche and Chugai decision to not assert patents in low-and middle-income countries during the pandemic (136 countries).</p> <p>https://assets.cwp.roche.com/f/126832/x/88e6ff18e5/20210816-roche-statement-global-actemra-supply.pdf</p>

1 The WHO **Therapeutics and COVID-19: living guideline** is updated regularly as new evidence emerges. For the latest version of the living guidelines, please refer to the [online platform](#).

2 See <http://tripsflexibilities.medicineslawandpolicy.org/> for more details on compulsory licenses for Covid-19 countermeasures. The US government uses non-voluntary use provisions in COVID-19 procurement contracts. See: <https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf>



Several patents on medicinal compounds or the process for making them have been granted in key producing countries, such as India, which may hamper access to affordable generics in many countries.

The need for each of these products in the current epidemiological situation, and their feasibility for use in specific country contexts, is to be determined by appropriate procedures in countries. Some therapies, for example, are intended for hospital use only, which may pose challenges in settings where access to hospitals is limited. Contraindications of the medicines might also limit the number of patients who will benefit. It should be noted that medical recommendations are beyond the scope of this paper; therefore, countries are advised to consult WHO living guidelines and decision-support tools noted in **Section 2** to plan and prioritize therapeutics.

The treatment guidelines cover medicines that are for hospitalized patients as well as for outpatient use. Each of these medicines has specific recommendations, for example, antivirals are currently only recommended for people with certain risk factors, such as older age and diabetes, and where a contraindication, such as pregnancy or breastfeeding, is not present.

3

Medicines Patent Pool licenses and sub-licenses

The Medicines Patent Pool (MPP) is a United Nations (UN)-backed public health organization that works to increase access to essential medicines through voluntary patent licensing.

It was founded by Unitaid in 2010 with the initial mandate of expanding access to HIV treatments but has since expanded to include all patented essential medicines.

At the end of March 2020, the MPP's mandate was extended to include any COVID-19 countermeasure where licensing could help the pandemic response. The MPP became an implementing partner of the WHO COVID-19 Technology Access Pool (WHO C-TAP, see **Section 4** on page 22).

MPP licenses facilitate the manufacturing of affordable generic versions of new medicines for sale in low- and middle-income countries. A first step that governments seeking to source COVID-19 therapeutics can take is to see if the needed medicine has been licensed to the MPP and, if so, if their country is within the license territory. If a country is in the territory, this means that generic producers operating under a MPP sublicense agreement can supply in the country, including through external procurement agencies. The MPP licenses are transparent and available on its website in full text.

To date the MPP has signed two licenses for WHO recommended COVID-19 therapeutics: In November 2021 for nirmatrelvir/ritonavir and in October 2021 for molnupiravir.³

As noted in the above Table 1, the licenses do not include all low- and middle-income countries. Unitaid, WHO and ACT-A partners have repeatedly called for the companies to expand the geographic scope.⁴

3.1 MPP Licenses for WHO recommended COVID-19 Therapeutics

MPP nirmatrelvir/ritonavir license

Nirmatrelvir/ritonavir is an oral antiviral that received a strong recommendation from WHO in April 2022 for mild/moderate cases of COVID-19 at highest risk of hospitalization. Refer to the [WHO living guidelines](#) for further details and current recommendations.

The nirmatrelvir/ritonavir license allows for the manufacture by generic companies selected by MPP and sale of nirmatrelvir/ritonavir in 95 countries⁵. It is royalty free for the duration of the Public Health Emergency of International Concern (PHEIC), after which royalties will be 5% of sales to public or governmental purchasers and 10% of sales to commercial entities.

Additionally, Pfizer has committed to not ever collect royalties on sales to low-income countries or in countries where the medicine is made and sold and no patent application, pending approval, granted patent or regulatory exclusivity is in place. **This means that MPP sublicensees are allowed to sell the product to the 95 countries included in the nirmatrelvir/ritonavir license, for supply in the public and/or private sector⁶, whether or not any patent is granted on nirmatrelvir/ritonavir by their patent office. Additionally, as shown in Annex 1, countries not included in the voluntary license territory may also be able to import the product from generic manufacturers if a patent for nirmatrelvir/ritonavir is not pending approval or in force (patent information available in [MedsPaL](#)).**

When the PHEIC is over, these countries will be able to continue to import nirmatrelvir/ritonavir, but in middle- or high-income countries included in the license territory where a patent is granted, or a patent application pending, or where regulatory exclusivity is in place, the prices may increase due to royalties.

³ In October 2022, MPP also aligned a license for ensitrelvir fumaric acid, another potential antiviral in the pipeline that is not yet under evaluation by WHO. In [May 2022](#), MPP on behalf of the WHO C-TAP initiative, also signed licenses on early-stage technology related to COVID-19 diagnostics, vaccines, and related research tools with the US National Institutes of Health in the context of C-TAP, but these are beyond the scope of this paper.

⁴ For example in the [ACT-A Transition Plan \(1 Oct 2022 – 31 Mar 2023\)](#), the [ACT-Accelerator Facilitation Council Working Group Report on Diagnostics and Therapeutics](#), and various statements ([here](#) and [here](#)).

⁵ The countries are: Afghanistan, Algeria, Angola, Armenia, Bangladesh, Belize, Benin, Bhutan, Bolivia, Botswana, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo, Dem. Rep., Congo, Rep., Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, The Gambia, Georgia, Ghana, Country Classification Guatemala, Guinea, Guinea-Bissau, Haiti, Honduras, India, Indonesia, Iran, Jordan, Kenya, Kiribati, Korea, Dem. People's Rep., Kosovo, Kyrgyz Republic, Lao PDR, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Samoa, São Tomé & Príncipe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Africa (public sector only), South Sudan, Sri Lanka, Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Timor-Leste, Togo, Tonga, Tunisia, Uganda, Ukraine, Uzbekistan, Vanuatu, Venezuela, Vietnam, West Bank and Gaza, Yemen, Rep., Zambia, Zimbabwe.

⁶ In South Africa, the voluntary license territory applies to the public sector only.

The MPP license also includes a data exclusivity waiver in order to facilitate registration of generic versions in the 95 countries of the license territory. As of December 2022, the MPP holds sub-licensing agreements with 38 generic manufacturers in 13 countries (Bangladesh, Brazil, China, Dominican Republic, India, Israel, Jordan, Republic of Korea, Mexico, Pakistan, Serbia, Ukraine, and Vietnam) for the manufacture and supply of nirmatrelvir/ritonavir in the 95-country license territory. Of them, six can produce the raw ingredients, nine can produce the finished drug, and the remaining 23 can do both. The current status of generic products under assessment can be found on the [WHO Prequalification website](#).

The full text of the nirmatrelvir/ritonavir license, the sub-license agreement, and up-to-date information on sub-licensees can be read on the MPP's [website here](#).

MPP molnupiravir license

Molnupiravir is an oral antiviral that received a conditional recommendation from WHO in March 2022 for treatment of mild/moderate cases of COVID-19 at highest risk of hospitalization. Refer to the [WHO living guidelines](#) for further details and current recommendations.

Prior to entering into a license with MPP, the patent holder (MSD) in April 2021 had [announced](#) bilateral licensing agreements with five Indian generics manufacturers for supply of molnupiravir in India and 'more than 100' low- and middle-income countries. Further details on these license agreements are not publicly available. The molnupiravir license between MPP and MSD allows for the medicine to be manufactured anywhere for sale in 106 countries⁷. As with the nirmatrelvir/ritonavir license, it is royalty free so long as the WHO PHEIC is in place, after which royalties of 5% on net sales are due for public purchases and royalties of 10% for commercial purchases.

This means that **MPP sublicensees are allowed to sell the product to the 106 countries included in the molnupiravir license, for supply in the public and/or private sector⁸, whether or not a patent is granted on molnupiravir by their patent office. Additionally, as shown in the roadmap in Annex 1, countries not included in the voluntary license territory may also be able to import the product from generic manufacturers if a patent for molnupiravir is not filed or in force (patent information available in [MedsPaL](#))**. When the PHEIC is over, these countries will be able to continue to import molnupiravir, but the prices may increase because of royalties that manufacturers will have to pay back to the patent holder. The MPP license also includes a data exclusivity waiver in order to facilitate the registration of generic versions in countries that [grant data exclusivity](#).

As of December 2022, the MPP holds sub-licensing agreements with 23 generic manufacturing companies in 11 different countries (Bangladesh, China, Egypt/Jordan, India, Indonesia, Kenya, Pakistan, South Africa, South Korea, and Vietnam) for the manufacture and supply of molnupiravir in the 106 license territories. The MPP notes that five of these companies can produce raw ingredients, eight can produce the finished drug, and the remaining 10 can produce both. The current status of generic products under assessment can be found on the [WHO Prequalification website](#).

The full text of the molnupiravir license, the sub-license agreement, and up-to-date information on sub-licensees can be found on the MPP's [website here](#).

7 The countries are: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroun, Central African Republic, Chad, Comoros, Congo, Dem Rep., Congo, Rep., Côte d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, The, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Kiribati, Korea, Dem. People's Rep., Lao PDR, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Myanmar, Namibia, Nepal, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Thailand [public sector only] Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, Rep., Zambia, Zimbabwe, Algeria, Bolivia, Egypt, Arab Rep, El Salvador, Honduras, India, Micronesia, Federated States, Moldova, Mongolia, Morocco, Nicaragua, Pakistan, Papua New Guinea, Philippines, Sri Lanka, Tunisia, Uzbekistan, Vietnam, Belize, Cuba, Dominica, Fiji, Grenada, Guatemala, Guyana, Indonesia, Iran, Islamic Rep, Iraq, Jamaica, Libya, Maldives, Marshall Islands, Paraguay, Samoa, St. Lucia, St. Vincent and the Grenadines, Suriname, Tonga, Venezuela, RB.

8 In Thailand, the voluntary license territory applies to the public sector only.

3.2 Options for countries not included in MPP license territories to access generics

The WHO, Unitaid and ACT-A partners have called on companies that signed licenses with the MPP to add more countries to their license territories in the near future. In the meantime, given the MPP licensing terms, countries not included in the licenses have several options to access generic versions of the COVID-19 therapeutics, depending on their patent status in the country in question.

No relevant patents pending or in force: Countries where patents on nirmatrelvir/ritonavir or molnupiravir are not pending approval or in force could import generic versions of these medicines regardless of whether the country is included in a voluntary license.

Such countries could purchase from any generic manufacturer, including from companies that produce under an MPP license, noting restrictions on generic manufacturers that use the technology transfer from the originator company (see **Section 3.2.1** for details). This is possible because the MPP license provides that licensees may engage in activities outside the license territory where such activities would not infringe the patents and/or any other intellectual property rights.

However, if in those countries there is regulatory exclusivity, such as Chile or Peru, generic manufacturers may have to wait for the expiration of such regulatory exclusivity [see Box 1] to launch their product on the market.

Box 1 – What is regulatory exclusivity or test data exclusivity?

A pharmaceutical company that wants to introduce a medicine to the market needs to first secure marketing approval from the relevant regulatory authority. Regulatory agencies require drug companies to submit test data that shows efficacy, safety and quality of the medicine they want to put on the market. Assuring efficacy, safety and quality of medicines, be it originator products or generic medicines, is an important public service meant to protect consumers and patients.

A generic company applying for marketing authorization for a generic product has to demonstrate that its product is 'bioequivalent' to the originator product (that is, that it is clinically interchangeable with the originator product). In order to assess that, the regulator may rely on the clinical test data of the originator's product (the reference product).

Also, applicants for generic biologic medicines, called biosimilars, can rely on safety and efficacy data of the originator's product. The WHO's [Guidelines on Evaluation of Biosimilars](#) provides detailed recommendations on the requirements for a biosimilar to be able to demonstrate similarity to the reference product.

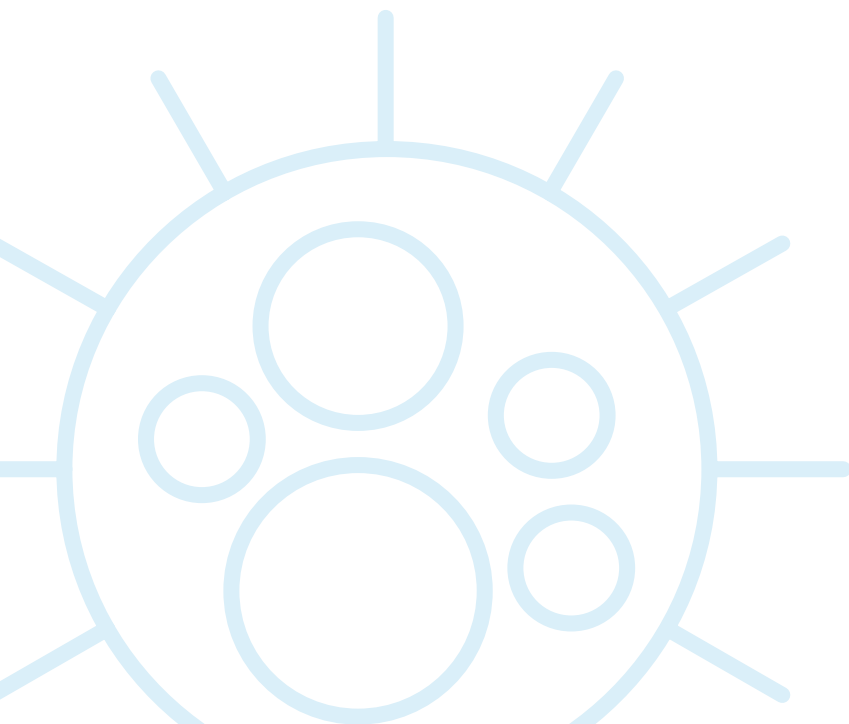
Relying on existing test data for generics or biosimilars avoids unnecessary repetition of clinical trials already carried out with the reference medicine, which would be costly and would be considered unethical. Providing data exclusivity protection is not required under the TRIPS agreement, and in practice, many low- and middle-income countries do not provide it.

Regulatory exclusivity regimes delay access to affordable generic versions of new medicines by prohibiting that regulatory authorities rely on that test data for the purpose of registering a competitor product while the exclusivity period is in force⁹. It has the effect of providing market exclusivity, in some cases, even when no patent is in effect. For example, regulatory exclusivity may also dull the effect of a compulsory license: a compulsory license allows those other than a rights holder to use a technology, but does not override exclusivity granted over test data unless the law provides for a waiver of data exclusivity.



Assuring efficacy, safety and quality of medicines is an important public service meant to protect consumers and patients.

9 See WHO's [Promoting Access to Medical Technologies and Innovation](#) for further details.



Box 2 – Compulsory licensing of COVID-19 Countermeasures

In the last two years, there have been ten instances of compulsory licenses being invoked in the context of COVID-19, of which so far six have been executed. Five of these concerned therapeutics, though not the therapeutics that are the subject of MPP licenses.

The remaining four compulsory licenses are pending, including for nirmatrelvir/ritonavir in Chile, Colombia, the Dominican Republic, and Peru. These four countries are not included in voluntary licenses; however, if the compulsory licenses are executed, MPP sub-licensees and other legitimate generic manufacturers will be able to supply those markets.

Relevant patents pending or in force:

Countries which have granted patents on the required product, for example, nirmatrelvir/ritonavir, but then circumvented the patent barrier by issuing a compulsory licence (see Section 5) would be able to import generic versions of these medicines from MPP licensees even though they are not included in the territory of the license. This is because the MPP licenses allow sub-licensees to supply the products to countries outside the territory if such countries have granted a compulsory license [see Box 2]. Imports under a compulsory license would also be possible from companies manufacturing the products without a license in countries with no granted patent or pending patent application.

In case data exclusivity has been granted the national legislation determines if data exclusivity applies in case a compulsory license or government use license is issued. In Colombia, Chile and Malaysia, compulsory licenses or government use licenses automatically waive any data exclusivity to enable registration of the generic product procured or imported with the license. In other jurisdictions, regulatory exclusivity could be a challenge for generic manufacture (see Box 1).

3.3 Generic products readiness

Generic versions of nirmatrelvir/ritonavir and molnupiravir are becoming available at a fraction of the originator prices. For example, [National Public Radio released the contract price](#) of the United States Government of US\$530 per treatment course for Pfizer's nirmatrelvir/ritonavir. However, as part of **Unitaid-funded work** to facilitate product introduction, [CHAI has signed agreements with generic manufacturers](#) to make the treatment available at under US\$25 per course, and others are expected to decrease prices even further.

Before generic products are accessible for procurement and use by countries, however, generic manufacturers must obtain the necessary regulatory approvals, which could be hampered by regulatory exclusivity (see Box 1) in countries that grant such exclusivity.

3.3.1 Technology transfer

MPP's licenses for both nirmatrelvir/ritonavir and molnupiravir contain a possibility for obtaining know-how and technology transfer packs. It is important to note the following provision included in both MPP licenses clarifying that: "Nothing in this Agreement shall be construed to prevent the Licensee from engaging in activities inside or outside the Territory where such activities would not (1) infringe the Patents and/or any other intellectual property rights; and/or (2) use or misappropriate Licensed Know-How; and/or use or require the use of any ... Confidential Information, including where a compulsory license has been issued," which means that licensees can supply outside the territory if this does not constitute any IP infringement or if a compulsory license has been issued, **and if the licensee has not made use of any technology transfer.**

As such, countries outside the license territory will not be able to be supplied by generic companies that have used the technology transfer from the originator company, even if they would not infringe any IP rights or if a compulsory license has been issued in the importing country (as in point (2) in the text above).

Box 3 – IP issues in Research and Development

In addition to being a potential barrier for use of therapeutics to treat COVID-19, IP can also impede research and development.

For example, the non-profit Drugs for Neglected Diseases initiative (DNDi) was seeking to [conduct complementary evaluations](#) of nirmatrelvir/ritonavir in different treatment strategies for outpatients in low- and middle-income countries, but [was refused](#) access to the drug substance for the studies from Pfizer, while additionally a clause in the Pfizer licences that could be interpreted as requiring generic licensees to obtain permission from Pfizer before making their products available to researchers made sourcing [from generic companies](#) also challenging. Addressing IP barriers is therefore also essential to advance the therapeutics landscape.

As of December 2022, generic molnupiravir and nirmatrelvir/ritonavir were both prequalified and are available to countries via the Access to COVID-19 Tools Accelerator (ACT-A) Therapeutics Pillar partners.

3.3.2 Regulatory approval

WHO Prequalification is assessing generic nirmatrelvir/ritonavir and molnupiravir, along with other COVID-19 medicines and active pharmaceutical ingredients, on a rolling basis. As of December 2022, molnupiravir has been prequalified and is available to countries via the Access to COVID-19 Tools Accelerator (ACT-A) Therapeutics Pillar partners. Generic nirmatrelvir/ritonavir is expected to be available in the first quarter of 2023. The current status of generic products under assessment can be found on the [WHO Prequalification website](#).

WHO Prequalification is required for procurement by UN agencies working under the ACT-A partnership. Recipient countries will also need to provide in-country marketing authorizations. WHO has a program for regulatory reliance, the [Collaborative Procedure for Accelerated Registration](#), where countries may base their national market authorization on the WHO assessments.

Both the nirmatrelvir/ritonavir and molnupiravir MPP licenses originally required that sub-licensees obtain WHO Prequalification or other stringent regulatory authority (SRA) approval or an equivalent emergency use authorization before marketing products under the license. In the case of molnupiravir, a [waiver](#) has now been signed that acknowledges there may be situations in which an MPP sub-licensee “is ready to make available the Product with the necessary regulatory approvals in the country of manufacture and sale... but has yet to receive either WHO Prequalification or SRA approval for the Product.” The waiver was made to prevent countries from facing any delays in procuring for themselves (rather than through UN agencies) due to pending WHO Prequalification or SRA approvals. For nirmatrelvir, there is not yet a waiver published for the Prequalification/SRA requirement.



The waiver was made to prevent countries from facing any delays in procuring for themselves (rather than through UN agencies) due to pending WHO Prequalification or SRA approvals.

4

The COVID-19 Technology Access Pool (C-TAP)

In May 2020, WHO, the Government of Costa Rica and other partners, including UNDP, UNAIDS, and Unitaid, launched the WHO COVID-19 Technology Access Pool (C-TAP) to facilitate timely equitable and affordable access to COVID-19 health products for people in all countries. C-TAP, which is currently endorsed by 44 WHO Member States, was a response to the global Solidarity Call to Action.

C-TAP provides a single global platform for the developers of COVID-19 therapeutics, diagnostics, vaccines, and other health products to share their intellectual property, knowledge, and data with other entities including for quality-assured manufacturing, through public health-driven, transparent, voluntary, non-exclusive, and worldwide licenses. It also provides support for technology transfer agreements. Through voluntary licensing and patent pooling, patent holders can reach new markets and scale up production using untapped capacity of manufacturers around the world, while securing appropriate royalties.

WHO C-TAP has been promoting discussions among WHO Member States on how to further incentivise voluntary sharing of technologies and calling on funders of health R&D to develop access policies and specific access provisions in funding agreements.

COVID-19 candidate technologies/products are included in the C-TAP technology transfer pool following a technical assessment of the relevant information and data made available to C-TAP. Candidate technologies from all C-TAP streams (in vitro diagnostics, vaccines, medical devices, and medicines) are categorized into five C-TAP Categories on the basis of provided evidence of the product/technology's potential to meet the clinical/performance/intended use/label claims, as applicable.

In November 2021, under the auspices of WHO's COVID-19 Technology Access Pool (C-TAP), the Medicines Patent Pool signed a worldwide, non-exclusive license with the Spanish National Research Council (CSIC) for a COVID-19 serological antibody diagnostic test available here. The diagnostic test effectively checks for the presence of anti-SARS-CoV-2 antibodies developed either in response to a COVID-19 infection or to a vaccine. A South African manufacturer received a sublicense to benefit from transfer of IP, know-how and materials to scale up manufacturing in that region.

In May 2022, WHO's COVID-19 Technology Access Pool (C-TAP) received from the United States National Institutes of Health (NIH) 11 early-stage technologies for the development of therapeutics, vaccines and diagnostic tools for COVID-19, detailed information and worldwide licenses available here. These licenses are now allowing further negotiations with other technology holders.

5

Bilateral licensing agreements

Bilateral voluntary licenses, signed between the originator company and one or several licensees, can also facilitate supply of generic COVID-19 treatments. There have been several cases of bilateral licenses during the pandemic.

For example, Gilead in May 2020 signed deals with nine generic manufacturers in India, Pakistan and Egypt allowing the supply of its remdesivir in 127 countries. Additionally, prior to signing with the MPP, in April 2021 MSD announced bilateral licensing agreements with 5 Indian generics manufacturers for supply of molnupiravir in India and ‘more than 100’ low- and middle-income countries. While the full text of the Gilead bilateral license is available online, the full text of the MSD license is not publicly available, and therefore the scope of the licenses is unclear.

Finally, Eli Lilly signed six voluntary licenses with Indian manufacturers in May 2021 for supply of its drug baricitinib within the Indian domestic market. Interestingly, shortly before the announcement of the voluntary license agreement with Eli Lilly, Indian generic manufacturer Natco sought a compulsory license for baricitinib; Natco later became part of the bilateral licensing deal for the domestic market in India. Invoking the potential of a compulsory license (see **Section 5.2**) can often be useful even if it is not executed as it may encourage licensing.

Bilateral licenses might not always offer access-oriented provisions, they are usually not publicly available, and may contain additional restrictions or limited geographical scope such as in the case of baricitinib’s licenses for domestic use in India only. Bilateral licenses may not allow licensees to supply outside the patent territory when no patent barriers prevent them doing so.

The World Health Assembly in 2019 adopted a resolution on improving transparency in medicines markets, and in particular highlighted the importance of transparency around patent status and licensing information. For example, the license agreements of MSD and Eli Lilly are not publicly available and may contain additional restrictions.

6

Use of TRIPS Flexibilities

The World Trade Organization's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) contains several flexibilities that can be invoked for public interest purposes including for the protection of public health.^{10, 11}

The objective of the TRIPS Agreement is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology. The TRIPS Agreement has as a key principle that countries may adopt measures necessary to protect public health.¹²

The impact of the flexibilities in TRIPS depend on how specific aspects of the intellectual property regime are regulated domestically. Such aspects include: the definition of patentable subject matter, exclusions from patentability, patentability criteria, options for patent grant oppositions, exhaustion regimes, compulsory licenses and other limitations and exceptions to patent rights. For example, the regulatory review exception (Bolar) allows generic manufacturers to use a patented invention without the consent of the patent owner for the purpose of obtaining marketing approval for a generic product. The objective is to facilitate timely entry of competitors upon expiry of the patent. Failing to have such an exception would lead to a de facto continuation of the monopoly position of the patent holder after patent expiry while marketing approval of the generic is processed.

Government-use authorizations and compulsory licenses have been used to import or locally produce generic versions of needed medicines, as well as to remedy anti-competitive practices. See more details in **Section 6.1** below.

Pre-grant and post-grant patent oppositions allow third parties to file oppositions against a patent before or after the grant, or even to file observations during the patent examination process. These procedures promote patent quality.¹³ Various WHO and UN resolutions have endorsed the use of these flexibilities to promote and protect public health, including the ones on COVID-19 response and local production.

The flexibilities described in the following sections are particularly relevant for the procurement of COVID-19 therapeutics.

10 The ML&P's [TRIPS Flexibilities Database](#) documents the use of TRIPS flexibilities for public health and in the last year and a half the 10 new instances of compulsory licenses concerned COVID-19 products. Selected country experiences with compulsory licenses and government-use licenses have been included in the WHO-WIPO-WTO Trilateral Study (Second Edition) page 239 to 241.

11 The Flexibilities in the TRIPS agreement go beyond the specific actions discussed here but discussing them all is beyond the scope of the paper. For more information, see the most recent Trilateral Report here: <https://www.wipo.int/publications/en/details.jsp?id=4511>

12 Articles 7 of the TRIPS Agreement titled Objectives reads: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 8 TRIPS Agreement titled Principles reads: 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. ; 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

13 MSF maintains a database of patent oppositions for public health: <https://www.patentoppositions.org/>

6.1 Compulsory licensing and government use of patents

Government authorities have the right to issue compulsory licenses to overcome patent barriers. These licenses authorize the government itself or a third party to use the patented invention without the consent of the patent holder, against payment of “adequate remuneration.” A ‘government use’ is a particular form of a compulsory license issued by a government for its own use or for use by a third party on its behalf. Government use licenses can, for example, be used to supply a generic version of a patented medicine to the public health sector.

The right to issue these licenses is contained in Article 31 of the TRIPS agreement. Under normal circumstances, the would-be user of the patented product should make efforts to obtain permission from the patent holder in the form of a voluntary license and then only seek a compulsory license if these efforts are not successful. But this is waived in the case of emergency (such as a pandemic) or in the case of public non-commercial use (e.g., government use). Compulsory licensing, including government use of patents, is most relevant in situations where licenses are not available or for countries that are not included in voluntary licenses discussed above.

Several countries took measures to facilitate the use of these flexibilities during the pandemic. For example, in 2020 the Hungarian Government declared a special legal order based on Article 31bis of the TRIPS agreement creating a public health compulsory license and also issued three compulsory licenses for use of remdesivir. Russia also issued a compulsory license on remdesivir. In 2020, Canada amended its Patent Act to allow for the supply of a patented invention to respond to public health emergencies of national concerns; Germany and Italy passed similar legislation. In 2021, Bolivia and Antigua and Barbuda notified the WTO of their intention to use Article 31bis of the TRIPS agreement to import COVID-19 countermeasures. For a complete list of intellectual property measures taken by WTO member states under COVID-19, see the [WTO’s database here](#).

In light of the COVID-19 pandemic, negotiations have been ongoing regarding additional TRIPS flexibilities for tools to combat COVID-19 at the WTO (see box 4).

6.2 TRIPS flexibilities for Least Developed Countries

Least developed countries (LDCs) that are members of the WTO benefit from a special transition period related to pharmaceutical products and processes; specifically, they are not required to grant or enforce rights related to patents or undisclosed test data on pharmaceuticals. This transition period is currently set to last until 1 January 2033 or until a country ceases to be classified as an LDC.

This means that if an LDC has a granted patent or test data exclusivity that interferes with the import of a medicine from a generic company, they can simply declare that they will use the transition period and that barrier will be lifted. This can, for example, be helpful when procurement agencies seek assurances that they can supply without concerns about patent infringement.

6.3 TRIPS Article 73

One other provision that has been discussed as potentially useful during a pandemic is Article 73, ‘Security Exceptions.’ In particular, this article reads that “Nothing in this Agreement shall be construed to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests... taken in time of war or other emergency in international relations.”

Early on in the pandemic, the intergovernmental agency the South Centre [published a paper](#) explaining that the COVID-19 pandemic can justifiably be considered an ‘emergency in international relations’ and thus that any World Trade Organization (WTO) member state choosing to circumvent intellectual property rights in order to increase access to COVID-19 countermeasures would be acting within their rights under the TRIPS Agreement.



Box 4 – A note on the WTO TRIPS Decision

In October of 2020, India and South Africa supported by many other countries proposed at the WTO's TRIPS Council a temporary waiver of certain provisions of the TRIPS Agreement to facilitate manufacture of and access to COVID-19 countermeasures.

Almost 20 months later, the WTO's 12th Ministerial Conference, held in Geneva from 12-16 June 2022, adopted a Ministerial Decision on the TRIPS Agreement. The Decision deviates significantly from the approach originally proposed; it is a waiver of the requirement (in Art.31.f of the TRIPS Agreement) that a compulsory license will be predominantly for the supply of the domestic market. In addition, the Decision only applies to vaccines for the moment, but determined that Members would decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics no later than 17 December 2022.¹⁴ Therapeutics are better candidates for compulsory licensing than vaccines; expanding capacity of production of small molecule medicines can be achieved without know-how transfer which can rapidly increase manufacturer supplier base and lower prices.

WTO Members would need to implement the Decision at the national level as soon as possible to be able to benefit. A footnote to the Decision stipulates that while all developing country members are eligible to use the waiver, those with existing production capacity are encouraged to make "a binding commitment" not to. If such binding commitments are made in countries with existing manufacturing capacity, the effect of the Decision will be limited. It will be important for countries with production capacity to not opt-out. For a more in-depth analysis of the WTO Decision see here.

¹⁴ At the time of writing this deadline had passed. The WTO General Council is expected to rule on the extension of the deadline.

7

Conclusions

Countries needing to access COVID-19 therapeutics from generic sources have several options they may pursue in order to do so, which are summarized in the chart on the first page of this document.

Countries can also take advantage of various publicly available information sources to learn about WHO's latest recommendations for COVID-19 therapeutics, WHO Prequalification status, the current statuses of patents and licenses, and possible public health flexibilities included in the TRIPS Agreement. Resources, including those noted in this document, are listed in **Annex 2**.

However, operationalizing options to overcome patent and other IP barriers in the midst of a pandemic may be cumbersome. It is therefore important that countries ensure that regulation to issue compulsory licenses when needed is in place. It is also hoped that voluntary licensing of IP and know-how of medical technologies needed to address future health emergencies becomes the norm, such as through the work of the WHO Intergovernmental Negotiating Body which is negotiating the pandemic treaty.^{15, 16}

¹⁵ For details see: <https://inb.who.int>

¹⁶ For some suggestions on how this might be achieved, see the recent paper in BMJ Global Health, <https://gh.bmj.com/content/7/7/e009709.info>

A

Annexes

Annex 1: Roadmap of alternatives to access COVID-19 therapeutics

Roadmap of alternatives to access COVID-19 therapeutics

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Introduction

- SDG 3.8 Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all
- UHC is WHO's current top priority and access to essential medicines and health technologies is a key component of UHC
- It has been proven that competition is the best way to reduce prices, however some exclusivities including patent protection may impact the generic entry of medicines into the market (Standard patent protection of 20 years; secondary patents; patent term extensions; data exclusivity protection; other market exclusivities)
- The following steps would guide in assessing how to get access to new COVID-19 therapeutics.

A blue circle containing the text 'STEP 1' in white.

STEP 1

Verification of patent status of the product in your country or territory

1.1. Preliminary patent search

Publicly available user-friendly databases that include International Non Proprietary Names (INN) of the products e.g.:

- WHO Technology Access Pool Database: [COVID-19 technology access pool \(who.int\)](https://www.who.int/teams/essential-medicines/technology-access-pool)
- MedsPaL: www.medspal.org
- Orange Book database: [Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations \(fda.gov\)](https://www.fda.gov/oc/industry/orange-book)
- Health Canada database: [Search criteria – Drug Product Database online query \(canada.ca\)](https://www.hc-sc.gc.ca/health/life/meds/meds/meds-eng.php)

1.2. Verification of the patent status and other market exclusivities in your country or territory

Contact your patent office and provide the information found in step 1.1 to facilitate the search.

1.3. If applicable according to your national legislation

The verification of other market exclusivities for that specific product in your territory: information may be available in the databases referred in 1.1. but it is recommended to verify with the national regulatory authorities, for example for data exclusivity protection.


 STEP
2
STEP 2**Patent, patent application or other market exclusivity not found in your country**

If there is no patent granted or if there is a patent that has been rejected by your patent office; if there is no patent application*; and if there is no other market exclusivity e.g. data exclusivity protection for that specific product.

*Note: For Member States that are part of the WIPO Patent Cooperation Treaty (PCT) they should also check the WIPO PATENTSCOPE database [PATENTSCOPE \(wipo.int\)](http://PATENTSCOPE(wipo.int)) to see if there is not a pending patent application that is still in the deadline and susceptible to enter the national phase.

[GO TO STEP 7](#)


 STEP
3
STEP 3**Patent, patent application or other market exclusivity has been found in your country****3.1. Patent granted**

Verify the expiry date in your country. You may need to find out if your country has been included in the geographic scope of any voluntary license (STEP 5) and if the terms and conditions fit your purposes (if the text of the license is publicly available). You may also request government use without the authorization of the patent holder according to the national legislation for that purpose in your country (STEP 6).

Note: The existence of post-grant oppositions in some national legislations or appeal processes in case there are arguments against the validity of the patent.

3.2. Patent application or pending PCT application

In some legislations the mere fact of having a patent application already represent an obstacle for access because there may be some retroactive effect if the patent is granted.

3.3. Other market exclusivity for that product in your country

Information may be available in the databases referred in 1.1 but it is recommended to verify with the national regulatory authorities for example for data exclusivity protection* if applicable in your country.

*Note: Important to note that Data Exclusivity Protection is not an obligation under the WTO TRIPS Agreement.

[GO TO ALTERNATIVES IN STEP 5 OR STEP 6](#)


 STEP
4

STEP 4 Least Developed Countries (LDCs) exemption

The country is a Least Developed Country (LDC) according to WTO ([WTO | Understanding the WTO – least-developed countries](#)) if it is allowed to directly use the transition period for LDCs. According to the TRIPS Agreement and subsequent extensions of the deadlines, LDCs are given an extended transition period to protect intellectual property under the WTO's TRIPS Agreement.

This is in recognition of their special requirements, their economic, financial and administrative constraints, and the need for flexibility so that they can create a viable technological base. LDCs should not implement patent protection and/or not enforce patents or patent applications for pharmaceutical products and processes. They are allowed to manufacture or import generics from all available sources.

[GO TO STEP 7](#)


 STEP
5

STEP 5 Voluntary licenses

5.1. C-TAP or MPP licenses

Verify if your country is included in the geographic scope of the license (Texts of C-TAP or MPP licenses are always fully available on their websites, verify annex with the territory) e.g. nirmatrelvir/ritonavir or molnupiravir MPP licenses.

- WHO Technology Access Pool Database: [COVID-19 technology access pool \(who.int\)](#)
- MPP Licenses: [MPP \(medicinespatentpool.org\)](#)

5.2. Bilateral licenses

Verify with the companies that signed the license (generally not publicly available information) if your country is covered by the license (e.g. remdesivir).

5.3. Non-enforcement commitments

In some cases the patent owners decide to offer not to enforce their patent rights for some countries and/or some specific time, so it would be important to verify on the company's website if they have made such non-enforcement commitments (e.g. ritonavir).

Note: Important to understand terms and conditions of the licenses because they may contain other contractual restrictions e.g. some sublicensees may be able to manufacture in a country but not sell in the same country. Waivers to data exclusivity may also be found in some of the licenses.

[GO TO STEP 7 IF THE COUNTRY IS COVERED BY ANY OF THE ABOVE SUB-ITEMS](#)
[GO TO STEP 6 IF THE COUNTRY IS NOT COVERED BY ANY OF THE ABOVE SUB-ITEMS](#)


 STEP
6
STEP 6**Allowed uses without the authorization of the IP holders:
Government use; Compulsory License; security**

Articles 30, 31 and 31bis of the TRIPS Agreement provide for exceptions and limitations to the rights, and these provisions set out the conditions under which they may be applied. Countries have implemented these provisions in different ways in their domestic legislations.

6.1. Government use (GU) or compulsory license (CL)

Governments are allowed to issue a compulsory licence or grant authorization for public non-commercial use (government use) to allow manufacture or import of generics from all available sources

6.2. TRIPS Waiver Decision [directdoc.aspx \(wto.org\)](#)

“2. For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder’s consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the “law of a Member” referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.”

6.3. Security reasons: TRIPS Agreement Article 73

In emergencies, a country can invoke TRIPS Article 73, which allows countries to circumvent intellectual property rights for security reasons. This would then allow manufacture or import of generics. For more information on how this applies to COVID-19, [see here](#).

Note: Information on these measures in countries can be found in the following places:

- WHO Technology Access Pool Database: [COVID-19 technology access pool \(who.int\)](#)
- WTO COVID-19 IP Tracker: [COVID-19 IP Policy Tracker \(wipo.int\)](#)
- WIPO provisions on flexibilities in countries: [Microsoft Word – SASQCDIP_5_4_Annex II.doc \(wipo.int\)](#)
- Medicines Law and Policy database on TRIPS flexibilities: [TRIPS database – Medicines, Law & Policy \(medicineslawandpolicy.org\)](#)

GO TO STEP 7

**STEP
7****STEP 7****Allowed to produce or import generics to the country****7.1. Manufacturers: Information about manufacturers is available in the following places**

- WHO PQ database: [WHO – Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#) | [WHO – Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)
- WHO Technology Access Pool Database: [COVID-19 technology access pool \(who.int\)](#)
- MPP Licenses: [MPP \(medicinespatentpool.org\)](#)

7.2. Technical assistance from WHO for the application and management of intellectual property is provided in line with the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA-PHI) and many other WHA Resolutions

“There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.”

- [Health products policy and standards \(who.int\)](#)
- [Global strategy and plan of action on public health, innovation and intellectual property \(who.int\)](#)

7.3. Addressing the global shortages of, and access to, medicines and vaccines

WHO’s Access Roadmap includes activities, actions and deliverables for 2019–2023 (e.g. R&D; Pricing policies; Application & management of IP)

- [Roadmap for access to medicines, vaccines and health product 2019-2023: comprehensive support for access to medicines, vaccines and other health products \(who.int\)](#)

Annex 2: Resources

WHO COVID-19 Therapeutic Recommendations, Guidance and Prequalification Status

WHO Therapeutics and COVID-19: Living Guideline: www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4; www.bmj.com/content/370/bmj.m3379

WHO MATCH-IT Tool: <https://magicevidence.org/match-it/220404dist-covid-meds/#/>

WHO Prequalification Status: <https://extranet.who.int/pqweb/news/status-covid-19-medicines-and-active-pharmaceutical-ingredients-apis-updated>

WHO Guidelines on the Evaluation of Biosimilars: <https://www.who.int/publications/m/item/guidelines-on-evaluation-of-biosimilars#:~:text=These%20WHO%20Guidelines%20are%20intended,on%20a%20full%20licensing%20dossier.>

WHO Collaborative Procedure for Accelerated Registration: <https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration>

Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response: <https://apps.who.int/gb/inb/>

COVID-19 Technology Access Pool (C-TAP)

WHO COVID-19 Technology Access Pool: <https://www.who.int/initiatives/covid-19-technology-access-pool>

Solidarity Call to Action: <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>

Patent and Material License Agreement by and between Agencia Estatal Consejo Superior De Investigaciones Científicas M. P. and Medicines Patent Pool: https://cdn.who.int/media/docs/default-source/medicines/c-tap/c-tap-mpp---csic-licence.pdf?sfvrsn=6adf5560_1

Patent and Material License Agreement by and between Medicines Patent Pool and Biotech Africa:

https://cdn.who.int/media/docs/default-source/medicines/c-tap/sublicence-agreement-mpp-biotech-africa.pdf?sfvrsn=59cc142e_1

US NIH Licenses to C-TAP: <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licences>

License and Patent Information

The Medicines Patents and Licenses Database (MedsPaL): www.medspal.org/?page=1

MPP Nirmatrelvir License: <https://medicinespatentpool.org/licence-post/pf-07321332>

MPP Molnupiravir License: <https://medicinespatentpool.org/licence-post/molnupiravir-mol>

MPP Ensitrelvir License: <https://medicinespatentpool.org/licence-post/ensitrelvir>

Other Useful Resources

List of WTO LDC members (Medicines Law & Policy): <https://medicineslawandpolicy.org/tools/model-uses-of-paragraph-7/>

Promoting Access to Medical Technologies and Innovation (WHO): <https://www.who.int/publications/i/item/9789240008267>

The TRIPS Flexibilities Database (Medicines Law & Policy): <http://tripsflexibilities.medicineslawandpolicy.org/>

The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic (South Centre): <https://www.southcentre.int/research-paper-116-august-2020/>

The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?: https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf

MSF Patent oppositions database: <https://www.msf.org/patent-opposition-database>



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