



# **TRIPS Waiver & What can WHO contribute to making Covid-19 vaccines, treatments and technologies global public goods?**

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## **COVID-19 Medical Products: Disparity in Access**

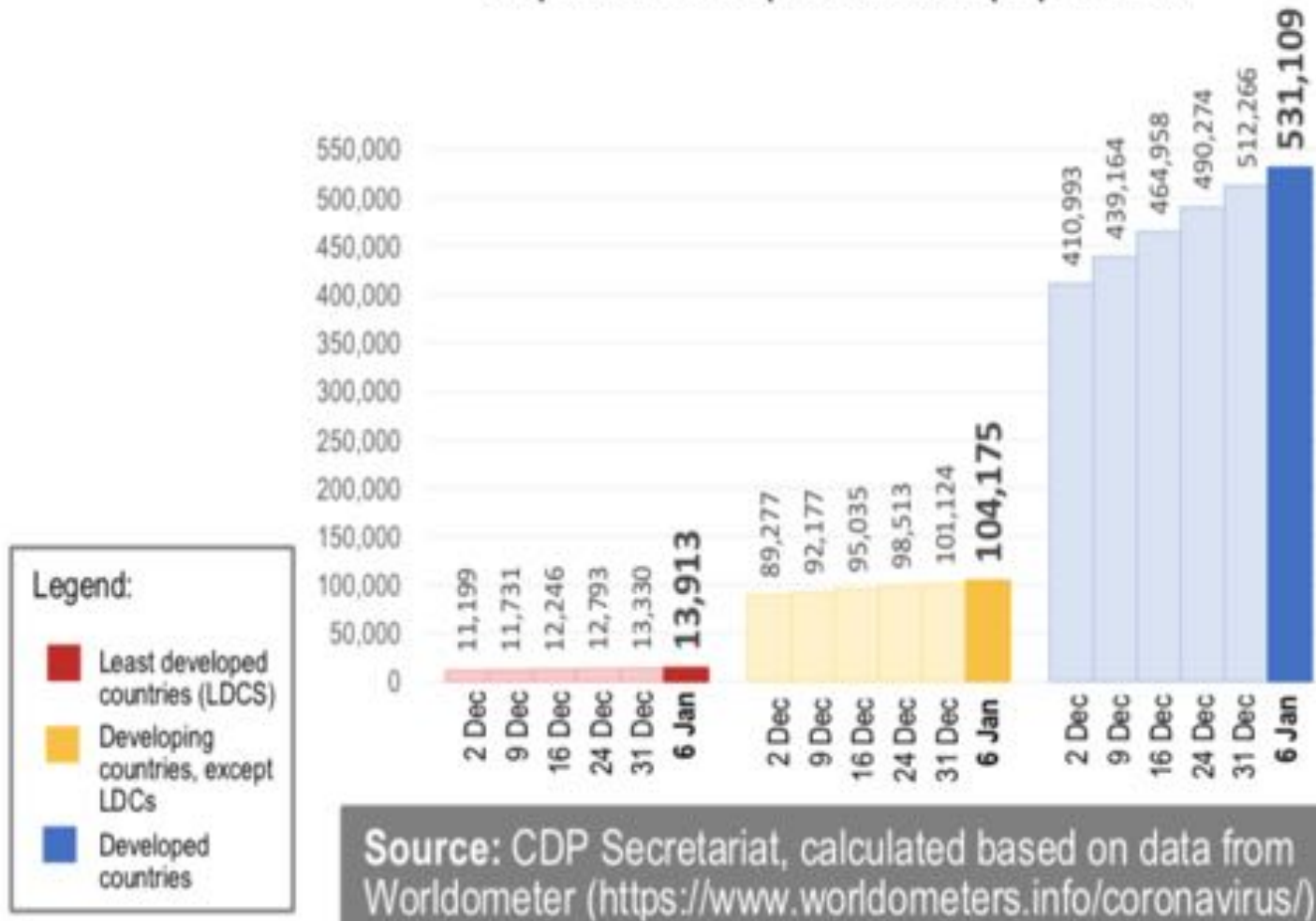
## UNCTAD Global Trade Update Oct 2020

“Nevertheless, the increase in supply of COVID-19 related products has been largely to the benefit of wealthier countries. There is substantial evidence that **middle- and low-income countries have been largely priced out from access** to COVID-19 related products. Despite efforts to facilitate access to COVID-19 supplies<sup>3</sup>, trade statistics show that only a tiny fraction of the additional world production of COVID-19 related supplies have reached low income countries.

Since the onset of the pandemic, **each resident of high-income countries has benefited, on average, from an additional US\$10 per month of imports of COVID-19 related products. This number is much lower for middle income countries- at about US\$1, and lower still for low income countries – a mere US\$0.10.** In other words, per capita imports of the medical goods essential to mitigate the COVID-19 pandemic have been about 100 times larger in high income countries in comparison to low income countries. While it should be expected that the increase of per capita imports of COVID-19 products would be larger for wealthier countries, **the sheer difference is staggering.**<sup>5</sup>

A vaccine appears to be the most promising way to assuage the pandemic and revive the global economy. Still, for any recovery to be truly global and inclusive, it is important for the vaccine to be affordable and widely available. **The ongoing initiatives to make vaccines available in developing countries may not be sufficient.**

## Reported tests per 1 Million population



## Covid Testing

Source:

<https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC-testing-6-Jan.pdf>

# Reshaping the monoclonal antibody world

Today's global market for monoclonal antibodies is highly unbalanced.





**“Wealthy nations representing just 13 percent of the world’s population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates. ...**

**Even in the extremely unlikely event that all five vaccines succeed, nearly two thirds (61 percent) of the world’s population will not have a vaccine until at least 2022.”**

Oxfam analyzed the deals that pharmaceutical corporations and vaccine producers have already struck with nations around the world for the five leading vaccine candidates currently in phase 3 clinical trials, based on data collected by Airfinity.

**<https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19>**





## **Pfizer vaccine: Over 80% of doses already sold to world's richest countries**

Equitable distribution of Covid-19 vaccines globally would prevent 61 per cent of subsequent deaths, compared to 33 per cent of deaths avoided if doses are shared with rich nations first, research shows

<https://www.independent.co.uk/news/health/covid-pfizer-vaccine-doses-latest-uk-supplies-b1721162.html>

<https://www.globaljustice.org.uk/news/2020/nov/11/most-pfizers-vaccine-already-promised-richest-campaigners-warn>

### **Over 80% of vaccine doses bought by governments with only 14% of global population**

The vast majority of US pharma giant Pfizer's Covid-19 vaccine has already been bought by the richest governments in the world, Global Justice Now warns today. Over 1 billion doses have already been sold to rich governments, 82% of the 1.35 billion doses Pfizer says it has the capacity to produce by the end of next year.

Big purchases include the EU with 200 million doses and an option for a further 100 million, the UK with 40 million and the USA with 100 million, and an option to buy another 500 million. Yet the countries that have secured advanced supplies of the Pfizer vaccine represent just 14% of the global population, campaigners warn.

Pfizer is likely to offer some doses to developing countries in the coming weeks through the global COVAX Facility, but these are likely to represent a small fraction of the vaccines produced. While rich countries, including the UK, have joined international efforts to ensure fair distribution, they have undermined these schemes by mass purchases of the vaccine doses outside of the scheme.

Campaigners claim the situation is exacerbated by the failure of these same rich governments to heed calls to suspend global patent rules and encourage countries everywhere to manufacture generic versions of Covid-19 treatments and vaccines.





## ➤ COVID-19: Drivers of Disparity

- WHO Equitable Allocation in Theory, Reality is very different
- Advance Purchase Agreements by Rich Countries
- Lack of legal commitment on the part of pharmaceutical companies to supply needed medical products to developing countries (unlike Pandemic Influenza Preparedness Framework);
- Refusal to share technology, knowledge and related IP
  - WHO Technology Access Pool: rejected with pharmaceutical industry
  - Objecting to TRIPS Waiver
- Lack of transparent, reasonable voluntary licensing;
- where VLs exists they are non-transparent, exclusive, limited and restrictive
  - e.g. remdesivir
  - e.g. Astra Zeneca license to Serum Institute for one billion doses to supply LMICs – is it sufficient to address need in developing countries
  - E.g. Pfizer/BioNTech, Moderna: no global open licenses
- **Essentially: “Business as usual”...limiting competition, artificially limiting supply...focus is to maintain market monopoly and not equitable and affordable access.**



➤ Covax Facility:


- Led primarily by Gavi (vaccine alliance), decisions taken by Gavi
- Entering into agreements with manufacturers to pre-book supply for vaccines within portfolio (presently 9 candidates).
- Self-financing countries (HIC & UMIC) can pre-book 10-50%, paying upfront & providing guarantees
- LMICs – cost sharing. Vaccine allocation – 3% first phase, up to 20%
- Developed countries – mostly relying on bilateral deals for supply
- There are issues of equity, transparency, accountability, and skepticism whether the facility will deliver in view of bilateral deals, and ability of manufacturers to deliver
- Aim 2 billion doses by end of 2021 (vaccinating 1 billion people (500 mill –LMICs)). Very short term plan.
- No commitment to sharing IP, know-how and technology transfer.




**Availability & Affordability =**

**Scale-Up Global Manufacturing + More Diverse Suppliers Globally**





The Waiver Proposal (IP/C/W/669) is available  
at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

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- **Legal Basis:** paragraphs 1, 3 and 4 of Article IX of the WTO Agreement
  - **Scope:** implementation and application of **Sections 1 (Copyright), 4 (Industrial Designs), 5 (Patents), and 7 (Protection of Undisclosed Information) of Part II of the TRIPS Agreement** and **enforcement** of these sections under Part III of TRIPS (which is on enforcement) **in relation to prevention, containment and treatment of COVID-19.**
  - **Duration:**
    - Specific duration to be determined. Proposal states: until widespread vaccination is in place globally, and the majority of the world's population has developed immunity

## Examples of Intellectual Property that can affect access

Medical products needed to deal with COVID-19	Type of IP protecting this technology
Test kits	<ul style="list-style-type: none"><li>• Trade secrets, patents</li></ul>
Masks	<ul style="list-style-type: none"><li>• Patents, Industrial Designs</li></ul>
Medicines to treat COVID-19	<ul style="list-style-type: none"><li>• Patent, copyright</li></ul>
Vaccines, monoclonal antibodies (mAbs)	<ul style="list-style-type: none"><li>• Patent, trade secrets, copyright</li></ul>
Ventilators	<ul style="list-style-type: none"><li>• Control mechanisms etc - patents</li><li>• (replacement) valves – patents, industrial designs, copyright (e.g. on the CAD file)</li><li>• Software – copyright</li><li>• Machining templates and quality assurance protocols etc – trade secrets</li></ul>
Artificial intelligence	<ul style="list-style-type: none"><li>• Algorithms – copyright and trade secrets</li><li>• Patents</li><li>• Dataset and training process – copyright, database rights and trade secrets</li></ul>





## Current Tools Available:

- TRIPS flexibilities e.g.
  - Compulsory licensing
  - Article 31*bis* mechanism, countries with insufficient manufacturing capacity. Several High Income countries have opted out from using the mechanism.
  - Article 73: security exception
  - Available but there are challenges in its use (flexibilities subject to conditions)
  - Political pressure
- Voluntary licensing
  - its voluntary, terms determined by IP holder (e.g. allow supply only to some countries, lock in generic manufacturers on certain terms etc.)
  - unaccountable non-transparent VL that excludes many manufacturers and countries from supply
  - WHO's Covid-19 Technology Access Pool – to date no company has endorsed the C-TAP. In fact, pharmaceutical companies have objected to participation.
- **Current tools are insufficient**

- Question: Isn't a Waiver of IPR difficult?
  - No. Its been done 3 times before in the WTO.

Decision number	Provisions waived	Beneficiaries	Grounds of the waiver	Duration
<a href="#">WT/L/478</a>	TRIPS Agreement Article 70.9 with respect to pharmaceutical products	LDC members	In accordance with <a href="#">Paragraph 7</a> of the Doha Declaration on the TRIPS Agreement and Public Health, LDC members do not have to implement, apply or enforce Section 5 (on patents) and Section 7 (on protection of undisclosed information) of the TRIPS Agreement.	Until 1 January 2016 (about 13 years)
<a href="#">WT/L/540</a>	TRIPS Agreement Paragraph 6 decision waiving Paragraphs (f) and (h) of Article 31	All WTO members except those who opted out	The need to implement <a href="#">Paragraph 6</a> of the Doha Declaration on the TRIPS Agreement and Public Health to find a rapid solution to help countries with insufficient or no manufacturing capacities in the pharmaceutical sector make effective use of compulsory licenses.	Until the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that member
<a href="#">WT/L/971</a>	TRIPS Agreement Article 70.8 and 70.9 with respect to pharmaceutical products	LDC members	In line with the waiver decision WT/L/478, reaffirm that LDC members do not have to implement, apply or enforce obligations under Article 70.8 and 70.9 of the TRIPS Agreement with respect to <a href="#">exclusive market rights and mailbox obligations</a> .	Until 1 January 2033, or until a country graduates from the LDC status (about 17 years)





## What will a Waiver Achieve?

- Main idea: Recognition at WTO level countries have the option of freedom to operate by suspending implementation and enforcement of relevant IP for purpose of containing COVID-19.
- avoid procedural and administrative delays in addressing IP barriers.
- Allows regional, south-south & international collaboration with respect to development, production and supply of needed medical products.
- Facilitates economies of scale
- Supports countries with insufficient manufacturing capacity



## State of Play:

- Strong global support from civil society, international organizations (UNAIDS, UNITAID, WHO), human rights experts, academics;
- Supported by majority of developing countries including China
- Opposed by developed countries: US, UK, Canada, EU, Switzerland, Australia, Japan, Brazil
- A few other countries questioning need: Chile, Mexico, Ecuador
- Some countries: position unclear;
- Several formal and informal meetings of TRIPS Council have been held.
- Proponents of Waiver have tried to address issues and concerns raised.
- Next meetings: 19<sup>th</sup> Jan, early Feb, March.


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- ▶ Some common arguments against TRIPS Waiver:
    - ▶ Scope is too broad and uncertain
    - ▶ IP is not a barrier
    - ▶ Even if there are patents, trade secret and IP exists, IP are not a barrier. There are many barriers like health system, distribution challenges etc. So waiver will not resolve the challenges.
    - ▶ Current options in TRIPS Agreement are sufficient,
    - ▶ Article 31*bis* of TRIPS mechanism works,
    - ▶ IP has been incentive for COVID innovation
    - ▶ Will impair IP system,
    - ▶ Companies are doing VLs, preferred option
    - ▶ What is the evidence there are shortages? These have been resolved early on in pandemic.
    - ▶ There are solutions in the form of ACT-A and COVAX to ensure equitable access.

## Waiver Proposal has received global support:

- **MSF:** <https://msfaccess.org/landmark-move-india-and-south-africa-propose-no-patents-covid-19-medicines-tools-during-pandemic/>;
- **Drugs for Neglected Diseases initiative (DNDi):** <https://dndi.org/statements/2020/dndi-statement-india-south-africa-request-wto-waive-ip-rules-covid-19-health-tools/>;
- **UNITAID:** [https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-covid-19-products/#en](https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-covid-19-products/#en;);
- **UNAIDS:** [https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201015\\_waiver-obligations-trips-agreement-covid19](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201015_waiver-obligations-trips-agreement-covid19)
- **WHO :** <https://twitter.com/drtedros/status/1317449471727407104?s=24> & <https://www.thehindubusinessline.com/economy/who-lends-support-to-ip-waiver-proposal-from-south-africa-india/article32885984.ece>
- **H.E. Archbishop Ivan Jurkovič, Permanent Observer of the Holy See:** <https://nuntiusge.org/wp-content/uploads/2020/10/HOLY-SEE-Statement-WTO-TRIPs-Council-India-and-South-Africa-proposal-for-WTO-waiver-from-intellectual-property-protections-for-COVID-19-related-medical-technologies-1.pdf>
- **More than 400 civil society organizations:** [https://www.twn.my/announcement/signonletter/CSOLetter\\_SupportingWaiverFinal.pdf](https://www.twn.my/announcement/signonletter/CSOLetter_SupportingWaiverFinal.pdf)
- **Progressive International;** <https://progressive.international/blueprint/b6cf1166-724d-46de-884e-058f771562ff-covid-19-response-group-to-wto-ensure-equitable-and-affordable-access-to-all-covid-19-health-technologies/en>



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- **South Africa-Affiliated Academics, Researchers and Teachers Letter to President Ramaphosa;** <http://infojustice.org/archives/42692>
  - **Brazilian CSO** at [https://www.uaem.org/carta\\_da\\_sociedade\\_brasileira](https://www.uaem.org/carta_da_sociedade_brasileira) (in English at <https://drive.google.com/file/d/1IQmloturO7GrT4V4BbMgL65vBCuBoQHi/view>)
  - **Chilean House of Representatives passes a Resolution** requesting the Government to support at the Trips Council the Indian and South Africa proposal; <https://innovarte.org/chilean-house-of-representatives-passes-a-resolution-requesting-the-government-to-suppoort-at-the-trips-council-the-indian-and-south-africa-proposal-regarding-a-waiver-of-trips-obligation-to-fight-covid/>
  - **Statement by UN Human Rights Experts** Universal access to vaccines is essential for prevention and containment of COVID-19 around the world\* [https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E#\\_ftn16](https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E#_ftn16)
  - **Statement Human Rights Watch (anniversary of Doha Declaration on TRIPS & Public Health)** <https://www.hrw.org/news/2020/11/16/waiving-intellectual-property-rules-key-beating-covid-19>




## Op-Eds

- ▶ We can't let the WTO get in the way of a 'people's vaccine'  
<https://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?ref=hyper.com>
- ▶ The Indian/South African Proposal For a WTO Waiver On IP For COVID-19 Related Health Products – What It Means? <https://healthpolicy-watch.news/77719-2/>
- ▶ Avoiding patents for Covid-19 vaccines <https://www.deccanherald.com/opinion/in-perspective/avoiding-patents-for-covid-19-vaccines-900688.html>
- ▶ Simon Lester from Cato Institute "Who Will Get the Coronavirus Vaccines and When?": Waiving TRIPS Rules To Fight COVID-19 at <https://ielp.worldtradelaw.net/2020/10/who-will-get-the-coronavirus-vaccines-and-when-.html>.
- ▶ The Covid vaccine will benefit humanity – we should all own the patent at [https://www.theguardian.com/commentisfree/2020/nov/12/covid-vaccine-patent-pharmaceutical-industry-profits-public-sector?CMP=share\\_btn\\_link](https://www.theguardian.com/commentisfree/2020/nov/12/covid-vaccine-patent-pharmaceutical-industry-profits-public-sector?CMP=share_btn_link)



## Resource Materials:

- [https://www.twn.my/title2/intellectual\\_property/trips\\_waiver\\_proposal.htm](https://www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm)
- <https://msfaccess.org/>
  - <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies>
  - <https://msfaccess.org/5-reasons-new-proposal-india-and-south-africa-could-be-gamechanger-covid-19-response>
  - <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access>

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- ▶ **What can WHO contribute to making Covid-19 vaccines, treatments and technologies global public goods?**
    - ▶ Show strong support for Waiver Proposal
    - ▶ Call for and provide transparency in available production capacity, VL deals and COVAX deals with manufacturers;
    - ▶ Obtain legal commitment from manufacturers reserving supply for developing countries leveraging on principles of the Convention on Biological Diversity and Nagoya Protocol on Fair and Equitable Benefit Sharing: Linking access to pathogens and sequences to fair and equitable benefit sharing i.e. access to diagnostics, anti-virals and vaccines (precedent: PIP Framework)
    - ▶ COVAX should promote for manufacturing in developing countries and regional production, addressing issues of IP and sharing of technology and know-how (for e.g. in Africa and Latin America)
    - ▶ Develop abbreviated pathway for the approval of COVID vaccines across all platforms (Inactivated, DNA, mRNA);
    - ▶ Update guidelines for approval of biosimilars, (limiting need for head to head clinical trials)



Thank You

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