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# TRIPS waiver

## Main messages

- Universal and fair access to COVID-19 vaccines and treatments is a **top priority** for the European Union. The EU is a leader when it comes to deliveries of effective vaccines to the rest of the world. By mid-September, over **730 million finished vaccine doses have been exported out of the EU**. At least **40 million doses have been shared** by the EU Member States. We are also a major financial contributor to the COVAX Facility.
- The **global production of vaccines is rapidly increasing**. It is estimated that 12 billion doses of COVID vaccines will be produced by the end of 2021. While the vaccine production is increasing rapidly, the **common goal of global equitable access to COVID vaccines is yet to be achieved**. There is no single solution. A successful fight against COVID depends on strong international solidarity and good cooperation.
- Discussions in the WTO are on-going in the run-up to the Ministerial Conference (MC12) to find a common understanding of WTO Members on **how the WTO can contribute to an effective response to any pandemic**, not only the current one.
- The discussions focus **on export restrictions, trade facilitating measures, transparency and monitoring**, possible role of services, inter-organizational cooperation and the **intellectual property** dimension.
- The EU, together with other 25 WTO members, has made proposals on elements that could be part of the MC12 Ministerial Declaration. These should include actions or commitments on **export restrictions, commitments to enhance transparency in this regard, increase international cooperation and work on trade facilitation measures.**
- On **intellectual property**, we consider that it continues to play an important role as an enabler that contributes to our overall objective of ramping up production of COVID vaccines and medicines. However, it is not and should not be a barrier to achieve this objective. We have been clear that in a global emergency like this pandemic, if voluntary licensing fails, compulsory licensing is a legitimate tool to scale up production and that we are ready to facilitate this.
- This is why the EU proposed an **alternative to the TRIPS waiver proposal**. This proposal is targeted and pragmatic and aims at ensuring that governments can resort to compulsory licences, including to export to

countries with no or limited manufacturing capacities, in the most effective manner adapted to the circumstances of a pandemic.

- The current debate must focus on **how to increase the rate of vaccination against COVID in the most vulnerable members**. WTO itself, and its Director-General, has been active in bringing all major actors, manufacturers, vaccine developers, funding providers, regulators to identify existing bottlenecks, exchange information and promote private-public partnerships.
- There are **major international efforts to support the inclusion of Africa** in the production and trade of vaccines and medical products. The July announcement by Pfizer about setting up of production of mRNA vaccines in South Africa is a major step forward in this regard.
- Hopefully, all these efforts will also bring us **closer to an agreement in the WTO on the response to the pandemic.**

**<u>Defensives</u>**

***The proposed EU action points on compulsory licensing are redundant or too limited to make a difference.***

- Our proposal on compulsory licensing needs to be examined in the context of the **comprehensive proposal put forward by the EU**, which addresses the actual bottlenecks that affect the speed of manufacturing and supply of vaccines.
- The use of compulsory licence **can only be effective if intellectual property – and not other factors – is the barrier to the expansion of production**.
- In the ongoing discussions in the WTO, a number of countries have referred to uncertainties about the framework for the use of compulsory licensing under the TRIPS Agreement, including for exporting purposes. We agree that WTO Members should have **absolute legal certainty on the use of compulsory licensing** in the context of this or future pandemics.
- Our proposal addresses the identified intellectual property issues. It can be adopted swiftly and have immediate impact on the ground.
- We remain **open to examining other issues related to compulsory licensing** that could be streamlined further to make the system work in the lighter and most efficient manner possible.

***What according to the EU can be the way forward now that two proposals are on the table in the TRIPS Council?***

- The EU has engaged and will continue to constructively engage in the process to find a way forward in this discussion on the role of intellectual property in enhancing access to affordable COVID-19 vaccines and therapeutics. The objective is to identify **concrete and pragmatic short and medium term solutions** to enhance universal access to COVID-19 vaccines and therapeutics at affordable prices.
- In our view, only a **multi-pronged approach addressing the identified bottlenecks** such as limited manufacturing capacity and access to raw materials but also obstacles to the equitable distribution of vaccines can bring about a real change. Intellectual property is only part, and not the key part, of the solution.
- The EU is ready to continue discussing the waiver proposal though we continue to think that **the waiver proposed by a number of WTO members is not the right response to the pandemic**.
- The EU's proposed approach is pragmatic and targeted, focusing on facilitating the use of compulsory licensing. This approach can bring **legal certainty** to Members that are ready to produce COVID-19 vaccines and medicines on the basis of compulsory licences and to those that would be interested to import those.
- The EU will continue to maintain that **its proposed approach is an alternative to the waiver**. We do not see those two tracks proceeding in parallel.

***What is the EU position on the proposed TRIPS waiver, following the announcement of the US support for a waiver in relation to COVID vaccines?***

- The priority for the EU is to ensure global equitable access to COVID vaccines. The EU is at the forefront of deliveries of effective vaccines to the rest of the world.
- We have no comment on the US position since as the US has not put concrete ideas on the table. We would need to have more information to assess the US position and how it compares to the proposal already made by India and South Africa at the World Trade Organization.
- The EU is open to examining all options including proposals on intellectual property, as long as they contribute towards the objectives of expanding

production and facilitating equitable access to COVID-19 vaccines and therapeutics.

***What are the reasons for the EU to oppose the proposal of India and South Africa to waive the core provisions of the TRIPS Agreement for all COVID-related health technologies?***

- As regards the broad waiver proposed by a number of WTO members, the European Union, while ready to discuss any option that helps end the pandemic as soon as possible, is not convinced that it will help reach the objective of wide and timely distribution of COVID-19 vaccines that the world urgently needs. Rather the opposite. The EU's proposals aim at achieving that objective in a swift and effective manner.

***What initiatives has the EU taken to increase access to vaccines in Africa and other vulnerable countries?***

- The EU and its Member States are taking action to provide a comprehensive support to African partners to tackle barriers to manufacturing and access to health products and technologies in Africa. The initiative has been allocated €1bn from the EU budget and the European development finance institutions such as the EIB. This amount will be further enhanced by contributions from Member States.

- We are mobilising bilateral support packages for Senegal, South Africa and Rwanda in the context of the COVID-19 pandemic, expanding existing capacities (viral vector) and establishing new ones for mRNA.

- The EU is a leading donor to the COVAX Facility – with 3.2 billion € allocated.

- Team Europe (the EU, its institutions and all 27 Member States) has a goal to share 200 million doses of COVID-19 vaccines with the countries that need them most, by the end of 2021.

***What has the EU proposed to the WTO TRIPS Council as an alternative to the TRIPS waiver?***

- On 4 June, the EU submitted a **communication on intellectual property to the WTO TRIPS Council**, proposing to clarify aspects related to the use of compulsory licensing under the TRIPS Agreement, provide more legal certainty and enhance the effectiveness of the system.

- The EU's approach focuses on **measures that WTO Members can take to facilitate the use of the compulsory licensing system** provided for in the TRIPS Agreement. This can be presented as clarifications of the current TRIPS framework of compulsory licensing and could either form part of a comprehensive declaration on health or be a self-standing instrument.

- The EU proposes that all WTO Members **agree on the following clarifications of the compulsory licensing system set out in Articles 31 and 31bis** and in the Annex of the TRIPS Agreement:

  (a) the pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived;

  (b) to support manufacturers ready to produce vaccines or medicines at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holders should reflect such affordable prices; and

  (c) the compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX Facility.

- The EU has expressed **openness to discussing other aspects** of compulsory licensing that go beyond our proposal.

***How does the compulsory licence system under the TRIPS Agreement work?***

- The intellectual property framework is a system of checks and balances. There are **limitations and exceptions to every intellectual property right** foreseen in the TRIPS Agreement, as well as the domestic implementing legislation.

- The TRIPS Agreement provides for relevant exceptions and flexibilities necessary for WTO Members to ensure that, in particular, access to medicines

is not hindered. The 2001 WTO **Doha Declaration** on the TRIPS Agreement and Public Health acknowledges the link between the obligations under the TRIPS Agreement and the public health needs of the WTO Members.

- The Doha Declaration identifies specific options already in the TRIPS Agreement, open for governments to address public health needs - also known as **"flexibilities."** Among those flexibilities, least developed countries are not obliged to implement the TRIPS Agreement until 1 July 2034 (latest extension agreed in June 2021) and are specifically exempted from implementing the provisions relating to pharmaceutical products until 2033.

- The main type of flexibility under the TRIPS Agreement is a **compulsory licence.** The two main types of compulsory licences are:

    - Licences for **predominantly domestic supply** (Article 31) – products manufactured under the licence are designated predominantly for the domestic market.

    - Licences **for exports** (Article 31bis) – products manufactured under the licence can be exported to countries that lack manufacturing capacity. This compulsory licence for export applies to pharmaceutical products only and sets out mainly procedural requirements; for example, specific notifications to the WTO by the importing and the exporting member.

***Can compulsory licensing be an effective tool in ensuring access to medicines and vaccines? Has compulsory licensing worked in the past?***

- Compulsory licensing can be effectively used in a situation where intellectual property, and in particular patents, are used as means to prevent other companies from producing patent-protected products, including vaccines or medicines.

- The use of compulsory licence **can only be effective if intellectual property – and not other factors – are a barrier to the expansion of production**. There may be a barrier when a company that is willing and ready to produce products that are patent-protected cannot obtain a voluntary licence from the patent holder. A government must then assess whether the conditions for a compulsory licence are met and may grant it under the domestic rules that implement the TRIPS Agreement. The conditions for a compulsory licence

include that the scope and duration of use under the licence is limited to the purpose for which it was authorised, while the use must be non-exclusive.

- The compulsory licensing system **has been used several times in the past**. Many examples of compulsory licences result from the HIV/AIDS crisis. New anti-viral products against HIV/AIDS were not available at the time or simply unaffordable for some of the low and middle-income countries after almost a decade since their launch in the high-income countries. Brazil, Congo, Cuba, Ecuador, Gabon, Ghana, Georgia, Indonesia, Malaysia, Mozambique, Myanmar, Pakistan, Philippines, Thailand, Ukraine, Zambia and Zimbabwe are examples where compulsory licences for HIV/AIDS medicines were issued between 2000 and 2012. Many of these became either voluntary licences or sales at discounted prices. The crisis also led to the change in the practice by the pharmaceutical companies (e.g. sales at tiered pricing) and the creation of the Medicines Patent Pool - which helps the producers of generic medicines to obtain voluntary licences.

- Ecuador, Thailand, Italy, India, Russia and Taiwan have all issued compulsory licences for other medicines for the treatment of cancer, arthritis, kidney diseases, avian flu, bacterial infections, etc. In a number of other cases - including in Canada, the US, the UK, South Korea, Switzerland and several other countries - recourses to compulsory licences also helped obtain access to medicines, even in the absence of a formal decision.

- During the HIV/AIDS crisis, the only compulsory licence for export was issued in a case between Canada and Rwanda in 2007.

***What if intellectual property (e.g. patents, trade secrets) held by the pharmaceutical companies on COVID-19 related technologies become a barrier to fighting the pandemic?***

- There is no evidence that intellectual property issues have been a barrier in relation to COVID-19-related medicines and technologies. Spikes in demand and lack of manufacturing capacity, fragile and underfunded healthcare and procurement systems, a limited number of health workers and export restrictions have more negative impact on the access to COVID-19 related technologies than any IP-related issues.
- If voluntary solutions fail and intellectual property becomes a barrier to treatments or vaccines against COVID-19, the necessary mechanisms are already available. The EU has supported the use of the flexibilities provided

under the TRIPS Agreement and the Doha Declaration with the objective of ensuring effective access to medicines in countries in need.

- The TRIPS Agreement provides for the necessary flexibilities that can be used under clear rules and when there is a public health related reason. In particular, the TRIPS Agreement provides for the possibility, under certain conditions, of issuing a compulsory licence for local consumption of medicines and provides for fast-track procedures in health emergencies.
- WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector can make use of the special compulsory licensing regime under Article 31*bis* of the TRIPS Agreement. A country with insufficient or no manufacturing capacity (importing country) in need of a specific medicine is only required to notify this to the WTO and any willing country (exporting country) can issue a compulsory licence to produce and export that medicine to the importing country.
- This is accompanied by other inbuilt TRIPS flexibilities, applying to the various intellectual property rights, including a broad waiver that exempts all least developed countries Members of the WTO from being subject to intellectual property rules.

***How does the discussion on access to COVID-19 vaccines compare to the discussion on access to medicines in the context of the AIDS/HIV crisis?***

*[Note: in general it is better to avoid this comparison]*

- The HIV crisis occurred at the very beginning of the functioning of the TRIPS Agreement in the 90s. Lessons were learnt and the WTO Members agreed on the Doha Declaration on the TRIPS Agreement and public health in 2001 clarifying the link between the TRIPS Agreement and access to medicines.
- It is clear that we cannot repeat mistakes of the past. The COVID pandemic has already been dealt with very differently than any other health crisis in the past, in particular with the creation of the COVAX facility and significant financing pledged immediately. The EU has been leading the global response.
- The intellectual property protection is not absolute. The international intellectual property system, based on the TRIPS Agreement, is a system of checks and balances.
- The Doha Declaration identifies specific options already in the TRIPS Agreement which are open for governments to address public health needs, also termed "flexibilities". In particular, the TRIPS Agreement provides for the possibility, under certain conditions, of issuing a compulsory licence for local

consumption of medicines and provides for fast-track procedures in health emergencies.

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- These flexibilities are legitimate tools to use for the countries in need.

## Background

- This line to take was developed as a response to a proposal of 2 October 2020 by South Africa and India to waive certain parts of the TRIPS Agreement for measures having as their objective prevention, containment and treatment of COVID-19. It was updated following the EU proposal to the WTO on 4 June calling for an urgent multilateral response to the COVID crisis.
- The debate on IPR and access to health products is not new, highly complex and currently, in the times of the pandemic, reinvigorated by those who claim IPR to be a major impediment in timely access to affordable medicines. This is a very sensitive and highly political matter.
- For more background information, refer to the DG TRADE/Unit B3 in charge of the file.