



**Council for Trade-Related Aspects of
Intellectual Property Rights**

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**WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION,
CONTAINMENT AND TREATMENT OF COVID-19**

COMMUNICATION FROM THE AFRICAN GROUP, THE PLURINATIONAL STATE OF BOLIVIA, EGYPT, ESWATINI, FIJI, INDIA, INDONESIA, JORDAN, KENYA, THE LDC GROUP, MALAYSIA, MALDIVES, MOZAMBIQUE, MONGOLIA, NAMIBIA, PAKISTAN, SOUTH AFRICA, VANUATU, THE BOLIVARIAN REPUBLIC OF VENEZUELA AND ZIMBABWE

1 INTRODUCTION

1. On 21 May, the co-sponsors presented a revised decision text in document IP/C/W/669/Rev.1 (waiver proposal) with respect to the proposal to waive the application, implementation, and enforcement of TRIPS provisions on copyright (Section 1), industrial designs (Section 4), patents (Section 5) and protection of undisclosed information (Section 7) circulated in document IP/C/W/669 and co-sponsored by 63 WTO Members.
2. Co-sponsors introduced document IP/C/W/669/Rev.1 during an informal TRIPS Council meeting on 31 May 2021 and the formal meeting on 8-9 June 2021. In the context of text-based negotiations, informal open-ended meetings were held on 17 June, 30 June, 6 July and 14 July, and between these meetings, small-group consultations took place.
3. This communication contains a summary of the co-sponsors' interventions in explaining the basis for the waiver proposal. The co-sponsors of the waiver proposal have engaged positively and responded in detail to questions raised by some WTO Members.

2 CONTEXT

4. The extent of the current health crisis posed by COVID-19 is as undeniable as the current global response is untenable. Given the ongoing absence of sufficient engagement by the pharmaceutical industry to voluntarily and openly allow the use of their intellectual property rights, data and know-how with all possible manufacturers, to address the pandemic, mechanisms are needed to remove existing and potential legal barriers to scale up manufacturing and diversify sources of supply.
5. The WTO needs to act now to arrest the rising human toll and economic strain from the COVID-19 pandemic. Global solidarity is required to ramp up and diversify global production of vaccines, therapeutics and diagnostics to effectively deal with the spread of the COVID-19 virus and to leverage the under-utilized manufacturing capacity in developing countries. Sustainable global economic recovery will only be possible when we end the health crisis. Ending the pandemic in a timely manner should be the overarching priority for the WTO. There is an overwhelming ethical, epidemiological, and economic case for urgent collective action and hence the motivation for the TRIPS waiver proposal.
6. The waiver proposal is a necessary, timebound and proportionate legal measure directed at addressing intellectual property (IP) barriers in a direct, transparent and efficient fashion, which is consistent with the WTO legal framework. Waivers are part and parcel of the WTO toolbox. Adopting this waiver allows companies the world over the freedom to operate and to produce covered COVID-19 health products and to use health technologies without the fear of infringing another party's IP rights and the attendant threat of litigation. Furthermore, adoption of a TRIPS waiver acts as an important political, moral and economic lever towards encouraging solutions aimed at global

equitable access to COVID-19 health products and technologies including vaccines, therapeutics and diagnostics, which is in the wider interest of the global public. This outcome is also consistent with the Covenant on Economic, Social and Cultural Rights, especially Article 12 which recognizes the "*human right of everyone to the enjoyment of the highest attainable standard of physical and mental health*" and obligating the taking of steps to fully realize this right, including "*those necessary for ... the prevention, treatment and control of epidemics, endemics, ... and other diseases*".

7. In the context of COVID-19 and the 2030 Sustainable Development Goals, SDG 3 was adopted by UN Member States to ensure health and well-being for all, including a bold commitment to end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases by 2030. It also aims to achieve universal health coverage, and provide access to safe and effective medicines and vaccines for all.

8. Right now, billions of people in Asia, Africa and Latin America remain unvaccinated and have no prospect of being vaccinated in the foreseeable future. There can be no solution to the global crisis in access to health products and technologies including vaccines, therapeutics and diagnostics, unless we waive intellectual property rights to lift the legal monopoly over the technology in order to have more manufacturing everywhere.

3 PRODUCT SCOPE OF THE WAIVER

9. The TRIPS waiver proposal is motivated by the need for swift ramping up of manufacturing, to alleviate the supply side concerns for timely availability, accessibility and affordability of the required products to prevent, treat and contain COVID-19. Hence, the starting point in determining the scope of health products and technologies to be covered by the decision text is to determine what is needed to prevent, treat, and contain COVID-19. Any strategy that does not address these three elements simultaneously would fall short of yielding any positive results.

10. We have learnt from the experiences of the past year and a half that it is critical to scale up production and access to personal protective equipment (PPE), masks, diagnostics, ventilators, and therapeutics, apart from vaccines, to prevent the spread and to treat the disease and prevent deaths. These resources have been in acute shortage in many countries leading to very limited accessibility. The scope of products is also reflective of national COVID-19 response strategies of many countries that acknowledge that the prevention, treatment and containment of COVID-19 involves a range of health products and technologies. Vaccines are necessary but not sufficient to respond to the pandemic. No country adopts only one intervention in this and any pandemic. Vaccinations, test and treat strategies and their related health products and technologies are urgently needed alongside other interventions.

3.1 'Health products and technologies'

11. The waiver proposal covers "health products and technologies" for COVID-19 as there is a range of products and technologies that are critical for the prevention, treatment and containment of COVID-19, such as those listed in WHO's list of priority medical devices for COVID-19 response.¹ This list describes the range of priority medical devices required for the clinical management of COVID-19 and WHO's Emergency Global Supplies Catalogue (COVID-19)² includes the range of health products and technologies critical to respond to the COVID-19 global health emergency.

12. Notably, WHO's COVID-19 Strategic Preparedness and Response Plan pillars 5, 7 and 10 underline the importance of diagnostics, therapeutics, vaccines and other supplies for an effective COVID-19 response.³

13. The term "health products" is inspired by the World Health Assembly Resolution on "Improving the transparency of markets for medicines, vaccines, and other health products"⁴ which defines health products to "include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies".

¹ <https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>

² (<https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue>)

³ (<https://www.who.int/publications/i/item/WHO-WHE-2021.02>)

⁴ https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

14. Based on the above it is quite clear that the concept of health products and technologies is well understood and used within the international health lexicon.

3.2 Diagnostics

15. Pillar 5 of WHO's Strategic Preparedness and Response Plan for COVID-19 considers testing to be the cornerstone of the management of the COVID-19 pandemic. Testing is critical to detect cases and investigate clusters of cases so that public health actions can be rapidly taken to isolate those infected, quarantine contacts and break chains of transmission. Testing allows for new COVID-19 variants to be identified to begin to build vaccines and therapeutics that can prevent or treat infection. Major gaps in testing are still putting lives at risk and threatening progress to end the pandemic. In high-income countries there are 603 tests per 100 thousand of population compared to about 100 tests in middle income countries and about five tests in low-income countries.⁵ There is an urgent need to scale up testing and ensure immediate, equitable access to diagnostic tools in every country across the world.

16. The co-sponsors have provided examples highlighting IP challenges in previous TRIPS Council meetings (see paragraphs 42-46 of document IP/C/W/672 as well as paragraph 65 of document IP/C/W/673).

3.3 Therapeutics

17. The spectrum of medical therapies to treat COVID-19 is growing and evolving rapidly. It includes antivirals, monoclonal antibodies, immunomodulators, antithrombotic therapies.⁶ WHO's consultations on COVID-19 therapeutics reveals that "[d]espite the great success of COVID-19 vaccine development, therapeutics are still urgently required" and that a range of therapeutics will be required including "drug combinations targeting specific aspects of infection , as well as suites of treatments targeting different disease processes (such as antivirals, immunomodulators and anti-coagulants)"⁷.

18. The EU COVID-19 therapeutic strategy also states that "*vaccines will not eliminate the disease overnight and therapeutics will still be needed for patients in hospitals and at home, including people suffering from 'long COVID' (the long-term effects of COVID-19 infection). For these reasons, therapeutics will continue to play a significant role and complement the EU strategy for vaccines.*" Notably, several therapeutics have been approved, registered and have received national Emergency Use Authorization or qualified for the WHO Emergency Use Listing.

19. Since the currently available vaccines are not able to prevent infections (which may be the case for second or third generation vaccines) – therapeutics play an important role in our effort to contain and treat COVID-19. Further, therapeutics are also important to address animal virus spill over and possible resurgence of virulence in humans.⁸

20. In document IP/C/W/670, the co-sponsors have presented a preliminary patent landscape providing a non-exhaustive snapshot of the patent filing and granting status of five selected therapeutics candidates for COVID-19. In document IP/C/W/672 (e.g. paragraphs 37-41) and in document IP/C/W/673 the co-sponsors have highlighted IP-related challenges in the area of therapeutics and how restrictive voluntary licensing practices continue to pose supply challenges for countries.

3.4 Vaccines

21. As noted above, the disparity in access to vaccines remains vast as supply remains constrained. Eight vaccine manufacturers are listed in WHO's Emergency Use Listing. Of these five are from OECD countries.⁹ According to the UNICEF dashboard 137 manufacturing agreements have been signed,

⁵ <http://www.finddx.org/covid-19/test-tracker/>

⁶ <https://www.covid19treatmentguidelines.nih.gov/therapies/>

⁷ Pg. 5 https://cdn.who.int/media/docs/default-source/blue-print/06_therapeutics_full-achievements-report.pdf?sfvrsn=d6cdb802_3&download=true. See also pgs 12 and 13.

⁸ [https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964\(21\)00082-7/fulltext](https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00082-7/fulltext)

⁹ <https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations>

out of which 73 are contract manufacturing agreements. 64 agreements are classified as technology transfer, but 28 agreements are from just one company.¹⁰ Details of the agreements are unknown but this shows the heavy concentration of production and supply of COVID-19 vaccines. Prices of COVID-19 vaccines also remain high within a range of USD 2-40 per dose.¹¹ There is an urgent need to bring down the price through competition, which can be achieved by diversifying production.

22. The emerging landscape of both background and foreground IP on key vaccine technologies, and the IP disputes (see para 53 of document IP/C/W/672) that have already occurred during the pandemic, underline evident IP challenges in ensuring legal certainty for vaccine development and supply, especially when some of the main vaccine producers continue to pursue monopolistic approaches in their IP management. Past experience¹² shows that patents can hinder the introduction of affordable vaccines in developing countries as generally broad patent claims are applied for or granted across the entire spectrum of vaccine development, production and use, including in relation to vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; vaccination age groups; methods of using vaccines; and vaccine schedules and presentations. The impacts of these patents are documented and create legal uncertainty and costs which ultimately result in delayed competition, insufficient supplies and high prices which hinder access.

3.5 'Medical devices, personal protective equipment'

23. The WHO's list of priority medical devices for COVID-19 response describes the range of priority medical devices required for the clinical management of COVID-19.¹³ It describes priority medical devices required for the clinical management of COVID-19, selected and prioritized according to the latest available evidence and guidelines. For example, beginning from clinical assessment, medical imaging, clinical laboratory, clinical care and protective equipment, the list identifies priority medical devices that are needed, including pulse oximeters, equipment for medical imaging, oxygen concentrators, patient monitors, various types of ventilators such as for transport, for acute care and for sub-acute care, infusion and suction pumps, medical/surgical mask etc.

24. The WHO's Emergency Global Supplies Catalogue (COVID-19)¹⁴ lists the following medical devices in its catalogue: oxygen delivery devices – nasal cannula and catheters; oxygen delivery devices – masks; various types of patient monitors, pulse oximeters and infrared thermometer for monitoring; oxygen therapy sources including the oxygen concentrator and its accessory the flow splitter; various types of ventilators and related accessories; protective equipment such as various types of apron/gowns, gloves, face shield, goggles, respirator, mask FFP2/KN95, Biohazard Bag, sample collection kits, PCR machines, rapid diagnostics, power accessories.

25. Clearly what is specified in the waiver proposal finds international support for the clinical management of COVID-19 based on the latest available evidence and guidelines.

26. In document IP/C/W/672 (paragraphs 50- 52), the co-sponsors have provided examples of IP barriers to medical devices and protective equipment such as masks and ventilator valves.

3.6 'Their materials or components, and their methods and means of manufacture'

27. The rationale of the revised decision text is to address any IP constraints in the way of scaling up of the production of COVID-19 health products and technologies. IP protection can prevent the supply of raw materials, components, machineries and equipment, parts of machinery and equipment, process of production etc.

28. Materials and components refer to parts of the health products and technologies. These include, for instance, raw materials, active and inactive ingredients of the drug substances used in the formulation of therapeutics or vaccines and reagents in the case of diagnostics used for the detection or screening of a disease. While in the case of medical devices and other health technologies it would

¹⁰ <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>

¹¹ <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>

¹² <https://msfaccess.org/sites/default/files/2018->

06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf

¹³ (<https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>).

¹⁴ <https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue>

refer to parts of the products or technology such as ventilator valves. IP constraints may emanate in the following context, which are addressed in the revised text, for example:

- the raw materials for the production of vaccines, diagnostics or therapeutics such as lipids for mRNA vaccines, adjuvants for vaccines, starting materials for the active pharmaceutical ingredient of therapeutics, chemical reagents and solutions for diagnostics etc. (The word "materials" cover this aspect);
- components used for the production of medical devices such as electronic or mechanical components required for the production of medical devices including ventilators, oxygenators, oximeter etc. (The word "components" covers this aspect);
- machineries and equipment used for the production of various health products (the words "method and means of production" cover this aspect);
- parts of the machinery and equipment deployed for the production process such as bio-bags, bio-reactors, equipment for lipid coating etc. (the words "method and means of production" cover this aspect); and
- technologies used for the production of these health products such as mRNA technology, diagnostic techniques like improvements on PCR technology etc. (the word "technologies" covers this aspect).

29. Methods and means of manufacture refer to the process and equipment used for the manufacture of the health products and technologies covered by the scope of products.

3.7 '... the prevention, treatment or containment of COVID-19'

30. Prevention refers to products and technologies to prevent the infection of COVID-19. Treatment refers to products and technologies to treat a patient who has been infected with COVID-19. Containment refers to products and technologies to control the spread of COVID-19.

4 INTELLECTUAL PROPERTY SCOPE OF THE WAIVER

31. The proposal calls for a waiver of the application, implementation, and enforcement of TRIPS provisions on copyright (Section 1), industrial designs (Section 4), patents (Section 5) and protection of undisclosed information (Section 7). The waiver proposal only focuses on categories of intellectual property that are relevant to the production, supply, and access to COVID-19 health products and technologies. The co-sponsors have pointed out to paragraph 3 of the revised decision text which makes explicit that the waiver will not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.

32. The co-sponsors have made several submissions highlighting the relevance of addressing existing and potential intellectual property issues in the area of copyright, industrial designs, patents and protection of undisclosed information. In document **IP/C/W/673** the co-sponsors responded to eight questions raised in document IP/C/W/671 by Australia, Canada, Chile and Mexico. Examples of IP challenges and barriers are detailed in document **IP/C/W/670**, in which both the emerging IP landscape of pipeline medical products and limited, restrictive voluntary licensing practices have presented ongoing challenges for the prediction, preparation and management of procurement options for countries. Document **IP/C/W/672** contains interventions of the co-sponsors in responding to questions raised with respect to the proposal including on the scope of IP.

33. **Patents** grant monopoly rights over a protected subject-matter, preventing other manufacturers from using the patented subject-matter. The patent status of each product and components of the product will vary country by country with a single product often involving a large number of patent applications and grants, that differs from country to country. In the case of COVID-19, the patent landscape remains quite uncertain as many patent applications have yet to be published because patent applications are not typically made public for 18 months. A recent paper in the International Journal of Biological Sciences¹⁵ has observed that there has been a rapid increase in human coronavirus patents, especially COVID-19 patents; "treatment and prevention" accounting

¹⁵ Kunmeng et al "Global landscape of patents related to human coronaviruses." 2021; 17(6): 1588–1599. [published online 2021 Apr]] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8071764/>

the largest proportion (57.89%), followed by "diagnosis of viral infection" (20.64%), "disinfection" (8.12%), "medical devices" (7.00%), and "virus cultivation" (1.32%).

34. The patent system contains flexibilities such as opposition systems and compulsory licenses. However, challenging each and every patent application or grant everywhere they may exist is not a practical or sustainable option. The co-sponsors have also on numerous occasions illustrated in significant detail the inadequacies and difficulties in relying on Article 31 and 31*bis* of the TRIPS Agreement (see paragraphs 28-53 of document IP/C/W/673) to scale up manufacturing. It is even more so, when dealing with a complex global web of patent holding. For instance, in the case of mRNA vaccines larger companies involved in product development may have a patent portfolio, but the patent portfolio to the underlying technology is held by numerous other academic laboratories or small biotech companies.¹⁶

35. **Protection of Undisclosed Information** is another hurdle to access various health products and technologies. With respect to vaccines, and bio-therapeutics in particular, the manufacturing methods and techniques (know-how) tend to be protected by trade secrets. This includes regulatory dossiers submitted for purposes of obtaining marketing approval. These dossiers will usually include robust information regarding the manufacturing process, formulation and dosage, method of delivery, storage conditions, indicated uses along with safety and efficacy information. Hence the importance of addressing protection of undisclosed information required under Article 39 of the TRIPS Agreement.

36. Lifting trade secret protection would facilitate expanding and diversifying global production. For instance, by waiving trade secret protection, and as a start facilitating the sharing of regulatory dossiers with potential manufacturers, existing production capacity especially in developing countries can be mobilised. As demonstrated by the event hosted on 14 April 2021 by the Director-General of the WTO, Dr Ngozi Okonjo-Iweala, whereby interaction with several pharmaceutical companies revealed unused capacities in several developing countries.¹⁷

37. The slow roll out of vaccination in developing and least developed countries is testament to the fact that the current system of production and supply is not working to deliver equitable access. Numerous examples have been reported of the industry turning down offers of help from other drug makers, including those from developing countries, to boost global manufacturing and supply.¹⁸

38. In the case of diagnostics, shortages of testing materials in developing countries cannot be overcome as the formulation used for diagnostic testing is protected as a trade secrets, preventing laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer (see para 43 of document IP/C/W/672 and para 65 in document IP/C/W/673).

39. In document IP/C/W/673 paragraphs 66-69, the co-sponsors have raised the issue of developing countries constantly facing pressure from developed country members, advocating restrictive interpretations of Article 39 and hampering the use of flexibilities. Hence there is a lack of clarity with regard to available flexibility provided by Article 39, which creates a chilling effect on its use. As such, a waiver will support countries to take appropriate actions with respect to COVID-19.

40. **Copyright and industrial designs** are also categories of IP that may hinder production and supply. In document IP/C/W/673, the co-sponsors responded in detail from paragraphs 54 to 63 on the industrial design and copyright challenges faced by members in production of COVID-19 products. Copyright issues may also arise in other situations such as with respect to software in medical devices, diagnostic kits, compilation of data, algorithms, product information documents or product labelling. For instance in India, Roche asserted copyright infringement with respect to use of the product information of the originator product Herceptin (breast cancer treatment) on the package insert and carton of a biosimilar product¹⁹

¹⁶ A network analysis of COVID-19 mRNA vaccine patents

<https://www.nature.com/articles/s41587-021-00912-9>

¹⁷ https://www.wto.org/english/news_e/spno_e/spno9_e.htm

¹⁸ <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jobs/>

¹⁹ <https://indiankanoon.org/doc/99133603/?type=print>

41. In paragraphs 59-63 of document IP/C/W/673, the co-sponsors have pointed out that the exceptions in Article 13 and Article 26 of TRIPS are inadequate and there is uncertainty as to their application to protect public health. In addition, identifying the various IP claims involved with respect to a particular product or technology, and negotiating the terms of use involve a costly, time-consuming and complex process as products and technologies involve multiple IP holders. IP holders may also simply refuse to license their IP. In times of an emergency, such legal issues should not hinder an urgent public health response.

42. The waiver being sought is for a limited period and that too only from some specific TRIPS provisions. This is not an ideological debate on the IP regime per se. Instead, it shows that in exceptional circumstances, the IP system can be flexible and accommodating, and one that can be appropriately invoked to address the unprecedented challenges posed by the pandemic.

5 DURATION

43. The rationale for the proposed duration has been clarified in the revised decision text contained in document IP/C/W/669/Rev.1. Since SARS-CoV-2 is a new virus, there are still many uncertainties. There are emerging variants and mutations and while we are better off in our understanding of the virus than last year, still many unknowns remain such as the duration of immunity provided by the vaccines, effectiveness of these vaccines against new variants, effectiveness of vaccines on children, the need for a booster dose or annual vaccination. All these elements will determine the scale of manufacturing and supply needed to control the pandemic and this is just for the vaccines.

44. In order to tailor the waiver duration to prevailing circumstances and the uncertainties attached thereto, the co-sponsors have specified a minimum duration period of three years from the date of the decision. Thereafter, the waiver will be reviewed by the General Council to determine whether exceptional circumstance justifying the continuation of the waiver still exist. The difficulty with setting criteria is the uncertainty of the situation as explained above.

45. There is also very little WHO guidance on the situation of a pandemic and when that situation comes to an end. The International Health Regulations (IHR) of the WHO does not use or define the term "pandemic". It uses the term "public health emergency of international concern" (PHEIC). In determining whether an event constitutes a PHEIC, the WHO Director-General, Dr Tedros Adhanom Ghebreyesus, considers the advice of an Emergency Committee convened for the purpose. If a PHEIC is recommended, the WHO Director-General has the final authority to make a declaration, taking all information into account.

46. Article 49 (6) of the IHR states the following: "*The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee.*"

47. It does not provide concrete guidance as to what factors should be taken into account and seems to operate on a case-by-case approach. The declaration of PHEIC under the IHR has drawn significant criticism.²⁰ The recent Independent Panel for Pandemic Preparedness and Response has recommended that the definition of a new suspected outbreak with pandemic potential needs to be refined.²¹

48. With COVID-19, several considerations and uncertainties have to be taken into account for example:

- What proportion of the population needs to be vaccinated for herd immunity from COVID-19? The proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known. This is an important area of research and will likely vary according to the community, the vaccine, the populations prioritized for vaccination, and other factors. It would be difficult to reach herd immunity without vaccinating children in countries with young demographics.

²⁰ [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30401-1/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30401-1/fulltext)

²¹ Pg. 26, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

- How long do COVID-19 vaccines protect people? Is it eight months, 12 months or longer? This information is not yet known. If boosters are needed, it is still unknown how often they will be needed. On this point the WHO in December 2020 said "*we don't actually know for how long the protection of these vaccines will last... But by necessity, they've only been able to follow up people for a period of months following their immunization. We really do need to know whether or not these vaccines last for only a period of months in terms of their protection or potentially years....*"²²
- On the question of the need for booster shots, a few examples of various diseases may suffice. Measles does not change, so does not need booster vaccines for variants. Influenza needs a new vaccine each year because of variants. "*Now for SARS-CoV-2 we're still learning, we're still observing things and our knowledge is evolving. . . the more we give it a chance to spread and to multiply within humans, the more chances it's going to have to keep changing itself, that's its natural property.*"²³ And "*there's some data coming showing that vaccines may be less effective in preventing against some of these variants.*"²⁴
- How much COVID-19 vaccine production capacity exists? Most developing countries are nowhere near the levels of vaccination required to address their basic needs. Halfway through 2021 COVAX has only managed to deliver 95 million doses to date²⁵, i.e. 4.8% of the 2 billion doses to be delivered in 2021. The supply gap justifies the duration proposed. If countries are already procuring 'booster' doses to deal with new variants or have moved to vaccinating children, the waiting period for sufficient vaccination in developing countries will be much longer. There are varying reports on how long it will take to roll out vaccination globally. Some reports suggest that based on the current rate of vaccination, it may take five to seven years for global vaccination to be realized.²⁶ But the situation is even more complex. Emergence of new highly transmissible variants can at any time render any of the currently registered vaccines ineffective.

49. The complexities of the current pandemic as well as learning from the past, suggest the need for a practical and flexible duration, and one that creates an enabling environment for the scale-up of manufacturing and diversifying suppliers. It is noteworthy that the 30 August 2003 decision that waived Article 31(f) and (h) of TRIPS contained in document WT/L/540 does not contain a specific timeframe, instead it states the duration of the waiver is until "*the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member*".

50. Co-sponsors have been asked the relation between the mechanism to terminate the waiver in paragraph 2 and the yearly review in the General Council in paragraph 5. The annual review is a requirement under Article IX.4 when waivers are granted for a period of more than a year whereas paragraph 2 is for determining the date of termination of a waiver. It is common for waiver decision to contain these two aspects. For instance, see decision text WT/L/971 with respect to the waiver of Article 70.8 and 70.9 of TRIPS for least developed countries with respect to pharmaceutical products.

6 IMPLEMENTATION ISSUES

51. Among WTO Members there is a diversity of legal systems, hence national implementation of a waiver depends on a country's constitutional and or administrative arrangement. Similarly, the parameters and conditions of implementation should be a national decision. Each country will need to decide what is needed nationally to curb COVID-19 and the parameters of implementation of the waiver. One size does not fit all as the legal systems, needs and conditions vary from country to country.

52. Generally, the relationship between international law and national law is based on theories of monism and dualism. In monist countries international law is applicable nationally, without intervention of the legislature and international law may take precedence over national law. On the

²² <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-15---vaccine-distribution>

²³ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-20---covid-19---variants-vaccines>

²⁴ February 2021, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-27---vaccines-variants-herd-immunity>

²⁵ <https://www.qavi.org/covax-facility>

²⁶ <https://www.aljazeera.com/news/2021/2/19/vaccine-nationalism-why-hoarding-shots-could-prolong>; <https://www.smh.com.au/politics/federal/it-will-be-six-years-before-the-world-is-vaccinated-against-covid-19-experts-20210210-p5718i.html>

other hand, in dualist systems, international laws need to be translated into national law for them to be applicable. In some countries this distinction tends to be blurred.

53. The diversity of legal systems is apparent. In order to expeditiously implement the waiver each WTO Member should decide on what is the best approach in the context of their respective legal systems and this need not involve an amendment of their intellectual property laws.

54. For instance, countries could use emergency powers. Some countries have invoked emergency provisions or enacted legislation to implement the wide range of measures required for effective response to COVID-19. According to ICNL, 108 countries declared emergency as part of an effective COVID-19 response.²⁷ Such legislation may also provide governments the discretion to implement measures with respect to existing laws or privileges, and such provisions could be used for the implementation of the TRIPS waiver. In some countries, emergency legislation has been utilised to make changes to intellectual property laws.

55. Apart from emergency powers the executive may also have certain powers under the Constitution to issue orders suspending or amending the legal provisions. WTO Members may also have disaster management laws to organise an effective response to disasters including a pandemic. These laws may also contain provisions providing powers to the government to suspend the operation of legislation to take effective measures. For instance, India invoked provisions of the Disaster Management Act to respond to COVID-19.

56. There is also the option of amending national intellectual property legislation. Such an amendment need not be a time-consuming exercise. Indeed in this pandemic governments have fast tracked enactment of legislation as required for controlling the pandemic.

57. Governments have taken extraordinary measures such as lockdowns, quarantine, nationalising private hospitals, border closures and other measures to curb the spread of COVID-19. Addressing intellectual property concerns should not be any different. These are just some possibilities for the implementation of the TRIPS waiver. Each Member will have to decide for itself what is the most expeditious approach for implementation. As mentioned, in some legal systems international law may directly be applicable at the national level.

²⁷ <https://www.icnl.org/covid19tracker/?location=&issue=5&date=&type=n>