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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 23 FEBRUARY 2021

Chair: H.E. Ambassador Xolelwa Mlumbi-Peter

Addendum

The present document contains the statements made during the Council for TRIPS held on 23 February 2021.

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AT THE MEETING OF COUNCIL FOR TRIPS 23 FEBRUARY 2021*

* A record of statements as delivered in the formal session of the Council. Some statements have been lightly edited as appropriate to ensure the consistency of presentation.

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

1.1 Chile

1. Chile would like to acknowledge those who have referred to its work during the discussions on this subject, and express its gratitude for the facilitation of the discussion and the search for consensus. Our delegation can support the draft report that has been presented, in that it provides a factual presentation of the discussions that have been held in this committee.

2. Chile reiterates its position on this matter and would like to emphasize from its report to the General Council that the membership shares the objective of achieving timely and secure access to effective, reliable and high quality vaccines and medicines for all. This point in its report is not insignificant and should be the starting point for the search for creative solutions within the IP system that are able to tackle the issue. It also allows us to be open to considering the possibility of seeking solutions together with the pharmaceutical industry that enable the production and distribution of vaccines to be increased worldwide.

3. For Chile, the WTO is a relevant actor and an appropriate forum that could promote a dialogue with the industry, especially now that we have a new Director General.

1.2 Tanzania on behalf of the African Group

4. On behalf of the African Group I would like you to thank you for your efforts and the manner in which you are inspiring the way of this Council. Also let me take this opportunity to congratulate the LDC Group for also joining the proponents as the co-sponsors of this proposed waiver, as the African Group has also done.

5. The world is faced with the insurmountable challenge of COVID-19 pandemic and it is not predictable when this challenge will cease. Economic strides achieved by Members over a decade are being now slumped. Governments are struggling to protect the lives of their citizens in the midst of this economic crunch.

6. It is of interest to all Members to prevent COVID-19 from continuing to spread the damage it is causing which is already epic. To win this battle, WHO has called for international solidarity and cooperation, as the only effective way to fight COVID-19, particularly by scaling up research and production of vaccines, medical kits and medicines for COVID-19. As we have previously mentioned, the WTO has an essential role in this fight, as the custodian of the multilateral TRIPS Agreement. During the pandemic more flexibilities of TRIPS Agreement are needed in addition to the existing ones. The current exiting flexibilities have clear limitations as the proponents have explained in the past. Therefore, intellectual property should not become a barrier for scaling up production of vaccines, medical kits and medicines for COVID-19.

7. In the previous TRIPS Council meetings, the African Group has supported the proposal for a waiver of certain provisions of TRIPS Agreement for the prevention, containment and treatment of COVID-19. We also informed the Council that the Group was consulting internally with a view of co-sponsoring the proposal. This matter was taken to the highest level of engagement and discussed during the Assembly of the African Union held from 6 to 7 February 2021. Consequently, a decision was taken that due to the exceptional circumstances we are faced with, Members of the African Union should support the proposed waiver. Following that decision and considering the mounting challenges that Africa is facing today on COVID-19 vaccines, we are joining the proponents as co-sponsors in seeking a swift decision on the waiver at the TRIPS Council and ultimately the General Council.

8. In the last TRIPS Council meeting, many delegations including the African group, indicated the need to move to a text-based negotiation. We want to once again reiterate the call for an urgent shift from discussion to text-based negotiations. Further delay of a decision on the proposed waiver is inappropriate as the death tolls across the globe caused by COVID-19, are rising.

1.3 South Africa

9. We thank you for your report on the activities of the TRIPS Council's consideration of the Waiver Proposal and further consultations you held in small group formation as well as the details put forward in the proposed oral report to be presented to the General Council in March 2021. We would like to welcome the African Group and LDC Group to the fold of co-sponsors, the increased numbers of delegations in our ranks demonstrate the growing importance of the Waiver Proposal and the need to scale up production in order to ensure equitable and timely access to COVID-19 medical products, including vaccines, therapeutics, diagnostics and other equipment.

10. Moving forward, discussions cannot continue to be mired in the evidentiary loop that we have been engaged in over the last few months. Co-sponsors have also made it clear that we want to move to text-based discussions, we stand ready to discuss the scope and duration of our proposal in light of comments and observations that Members have made.

11. A pandemic like COVID-19 has not been seen in a century, and much remains unknown and evolving about the situation and the virus that causes it. While many regard the virus as a sort of black swan, it was not entirely unexpected and was preceded by several other viruses and semi-global pandemics in recent times. As much as we may hope that something like this will not happen again, the probability is there that the next event may be even more cataclysmic. Many of the most serious global threats today involve a high degree of uncertainty. Under such conditions, people are notoriously unwilling to make sacrifices for others when the benefits are uncertain. A good example of this type of behaviour is vaccine nationalism, which denotes self-prioritization to the exclusion of others, as many rich government have done on the assumption that individual action can yield results on its own. However, this is not the case, the idea that a vaccine rollout will be the *deus ex machina* is misplaced, we cannot put the virus back into its bottle, we just cannot go back to the old normal.

12. According to available data, the United States, the United Kingdom and the European Union account for about 50% of the over 200 million vaccines administered globally as at 22 February. Countries opposing the TRIPS Waiver Proposal account for 60% of the globally administered COVID-19 vaccines. Reportedly, just ten countries have administered 75% of all COVID-19 vaccines. More than 130 countries have not received a single dose. The WTO has to pay heed to the caution of the Director General of WHO: "The longer it takes to suppress the virus everywhere, the more opportunity it has to change in ways that could make vaccines less effective – an opportunity to mutate".[1]

13. Sir Jeremy Farrar, the head of Wellcome Trust has also highlighted that "Immunising a lot of people in a few countries while leaving the virus unchecked in large parts of the world would simply allow more variants to emerge in these places. And the more that happens, the higher is the risk that the virus will evolve to an extent that our vaccines, treatments and tests are no longer effective" adding that "We've got to understand this is a global problem that must be dealt with globally."[2] Our TRIPS Waiver offers a global solution. The world is facing its worst ever crisis since perhaps World War II, and the response of WTO Members opposing the Waiver Proposal is to engage in "business as usual" approaches, and for WTO to do nothing to address IP monopolies around the technology and know-how, to scale up production and to bring this crisis to an end.

14. Many of the opposing WTO Members, under pressure from their pharmaceutical industry have for more than two decades, been known to dissuade developing countries from incorporating TRIPS flexibilities in their national law and using such flexibilities to promote access, and yet now insistently assert that such sufficient flexibilities exist, although we have presented concrete arguments against it.

15. These same WTO Members stress on "business as usual voluntary licensing" as the way out of this pandemic and yet one year on, this "business as usual" approach premised on voluntary, secretive, limited and restrictive licensing has failed to leverage global expertise and capacity to scale-up manufacturing and deliver equitable access. Instead this approach has limited competition,

[1] https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-munich-security-conference---19-february-2021

[2] https://www.theguardian.com/world/2021/jan/31/jeremy-farrar-until-we-are-all-safe-no-one-is-safe-covid-is-a-global-problem

and is artificially constraining global supply. These "business as usual" approaches championed by opposing countries is not the global solution but really the root cause of why to date we have vaccinations that are "wildly uneven and unfair" as pointed out by the UN Secretary General.[3] At the current vaccination rate, it will take an estimated 4.8 years to cover 75% of the population with a two-dose vaccine, according to Bloomberg on the path to immunity around the world[4]. And sadly, this is probably an optimistic scenario. Co-sponsors have often called for the open sharing of vaccine manufacturing technology, IP and know-how through the COVID-19 Technology Access Pool (CTAP).

16. We want to clarify that as co-sponsors of the Waiver Proposal, we have always said that we welcome global multilateral cooperative initiatives such as the ACT-Accelerator. The objective of COVAX, its vaccine arm, is laudable, as are financial contributions from WTO Members to this end. However, we have to confront the limits of the architecture of such an approach, it is not meant to address all the needs of developing and least developed countries. A rather large gap exists between what COVAX or ACT-A can deliver and what is required in developing and least developed countries. In this case demand-side requirements outstrips supply-side constraints. Irrespective of the amount of money any of the donor country may throw at the problem, the model of donation and philanthropic expediency cannot solve the fundamental disconnect between the monopolistic model it underwrites and the very real desire of developing and least developed countries to produce for themselves. The problem with philanthropy is that it cannot buy equality. Yesterday the DG of WHO warned that: "Money is not the only challenge we face. If there are no vaccines to buy, money is irrelevant. Even if we have the funds, we can only deliver vaccines to poorer countries if high-income countries cooperate in respecting the deals COVAX has done, and the new deals it is doing."[5] Even in light of all the additional pledges of monetary support, the ACT Accelerator still faces a gap of at least 22.9 billion dollars to fully financed.

17. The Waiver Proposal constitutes a very real compromise that will immediately enable countries to tap into unused production capacity by accessing spare capacity in the developing world which will satisfy the ongoing demand for COVID-19 vaccines (including therapeutics and diagnostics) and will also negate the need for any donations from rich countries. Take the African continent for example: as a whole, Africa currently imports more than 80% of its pharmaceutical and medical consumables. This is unsustainable and puts the continental population of 1.3 billion people at the mercy of a few monopolistic companies. This is a recipe for disaster as we have witnessed not only with the COVID-19 pandemic but with all other diseases and pandemics that continue to affect the continent.

18. We recalled in our intervention of 4 February 2021, in which we quoted a study commissioned by the international Chamber of Commerce (ICC) Research Foundation which found that the global economy stands to lose as much as USD 9.2 trillion if governments fail to ensure developing country economies access to COVID-19 vaccines. We have already argued that there are good moral and legal grounds, as recognized under the TRIPS Agreement, to pass the Waiver Proposal. In addition, this study underscores the importance of ensuring access by developing countries to effective vaccines in order to mitigate the economic and social consequences in the years ahead. We have already indicated that the artificial shortage of vaccines is primarily caused by the inappropriate use of intellectual property rights. This cannot be allowed to continue. It is now apparent that poor countries would have to wait a long time to access vaccines, during this time the virus will mutate giving rise to strains that will undermine the efficacy of existing vaccines. COVID-19 does not respect national borders; nor does it care about the gross domestic product of a country, no country in the world can insulate itself, even the best plans will be laid to waste. Let us ensure that everyone has access to effective vaccines in the shortest possible time.

19. In closing, as many co-sponsors have reiterated, we are ready to go to a text-based discussion in order to arrive at an immediate solution. This will not only save lives but also enable us to return to a situation of relative normalcy. No one is safe until everybody is safe.

[3] https://news.un.org/en/story/2021/02/1084962

[4] https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/

[5] https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-22-february-2021

1.4 Egypt

20. At the outset, Egypt aligns itself with the statement to be delivered by Tanzania on behalf of the African Group and we welcome the African and the LDCs groups as co-sponsors of the Waiver Proposal. We also would like to thank you Madame Chair for the oral report and we support its adoption by the TRIPS Council.

21. Many countries, even in the developed world, have been reporting shortages of COVID-19 vaccines and had to suspend their immunizations – or slow them for lack of doses. These shortages in supply of vaccines, coupled with vaccine nationalism and export controls, mean that the vast majority of people especially in developing and least-developed countries will not be able to access a COVID-19 vaccine in 2021, and possibly for multiple years ahead. It is clear that we are facing a huge problem especially in the production and distribution of COVID-19 vaccines that will hinder the global fight against this pandemic.

22. We believe that we cannot continue to ignore the severity of the current crisis and we urge all Members to engage constructively in text-based negotiations in this house in order to reach consensus on this Waiver Proposal as soon as possible to prove that this organization can make a difference during this unprecedented crisis. The adoption of the TRIPS Waiver will be beneficial to the global economy, as it helps ramping up the global production of vaccines in order to put an end to this pandemic.

1.5 Colombia

23. Colombia reiterates its thanks to the co-sponsors of document IP/C/W/669 for bringing the attention of all Members to the effects on the public health and the economies of countries caused by the SARS COV 2 virus (COVID-19), and for encouraging the global review of possible alternative action to be taken in relation to intellectual property which could help overcome the crisis that we are experiencing.

24. Bearing in mind the impact of the decisions taken on this subject, it is crucial to comprehensively review the proposal for a "Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19", while exploring how to use the flexibilities enshrined in this Agreement without fear of retaliation or excessive costs. As stated on previous occasions, it is essential for the Colombian Government to ensure a coordinated international response on access to inputs, treatments and vaccines. Achieving the desired level of immunity requires all countries to stop the spread of the virus.

25. We believe that the discussion that has been generated is constructive and we again call for special attention to be given to the strengthening of production and supply, vaccines, inputs, and medicines, as it is on the weakness of production and supply chains that we must focus our actions. We need to better understand the relationship between intellectual property and weak production and supply chains in order to have better tools to strengthen them and thus ensure the effective, expeditious and universal distribution of vaccines and other inputs in times of crisis.

26. For this reason, it is important to discuss alternatives to address sudden surges in demand for medicines, vaccines or other goods needed to address an emergency, based on the transfer of information, knowledge and technology to ensure that all populations meet their needs. It is desirable to find a concerted and voluntary way to share information and make legitimate use of intellectual property rights in the midst of this pandemic.

27. The decision whether or not to grant a waiver should be based on a thorough review of the benefits and implications that it may have. The knowledge and technology needed to respond to an emergency must be easily accessible to all countries, especially during times of calm, which is when they must prepare for crises. This is a decision of the utmost importance, as we must always bear in mind that we must not only respond to current crises, we must also ensure a sustainable system that allows for innovation in order to address future crises.

28. We would also like to express our support for the proposed oral report to be submitted to the General Council, which represents the progress made in the discussions.

29. I wish to conclude by reiterating Colombia's willingness to continue the discussion in a constructive manner, while remaining open to all options to ensure access to goods that improve the health of the population.

1.6 Chad on behalf of the LDC Group

30. On behalf of the LDC Group, I would like to reiterate our gratitude to the authors of the proposal for this initiative on the "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19".

31. The objective of this proposal concerns us all: developed countries, developing countries and least developed countries. Life has meaning only when you are in good health. If you are sick and you do not have access to health care, then you can expect the worst. We must save lives and ensure that the COVID-19 pandemic does not further exacerbate the current situation, claiming a large number of victims, forcing states to take measures that restrict the movement of people and goods, slowing down global activity and global demand, disrupting economies, and causing turmoil and uncertainty for economies and world trade.

32. The Director General of the World Health Organization (WHO), Tedros Adhanom Ghebreyesus, warned last January that "the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries".

33. The trends that we are observing are deeply concerning, and we often say that no one will be safe until everyone is safe. Vaccine nationalism will not work, as COVID will resurface through variants, as we can already see.

34. We must therefore ensure that everyone has affordable access to vaccines, medicines and other new technologies needed to control the pandemic. It is necessary for everyone's safety and it is the vital challenge before us.

35. Voluntary transfer through initiatives by companies has produced limited results. Vaccine manufacturing agreements with some enterprises lack transparency on costs, and other companies have shown no interest in licensing or transferring technology for their patented products. We will only be able to provide an effective response to this global challenge through multilateralism. Our collective interest depends on it.

36. It is clear that this proposal is aimed at the common good and meets the expectations of world opinion. The debate, the reactions, the positions and the proposals that it has generated throughout the world are proof of this. The very fact that world opinion has taken up the matter demonstrates the need for WTO Members to find a consensual solution to this situation.

37. The proposed Waiver is an opportunity to take concrete measures to help prevent another tragic repetition with regard to access to life saving treatments.

38. The debate within the Council for TRIPS must enable all to ensure that barriers to accessing these types of products and trading in them are minimized, in order to make our economies and populations more resilient to such a pandemic crisis, but also to build a fairer, more equitable, transparent and inclusive system that truly responds to global public health needs. And this is what the communication seeks to do.

39. We must ensure that intellectual property rights do not create barriers to timely access to affordable medical products, including vaccines, or to increased research, development, manufacturing or provision of medical products that are essential for combating COVID-19.

40. Since the emergence of the COVID-19 pandemic, many developing countries and LDCs have become more vulnerable and have had difficulty accessing medical supplies. The significant imbalance between countries raises serious concerns about the availability and accessibility of medical products needed to tackle COVID-19.

41. In these exceptional circumstances, we believe it is important to remove potential barriers related to intellectual property rights. It is important to take all the necessary steps to ensure that everyone has access to affordable medicines and/or vaccines.

42. Moreover, the LDC Group, having spoken with the authors of the proposal and received feedback from our various capitals on the importance of this proposal, joins the proponents as co-sponsors of the communication on the "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19".

43. In light of the significant health challenges before us, the LDC Group calls for a swift decision by the Council for TRIPS and the General Council.

1.7 Pakistan

44. Pakistan would like to thank you for convening this meeting, and to commend you on your hard work to allow open exchange on this topic. Pakistan has no objection to the draft report you have presented. At the outset, we wish to welcome the new co-sponsors, in the entire African group and the LDC group. The growing support for this proposal, is testament to the importance and urgency of this proposal in present times. We therefore wish to recall all our previous statements in the formal and informal meetings of this Council on the issue.

45. Since we started debating this issue last year, significant time has elapsed. During this time, we have seen that the assurances given by those who opposed this Waiver, that the COVAX facility would take care of vaccine dissemination to developing countries; that partnerships and voluntary licenses were the only way and would adequately cover the needs of the large developing country populations; those assurances have fallen flat. Instead, vaccine hoarding has now become established. At the same time, supply constraints have emerged even in developed countries that had secured enough doses to vaccinate one person many times over. Most recently, reports have surfaced that export restrictions on vaccines may be placed by countries that have them and control their supply.

46. According to a latest estimate, a handful of rich countries have secured over three billion doses of the available vaccines, which is over one billion more than the collective requirement of these countries put together.

47. Meanwhile, the disease remains rampant. New mutant strains are being reported every day, and there are no signs of abatement. The consequences of such developments, are noteworthy. Only last night, it was reported that the richest country in the world has now suffered half a million deaths due to the disease. This, on top of the fact that this country has one of the best healthcare delivery systems in the world. An extrapolation of this number as a percentage of the population across the entire globe would present unimaginable and alarming numbers in the coming months, if the vaccines do not become available to the poorer countries in time.

48. Other than the loss of lives, and as mentioned in the statement by South African earlier, it is estimated in a recent study by the International Chamber of Commerce, that the global economy is set to lose as much as USD 9.2 trillion if developing countries' access to COVID-19 vaccines cannot be ensured. The study further finds that no economy, even in the developed world, can fully recover from the effects of the pandemic unless vaccines are equally accessible in all developing countries.

49. While developing countries are making a strong case for access to vaccines, we are already hearing mentions of COVID or vaccine passports in those that have access to vaccines. Such steps, in a very preliminary understanding, could only lead to more restrictions on already restricted travel, seriously affecting supply chains and curtailing movement of natural persons. Economies dependent on such movements could face serious damage. We fear that the world would create yet another divide between the vaccinated and non-vaccinated. Only this time, the effects would be felt by everyone, regardless of their development status.

50. A good solution is what we, the co-sponsors, have proposed. To remove this artificial vaccine famine we must utilise all the production capacity in various countries in the Global South, and allow them to manufacture vaccines and other essential medicines and equipment *en masse* by removing

the various IP restrictions. This would allow us to reach the figures required to break the chain of the virus spread and avoid the impending crises.

51. We have made a very robust and thorough case for this Waiver. We have provided detailed explanations regarding its necessity, scope, and applicability. We have also put forth detailed evidence on how and why this Waiver is necessary. We have stressed in our explanations that the quest to perpetuate monopoly power using IP, especially trade secrets, must be abandoned, in order to massively scale up the production of vaccines within the shortest possible time.

52. In opposition, we have heard among other things that, intellectual property is not barrier. At the same time, the same Members have argued that the real barrier is the transfer of technology and know-how and that the underlying IP is required for purposes of licensing. These are contradictory statements, at best.

53. It is a known fact that much of the vaccine and monoclonal anti-body technology and know-how is protected by intellectual property, particularly patents and trade secrets. We have detailed in documents IP/C/W/671 and IP/C/W/673 this known patent landscape for therapeutics and vaccines. While patents are obtained on many aspects of vaccine technologies, trade secrets work to deny access to the biomaterials and manufacturing processes. Patent information, therefore, is insufficient to facilitate non-originator manufacturing of COVID-19 vaccines. Additionally, as pointed out before, compulsory licenses under TRIPS Article 31 are only applicable for patents, and are not explicitly provided for under Article 39 of TRIPS.

54. Lifting IP monopolies around technology and know-how will facilitate the sharing of such technology, expedite production, and also give potential manufacturers legal certainty and freedom to operate. It is, therefore, important to ask whether the regulatory agencies of the developed countries are ready to share the vaccine regulatory dossiers to scale up vaccine production.

55. Based on the foregoing, it is high time that we conclude the debate, and move towards concrete text-based solutions to the Waiver to be put it into effect. Endless deliberation to stall this issue will only cause further problems for the entire globe. As we have indicated before, we are ready to explore possibilities on the text of the proposal to make sure that it adequately addresses the challenges we face.

1.8 Bangladesh

56. The delegation of Bangladesh supports the draft statement presented in this meeting which will be further delivered orally at the General Council by the TRIPS Council Chair.

57. My delegation endorses the statement delivered by Chad on behalf of the LDCs. With all the co-sponsoring Members, including the LDC group, Bangladesh attaches high importance and welcomes discussion of the proposal contained in document IP/C/W/669. My delegation once again thanks the proponents for their previous submissions with evidences and explanations.

58. We live in an interdependent and interconnected world, and therefore, my delegation believes that the issues of public health are concerns for everyone in the world. A threat to public health in one society puts humanity at risk everywhere. As we have noticed, the ongoing pandemic is primarily a health issue, but evidently has far reaching impact on our societies and economies. No one is certain when this pandemic will end actually. Enough damage has already happened to the world, and as consequences, the LDCs particularly are becoming the worst victims. In addition, the new variants of the virus are threatening us. We need collective efforts to support each other, irrespective of our development status, for the interest of our survival.

59. My delegation earlier stated that unconditional, affordable, equitable and timely access to vaccine and other curative measures against the virus must be a priority of the time. Production and distribution of vaccine and other medical equipment for prevention, containment, and treatment of COVID-19 must be open to all, so that people of the world can easily access these facilities. The TRIPS or any other regulatory framework should not be brought as a hindrance to the most urgent needs of the humanity today.

60. The proposal has clearly presented its objectives. Members have also discussed the contents of this submission in several occasions and heard each other loud and clear. This is a high time now, to start a text-based discussion. The delegation of Bangladesh looks forward to engaging constructively with Members and once again requests a favourable consideration of the proposal.

1.9 Mozambique

61. From December 2019 to February 2021, more than 2.4 million of people have died from COVID-19, out of more than 110 million who contracted the virus. As is well-known, this virus does not only affect health, but all other aspects related to human life, in the social and economic area. The world is facing an unprecedented challenge that calls for unprecedented collective measures.

62. As the world is now organized, it will not contain the spread of the virus only with public health measures. We reiterate the need to put in place other measures to guarantee that billions of vaccine doses are produced and made available to everyone, at affordable prices and in a short period of time.

63. The developing countries have already been left behind and the way out is the Waiver certain provisions of the TRIPS Agreement for prevention, containment and treatment of COVID-19, to ensure that the intellectual property rights do not restrict rapid scaling up of manufacturing and do not hinder an equitable and affordable access for diagnostics, medicines, vaccines and other necessary goods.

64. The application of this measure would not invalidate existing IP rights, and would open space for further collaboration and transfer of technology. My delegation would like to remind that behind the figure of 2.4 million deceased, there are health workers, care givers, teachers, fathers and mothers, a long list of professionals who left an empty hole in their communities, and we need to put urgently an end to this pandemic.

65. We reiterate our appeal to Members to avoid putting in place restrictive measures to exports at a time they are needed most. Since this dialogue started, many Members have positively engaged. We commend and welcome the proposals put forward so as to move this dialogue ahead. We welcome the proposal for a text based dialogue. We thank and welcome all new co-sponsors this initiative, so valuable to assist and respond to all needs.

1.10 India

66. We would like to thank you for your report, which is factual and reflects the developments that have taken place since the last report to General Council in December 2020. We look forward to the discussions in the General Council on the report. We would like to thank and welcome the Africa Group and the LDC Group as the latest co-sponsors of the Waiver Proposal. The Proposal now reflects the voice of 57 WTO Members with many more supporting from the floor since its introduction in this Council in October 2020.

67. So far around 200 million vaccine doses against COVID19 have been administered worldwide. The UN Secretary General, in his press briefing last week[6] noted that the progress on vaccinations has been wildly uneven and unfair, more than 130 countries have not received a single dose. He warned "If the virus is allowed to spread like wildfire in the global South, it will mutate again and again and that this can prolong the pandemic significantly, enabling the virus to come back to plague the global North."

68. When we introduced the Waiver last year, we had cautioned against such a scenario and therefore made the case for removing IP barriers temporarily to ramp up rapid global manufacturing. It is unfortunate that our apprehensions, subsequently supported by evidences, were dismissed as hypothetical as the vaccines were yet to arrive at that time. We are not feeling happy about being proven right in raising concerns in advance. Today our fears have not only proven to be true but the very Members who dismissed our argument in this Council that there would be shortages of vaccines if manufacturing remains limited, are themselves facing shortages in their jurisdictions even after

[6] https://www.un.org/press/en/2021/sc14438.doc.htm

having successfully negotiated advance purchase agreements of volume way beyond their need. That the situation could be this worse, even the proponents of Waiver did not predict.

69. On its part, India has supplied 28.84 million vaccine doses to 26 countries as on 21 February 2021 under its "Vaccine Maitri" i.e. Vaccine Friendship Initiative. 48 more countries will be supplied in the coming days ranging from Europe, North America, Latin America, and Caribbean to Africa, SE Asia and the Pacific Islands. India has also gifted 200,000 doses for the UN Peacekeepers. The UN Secretary General has stated that India has been a global leader in pandemic response efforts having provided critical medicines, diagnostic kits, ventilators and personal protective equipment to more than 150 countries. Despite scarce resources and a population of more than 1.3 billion, we are doing our bit towards equitable delivery of vaccines. If the existing global manufacturing capacity can be used for mass manufacturing by providing legal certainty to manufacturers over use of COVID-related IP, which is the chief objective of the Waiver, then humanity can accelerate the fight to win over the virus.

70. As we reiterated at the past meeting, proponents answered all questions posed in various sessions of the TRIPS Council, yet certain delegations have this tendency to ask further questions and delay the start of text-based negotiations. With the experience learnt during the last four months after the first emergency use authorisation of vaccines, we need to close the evidentiary loop and get down to textual negotiations that can further refine the Waiver Proposal that we tabled. What we have seen in last few meetings is a repetition of similar questions and maybe answers to some of those questions lie in text-based negotiations. Moving to a text-based negotiation may appear to be yielding from the high moral ground of being the sole protectors of IP rights for some Members, but not doing so means a willingness to stand by a poor choice, devoid of ground realities and just opposite to what is the need of the hour.

71. The delegations that oppose the Waiver have argued on one hand that the Waiver, if granted, will not result in augmenting the manufacturing capacity and on the other hand, they argue that the Waiver will impact the commercial interests of existing IP holders as lot of manufacturing could come into play without agreement with the IP holders. We would like to understand this dichotomy that if the Waiver will not lead to an increase in manufacturing capacity, meaning, no new manufacturers will enter into production of COVID products even with the proposed Waiver in place, then how will the commercial interests of existing IP holders be impacted? On the other hand, if manufacturing is going to increase significantly and are thereby impacting commercial interests of IP right holders, then are we not agreeing that final objective in the present scenario is to increase manufacturing.

72. Moving on to COVAX - even its creators have admitted the issues with the mechanism like lack of funding and its inadequacy to address supply side constraints. DG, WHO in a recent statement[7] said and I quote, 'The ACT Accelerator and COVAX Facility were created to increase equity. But with every passing day, that goal is at risk.' He called on all countries to respect COVAX contracts and not compete with them. He also mentioned that 'we need an urgent scale-up in manufacturing to increase the volume of vaccines'. There is no alternative to augmenting manufacturing to address supply side constraints of goods critical for prevention, containment and treatment of COVID-19, and allocation of money alone for securing such supplies would not suffice. The Waiver Proposal, which seeks to address supply-side bottlenecks, will thus further help the COVAX mechanism to achieve its goal.

73. Regarding the proportionality of the Waiver, almost every country implemented lockdown in some form or other to curtail the spread of COVID. That does not mean that authorities were against the principle of "right to freedom of movement". Similarly, governments worldwide intervened to suspend air transport and restrict mobility in order to prevent the spread of coronavirus. Sectors like civil aviation, travel and tourism, hospitality and even small business activities are facing continued restrictions and thereby being severely impacted by such state interventions. These sectors are also important for the global economy, for growth, for employment. Certainly, governments are not against the interest of these sectors. We would like to ask the membership that why commercial interests of only few companies are so sacrosanct? If it is to preserve incentives to innovate, then such commercial loss, to the tune of few tens of billions of USD at the maximum, can always be compensated by further incentives through public funding. In any case, such loss to few companies is significantly lower than the overall loss to global economy, estimated to be USD 9.2 trillion if the

[7] https://www.who.int/director-general/speeches/detail/who-director-general-s-introductory-remarks---act-accelerator-4th-facilitation-council

international community fails to ensure developing economy access to COVID-19 vaccines, as per the study by International Chamber of Commerce. The global community has resorted to exceptional measures in the exceptional circumstances of COVID pandemic, and the Waiver should be seen in similar vein.

74. The TRIPS Agreement has been in force since 1995. But never, in the history of medical science, have vaccines been developed in such a short span of time of less than one year. This proves that it is not the IP system alone that has delivered, but also the public funding, the institutional support in terms of research contributions by public universities, the global collaboration in sharing of genome sequencing data and public health information that has led to the development of successful vaccines in record time. The proponents respect the intellectual property rights and their value as incentives for innovation, but COVID19 pandemic being unprecedented as it is, where research and innovation has mostly been spearheaded by massive public funding, expedited regulatory approvals, and global collaboration, we need to put lives before private profits.

75. Some Members have questioned that how fast manufacturing can be ramped up once the Waiver is granted. Once the Waiver is in place, the existing manufacturing capacity worldwide can be put to immediate use for production of COVID products. Our past experience suggests that if supported with adequate regulatory framework, vaccines are relatively quick and inexpensive to make. The other option is to scale up the existing capacity through brown-field investments which can be done in a few months. Yet another option is to invest in creating new capacity through green-field investments, a matter of a few quarters.

76. Some other countries have questioned that how the abuse of Waiver would be avoided and how would it be ensured that it does not become permanent. We are seeking a temporary Waiver, and we have left the time period to be negotiated by Members in TRIPS Council. Moreover, Waiver, once granted, will be reviewed annually by the General Council. The duration could be some fixed number of years together with a conditional criteria for termination. We want to have frank discussions on the text of the Waiver, relating to both its duration and scope, in order to find answers to these questions and to find a landing zone to operationalise the Waiver in the shortest possible time. We cannot continue to engage in endless discussions while millions of lives are lost to the coronavirus pandemic. We need concerted efforts by all WTO Members to ensure that the WTO makes a meaningful contribution to defeat COVID-19. COVID-19 has shown that our fates are inextricably linked. Whether we win or lose, we will do so together. The Waiver provides an opportunity to make a winning attempt, and we hope Members will make that attempt.

1.11 Indonesia

77. We join others in thanking you, Madam Chair, for convening this meeting and your leadership during the course of the discussion of this proposal. The discussion has been very insightful to broaden our understanding of the proposal tabled by India and South Africa.

78. We also would like to thank you, Madam Chair, for the draft of Status Report in document JOB/IP/42. We fully support the draft status report as now been revised to reflect additional co-sponsors.

79. As the discussions have been extensively rolling in the Council, we collectively understand that IP creates a visible barrier in the access of vaccines, therapeutics, and diagnostics for the prevention, containment, and treatment of COVID-19. The WTO, as the only umbrella which governs the balancing of IP protection and public health through TRIPS flexibilities, arguably is believed to be the solution to address this problem. However, in practice, such flexibilities are not easily acquired by countries.

80. In the previous meeting, Indonesia shared our experience on the difficulties of using voluntary licensing of Remdesivir. We failed to convince the patent holder to extend the production to Indonesia to address shortages and the product's high price. Relying on importation alone will add more time and cost, creating an obstacle for our government to provide essential medicines in a timely and affordable manner.

81. As we have addressed in previous meetings, the patent approach is not enough in combating the COVID-19 pandemic. Many countries experienced shortages in medical equipment such as

ventilators, respirators, and test kit, causing the price to increase and create massive turbulence in the market. This is a clear example that the lack of flexibility in these products' IP areas should be addressed.

82. International collaboration present today is a breath of fresh air and a form of global solidarity. Still, the lack of transparency, equitability, and accessibility, in the system might create uncertainty for developing countries and LDCs to have equitable access of medicines and medical equipments. These collaborations might also face limitations primarily due to the voluntary system being adopted.

83. In this part, we believe the Waiver offered by the proposal will be a possible solution of these issues by eliminating certain IP barriers and scaling up the production. The Waiver will also prevent the possible monopoly created by the IP system and will provide a larger access of medical products to people in dire needs.

84. Therefore Indonesia would like to reaffirm our position to support the discussion of a possible Waiver until we find concrete solutions that are certain, transparent, equitable, and accessible to combat the world catastrophe created by the COVID-19 Pandemic.

85. Finally we urge those Members who are still against the proposal to also provide written replies to the questions posed by co-sponsors in document IP/C/W/674 to reflect our intention to move forward with this proposal.

1.12 El Salvador

86. As we stated at the outset of the discussion of this proposal, El Salvador considers the comprehensive handling and management of the COVID-19 health crisis to be of vital importance. The Government of El Salvador has stepped up its efforts to support affected sectors of the population in terms of health, as well as the harsh economic and social impact that has affected most of the population.

87. In this context, our country has been analysing in detail the proposal in question from a social and health perspective, as well as from a legal perspective. El Salvador has legal institutions that afford protection for all areas of intellectual property at the national level, in addition to our international commitments in this area, of which we are faithful guarantors.

88. Promoting and incentivizing innovation as a tool for boosting and accelerating our country's development is a top national priority. El Salvador's scientific and technological progress and modernization are becoming increasingly important in these times of crisis and for economic recovery. In this context, we find it difficult to reconcile such a broad Waiver in the application of intellectual property rights with the objectives that we have set as a country.

89. We consider that the discussions that we have held on this proposal, provide important inputs for a practical and profound dialogue within the competence of this Council, to improve the intellectual property system, while identifying the specific barriers that some Members have faced in addressing their priorities and seeking solutions within the multilateral system.

90. We consider it essential to continue to intensify dialogue and cooperation among Members on this important subject in order to find a balanced solution for all partners. El Salvador will continue to engage constructively in this discussion.

1.13 Venezuela, Bolivarian Republic of

91. We would like to begin by reiterating our appreciation of the manner in which you have conducted the work of this Committee, which is reflected in the report that we have adopted in this meeting for consideration by the General Council.

92. We would also like to welcome the African Group and the LDC Group, as co-sponsors of this proposal. The large increase in co-sponsors of this proposal is a clear indication of its importance. We would like to take this opportunity to call on those countries that approve of the proposal to also take a step forward.

93. Under your leadership, we have held a number of consultations that now enable us to be clear about the concerns of those countries that oppose it, as well as the objectives of those who are co-sponsoring it. As a result, we consider that it is now time to move to text-based negotiations. We could start with the scope and duration of the proposal, taking into account the comments and recommendations received, in the best spirit of compromise and reconciliation of positions. We must rise to the current challenges and be ready to provide options for responses aimed at ridding the world of this COVID-19 pandemic and its variants.

1.14 Sri Lanka

94. First my delegation wishes to extend its congratulations to the African Group and the LDCs for joining India, South Africa and other original co-sponsors in co-sponsoring the Waiver Proposal.

95. While my delegation is strongly contemplating to join others as a co-sponsor of this Waiver Proposal, it has been strongly supporting the initiative and urging all Members to be on board in addressing the issues, which are very well presented and justified in the proponents' proposals aimed at prevention, containment and treatment of COVID-19.

96. The biggest aim right now should be to vaccinate and prevent the deaths caused by the virus, as the medical research undertaken so far by many countries indicates that it not only guarantees the slowing down the spread of the virus among the communities, but also builds the required immunity in the persons who get vaccinated, so that their symptoms get milder and it prevents the persons from hospitalization or dying from the virus.

97. New strains of the coronavirus could be more infectious. This therefore requires Sri Lanka and all those countries which have declared having the presence of various mutated forms of COVID virus to go back to aggressive measures of testing, contact tracing, and isolating infections, while pursuing a vigorous vaccination programme in their countries.

98. As per the recent revelations, the UK and California variants of the coronavirus appear to have combined into a heavily mutated hybrid, sparking concern that we may be entering a new phase of the COVID-19 pandemic.

99. Two variants of the SARS-CoV-2 coronavirus that causes COVID-19 have combined their genomes to form a heavily mutated hybrid version of the virus. The "recombination" event was discovered in a virus sample in California, provoking warnings that we may be poised to enter a new phase of the pandemic.

100. The hybrid virus is the result of recombination of the highly transmissible B.1.1.7 variant discovered in the UK and the B.1.429 variant that originated in California and which may be responsible for a recent wave of cases in Los Angeles because it carries a mutation making it resistant to some antibodies.

101. Recombination could lead to the emergence of new and even more dangerous variants, although it isn't yet clear how much of a threat this first recombination event might pose. Recombination commonly occurs in coronaviruses, because the enzyme that replicates their genome is prone to slipping off the RNA strand it is copying and then re-joining where it left off. If a host cell contains two different coronavirus genomes, the enzyme can repeatedly jump from one to the other, combining different elements of each genome to create a hybrid virus.

102. The recent emergence of multiple variants of the new coronavirus may have created the raw material for recombination because people can be infected with two different variants at once. The scientists predict that such recombination could allow the virus to have coupled a more infectious virus with a more resistant virus.

103. We are also concerned that though the vaccines will continue to be effective against the new variants of the virus, their efficacy might be less. Despite these setbacks, getting vaccinated is a must.

104. Though Sri Lanka began to witness cases at a very slow pace, since 4 October 2020, it has been witnessing the spread of the virus in an unprecedented speed creating serious concerns as to whether it has gone out of control.

105. During the period of 4 October 2020 to 22 February 2021, the total number of cases has surged from 3,402 to 80,517 recording 2,267 % increase, active cases from 131 to 4,957 recording 3,784 % increase and overall deaths from 13 to 450 recording 3,362 % increase. These data are very disturbing for a small country such as mine.

106. Thanks to the generosity of the Government of India, Sri Lanka received 500,000 doses of the Oxford–AstraZeneca COVISHIELD vaccines in late January 2021. The vaccination drive in Sri Lanka began on 29 January 2021. As of yesterday, a total number of 302,857 vaccines out of these 500,000 vaccines have been administered.

107. Sri Lanka is expecting a further 1.6 million vaccines of the Astra Zeneca variety under the WHO'S COVAX facility which are expected arrive in the country in three to four batches commencing from early March 2021.

108. Sri Lanka is also working closely with India to sign agreements to purchase a further ten million doses from the Serum Institute in India using the funds that have been allocated by the government especially for this purpose. Once confirmations are received, an agreement will be signed between the Serum Institute in India and the Sri Lanka Pharmaceutical Corporation who will procure the vaccines for Sri Lanka. These ten million vaccines will be utilized to vaccinate five million people, under the first phase.

109. Since the tourism sector contributes substantially to the backbone of the economy, Sri Lanka took a very bold, but a painful decision to open the country to foreign tourists since 21 January 2021 under strict guidelines, despite the rising number of infections within the country. Accordingly, Sri Lanka has also decided to include the personnel served in the tourism industry and directly interacting with the foreign tourists in the priority list of the vaccination programme enabling them to receive the vaccines first, before including other non-vulnerable population groups in the programme. Under this programme, around 1,500 airport staff including security personnel at the Bandaranaike International Airport has been vaccinated as of yesterday.

110. These are some of the initiatives taken by Sri Lanka to face the many economic challenges of the pandemic, but it is concerned whether it is likely to face serious setbacks after hearing the news from Serum Institute of India (SII), which is the world's biggest vaccine maker by volume, on Sunday asking for patience from foreign governments awaiting their supply of COVID-19 shots, saying it had been directed to prioritise India's requirements.

111. Many low-and middle-income countries, ranging from Bangladesh to Brazil, are depending on SII's AstraZeneca vaccine, branded COVISHIELD by the Indian company. But demand is growing, including from Western countries like Canada, where Serum Institute has promised to deliver the COVISHIELD vaccine in the coming months.

112. In the meantime, Britain's drug regulator is also auditing manufacturing processes at SII, potentially paving the way for the COVISHIELD vaccine to be shipped from there to the UK and other countries.

113. All these developments indicate that the scarce supply of vaccines and drugs and other personal protective equipment used in combating COVID-19 pandemic around the world have precarious effects mostly on the developing countries and LDCs. South Africa indicated this aspect very eloquently today with empirical data. My delegation concurs with the facts presented by South Africa and others in this regard.

114. We have had sufficient and lengthy debate on the issue of the Waiver. The co-sponsors made the case in great detail describing the various challenges and problems which necessitate this Waiver. They have also listened and provided elaborate answers to all questions, concerns and clarifications in writing. They have also in turn, asked certain questions. These detailed answers and questions have been compiled in various documents before us.

115. In view of the continuously evolving situation, it is high time we learn lessons from our past, where we ignored the health care needs of millions in developing countries in the interest of maximizing profits for a few companies, and we do not repeat the same mistakes. The time is now ripe for a more forthright, solution-finding approach. This will be the most significant contribution that the WTO could make towards fighting the pandemic and saving human lives.

116. The proposal is seeking a limited-time, and limited-scope Waiver from certain obligations under the TRIPS Agreement only to deal with the global pandemic. It promises to help large populations in developing countries and particularly countries such as mine not having manufacturing capacity which hence is compelled to rely on imports, but would also allow export of medicines and medical equipment to developed countries where demands could remain unfulfilled otherwise.

117. It is high time we listen to the countless calls outside the WTO premises from all walks of life, for global solidarity and cooperation to help fight the pandemic which threatens humanity. We are open and look forward to more meaningful engagement from Members at this juncture, that aims at finding constructive solutions to address this issue.

1.15 Namibia

118. Let me take this opportunity to thank you, for your report and for directing the proceedings for the present TRIPS Council meeting and also thank the co-sponsors for this proposal.

119. On the outset, Namibia aligns itself with the statement which was delivered by Tanzania on behalf of the African Group. My delegation fully supports a call to move the discussions to text-based negotiations with a view to achieve a balanced outcome of the Waiver on certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19.

120. COVID-19 has no boundaries, therefore the longer we take in ensuring equitable access to medicine for all, the more we prolong the catastrophic health effect and rise in death rate globally due to COVID-19.

121. The current rate of the vaccine production and distribution calls for concern, a number of countries introduced export restriction on medicine and medical supplies causing havoc to non-producers of vaccines. We need to find an urgent solution to rapid scaling up of manufacturing to address capacity and supply constraints of the COVID-19 vaccine.

122. As net importer of medicine, Namibia reiterates its position in support of the proposal of the TRIPS Waiver. In addition, we implore other Members as a matter of urgency to support this proposal mindful that time is of the essence in addressing or suppressing the spread of COVID-19 virus in order to save human lives.

1.16 Nepal

123. My delegation wishes to associate itself with the statement delivered by Chad on behalf of the LDC group. First, my delegation thanks you, Madam Chair, for your draft report and supports the report.

124. I would like to refer to Nepal's statements delivered earlier in various meetings on this Waiver Proposal and reiterate our full support to this proposal for the benefit of the people at large across the globe. It would help save life of millions of people across the world and also contribute to the global economy. Therefore, the proposal has merit and deserves support of all WTO Members.

1.17 Nigeria

125. At the outset we would like to thank the co-sponsors of this proposal of which we are happy to be joined as co-sponsors.

126. More vulnerable countries continue to face challenges in ensuring timely, sufficient and affordable medicines, vaccines, diagnostics and other essential medical tools. These challenges are even heightened by the new corona virus variants discovered first in December 2020. Research has shown that it is the nature of RNA viruses such as the coronavirus to evolve and change gradually,

in other words mutate. A renowned professor in the field of medicine, Robert Bollinger, states that there is some preliminary evidence that it is more contagious due to the presence of a surge identified by scientists of cases in areas where the new strain appeared.

127. The Waiver Proposal presents an important opportunity for all governments to unite and stand up for public health, global solidarity, and equitable access through a concrete step at the international level that can provide an automatic and expedited solution to address IP and technology challenges. Governments need to take back the driver's seat and fulfil their core obligations of protecting public health and ensuring access to medicines for all. This Waiver is accessible to all Members and this should come as a good news since COVID-19 is a global pandemic and therefore a global issue. Withholding access to any region will definitely affect other parts of the world no matter the protective efforts in place.

128. In Nigeria for instance, we are already experiencing a second wave of the virus and this was seen to affect many of our citizens including persons from age ten to 35. Health authorities in Nigeria have currently confirmed a total of 130,000 cases of COVID-19, including 1,600 deaths. Up till now, Nigeria is still expecting to actually receive the first batch of doses of the new vaccines. Our government has requested for 41 million doses of a combination of COVID-19 vaccines and also, an additional 16 million doses of the AstraZeneca vaccine are expected this February from the COVAX programme which is backed by the World Health Organization. As Nigeria fights a second wave of COVID-19, officials are looking to multiple sources to secure more vaccines to inoculate its enormous population. Nigeria`s population is around 186 million, therefore from the statistics I have given, the quantity of vaccines are not nearly enough to fight the spread of the disease in Nigeria.

129. Some Members say IP is not a barrier for COVID-19 related tools, and therefore question the need for a Waiver. While we appreciate the concrete steps that owners of IP and rich countries have been making to ensure distribution of the vaccine to regions like Africa, we disagree with this claim because both past and present experiences have shown concretely that IP does pose a challenge in ensuring global equitable access to the effective tools needed in response to COVID-19, including vaccines. Governments have faced IP barriers over drugs, masks, ventilator valves and reagents for testing kits. In addition, more than 100 patents have been filed for the mRNA technology that is being used to develop a vaccine. A report by MSF found that patents pose a serious threat to access to affordable versions of newer medicines.

130. To address domestic need, countries are turning to local/regional production as a sustainable solution. However, multiple IPRs could pose barriers to such solutions. The existence of patents on products or processes generally prevents the acquisition of pharmaceutical products at low prices or in sufficient quantities. WTO Members have a role to play in striking an acceptable balance between, on the one hand, preserving the health of our populations and on the other, saving the lives of our people.

131. The TRIPS flexibilities contained in Articles 31 and 31*bis* were not designed to address a global pandemic of this level. For instance, the challenges of implementing the compulsory license system include the cumbersome procedures of actually acquiring the license at the national level. Similarly, a voluntary licensing system is not transparent, and oftentimes have stringent clauses that do not contribute to our global commitment of ensuring that Vaccines and COVID-related tools are accessible in a timely and cost-efficient manner. Also, in a voluntary licensing system, the licensee is oftentimes at the mercy of the IP owner.

132. Finally, we urge all Members who are yet to co-sponsor the proposal to do so as soon as possible. As South Africa and Norway has mentioned, no one is safe until everyone is safe. We encourage all Members to proceed to text based discussions in order to arrive at an acceptable outcome.

1.18 China

133. China would like to join others in thanking Madame Chair for convening this meeting and your hard work in steering the consultations on the Waiver Proposal during the past few months.

134. We have seen the development and deployment of COVID vaccines at an unprecedented speed. However, to ramp up the COVID vaccines manufacturing capacity and ensure fair and equitable

access to COVID vaccines for all Members is still an urgent call for global community. And if we cannot provide the feasible solutions within a reasonable but short period of time, the "vaccination gap" will further increase the "development gap".

135. So the Waiver Proposal is important in the sense that it constitutes a possible way to solve the problem. Though consensus has not been reached yet, the discussion of the proposal in the TRIPS Council demonstrates that Members share the common goal of ensuring the accessibility and affordability of COVID vaccines. China will continue to actively engage in further discussions in whatever format that could help forge the consensus on this important issue.

136. China believes the most feasible solution, to increase the accessibility and affordability of COVID vaccines, if not the sole one, is through multilateral cooperation. China notes that by 19 February 2021, public and private entities have committed 10.3 billon dollars to the WHO ACT-Accelerator, and 190 countries have joined the COVAX.

137. For China, as we stated at various occasions, we are committed to making COVID vaccines global public goods and we have made best efforts to honour this commitment. For example, China joined COVAX and decided to provide ten million doses of Chinese vaccines, mainly to meet the urgent demands of developing countries. We have also supplied vaccines to a number of developing countries through bilateral cooperation.

138. Containing the coronavirus is still the most pressing task for Members. China hopes Members can strengthen the cooperation, we will continue to work with all parties to tackle the production and distribution deficit of vaccines, and strengthen the global solidarity in your fight against the pandemic.

1.19 European Union

139. Madame Chair, we would like to thank you, the Secretariat and all the delegations for the constructive engagement on the status report, which we fully support.

140. We would like to recall our statements made in the formal and informal meetings of the TRIPS Council, including the answers we provided to the questions that have been posed to us.

141. There is no doubt that all WTO Members agree on the objective in this global fight against the COVID pandemic: to rapidly develop and manufacture safe and effective therapeutics and vaccines and to distribute them equitably across the world as soon as possible. However, our extensive discussions have shown that our views as to the best way of achieving this objective are far apart.

142. I would like to emphasise that achieving the objective of equitable access to vaccines is a top priority of the EU. We believe that the main global mechanism to achieve such equitable access is the COVAX Facility. It just has received a major financial boost following the G7 meeting the previous week. We very much welcome the important financial contribution to the COVAX Facility made by the United States as well as additional contributions made by Japan and Canada.

143. The European Union has also announced an additional EUR 500 million for the COVAX Facility, doubling its contribution to date. These new pledges bring us closer to achieving COVAX's target to deliver 1.3 billion doses for 92 low and middle income countries by the end of 2021. Team Europe is one of the lead contributors to COVAX with over EUR 2.2 billion, including EUR 900 million pledged by Germany last week.

144. It is clear that this is only the start and that we will need to mobilise additional support as we move forward. It is not the time to find flaws in the COVAX Facility, the only viable solution we have to deliver the vaccines globally, it is time to support it and encourage the industry to step up and make their vaccines available and affordable to COVAX, so that there can be a timely global rollout.

145. Novavax, for example, announced last week that it signed a Memorandum of Understanding with Gavi, The Vaccine Alliance, to provide COVAX with 1.1 billion cumulative doses of its vaccine candidate. COVAX continues to actively negotiate with various suppliers to reserve three billion doses in 2021-2022, seeking to diversify the vaccine portfolio and to ensure the minimum coverage in all participating countries.

146. However, we see clearly that having a vaccine developed and reserved is not enough. The actual delivery of vaccines will depend on a number of factors which include timely regulatory approvals, country readiness, logistics and other factors. In the last few weeks, several emergency or conditional regulatory approvals of different COVID vaccines in the EU and across the world were granted.

147. Since our last meeting, two versions of the AstraZeneca/Oxford COVID-19 vaccine have been given WHO Emergency Use Listing (EUL). This follows the Emergency Use Listing for Pfizer/BioNTech vaccine. This announcement means that two versions of the AstraZeneca/Oxford vaccine, produced by AstraZeneca-SK Bioscience (AZ-SKBio) and the Serum Institute of India (AZ-SII), are now available for global rollout through the COVAX Facility. This is crucial for the functioning of its COVAX's distribution mechanism and we hope to see more vaccines approved for emergency use soon.

148. Other challenges related to actually delivering the vaccine to the people remain enormous and depend a lot on country readiness, including for example creating priority lists for vaccination, organising vaccination centres, with conditions such as storage at very low temperatures. Despite the efforts of everyone involved, this is not easy for any country.

149. At the moment, however, we are all still facing one major challenge – ensuring rapid and predictable production of the new vaccines, while simultaneously increasing levels of that production and maintaining the supply of all other medicines and vaccines.

150. We all agree that the ramping up of manufacturing capacity is a clear priority now. Any available manufacturing capacity anywhere in the world should be used to the full extent. Any indication of where underused capacity exists as indicated by some Members would be very welcome.

151. As set out in the Communication Towards HERA: making Europe's bio-defence capacities fit to deal with SARS-CoV-2 variants, the EU is taking action to facilitate the production of COVID-19 vaccines and to allow for a ramping up of production in the shortest possible time. The European Commission will continue to address potential bottlenecks in production and supply of raw materials and other essential input required for vaccines manufacturing. It will build on the ongoing mapping of existing industrial capacities for vaccine production in Europe, as well as facilities which can be potentially repurposed to produce vaccines.

152. Where such capacity exists and can be deployed quickly, the best way of using it to the fullest is by disseminating the technology and know-how of those who developed the vaccines through a collaboration with other companies that can contribute to the developers' manufacturing capacity. Intellectual property is a key factor in providing a framework that enables this collaboration.

153. This is because the IP system is crucial in providing a legal framework for the collaboration and dissemination of any new technology. The objective of an IP system is not merely to create exclusivity for the owner of intellectual property, but also to ensure the publication and dissemination of research results when otherwise they would remain secret. And this dissemination is precisely what we need now. The IP system enables commercialisation of the research results and their transfer through licensing agreements. Developers of vaccines can enter into manufacturing agreements, transfer technology and expand production with their licensees.

154. The increase of production capacity is happening, as developers of vaccines are entering into manufacturing agreements with producers, and are expanding global production by transferring their technology to licensees. We see this being done by AstraZeneca, Johnson & Johnson and we hope to see these collaborations grow and intensify.

155. No doubt more needs to be done in the weeks and months ahead, but, as we have already mentioned previously, there are many examples of collaboration and licensing to producers in the developing countries.

156. As was said before, we fully agree that all adequate manufacturing capacity must be used where possible. However, in this forum we have disagreed on the best way to tap into that potential manufacturing capacity. The proponents of the Waiver suggested that the Waiver would in fact

achieve that objective. We do not think that this is the case. It is through collaboration and the rapid transfer of technology and know-how that we can get there.

157. We consider that the TRIPS Agreement and the principles of the Doha Declaration can play a role in addressing this crisis, as they reflect a careful balance between protecting intellectual property on one hand, which is a crucial incentive to innovation, and promoting widespread access to medicines and health care, on the other hand.

158. As indicated in previous meetings, we believe that the concerns that have been raised in the current discussion can be addressed through the combination of, on the one hand, licensing and expanding manufacturing capacity via manufacturing agreements and, on the other hand, the framework of the TRIPS Agreement and the flexibilities it offers. These flexibilities are absolutely legitimate tools for Members in need as many are in the midst of this pandemic.

159. We have noted carefully the difficulties conveyed by some Members with regard to the implementation of these flexibilities, and we are very ready to discuss ways of overcoming them. Administrative burdens should not stand in the way of manufacturing and delivering vaccines to where they are needed. It is important to note that the TRIPS Agreement also provides for flexibilities and exceptions in relation to other relevant IP rights, not only patents. This includes copyright, industrial design and regulatory data protection. The principles of the Doha Declaration on the TRIPS Agreement and public health that direct countries to interpret the TRIPS Agreement in a manner supportive of their right to protect public health and to promote access to medicines for all are equally applicable to all types of IP rights.

160. Since questions have been posed to us on this matter, we would like to emphasise that the TRIPS Agreement does not stand in the way of the consistent application of the patent and regulatory data protection provisions to enable the application of compulsory licences. The EU, just as any other Member of the WTO, has the possibility of framing its legislation in this manner.

161. One of the main concerns with the suspension of intellectual property rights like the proposed TRIPS Waiver is that it will not enhance the ongoing voluntary collaboration and the needed transfer of technology and know-how. To the contrary, the lack of a framework that guarantees protection can effectively block such transfer, to the detriment of all at a time when we need it most.

162. In this forum, our focus is on intellectual property. However, as we have highlighted, intellectual property is only a small part of a broader massive financial, manufacturing and logistical response to COVID-19. The EU and its Members have been in the forefront of this response.

163. I would like to recall what we have already said on the role of public financing and its impact on the need to protect IP. Public financing does not mean that there is no financing or risk carried by private investors. In some cases, private financing may significantly exceed public support. IP makes possible licensing agreements in the pharmaceutical sector (which requires multiple partners) and the creation of partnerships. Pharmaceutical development requires trials, manufacturing developments and deployment-related logistics that are not necessarily publicly funded (or public funding is not enough), in this context IP does not only make licensing activities possible, but it is a critical loan collateral to obtain private financing.

164. We have also already said that, as part of their national or regional health and research policy, every Member has the right to attach certain conditions to the public funding it provides to pharmaceutical companies.

165. As a last remark, I would like to mention the agreements that the EU has entered into for purchasing of vaccines and I would underline again that we have invested in manufacturing capacity not only to guarantee vaccines for the EU citizens but also so that vaccines are more rapidly available to everyone, everywhere.

166. We are all facing significant difficulties during these first weeks of 2021. However, we are also hopeful that the situation will gradually improve with more vaccines coming to the market and more production of the already approved vaccines materialising. On 19 January, the European Commission announced that –- we are ready to set up an EU vaccine sharing mechanism, based on the "Team Europe" approach. This would allow the sharing of access to some of the vaccine doses secured by

the EU. Special attention would be given to the Western Balkans, our Eastern and Southern neighbourhood and Africa. This could primarily benefit health workers, as well as humanitarian needs. Details of that mechanism are currently being worked out.

167. As we have already said before, the EU is committed to an open and comprehensive dialogue with all WTO Members to explore how the multilateral rules-based trading system can best support universal and equitable access to COVID-19 vaccines and treatments as we seek to provide for a robust, rapid and universal response to the pandemic.

168. In that regard, and in order to facilitate a consensual, constructive and evidence-based discussion, we fully support document IP/C/W/671 submitted by the delegations of Australia, Canada, Chile and Mexico and the approach to the current discussion presented in this communication. We are ready to work together with the sponsors of this communication and all other Members to contribute to such an evidence-based discussion.

169. We have already indicated our willingness to discuss problems with the implementation and the use of the TRIPS flexibilities, in particular how the use of the flexibilities such as compulsory licensing can be facilitated. It is important that these flexibilities can be used when the need arises and are not hampered by administrative hurdles.

170. We are committed to cooperation mobilising the global manufacturing, trade, and delivery response that will end this crisis and help build a more resilient system for the future. We would also like to ask the Secretariat to add our previous statements to the minutes of this meeting.

European Union's statement at the informal meeting held on 4 February 2021

171. During the last four months, we had an intense schedule of exchanges in various formats of the TRIPS Council as well as the December General Council of the WTO. There is no doubt that all WTO Members agree on the objective in this global fight against the COVID pandemic: to rapidly develop and manufacture safe and effective therapeutics and vaccines and to distribute them equitably across the world as soon as possible. However, our extensive discussions have shown that our views as to the best way of achieving this objective are far apart.

172. I would like to repeat once again that achieving the objective of equitable access to vaccines is a top priority of the EU. We believe that the main global mechanism to achieve such equitable access is the COVAX Facility. The EU so far has been the COVAX's biggest donor with more than EUR 850 million provided by the EU and its Members. The larger Coronavirus Global Response beyond vaccines also remains crucial. For this purpose, a global recovery package of EUR 38.5 billion delivered under a common "Team Europe" approach has been supporting partner countries with emergency response to humanitarian needs, strengthening health systems and crucial health services, and assisting economic recovery and social support.

173. It is clear that this is only the start and that we will need to mobilise additional support as we move forward. We welcome the United States' recent decision to join COVAX and strongly encourage other WTO Members to help address the remaining financing needs.

174. The COVAX Facility is now well placed with nearly two billion doses of COVID-19 vaccine candidates reserved for 2021. COVAX continues to actively negotiate with various suppliers to reserve three billion doses in 2021-2022, seeking to diversify the vaccine portfolio and to ensure the minimum coverage in all participating countries.

175. However, we see clearly that having a vaccine developed and reserved is not enough. The actual delivery of vaccines will depend on a number of factors which include timely regulatory approvals, country readiness, logistics and other factors. In the last few weeks, several emergency or conditional regulatory approvals of different COVID vaccines in the EU and across the world were granted. However, only one vaccine – Pfizer/BioNTech – has so far completed the World Health Organisation Emergency Use Listing Procedure (EUL). The procedures for other vaccines are still pending, including those reserved by COVAX. This is crucial for the functioning of its COVAX's distribution mechanism.

176. Other challenges related to actually delivering the vaccine to the people remain enormous and depend a lot on country readiness, including for example creating priority lists for vaccination, organising vaccination centres, with conditions such as storage at very low temperatures. Despite the efforts of everyone involved, this is not easy for any country.

177. At the moment, however, we are all still facing one major challenge – ensuring rapid and predictable production of the new vaccines, while simultaneously increasing levels of that production and maintaining the supply of all other medicines and vaccines.

178. We all agree that the ramping up of manufacturing capacity is a clear priority now. Any available manufacturing capacity anywhere in the world should be used to the full extent. Any indication of where underused capacity exists as indicated by some Members would be very welcome.

179. However, the EU still considers that if such capacity exists and can be deployed quickly, the best way of using it to the fullest is by disseminating the technology and know-how of those who developed the vaccines through a collaboration with other companies that can contribute to the developers' manufacturing capacity. Intellectual property is a key factor in providing a framework that enables this collaboration.

180. This is because the IP system is crucial in providing a legal framework for the collaboration and dissemination of any new technology. The objective of an IP system is not merely to create exclusivity for the owner of intellectual property, but also to ensure the publication and dissemination of research results when otherwise they would remain secret. And this dissemination is precisely what we need now. The IP system enables commercialisation of the research results and their transfer through licensing agreements. Developers of vaccines can enter into manufacturing agreements, transfer technology and expand production with their licensees.

181. The increase of production capacity is happening, as developers of vaccines are entering into manufacturing agreements with producers, and are expanding global production by transferring their technology to licensees. No doubt more needs to be done in the weeks and months ahead, but, as we have already mentioned previously, there are many examples of collaboration and licensing to producers in the developing countries.

182. As was said before, we fully agree that all adequate manufacturing capacity must be used where possible. However, in this forum we have disagreed on the best way to tap into that potential manufacturing capacity. The proponents of the Waiver of the TRIPS Agreement suggested that the Waiver would in fact achieve that objective. We do not think that this is the case.

183. We consider that the TRIPS Agreement and the principles of the Doha Declaration can play a role in addressing this crisis, as they reflect a careful balance between protecting intellectual property on one hand, which is a crucial incentive to innovation, and promoting widespread access to medicines and health care, on the other hand.

184. As indicated in previous meetings, we believe that the concerns that have been raised in the current discussion can be addressed through the combination of, on the one hand, licensing and expanding manufacturing capacity via manufacturing agreements and, on the other hand, the framework of the TRIPS Agreement and the flexibilities it offers. These flexibilities are absolutely legitimate tools for Members in need as many are in the midst of this pandemic.

185. We have noted carefully the difficulties conveyed by some Members with regard to the implementation of these flexibilities, and we are very ready to discuss ways of overcoming them. Administrative burdens should not stand in the way of manufacturing and delivering vaccines to where they are needed. It is important to note that the TRIPS Agreement also provides for flexibilities and exceptions in relation to other relevant IP rights, not only patents. This includes copyright, industrial design and regulatory data protection. The principles of the Doha Declaration on the TRIPS Agreement and public health that direct countries to interpret the TRIPS Agreement in a manner supportive of their right to protect public health and to promote access to medicines for all are equally applicable to all types of IP rights.

186. Since questions have been posed to us on this matter, we would like to emphasise that the TRIPS Agreement does not stand in the way of the consistent application of the patent and regulatory

data protection provisions to enable the application of compulsory licences. The EU, just as any other Member of the WTO, has the possibility of framing its legislation in this manner.

187. One of the main concerns with the suspension of intellectual property rights like the proposed TRIPS Waiver is that it will not enhance the ongoing voluntary collaboration and the needed transfer of technology and know-how. To the contrary, the lack of a framework that guarantees protection can effectively block such transfer, to the detriment of all at a time when we need it most.

188. In this forum, our focus is on intellectual property. However, as we have highlighted, intellectual property is only a small part of a broader massive financial, manufacturing and logistical response to COVID-19. The EU and its Members have been in the forefront of this response.

189. I would like to recall what we have already said on the role of public financing and its impact on the need to protect IP. Public financing does not mean that there is no financing or risk carried by private investors. In some cases, private financing may significantly exceed public support. IP makes possible licensing agreements in the pharmaceutical sector (which requires multiple partners) and the creation of partnerships. Pharmaceutical development requires trials, manufacturing developments and deployment-related logistics that are not necessarily publicly funded (or public funding is not enough), in this context IP does not only make licensing activities possible, but it is a critical loan collateral to obtain private financing.

190. We have also already said that, as part of their national or regional health and research policy, every Member has the right to attach certain conditions to the public funding it provides to pharmaceutical companies. Beyond the financing, it is also clear that without the researchers and the industry we would not have the vaccines that we have at the moment.

191. As a last remark, I would like to mention the agreements that the EU has entered into for purchasing of vaccines and I would underline again that we have invested in manufacturing capacity not only to guarantee vaccines for the EU citizens but also so that vaccines are more rapidly available to everyone, everywhere.

192. We are all facing significant difficulties during these first weeks of 2021. However, we are also hopeful that the situation will gradually improve with more vaccines coming to the market and more production of the already approved vaccines materialising. On 19 January, the Commission announced that – in addition to our contribution to COVAX - we are ready to set up an EU vaccine sharing mechanism, based on the "Team Europe" approach. This would allow the sharing of access to some of the vaccine doses secured by the EU. Special attention would be given to the Western Balkans, our Eastern and Southern neighbourhood and Africa. This could primarily benefit health workers, as well as humanitarian needs. Details of that mechanism are currently being worked out.

193. As we have already said before, the EU is committed to an open and comprehensive dialogue with all WTO Members to explore how the multilateral rules-based trading system can best support universal and equitable access to COVID-19 vaccines and treatments as we seek to provide for a robust, rapid and universal response to the pandemic.

194. We have already indicated our willingness to discuss problems with the implementation and the use of the TRIPS flexibilities, in particular how the use of the flexibilities such as compulsory licensing can be facilitated. It is important that these flexibilities can be used when the need arises and are not hampered by administrative hurdles.

195. We are committed to cooperation mobilising the global manufacturing, trade, and delivery response that will end this crisis and help build a more resilient system for the future. European Union's statement at the informal meeting held on 4 February 2021.

196. I refer to the statements made by this delegation in the discussion under this *ad hoc* agenda item in the TRIPS Council's past five formal and informal meetings.

On procedure and the follow up:

a. We are flexible on the presentation of the status report of the TRIPS Council to the General Council, as long as the report presents the state of discussions in a factual and succinct manner; and

b. The EU is ready to engage in the discussions following the suggested format of small group consultations.

EU Vaccine export authorisation

197. This decision is a reaction to a possible breach of contracts signed with the EU, as doses that were initially targeted for the EU may have been exported to third countries. This would be a clear and unacceptable violation of legal obligations by the companies in question, while delaying the vaccination of EU citizens.

198. In order to prevent such violation, the Commission has decided that all vaccine manufacturers should declare exports to third countries. From 30 January, the customs authorities are checking all vaccine export declarations. They may also control the products and trace their origin to ensure that they do correspond to third countries purchase contracts. These checks and controls will ensure transparency in a sensitive market, and avoid reselling, litigations and traffics. They will be conducted in a speedy manner to avoid unnecessary additional delays.

199. These obligations are strictly targeted to vaccine manufacturers and are applicable until end of March 2021. They will be proportionate and will not slow down the vaccine trade between the EU and third countries.

200. These measures have been designed in a targeted manner to limit the impact on our trade partners and on the most-vulnerable countries. The legal decision adopted today explicitly rules out exports:

a. to the EEA countries, the Western Balkans, the Neighbourhood countries;

b. the 92 low- and middle-income countries covered by the COVAX facility, as well as those delivered through COVAX, UNICEF and PAHO to any COVAX participating country, as well as;

c. in the context of a humanitarian emergency response.

201. With these provisions, the EU stands to its commitments towards its partners.

European Union's statement at the informal meeting held on 19 January 2021

202. It is very clear, following the earlier discussions in the TRIPS Council and the exchanges in the General Council of the WTO, that in this global fight against the COVID pandemic, we all share one objective: to rapidly develop safe and effective therapeutics and vaccines, to manufacture them in required quantities as soon as possible and to distribute them equitably across the world. What we are discussing is the best way of achieving this objective.

203. We thank the delegations of from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe for their contributions to the debate presented in documents IP/C/W/672, IP/C/W/673 and IP/C/W/674. We are still studying the provided information and may come back with questions at a later stage. A number of questions have been posed in these documents to the European Union and we will do our best to respond to all of them.

204. I would like to repeat that delivering on the objective of equitable access to vaccines is a top priority of the EU. Out of the EUR 16 billion provided to the Coronavirus Global Response, nearly EUR 12 billion was pledged by the Members of the European Union, the European Commission and the European Investment Bank.

205. The EU and its Members have so far provided more than EUR 800 million to the COVAX Facility - which makes the European Union COVAX's biggest donor.

206. In the second half of December we received a good news from COVAX which confirmed that it had arrangements in place to access nearly two billion doses of COVID-19 vaccine candidates, on behalf of 190 participating economies. These arrangements will enable all participating economies to have access to doses in the first half of 2021, with first deliveries anticipated to begin in the first quarter of 2021.

207. This is a very good news but, to answer one of the questions, it is not enough. We are aware that this is only the start and that we will need to mobilise additional support as we move forward. We are working hard with our partners to procure the needed funding. We strongly encourage other WTO Members to help address the remaining financing needs, as underlined in the G20 Riyadh Leaders Declaration.

208. Over the last weeks, we received some good news on the regulatory approvals of several COVID vaccines in the EU and across the world. Particularly optimistic is the fact that the AstraZeneca vaccine enters the market, including in India, as this vaccine can be stored in a normal fridge temperature making it much more accessible to the developing countries. Importantly, a significant share of the AstraZeneca vaccine actually goes to the developing countries and the COVAX Facility.

209. The Novavax vaccine, the lion's share of which, we understand, is designated for the developing countries (according to reports Novavax reached an agreement with the Serum Institute of India that could enable them to produce as many as two billion doses a year) has not been approved yet but it began a last phase trials in December in the United States. The results from the last phase trials of the Johnson & Johnson vaccine are expected later this month. At the same time, it is clear that we will have to wait for a number of vaccines before they are ready to enter the market.

210. As we know, having a vaccine developed and approved is not enough. The challenges related to actually delivering the vaccine to the people remain enormous, in particular producing the vaccines at an unprecedented scale and then distributing them, organising vaccination centres, with conditions such as storage at very low temperatures.

211. Many countries face systemic and financial challenges such as fragile and underfunded healthcare and procurement systems, a limited number of health workers or inadequate cold chain equipment. These are, in addition to manufacturing, the main hurdles in the access to and the roll-out of the vaccines.

212. The TRIPS Agreement and the principles of the Doha Declaration can play a role in addressing this crisis, as they reflect a careful balance between protecting intellectual property on one hand, which is a crucial incentive to innovation, and promoting widespread access to medicines and health care, on the other hand.

213. A question has been asked about the role of public financing and its impact on the need to protect IP. We believe that we have answered this question in our previous statements. Just to recall that public financing does not mean that there is no financing or risk carried by private investors. It is the researchers and the industry with their know-how, previous and current investment that are delivering the new vaccines, including the running of clinical trials in parallel with investing in production capacity to be able to produce millions, or even billions, of doses of a successful vaccine.

214. We have already provided the example of the vaccines based on the mRNA technology which would not reach the market so quickly were it not for decades of work and investment in this novel technology undertaken at high risk of failure by researchers and companies. Finally, as part of their national or regional health and research policy, every Member has the right to attach certain conditions to public funding it provides to pharmaceutical companies.

215. As indicated in the previous meetings, we believe that the concerns that have been raised in the current discussion can be addressed through the combination of licensing, expanding manufacturing capacity via manufacturing agreements with the TRIPS Agreement and the flexibilities it offers. These flexibilities are absolutely legitimate tools for Members in need as many are in the

midst of this pandemic. I want to be very clear on the fact that the European Union never questioned the use of compulsory licences in the times of need.

216. We have noted carefully the difficulties conveyed by some Members with regard to the implementation of these flexibilities, and we are very ready to discuss ways of overcoming them. Administrative burdens should not stand in the way of manufacturing and delivering vaccines to where they are needed. We note a question in this regard addressed to some of our Members as to what data they relied upon when they decided to amend national laws to enable quicker use of compulsory licence.

217. We have in the past explained the nature of the amendments introduced in Hungary so will not repeat these details but would like to make certain clarifications regarding the changes in the law of the Federal Republic of Germany as the question posed is reflecting a factual misunderstanding. Last year, Germany did not modify the conditions for the granting of compulsory licences. The Patent Law was only amended to change the competence for the issuance of a government order (and again not the conditions for the issuance of a government order). Previously, a government order for the use of medicinal/pharmaceutical inventions required a decision by the Federal Cabinet (Kabinett-Beschluss). This has been changed. It is now the Ministry for Health which can issue such an order, provided that the (unchanged) requirements have been met.

218. More generally, we would like to clarify that the TRIPS Agreement requires no data or special justification to introduce rules on compulsory licensing, including fast track procedures in Member's legislation. Each Member has the right to have these rules.

219. It is important to note that the TRIPS Agreement also provides for flexibilities and exceptions in relation to other relevant IP rights, not only patents. This includes copyright, industrial design and regulatory data protection. The principles of the Doha Declaration on the TRIPS Agreement and public health that direct countries to interpret the TRIPS Agreement in a manner supportive of their right to protect public health and to promote access to medicines for all are equally applicable to all types of IP rights. Since questions have been posed to us on this matter, we would like to emphasise that the TRIPS Agreement does not stand in the way of the consistent application of the patent and regulatory data protection provisions to enable the application of compulsory licences. The EU, just as any other Member of the WTO, has the possibility of framing its legislation in this manner.

220. It seems that we all agree that what is most needed now, beyond developing vaccines, is the ramping up of manufacturing capacity, and a seamless follow through by the transport and distribution sectors. The best way of achieving that is by disseminating the technology and know-how of those who developed the vaccines through a collaboration with other companies that can contribute to the developers' manufacturing capacity. Intellectual property is a key factor in providing a framework that enables this collaboration.

221. This is because the IP system is crucial in providing a legal framework for the collaboration and dissemination of any new technology. The objective of an IP system is not merely to create exclusivity for the owner of intellectual property, but also to ensure the publication and dissemination of research results when otherwise they would remain secret. And this dissemination is precisely what we need now. The IP system enables commercialisation of the research results and their transfer through licensing agreements. Developers of vaccines can enter into manufacturing agreements, transfer technology and expand production with their licensees.

222. The increase of production capacity is already happening, as developers of vaccines are entering into manufacturing agreements with producers, and are expanding global production by transferring their technology to licensees. No doubt more needs to be done in the weeks and months ahead, but I would note that we have many examples of companies that have either accepted to produce at cost for citizens in developing countries or licensed production to producers in the developing countries. And then there are other examples of collaboration among different players.

223. A number of questions regarding the terms of licensing or manufacturing agreements have been posed by the proponents of the Waiver. We do not know the details of the terms of these agreements so cannot answer but can share our understanding of the situation. On the concern related to the choice of manufacturers – it is our understanding that the production of a vaccine is a very complex process and not all pharmaceutical manufacturers can step up to such production. This

is why in the EU, new production facilities are being set up and efforts are being made to use the facilities that can be used for the production of vaccines to the maximum.

224. We believe that constant close coordination between governments and the pharmaceutical industry is required to ensure that all the adequate manufacturing capacity is used where possible. The potential use of compulsory licensing is of course also a leverage that governments have in that regard.

225. One of the main concerns with the suspension of intellectual property rights like the proposed TRIPS Waiver is that it will not enhance such collaboration, that it will not enhance the needed transfer of technology and know-how. To the contrary, the lack of a framework that guarantees protection can effectively block such transfer, to the detriment of all. In this forum, our focus is on intellectual property. However, intellectual property is only a small part of a broader massive financial, manufacturing and logistical response to COVID-19.

226. This response includes close coordination with pharmaceutical companies, creating and maintaining complex, international supply chains to import crucial raw materials and equipment (in parallel to the production of vaccines, supplies of vials, syringes, and other ancillary materials must remain adequate). There may be a need for pharmaceutical companies globally to reallocate critical materials among themselves. Where some vaccines development projects fail, as they are bound to do, successful vaccines producers should be able to use the manufacturing capacity, glass vials, and other ancillary materials that had originally been reserved for failed projects. Where surplus of vaccines may occur, it would be important to set up arrangements allowing the reallocation of doses. The flows of the required raw materials and vaccines cannot be hampered by export restrictions and other impediments affecting supply chains.

227. In that regard I would like to recall again the work undertaken by the EU in the WTO to safeguard global supply chains. Under our "Trade and Health Initiative" WTO Members would jointly agree on a number of actions in response to the current crisis that would ensure free flow of essential goods which would facilitate an effective response to this and any future crisis.

228. A lot has been said in this forum about the agreements that the EU has entered into for purchasing of vaccines. We have invested in manufacturing capacity not only to guarantee vaccines for the EU citizens but also so that vaccines are more rapidly available to everyone, everywhere. Today in the European Parliament, the Commission informed on the ongoing work to propose a mechanism to share vaccines with other countries. We hope to be able to provide more detail soon.

229. We would also like to thank South Africa, India, Mozambique and Pakistan for their detailed questions and interest in the EU's policy developments, in particular two recent strategy documents: the Pharmaceutical Strategy for Europe and the IP Action Plan (both published very recently, on 25 November 2020). Both strategy documents are ambitious roadmaps covering a wide variety of issues and objectives to be attained in the short and mid-term. A number of concrete actions must be still agreed upon and their details worked out. But, to the extent possible, we are happy to provide more detail on the intentions and the objectives of the Commission.

230. Among its objectives, the Pharmaceutical Strategy indeed has a goal of ensuring access to affordable medicines – this goal is shared globally. It also focuses on addressing the unmet medical needs of patients, strengthening of the EU pharmaceutical industry, and enhancing EU's crisis preparedness. This strategy document sets out the priorities of the EU's future action in this area. Concrete steps will follow with all the necessary details, including on the creation of the new EU Health Emergency Response Authority which would be responsible for strategic investments for research, development, manufacturing, deployment, distribution and use of medicines. Details on any march-in rights or other conditions for receiving support from the new agency are also still to be worked out.

231. The Pharmaceutical Strategy proposes actions at EU level to promote the affordability of medicines and the sustainability of health systems. The Commission will support cooperation between national authorities on pricing, payment and procurement policies, to improve the affordability, cost-effectiveness of medicines and health system's sustainability. The Commission will also help improving transparency on methods used for establishing the R&D costs of medicines. Over the next years, this will help national public authorities to improve their capacities and take better

decisions. But it will also help the producers of high valued products to better make their case, and the EU patients to access cost-effective medicines in a timely, equitable and affordable way.

232. Closely linked and in complete synergy with the Pharmaceutical Strategy, the IP Action Plan outlines concrete areas of priority in the field of intellectual property for the EU. It highlights that intellectual property is a key driver for economic growth as it helps companies to valorise their intangible assets.

233. The IP Action Plan also highlights that the IP system must be balanced, meaning that access to critical technologies, where and when necessary, while ensuring an adequate return on investment for innovators, must be ensured. Therefore, the IP Action Plan fully supports all avenues of voluntary licensing in relation to COVID technologies, as endorsed in the World Health Assembly's Resolution of May last year. We believe that existing and effective patent pooling initiatives should be supported in the face of this crisis.

234. The Commission has recently signed a Memorandum of Understanding with the Medicines Patent Pool – the most known, experienced and effective public health organisation delivering medicines to low and middle income countries through licensing contracts. We will explore all ways to help the Medicines Patent Pool to continue delivering in the COVID crisis as well. Many pharma companies are supporting the Medicines Patent Pool with free or cost-based licensing. Medicines Patent Pool is one of the actors mentioned in the C-TAP initiative that calls upon holders of knowledge, intellectual property or data to existing or new therapeutics, diagnostics and vaccines to voluntary license and provide access to their proprietary assets. We note that MPP is an organisation with the working history and experience in pooling IP and concluding licensing agreements with pharma companies and a one that can deliver results, gather support.

235. In the EU, compulsory licences are regulated and granted by the EU Members. With the IP Action Plan, the Commission encouraged the EU Members to assess their domestic legislation and to make sure that the all the tools are indeed available.

236. Since the competence for compulsory licences remains national, the Commission considers that early coordination and information among the Members would secure maximum benefits whilst at the same time avoiding excessive distortions. This is a specific issue in the EU which other WTO Members may not face. As concerns the EU's status under Article 31*bis* of the TRIPS Agreement (i.e. the procedure set up for cases of insufficient manufacturing capacity), it must be noted that the EU possesses very extensive manufacturing capacity for pharmaceutical products. Nevertheless, we closely and constantly monitor the situation, together with our Members, to be able to address any issues that may arise.

237. The EU is committed to an open and comprehensive dialogue with all WTO Members to explore how the multilateral rules-based trading system can best support universal and equitable access to COVID-19 vaccines and treatments as we seek to provide for a robust, rapid and universal response to the pandemic.

238. We have already indicated our willingness to discuss problems with the implementation and the use of the TRIPS flexibilities, in particular how the use of the flexibilities such as compulsory licensing can be facilitated. It is important that these flexibilities can be used when the need arises and are not hampered by administrative hurdles.

239. Only international cooperation can mobilise the global manufacturing, trade, and delivery response that will end this crisis and help build a more resilient system for the future. We are committed to such cooperation.

1.20 United States of America

240. With respect to the Council's status report to the General Council for next week's meeting, the United States supports the compromise language reached.

241. As reflected by President Biden's pledge to COVAX last week, the United States is committed to working with international partners to end the devastating public health and economic effects of this pandemic. Furthermore, the United States will work with partners to identify practical ways to

catalyse the needed capacity to end this pandemic and respond to the next one. It is paramount that we collectively increase access to and facilitate equitable distribution of COVID-19 vaccines and that we support policies that drive the rapid development of new vaccines, medicines, and other health products.

242. The United States is committed to working constructively with Members to tackle this unprecedented global health crisis and end this pandemic. We look forward to engaging in further fact-based discussions on the questions that a number of Members have raised about the proposal, with the aim of finding multilateral solutions to amplify the public health and humanitarian responses to the ongoing crisis, while bearing in mind the importance of incentives for innovation.

1.21 Norway

243. Thank you, Chair, for having facilitated discussions on this important topic and for having secured consensus for your oral report to the General Council.

244. Norway agrees, and I do not think any Member disagrees, that nobody's safe until everybody's safe. Ensuring a fair and equitable distribution of vaccines, diagnostics and medicines should have our highest priority. Norway is working hard to make this happen through various international cooperative efforts.

245. As to the issue at hand, we have listened carefully to the views expressed by Members in both formal and informal settings. We would like to thank those Members who have presented concrete questions to the proponents, and we would like to thank the proponents for their response. We consider this engagement to be promising and hope that we can continue our deliberations in a constructive mode.

246. In this context, we have taken note of statements from proponents that they are willing to discuss the scope and duration of the Waiver. It would therefore be interested to learn from the proponents whether they are considering presenting a revised proposal as a basis for further deliberations.

1.22 Switzerland

247. Switzerland would like to thank you, Chair, for the consultations you held to build consensus on your oral report to the General Council.

Introduction

248. In the view of Switzerland, the proposed TRIPS Waiver would not facilitate global access to COVID-19 vaccines. On the contrary, we consider suspending large parts of the TRIPS Agreement would be counterproductive. It would undermine the efforts currently ongoing, to scale up manufacturing to achieve such global access.

249. We have set out our main arguments, explaining our view in past meetings, including in those of 19 January and 4 February 2021. We ask the Secretariat to include our statements from those two meetings in the present minutes.

Scale up manufacturing

250. Roughly 12 months after the world entered the pandemic, in record time, the first few vaccines have been developed and tested for their efficacy and safe use. Scaling up their manufacturing is the most important challenge now, as they are not available in sufficient quantities, yet. This comes not unexpected, as alleged by the delegation of India. It was hardly avoidable. Never before have such novel and highly complex biotech vaccines had to be made available to the whole of the world population in such a short time. This is a pioneering challenge. Progress is made, but we stand only at the beginning of this process.

251. The partnerships engaged in this manufacturing scale-up are built also on the TRIPS Agreement. By enabling licensing agreements, patents and other IPRs help to build bridges

between the various stakeholders and connect these partnerships, offering safe passages for know-how and technology transfer, thereby accelerating the manufacturing scale up.

252. If we were to suspend large parts of the TRIPS Agreement now, we would also suspend the bridges between these partnerships. The collaborations mentioned would be thrown into legal uncertainty, slowed down in their efforts and risk to stop functioning properly. Precious time would be lost and harm done to the fight against this pandemic, costing lives.

253. Negative impacts might be felt also on the international initiatives underway, such as ACT-A and COVAX, in which WHO, specialized organizations and the private sector are partnering up for making vaccines available for low and middle income countries.

254. Last week, the WHO listed a first COVID-19 vaccine for emergency use, giving the green light for these vaccines to be rolled out globally through COVAX. The vaccines are produced by SK Bio of South Korea and the Serum Institute of India, under licensing agreements from the vaccine innovator Astra Zeneca. With WHO's emergency use listing obtained, the joint UN-led COVAX initiative can now start to deliver vaccines to recipient countries.

255. In a recent interview in the newspaper The Guardian, Adar Poonawalla, the CEO of the Serum Institute of India was asked, whether the reason for the roll out having been slow was because of the developers who hold the patents on the vaccines having licensed too few manufacturers to make the vaccines. His answer was plain and simple: No – He said: "There are enough manufacturers, but the scale up simply takes times."

Mid and long term consequences of the TRIPS Waiver

256. Fighting this pandemic successfully is a marathon. We are on the way, but nowhere near crossing the finish line. There is worrying news about mutations of the virus and new variants, potentially more contagious or dangerous. Existing vaccines might have to be adapted, and new ones to be developed to fight this pandemic successfully. This requires keeping all stakeholders engaged and build on the existing innovation regulatory framework, of which the TRIPS Agreement is a key component.

257. Accordingly, the incentive to continue research and development, also during the pandemic, must be preserved in order for innovative activity to be able to contribute to the fight against COVID-19; Suspending the TRIPS Agreement at this critical stage would have serious consequences, for the fight against this pandemic and for world pandemic preparedness in the future.

258. Switzerland reiterates its openness to discuss with WTO Members how we can ensure a global, equitable and timely access to COVID-19 vaccines, treatments and diagnostics within the multilateral legal framework.

Responding to India

259. Just to note that India posed a number of questions including in relation to the statement of my own delegation from this morning. We will come back with answers to these questions at our next meeting, to do justice to them.

260. One question posed by India I would like to answer right away, however: India asked "on what side Switzerland really stands…":

261. It goes without saying, that Switzerland stands on the side of all those who want this pandemic to end as soon as possible, to prevent further loss of lives and to end the social and economic misery caused by this pandemic. Switzerland's position in the Council's discussion on the Waiver Proposal is to be seen and understood exactly on this background.

Switzerland' statement at the informal meeting held on 4 February 2021

262. I refer to the statements made by this delegation in the discussion under this *ad hoc* agenda item in the TRIPS Council's past five formal and informal meetings. Thus, I will not repeat our well-known position on the proposed Waiver request at length. Indeed, our position has not changed.

263. We do not support the Waiver Proposal because we firmly believe that it would not help us to achieve the goal of expeditious global access, that goal we all share. Much more, we are convinced that it would undermine the efforts currently under way to reach this objective. It is thus not a matter of prioritizing IP protection over expeditious and equitable global access to COVID-19 therapeutics, but simply a matter of the supposed solution not solving the problem.

264. My delegation would like to focus on the following arguments raised by proponents in documents IP/C/W/672, 673 and 674. Proponents argue that public research and also public funding have been key in the R&D of COVID-19 vaccines and other therapeutics. Accordingly, pharmaceutical companies would not deserve any patent rights on the resulting therapeutics.

265. My delegation agrees that cooperation between universities, public research institutions and pharmaceutical R&D companies have been instrumental in successfully developing an innovative vaccine or therapeutics in the current pandemic. We can now start to mass produce safe, quality and effective vaccines or therapeutic products to administer to patients and work towards immunity against COVID-19, mainly thanks to close collaboration and partnership between a wide range of stakeholders from the public and the private sectors.

266. Public universities, which deliver basic research, often lack the capacity and the finances to turn their basic scientific results into applied research and most often to develop them into tested, safe, effective, approved and marketable products. For this reason, they enter partnerships with other stakeholders, including those from the private sector, each contributing his or her particular expertise to this joint venture. And it is IPRs and thus the TRIPS Agreement which are a key prerequisite for these stakeholders being able and willing to do so.

267. Accordingly, IP rights and the TRIPS Agreement are not solely a privilege for R&D pharmaceutical companies to recoup the investment for their contribution to the resulting innovative COVID-19 vaccines or therapeutics, but are similarly used by public sector institutions engaged in such partnerships.

268. Governments that are funding such partnerships can, by fixing contractual arrangements about resulting novel vaccines or therapeutics, set the relevant terms and conditions about the ownership of respective IP right or determine other factors, like those concerning the affordable pricing or the distribution of these products.

269. By suspending large parts of the TRIPS Agreement - and thus the linchpin of the international IP system - we would deprive these partnerships of a key basis for their collaboration. Proponents also claim that the TRIPS Agreement and IP rights are a barrier to global access. We have not been presented with convincing evidence of this actually being the case in this pandemic.

270. Shortages in supply and issues in manufacturing processes were to be expected at the initial stage of mass production of vaccines, only very recently market approved in the first few countries.

271. Vaccines in general, and in particular novel vaccines from biotechnology, are highly complex products and bringing them from the laboratory to the process of mass manufacturing is a highly complex task, which is fault-prone, incurs huge responsibility and thus represents an enormous challenge.

272. This applies not just for their mass production, but also for their storage, international and domestic distributions, which includes the dispensing of these products to patients. Therefore, the collaboration of many stakeholders is needed for these production and delivery chains to work. The IP system builds essential bridges between various stakeholders, rather than constituting a barrier to access.

273. By waiving obligations under the TRIPS Agreement, we would suspend these bridges and this at a crucial juncture where numerous stakeholders are working together towards achieving global access. It is important to note that intellectual property protection is essential because it also allows the patent holder of the concerned health technology to guarantee for the quality and safety of its products.

274. Due to high quality requirements and patient safety, it must be thoroughly examined on a case-by-case basis, whether a licensee is at all capable of producing the respective product at the required quality standards, within a reasonable period and at an acceptable price. Furthermore, the licensee must have the necessary infrastructure to produce as well as to distribute the product.

275. Another argument mentioned by the proponents to which we would like to revert is the following: The TRIPS Agreement and IPRs would be barriers to the transfer of technology, sharing of know-how, and undisclosed information. Again, my delegation believes that this claim stands in stark contrast and contradiction to what we have experienced in reality, including in this pandemic.

276. In order to allow newly discovered innovations to be turn into marketable products, transfer of technology is crucial. Transfer of technology is not only crucial, but highly complex and requires a large number of specialized skills. This transfer of know-how takes place through partnerships between the originator companies and the generic manufacturers.

277. Waiving international obligations concerning intellectual property rights without securing the necessary technology transfer is like letting the well run dry: the required health technologies will hardly be able to get reproduced in a timely manner. Moreover, future incentives into the research and development of health technologies will be deterred.

278. It is exactly because the TRIPS Agreement and the IP system enable sharing of technology, know-how and trade secrets in a legally safe environment, that research and manufacturing partnerships are entered into and that such transfer and sharing actually happen.

279. Parties do so only if they feel safe and comfortable and if they can rely on a trustworthy national and international regulatory framework. Against this background, our delegation believes that suspending large parts of the TRIPS Agreement would not facilitate technology transfer and sharing of know-how. If now, in the midst of this tragic pandemic, the WTO should suspend a key component of the international regulatory framework – and moreover – its very own regulatory framework, we would do harm and no good.

280. Finally, my delegation would like to respond to the question raised in document IP/C/W/674 specifically addressed to Switzerland. Switzerland fully acknowledges that compulsory licenses are a flexibility that the TRIPS Agreement provides in its Article 31 for Members' use, as also confirmed in the separate Doha Declaration on the TRIPS Agreement and Public Health.

281. Under this Article, a compulsory license can be issued promptly and in the case of an emergency, like the COVID-19 pandemic, even without prior negotiations with the right holder. This being said, Switzerland is of the view that in most situations where there is a prompt need for access to an innovation, voluntary licensing agreements, e.g. through contractual licensing, are a more expeditious and more efficient approach to access and manufacture an invention still under patent protection.

282. Transfer of technology and know-how are regularly an important part of such licensing agreements. They are key components of actual and effective access to an innovation – and of the partnership entered into through such agreements. Switzerland takes this view not only in the WTO, but it shares it consistently with its partners at the multilateral level as well as the bilateral level.

283. To sum up: Switzerland remains open to discuss with all WTO Members how we can ensure a global and fast access to COVID-19 vaccines, treatments and diagnostics. This is indeed an enormous challenge, and we should address it in a holistic and sustainable manner, and within the rules-based multilateral trading system.

284. On the process, Switzerland remains open for discussions on how to best address the actual challenges that would be identified. This could be considered in a short, factual status report to the General Council to be held in March. Switzerland is ready to engage in the process leading us to such a report.

Switzerland' statement at the informal meeting held on 19 January 2021

285. There is positive news since we first started discussing under this *ad hoc* agenda item in the Council – there are now a number of vaccines in the manufacturing and rollout stage and a few more in the pipeline. Dozens of countries, both developed and developing, have launched mass vaccination programmes.

286. Only a couple of months ago, we would not have thought such quick progress possible as concerns new vaccines. Of course, this is only the beginning of overcoming the pandemic. The challenges ahead are enormous: to scale up manufacturing with a view to expeditiously respond to global needs, the logistics of distribution and safe and efficient administration.

287. Still, that we are at this point now, having tools available to combat the pandemic effectively, roughly one year after its breakout, is the result of unprecedented efforts and collaboration of many stakeholders involved: governments, international organisations, universities, scientists, research institutions, both public and private, public-private partnerships and the private sector. They are joining forces to address this global public health crisis.

288. IPRs and thus the TRIPS Agreement help build bridges between these stakeholders, help establish, organize and manage these partnerships. What is true for the research and development of the vaccines, is true for the tasks of scaling up manufacturing, distributing and administering the vaccines over the next few months and throughout 2021.

289. An example of such a partnership is the licensing agreement between Oxford University, the pharmaceutical company AstraZeneca (AZ) and the Indian generic manufacturer Serum Institute of India (SII). The SII produces the AstraZeneca vaccine in India. According to SII, millions of doses have already been stockpiled, and are ready for distribution to vaccination centres in India.

290. These are welcome news, and only one example of many that I could cite here from the past few weeks. Since these vaccines have only recently been approved for market entry and only in some Members, scaling up production will take time, naturally. As of today, we are still far from the goal that I understand we all share: fastest possible and equitable access to the new, safe and effective vaccines at global scale. We will only reach this goal through continued joint efforts and committed collaboration of all the stakeholders already engaged in this undertaking.

291. During the collective race towards this goal, we must not suspend these rules. Suspending large parts of the TRIPS Agreement would result in considerable legal uncertainty, disrupt existing partnerships and hamper the establishment of new ones. The bridges between the stakeholders I mentioned IPRs help to build, would be jeopardized. A safe regulatory framework has and will help them guide their collaboration. It will make it predictable and accountable.

292. The TRIPS Agreement underpins licensing agreements such as the one mentioned between Oxford University, AZ and the Serum Institute of India. It supports technology and know-how transfer. We need confidence in down-stream financing and delivery capacity for rollout of products, including in low and middle income countries).

293. I mentioned that the arrival of new vaccines against the novel coronavirus is positive news. There is also worrying news since we last met. News about the novel coronavirus mutating and building new variants, potentially more dangerous and contagious. This shows that the fight against COVID-19 is not a one-time effort. Rather, it is an ongoing challenge for months and years to come. And there will be future pandemics.

294. Therefore, we must ensure a safe, reliable, rule-based environment that encourages - today and in the future - the research and development of new vaccines and medicines, adapting existing ones to respond to mutations of viruses and develop innovative therapeutic products and diagnostics against them. The TRIPS Agreement is a key component of such a reliable regulatory environment. Our focus now is COVID-19, we must collectively mobilize and join forces in the fight against this pandemic. While doing this, we must keep in mind that our actions today will have an important impact on medical innovation tomorrow, including on our preparedness for a next pandemic.

295. In sum: The concern of fast and equitable access to those new vaccines and medicines for all is one my delegation fully shares with the proponents of the TRIPS Waiver request. Yet, my delegation has not been convinced and does not believe that suspending large parts of the TRIPS Agreement will help us meet this goal. On the contrary, we think it would prevent us from doing so. It is essential that we take into account all relevant factors that determine access, and continue to address the challenges that we are facing in a holistic and sustainable manner, and within the rules-based multilateral trading system. It is a global pandemic and there is no alternative to overcoming it together.

296. We thank the proponents for their three submissions with answers to questions raised in the Council's past discussion and questions of their own posed to other Members. We received these submissions late last Friday and are still examining them. As already stated, Switzerland is open to discuss concrete challenges related to IP with regard to access to health technologies relevant to COVID-19. We will come back on questions posed at our next meeting.

1.23 Mali

297. Mali would like to thank you, Madam Chair, for organizing this important meeting and we would like to thank all Members who have supported the proposal, which is no longer a South African or Indian proposal but is becoming universal. We hope that, at the next TRIPS Council meeting, an important decision will be taken to ensure affordable access to medicines and vaccines against COVID-19. As we have seen, national borders are no obstacle to COVID-19. We have seen discussions on "vaccine passports" in many countries and this would be a restriction on the right to freedom of movement.

298. In our view, we must implement Article 66.2. of the TRIPS Agreement effectively and we believe that if we are an effective organization, we will provide major support for our countries. Mali is a co-sponsor of this proposal, and we have suggested that all Members of the African Group and the LDC Group also support it individually because all African countries are Members of the African Group and all LDCs are in Africa, and this would give it more weight.

299. What we also suggest is that another meeting of the TRIPS Council be held and specifically dedicated to technology transfer and that provision be made for this under TRIPS Article 66.2; we believe that this will be an important step. Mali thanks all the countries that have supported the proposal.

1.24 Singapore

300. Thank you very much, Madam Chair, for convening the TRIPS Council so that Members can continue to deepen our evidence-based discussions on the Waiver Proposal. Allow me to make three points.

301. First, there is no doubt that Members recognize that there are real and ongoing challenges in ensuring equitable and timely access to COVID-19 diagnostics, vaccines and therapeutics (DVTs). But what is less clear is whether IP rights have been the actual obstacle. There is evidence that IP rights have played a key role in fostering an ecosystem that promotes continuous innovation by allowing the key stakeholders such as governments, researchers and pharmaceutical companies to collaborate in developing and producing COVID-19 vaccines. This has led to several collaboration success stories, including the Serum Institute of India (SII), which has become the largest COVID-19 vaccine manufacturer in the world.

302. My Swiss colleague has already referenced the interview in The Guardian but let me share the content again because I think it is worth the while. The CEO of SII, Adar Poonawalla said in a recent Guardian interview which posed the following question, and I quote: "Some people think the reason that rollout has been slow in many countries is because the developers who hold the patents on the vaccines have licensed too few manufacturers to make them. Do you agree?" Listen to what Poonawalla said, and I quote: "No. There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines." What Poonawalla said is significant because he has emphatically debunked the notion that vaccine developers have withheld licensing their patent rights to manufacturers. In other words, IP rights are not, and have not, been an obstacle. Hence, Members

would welcome more detailed information from the proponents on the tangible hurdles that their manufacturers have faced, which can be attributed to constraints posed by IP rights.

303. Second, and relatedly, it is not clear that waiving IP rights will provide a "silver bullet" to solve the challenges surrounding the complex issue of equitable and timely access to vaccines. There are still significant challenges in producing or ramping up production of vaccines in many countries, but these challenges have more to do with limited healthcare infrastructure, domestic regulatory deficiencies and supply chain blockages rather than IP rights. I believe that every Member agrees that ensuring equitable and timely access to vaccine is a crucial element of the global fight against the COVID-19 pandemic because no one is safe until everyone is safe. But if we are serious in finding a solution, we must avoid reducing the multi-faceted challenges to a single dimension that focuses only on IP rights. Instead, we must address systemic and deep-seated issues that require a holistic and comprehensive approach to find the right and effective solution.

304. Third, as new Director-General, Dr Ngozi Okonjo-Iweala, had rightly highlighted at the Special General Council (GC) meeting on 15 February 2021, we must find a "third way to broaden access". Rather than just focussing on a Waiver of IP rights, Members should seriously consider Dr Ngozi's call to "facilitate technology transfer within the context of multilateral trade rules, so as to encourage research and innovation, while at the same time allowing licensing agreements that help scale up manufacturing of medical products". We must pay close attention to Dr Ngozi's remarks as she brings extensive experience and deep understanding of the issue as former Chair of the Global Alliance for Vaccines and Immunisation (GAVI). Additionally, we must improve different aspects of the ecosystem by addressing supply-chain disruptions and encouraging more stakeholder partnerships, including between governments and industries to facilitate distribution of vaccines to those who need them.

305. Let me end by expressing Singapore's support for the draft of your oral status report to the General Council and we look forward to further productive discussions on this issue.

1.25 Canada

306. Canada is pleased that Members were able to agree to a way ahead for this important discussion, to which we remain fully committed with a view to identifying consensus-based solutions to any specific issues arising from the TRIPS Agreement in relation to COVID-19 diagnostics, therapeutics, vaccines, devices and equipment.

307. Canada would like to reiterate that it has not rejected the Waiver Proposal, and remains interested in understanding the specific nature and scope of any concrete IP challenges experienced by Members, related to or arising from the TRIPS Agreement, in their responses to COVID-19, such that concrete, consensus-based solutions can be found.

308. Canada would again like to thank the Waiver co-sponsors for their engagement on the questions posed by Canada and other Members, including through document IP/C/W/671, and their engagement such as through document IP/C/W/673. Pursuant to the oral status report of the TRIPS Council, and the direction of the General Council, we look forward to further discussion on these important issues, with a view to concretely identifying any IP-related challenges experienced by Members in their efforts to address COVID-19, including with respect to the operation of the TRIPS Agreement.

309. As noted at our most recent meeting on 4 February 2021, Canada took note of the indications by some Members that there currently unused or underutilized COVID-19 vaccine-production capacity. While acknowledging that this topic involves a range of complex considerations that may involve international bodies outside this Council, Canada looks forward to further discussion on any TRIPS or otherwise IP-related challenges faced in this area, and that Members could not address through the existing TRIPS Agreement flexibilities, or otherwise, and that have thus led to facilities being unused or underutilized. This, in our view, would help foster enhanced, mutual understanding of challenges faced by Members, and help guide us toward the most appropriate, consensus approaches. Canada would also be pleased to share our own experiences with respect to the utilization of manufacturing capacity, to help inform these discussions. We look forward to further discussion at the upcoming 10-11 March session of the TRIPS Council in this regard.

1.26 United Kingdom

310. The United Kingdom welcomes the text of the status report and is content for it to be delivered at the upcoming General Council. The UK thanks delegations for continued discussion on how to best deliver our shared objective of equitable, affordable, and timely access to COVID-19 related technologies and supplies.

311. Reiterating our position from the 4 February 2021 informal Council, we encourage Members to identify where idle capacity exists that can be utilised to address manufacturing demands, how IP is related to supply shortages, and how the proposed Waiver would be an immediate solution to identified production shortages. We are also interested in hearing responses to the queries we, and other delegations, raised at the previous informal Council. The UK stands ready to engage in continued evidence-based discussions.

1.27 Australia

312. We made a lengthy intervention at the last informal meeting on 4 February 2021. I do not plan to reiterate all of what we said on that occasion.

313. It seems to us that much of the discussion in this Council has been focussed on issues on which the membership appears to be in fierce agreement – including the scale of the health and economic challenge presented by COVID-19, particularly to developing countries, the need to scale up manufacturing to ensure timely and widespread access to vaccines, and the need for ongoing innovation to respond to variants and future pandemics.

314. To us, the key issue appears to be whether the international IP regime is itself a significant barrier to widespread access to health products, including vaccines, and therefore whether this proposed Waiver would assist in achieving these shared objectives. With a view to focussing discussion on this key issue, on 4 February, we asked the proponents to identify with specificity any underutilised global vaccine manufacturing capacity, and whether it is IP rules that are responsible for this underutilised capacity. We have also previously asked the proponents to clarify exactly what actions they would like to take, or could need to take, that they feel they are currently unable to take as a result of their obligations under the TRIPS Agreement and its flexibilities.

315. We look forward to receiving any further information the proponents are able to provide in this regard, and stand ready to engage with the proponents, including informally, at any time.

1.28 Japan

316. The delegation of Japan appreciates the efforts made by the Chair and the Secretariat to convene this TRIPS Council meeting and coordinate the draft status report to the General Council. We support the status report which reflects the discussion at the previous meetings.

317. Japan believes that ensuring timely, fair and equitable access to vaccines and medical treatments throughout the entire world is essential in the fight against COVID-19. Japan has put emphasis on Universal Health Coverage in response to COVID-19, and Japan is contributing to multilateral schemes such as the ACT Accelerator, including the COVAX Advance Market Commitment and Global Fund. The immediate challenge facing the ACT-Accelerator is to meet its financial needs. To achieve this goal, Japan announced at the fourth Facilitation Council meeting of ACT-Accelerator held on 9 February 2021 that Japan would increase its commitment and contribute USD 200 million in total to the COVAX Advance Market Commitment. Furthermore, Japan is going to contribute to the Medicines Patent Pool through Unitaid for promoting the distribution of medical products. We are convinced that these efforts are practical and effective for achieving timely, fair and equitable access to medical products.

318. Japan's position remains unchanged. If there were concrete challenges relating to the TRIPS Agreement experienced by Members in procuring COVID-19 vaccines, therapeutics, diagnostics and other medical products, we are prepared to have an evidence-based discussion. Japan remains committed to combatting COVID-19, together with the international communities.

1.29 Holy See

319. "The COVID-19 pandemic unexpectedly erupted, exposing our false securities. Aside from the different ways that various countries responded to the crisis, their inability to work together became quite evident. For all our hyper-connectivity, we witnessed a fragmentation that made it more difficult to resolve problems that affect us all".[8]

320. As emerged during the recent Executive Board of the World Health Assembly, "the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries".[9] Over the last weeks, we have experienced how some countries and companies continue to prioritize bilateral deals, driving up prices and attempting to jump to the front of the queue. Pope Francis warned about the risk of prioritizing access to the vaccine to the richest: "It would be sad if this vaccine were to become the property of this nation or another, rather than universal and for all".[10]

321. On the one hand, most countries of the world are experiencing delays in vaccine rollout programmes. Such situations have resulted from insufficient product manufacturing and the consequent lack of availability of the required number of vaccine doses. On the other hand, in many countries, a large number of manufacturing facilities, with proven capacity to produce safe and effective vaccines, are unable to utilize those capacities, due, *inter alia,* to IP barriers.

322. The financing of research has been provided by different sources, including investment of resources by states, and contributions from private entities. In the context of COVID-19, despite the billions of taxpayer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly made such a public commitment.

323. Nonetheless, given the absolute necessity of COVID-19 vaccines during this global public health emergency, it is appropriate to consider such vaccines "as a good to which everyone should have access, without discrimination, according to the principle of the universal destination of goods highlighted by Pope Francis . 'We [cannot] allow the virus of radical individualism to get the better of us and make us indifferent to the suffering of other brothers and sisters… letting the law of the marketplace and patents take precedence over the law of love and the health of humanity'".[11]

324. The existing mechanisms for compulsory licenses under Article 31 and Article 31*bis* of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licenses a complex process, thus causing difficulties for collaboration among countries. TRIPS flexibilities allow limited policy space for public health, but they never were designed to address a global health crisis, such as the one we are experiencing at present. Even during "normal" times, the Article 31*bis* mechanism, which was established to support countries with insufficient or no pharmaceutical manufacturing capacity, has been widely criticised due to its cumbersome procedures. In addition, the fact that it was used only once since its inception, in 2006, gives ample evidence of the difficulties associated with its use.

325. Policies and laws should maintain a perspective that is focused on the respect for, and promotion of, human dignity, in a spirit of solidarity within and among nations. This implies, *inter alia*, that, while recognizing the value of protecting intellectual property rights, we should focus on the purpose of such rights and on the limitations and potential negative consequences of the current system.

326. In his *Urbi et Orbi* Christmas message, Pope Francis stated that vaccines, if they are "to illuminate and bring hope to all, need to be available to all… especially for the most vulnerable and needy of all regions of the planet". The principles of justice, solidarity and inclusiveness, must be the basis of any specific and concrete intervention in response to the pandemic. The decision of granting a Waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19 would be

[8] Pope Francis, *Encyclical Letter Fratelli tutti*, para 7.

[9] Dr. Tedros Adanhom Ghebreyesus, Director General, World Health Organization, address to 148th meeting of the WHO Executive Board, 18 January 2021.

[10] Pope Francis, General Audience, 19 August 2020.

[11] Note of the Vatican Covid-19 Commission in collaboration with the Pontifical Academy for Life "Vaccine for all. 20 points for a fairer and healthier world", para. 7, 29 December 2020.

a strong signal demonstrating real commitment and engagement and thus moving from declaration to action in favour of the entire human family.

2 OTHER BUSINESS

2.1 United States of America

327. Under the discussions of the TRIPS Council at the February and October 2020 sessions and the upcoming March meeting concerning the theme of making MSMEs competitive through IP and Innovation, the Friends of IP and Innovation are organizing a virtual side event.

328. The event is on 9 March 2021 at 4-6 p.m. on the WTO Zoom platform. A registration link was sent around to the membership last week and is still open.

329. The event will have engaging speakers and moderators, focusing on how IP supports MSMEs in becoming more competitive in the green tech space and also focusing on LDC and LMIC partnerships to catalyse innovation and drive diffusion of technologies in the green tech field.

330. In an updated notice, more details will be provided on the speakers, including those from:

- The Climate Technology Center and Network through the UNFCCC;
- Ecotech Quebec;
- Cutting edge SME innovation in the green tech space, including their programmes and partnerships;
- IP office of the United Kingdom; and
- WIPO directors in the SME and green tech sectors as moderators for the event.

331. We look forward to seeing you virtually on 9 March at 4 p.m.