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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 20 JULY 2021

Chair: H.E. Ambassador Dagfinn Sørli (Norway)

Addendum

The present document contains the statements made during the Council for TRIPS meeting held on 20 July 2021.

Table of Contents

**INDEX OF THE STATEMENTS MADE
AT THE MEETING OF THE COUNCIL FOR TRIPS 20 JULY 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 South Africa

1. I would like to thank you for the transparency report that you delivered just a few minutes ago. I think this is very much in line with the activities and the processes that were carried out during this period and certainly the references to the meetings of 30 June, 6 July, 14 July and to 20 July, the formal meeting. We would also just like to stress that the arrangement that you referred to in terms of small group meetings which were convened on the 22, 24 and 28 June and also 9 July, enabled us to have discussions on various proposals presented. I think, as you have already pointed out, going forward it would be useful, beyond this period, to revisit some of the issues that we have discussed including those around product and IP scope with respect to vaccines and diagnostics and therapeutics, as well as trade secrets and technology transfer, including the treatment of regulatory data under Article 39.3. With regard to your draft oral status report, which has now been adopted, my delegation believes that it is an objective assessment of the process up to this point. We would like to thank Members for their constructive engagement in the small group process, both on 19 and 20 July, in trying to finalise and clear some of the language that you have just read out. This is a testament to the type of compromise that we can achieve, as Members, when we are united in the goals that we try to achieve and from this perspective. I think it bodes well for our further discussions.

2. Allow me to make a few comments in respect of our deliberations, given the fact that this is a formal meeting, and so for the record we would like to raise some issues. The co-sponsors have argued that the TRIPS waiver is a necessary, targeted and a time-bound proportionate measure directed at addressing intellectual property rights, in so far as they represent barriers to access. Passing this waiver will allow companies to ramp up and cooperate on the production of COVID-19 health products and to use health technologies without the fear of infringing another's IP rights and the attendant threat of litigation. Furthermore, passing this waiver will also act as an important political, moral and economic lever towards encouraging solutions and get global equitable access to COVID-19 health products and technologies including vaccines, therapeutics and diagnostics.

3. The urgency of passing this waiver has not abated. We are now very close to 4.1 million fatalities, as of 19 July, and as we previously indicated, many jurisdictions are now entering a third wave with drastic increases of infections and mortalities due to new variants. The World Health Organization (WHO) has also confirmed globally that cases, and deaths have increased by 10% and 3% respectively the previous week, and this is also the case for five out of the six WHO regions, while the delta variant is now in 111 countries. We also observe that 76% of vaccinations have taken place in only ten countries, with 1.4% in Africa, 9.6% in Asia, and in the European Union we see 42.6%, the United Kingdom is at 53%, the United States is at 48.2%, and Switzerland is at 43%. This puts things into stark perspective, given the fact that only 13% of the world's population is fully vaccinated, and this leaves much room for variants to emerge and this puts lower income countries at greater risk.

4. In the last nine months, the waiver proposal has been discussed extensively, and co-sponsors have responded to questions and requests from WTO Members, including the European Union. We have noted recently that the European parliament has approved a resolution calling for support of a pro-active, constructive and text-based negotiations for a temporary waiver at this Organization. We also would have seen in the previous week, the waiver getting support from at least 100 IP academics in an open letter which was addressed to relevant organizations. We have to also realize that intellectual property rights are not absolute, they are granted and recognised under a condition that they serve the public interest, and right now, it is in the global public interest to provide access to vaccines, therapeutics, diagnostics and other technologies that will assist us to defeat the scourge of COVID-19. This is a global, not a local pandemic, and we will have to keep this in mind as we see viruses spreading and the emergence of new variants.

5. Let me come back to some of the points that we would have raised in some of the meetings. We had an opportunity to have in-depth discussions on various aspects of the waiver proposal, including on the product scope of the waiver. We have explained that the waiver covers so-called health products and technologies and in these discussions we pointed to the fact that these terms are used in many organizations including in the terminology that the WHO uses. For instance, the term health

product is inspired by the WHO Resolution on Improving Transparency of Markets for Vaccines, Medicines and Other Health-Related Products, which also include medicines, vaccines, medical devices as well as diagnostics and other assistive products which include both cell and gene-based therapies and other health technologies. Furthermore, we have emphasised the fact that testing is critical to detect cases and to investigate clusters of infections and certainly also to ascertain whether a particular approach to disease management is appropriate and successful. So it has become increasingly clear that there is also a need to expand genomic surveillance and testing for new COVID-19 variants, both to identify those variants of concern, but also to start to build vaccines and therapeutics that can prevent or treat infections. Having an arsenal of complementary means to address COVID-19 is both necessary and practical and certainly we see that this type of approach is also supported by some of the global approaches. If we look at the WHO's list of priority medical devices for COVID-19, it describes a list of medical devices and equipment that would be needed to address COVID-19, and these include devices such as pulse oximeters, equipment for medical imaging, oxygen concentrators, and also includes specialised medical and surgical masks.

6. The waiver proposal does not only deal with finished products, but it also covers so-called intermediate products, which cover materials, all their components, the methods and means of production. IP protection can prevent the supply of raw materials, components, machines and equipment, part of those machines and processes of production. So, for instance, we have recalled that raw materials are active and inactive ingredients of drug substances that are used in the formulation of therapeutics or vaccines, and reagents as in the case of diagnostics for the detection and screening of diseases, can all be subject to IP protection, which could make it much more difficult to access these particular products. We have pointed these out, and I will not repeat them, in our landscape document IP/C/W/670. We will also note, as an update, that the WHO has recently authorised tocilizumab and sarilumab for patients with severe, or critical COVID-19 infection and both these are highly priced and limited in supply in developing countries. These are subject to very high pricing, and as a result they will remain inaccessible resulting from intellectual property protection.

7. We have also discussed, as we have indicated, the IP scope – and as we indicated – copyright, industrial designs, patents and protection of undisclosed information are all categories included in the waiver proposal. These categories of intellectual property rights are relevant, not only to the production but also to the supply and access to COVID-19 health products and technologies. Co-proponents have made several submissions to highlight the relevance of addressing existing and potential IP issues in the area covered by these particular IP rights. The COVID-19 landscape is rapidly changing, and we have seen that there is an under-supply currently in respect of vaccine demand, we have seen that producers have estimated that there would be a demand between ten to 14 billion doses. We have now seen just over 3.4 billion doses having been produced. Now of course, this situation is also subject to additional doses, so-called booster doses, will be needed. We have also seen jurisdictions starting to vaccinate children. All of this puts additional stress on supply and as a result we can expect supply shortages to continue. We have also seen that, in the absence of vaccines, we may want to ramp up production of diagnostics treatments, oxygen, personal protective equipment, in order to save lives.

8. We have also discussed the fact that the IP issues which we are faced with are complex in nature, and as a result, the waiver proposal is not just limited on patents. The revised text that we have discussed during the previous month or so also includes other types of IPRs which are essentially directed to ramp up production. We have also looked at issues around trade secrets. We, as co-sponsors, believe that lifting trade secret protection is essential for expanding and diversifying global protection. For instance, by waiving trade secret protection we can start to share regulatory dossiers with potential manufacturers, and this would essentially enable existing capacity to be increased. Co-sponsors have already set out this particular dimension in document IP/C/W/673.

9. We have also clarified the issue of duration and we have indicated that since the SARS-CoV-2 is a new virus, there are still many uncertainties that can affect, how the disease evolves. In order to tailor the duration of the waiver to the prevailing circumstances and the uncertainties attached thereto, the co-sponsors have specified a period of duration of three years from the date of decision and we have indicated that the waiver would not automatically terminate after three years, but only upon a review of the General Council. We have not specified any specific criteria, this is difficult to do, given the current complexity and novelty of this virus. Nonetheless, we do know that tailoring the period of a minimum of three years does accommodate at least some perspectives where it is assessed that some developing countries may have to wait three to seven years to access vaccines,

so this takes these factors into account. We have also explained the relationship between the mechanisms to determinate the waiver in paragraph 2 and the early review by the General Council in paragraph 5. These two elements do not contradict each other, they can also be found in other waivers that would have been issued, for example, the waiver in document WT/L/971 with respect to the waiver of Article 70.8 and Article 70.9 of the TRIPS Agreement for LDCs. It can also be found in decision of 30 August 2003 which waived Article 31.f and 31.h of the TRIPS Agreement.

10. On the implementation, we have also emphasised that we have a diversity of legal systems, and hence national implementation would have to take account of a country's political and constitutional arrangements. So, similarly, the parameters for implementation of the waiver would be subject to national decisions. We have indicated that there is a difference of approach between those jurisdictions that apply a so-called monist approach, and those that apply dualist approach. In the monist system international law applies directly in the national system, whereas in a dualist system, countries would still have to implement those particular provisions into their national laws, but we have seen that during this time, countries have been able to take decisions and to amend laws based either on state of the emergency that would have been declared, or disaster management legislation or the amendment of existing laws, so that it should be no different for implementing a waiver when it is passed.

11. Let me conclude by saying that we believe, as co-sponsors, that the previous cycle of small group meetings and informal meetings of the TRIPS Council was very useful and informative. We believe a similar process can be convened after the summer break to take up issues that we have not been able to complete, or to get back to topics that require more attention. Similarly, let me take this opportunity to thank you Chair for your stewardship and leadership in this process, and for your continued support for an inclusive and transparent process.

1.2 Chad on behalf of the LDC Group

12. I would like to congratulate South Africa on the presentation of the revised document and the proposal that was just voiced, regarding the small group work that was carried out. This is very important when it comes to bringing our discussions and negotiations forward. We support this approach whole-heartedly. My delegation, on behalf of the LDC Group, would like to recall that South Africa and India have submitted, already nine months ago, in October 2020, a proposal for a waiver for certain provisions of the TRIPS Agreement for the prevention and treatment and containment of COVID-19. It is a joint proposal IP/C/W/669 and the Group has co-sponsored this, calling for a temporary waiver. The existing flexibilities that we find within the framework of the TRIPS Agreement at present are not sufficient to face the very swift evolution of COVID-19. They are limited to pharmaceutical products and were not designed to be able to rise to the unique challenge of such a widespread, far-reaching pandemic. If you look at the ventilators, respirators that are essential to save lives, lives that are threatened by the unfolding pandemic. These are not covered by the existing flexibilities. Moreover, the demands, the requirements of the compulsory licensing regime are complex, cumbersome, onerous and slow, and they are not able to provide for a swift and efficient response in response to the urgency of the challenge that is currently under way. That is the reason why, as we see it, the temporary waiver which is being proposed is a very relevant proposal.

13. When it comes to scope and application, products and technologies such as test kits, masks, therapeutics, vaccines, respirators and components, such as the valves which are used in the manufacturing of the respirators, are very important, and are crucial when it comes to a swift and efficient response. These technology products are protected by four types of intellectual property rights that spring from the four sections of the TRIPS Agreement. Of course, there are patents, authors rights, copyrights, industrial designs, designs and the protection of undisclosed information. There is coherence of these various elements, when it comes to products and technologies that have been protected. This proposal was given a momentum when the trade representative Catherine Tai of the United States of America declared on 5 May 2021, that her delegation was favourable for a waiver for COVID-19 vaccines and that she would commit herself in the text-based negotiations to this end. At the same time, the co-author of the proposal, on 21 May 2021 also submitted a revised text in document IP/C/W/669/Rev.1 in order to reflect the comments that had been voiced, to maintain the momentum under way, and engage in text-based negotiations. In the meeting on 8 June 2021, the TRIPS Council examined the revised proposal and decided to launch a negotiation process on the text, and we would like, Chair, to thank you for having held a number of meetings

and for having seen to it that the deliberations of the Members of the Council could be brought forward very quickly.

14. There has been progress, it is true, but there are still some divergences of views at this time, and this also includes the approach to be used when it comes to responding to the pandemic. We would urge the Members of this Council to commit themselves in a more intense fashion, commit themselves to this process, bring it forward so that you, Chair, can also continue facilitating the work for a very swift conclusion of the work of this process, to bring this home. We are discussing this here in the Council. The discussions here have given rise to broad-based and in-depth attention, so we are all sharing in the destiny. In the new wave of COVID caused by the Delta variant, even countries that have vaccinated high number of their population are seeing their health situation worsen and the outlook for economic recovery looking remote at this time. We have to provide the international community with a response that is very strong, very swift and very efficient. In the interests of our populations, populations which are mainly living in countries which are the poorest and which, at the same time, must face up to the same scourge with very limited resources, which must be strengthened. It is a source of encouragement that, in less than nine months after the beginning of the COVID-19 pandemic, the scientific community was able to design vaccines. It is difficult to accept that 18 months after the start of this pandemic, and nine months after the submission of this proposal, we still are not able to see to it that these discoveries are accessible to all, and still not provide a response that can rise to this public health challenge. Therefore, what we are focusing on here is the relevance of the multilateral trading system. This is what is at stake here, and this is in the interest of the WTO as well.

15. Finally, we would like to thank you for your report that has just been adopted. Indeed, we received the initial preliminary version in document JOB/IP/47, even though these documents are not yet available in French, we work in both English and French in the LDC Group. The LDC Group would, at this time, like to thank you for the very fact-based approach you adopted when it comes to the substance and the content of the report. We once again would like to voice our concern and our regrets regarding the fact that the delays that are encountered because of the discussions in the WTO will expand the urgency of our needs, which concern all corners of the earth.

1.3 Tanzania on behalf of the African Group

16. First and foremost, the African Group would like to express its gratitude to you Chair for having guided Members well while steering the work of the Council on this subject matter. The African Group welcomes the Council's draft report to the General Council. We found the report reflecting the progress and the state of play. Since May 2021, we have had an opportunity to exchange views in various meetings and configurations, right after the start of the text-based process. The African Group has frequently expressed in the Council meetings, that COVID-19 is our biggest challenge, which we must address. It is disrupting the long and hard-earned social economic progress built over the decades.

17. African countries, like many other developing countries, are also grappling to contain the pandemic in order to lessen its effect. Recently, it has been reported by World Health Organization that the African continent has recorded the highest number of new COVID-19 cases. The third wave of COVID-19 seems to be a more deadly and contagious variant. However, irrespective of the resurgence of infections, the vaccination rate in Africa is still not satisfactory. For example, until the second week of July 2021, only a total of 50 million doses were administered in Africa, accounting for only 1.6% of doses globally. It has been further reported that only 16 million people in Africa are now fully vaccinated, accounting for less than 2%, leaving nearly 98% of people vulnerable to COVID-19 infection.

18. COVID-19 cases in Africa now have reached 5.7 million and 146,000 people have died, up to the 14 July report. The situation is worrying. To prevent and contain the pandemic from worsening further, we need a strong international commitment for collective efforts and collaboration for meaningful solutions. The African Group believes the proposed waiver will significantly contribute to the scaling up of production and supply of vaccines, diagnostic kits and therapeutics globally. The African Group has since been advocating for a swift adoption of the waiver to save the lives of many people vanishing due to COVID-19 pandemic. We still hope that Members will exercise more flexibility for adoption of the waiver soon. The African Group is ready to continue with engagement on the waiver under any arrangement and configuration for its conclusion.

1.4 Maldives

19. As we know, COVID-19 is continuing to spread around the world, and many countries seem to be entering yet another wave. According to the news, the new Delta variant has been confirmed in more than 100 countries, with the possibility of increasing in the upcoming weeks. Trends show that the pandemic is not over yet, and we have more waves coming our way. As a small island state, the Maldives depends on a fair and equitable distribution and supply of vaccines to fight this disease. More than a year into the pandemic, we are grateful to have vaccines as well as seeing the willingness from countries to donate vaccines through dose-sharing and COVAX. Though this has helped many countries, it is not enough. Too many people in the least developed countries, as well as other parts of the world, are still waiting for either their first or second dose of vaccines to protect them from COVID-19. Furthermore, these countries also need more supplies and therapeutics to address the needs of the increasing number of patients.

20. To meet the global vaccine requirement, it is vital to address the intellectual property challenges. We believe that an exceptional waiver will assist in equitable and timely access to affordable medical products including vaccines and medicines for all, and most importantly so we can scale up the production of vaccines across the globe and have equitable and timely access. Maldives, as a co-sponsor of the proposed temporary waiver from certain provisions of the TRIPS Agreement, welcomes the progress of text-based negotiations. We are hopeful that all WTO Members will work together in global solidarity and agree on moving forward on this matter, with the aim of providing universal access to COVID-19 vaccines, treatments, testing and other products to control the pandemic, and to reach the Sustainable Development Goals in a timely manner.

21. In this regard, I would like to echo previous speakers in calling for accelerated efforts to achieve a positive, substantive and constructive outcome with regard to the proposed waiver in the interest of time.

1.5 Bolivia, Plurinational State of

22. First and foremost, we would like to thank the Chair for the efforts you have deployed to arrive at a consensus to move ahead on the negotiations. However, we see that the advance is still very slow. We have seen in recent weeks that COVID-19 victims have increased and the delta variant is spreading. We see all too often that there is limited capacity for production, as well. There has been intensive work by the proponents and co-sponsors to try and bring this forward, and this text has more clarity in terms of the scope and objectives, and prevention is the main approach used here. Notwithstanding all of this, this proposal is broken down very often into questions and answers and proposals, and all too often it has been very difficult to arrive at tangible concrete results to save lives. We would like to thank all for the various proposals that have been made. We stand ready to discuss these, we will have to see how the proposal of the European Union will make it possible to rise to the challenge.

23. We are in the process of notification, which was started in May. We have made progress, but we have not seen any encouraging result and we are still seeing a lot of the deficiencies of the system. We think that public health is extremely important, and this shows that the mechanism that had been built into the organization is not effective, and we do not have a true political will. Intellectual property is the barrier, not the only barrier to ramping up production, but it is one of the most important ones. We have to open up pathways to increase production, to call on all the Members to accelerate their constructive discussion to arrive at a consensus before MC12 starting in November. We would like to thank you for the report, Chair, which we see as very balanced and we see as a good way forward.

1.6 Pakistan

24. We wish to thank you for your work and for your continued efforts in advancing the work of this Council. Thank you as well for your status report on the process held so far. We wish to align ourselves with the statement made by South Africa on behalf of the co-sponsors. The pandemic is far from over and new variants are emerging and spreading quickly. Not all countries have equitable access to medicines and therapeutics for COVID-19. The statistics provided by World Health Organization describe a large divide between vaccine supply and requirements in poor countries.

The data also show the wide gap in health therapeutics. The co-sponsors of the waiver have provided comprehensive answers to all concerns raised by Members. All Members have agreed to enter text-based negotiations in good faith. We therefore call on Members to meaningfully engage on the actual text-based elements of the waiver proposal and support it, as time is of the essence here. Through our collective efforts we can demonstrate the relevance of the WTO to provide a global response to address this pandemic.

1.7 Jamaica on behalf of the OACP Group

25. The ACP Group supports the draft oral status report to be delivered at the upcoming General Council. As would have been requested by Members, the report gives a factual and succinct status update on the developments relating to the ongoing discussions in the Council. The report is also consistent with the format of previous reports delivered in the General Council on this matter. The ACP Group wishes to express our commendation for your concerted efforts and dedication to this process. Over the past weeks, under your leadership, the small groups and informal open-ended meetings have facilitated deeper discussions and provided the opportunity for continued constructive engagements amongst WTO Members. It is only through such constructive engagements that significant progress will be achieved.

26. The ACP Group remains concerned the rate of vaccination for many members of our Group continues to be very slow. The Group is also concerned that some countries are currently experiencing another wave of the virus, and some are dealing with the impacts of new strains and variants. If members of the ACP Group and other developing countries are to experience herd immunity and be in a position to start rebuilding their economies, there has to be an increase in the rate of vaccination. The discussions within the TRIPS Council are of critical importance in finding an appropriate response aimed at increasing access to vaccines to combat the spread of the virus.

27. It is evident that all Members within the WTO agree that the Organization has a role to play in the response to this pandemic, but divergences remain on the best approach. The ACP Group is however encouraged by the robust discussions and exchanges on the waiver proposal, particularly as it relates to issues concerning scope, duration and implementation. Through these exchanges, Members have been able to have a better understanding of the various concerns of some delegations and they will serve as the basis for further discussions. The ACP Group again takes this opportunity to encourage all WTO Members to continue engaging in the various configurations with the aim of arriving at landing zones on this issue.

1.8 European Union

28. Thank you for your continued efforts on advancing the discussion on this important topic and on your report from our discussions. We fully support this report, both the factual and objective reflection of the complex situation that we are dealing with in this debate. We are also ready to continue the debate after the summer break in a similar manner as we have organised our exchanges in the last couple of weeks. The EU continues to be committed to achieving our common goal to continue ramping up production to share COVID-19 vaccines and medicines more widely and faster, and to ensure equitable access to these products for low- and middle-income countries. We already see incredible progress in the total global production of COVID-19 vaccines. According to Airfinity, a billion doses were produced by 12 April, another billion were produced by 26 May and the third billion by 22 June. It is clear, that the production is accelerating, and it is therefore realistic to expect that some ten billion doses will be produced by the end of 2021. For comparison, the total global output of all vaccines was only five billion doses.

29. But this is not enough. We need to continue our efforts to further ramp up production and to ensure equitable distribution of COVID-19 vaccines and medicines. In this context, we must focus our efforts where they can deliver best results in the shortest possible time. Setting up and ramping up the production of vaccines is a highly complex process which requires adequate facilities, trained personnel, raw materials and other inputs. It is a complex issue that cannot be solved by one simple solution. The overall strategy is not only within the WTO either. The World Health Organization, other organizations, institutions and initiatives such as the COVAX Facility are working on these solutions. In the WTO, we are collectively looking at possible measures to support the increased production of COVID-19 vaccines and medicines to the extent it is possible in the context of the WTO framework.

30. The intensive discussions in this Council, as well as in other fora have demonstrated that limited manufacturing capacity and restricted access to raw materials and other inputs are the main bottlenecks as regards the production and distribution of COVID-19 vaccines. In addition, having the required know-how is key due to the complexity of the production process of these vaccines. Information collected by the WTO on the bottlenecks regarding critical COVID-19 products indicate that one common theme emerges and that is that essential goods and inputs need to flow efficiently and expeditiously to support the rapid scaling up of COVID-19 production capacity worldwide. The delay of a single component may significantly slow down or even halt vaccine production given the globally integrated supply chains that underpin COVID-19 vaccine manufacturing. This is where we should focus our efforts because these are the real-life problems and in-points when it comes to the production of COVID-19 vaccines and medicines. And this is where trade-related measures, if agreed swiftly, could make a real difference.

31. In order to deal with these bottlenecks with the use of trade-related measures at our disposal at the WTO, the EU believes a multi-pronged approach is needed. We need to look into export restrictions, minimize barriers to trade and put forward trade facilitation measures. The European Union, together with other Members had been at the forefront of these efforts for a number of months in the context of the Trade and Health Initiative by the Ottawa Group. This Initiative provides pragmatic proposals on these issues as well as on enhancing partnerships between innovative companies and manufacturers with adequate production capacity. We would like all WTO Members to join this initiative. In addition, building on the idea also presented in the trade and Health Initiative on 4 June the European Union submitted to the WTO General Council a communication on urgent trade policy responses to the COVID-19 crisis, document WT/GC/231, calling for a multilateral and comprehensive response by trade-related measures to the COVID-19 pandemic.

32. Given the nature of the identified bottlenecks and particularly the fact that they are not related to intellectual property, we do not believe that the full suspension of the TRIPS Agreement is the appropriate and effective measure to increase production and enhance the global, equitable and affordable access to COVID-19 vaccines and medicines. It is a false path, not only it will not increase production of vaccines and medicines as it will not address any of the existing bottlenecks, but also it will have counter-productive effects on our common efforts to enhance access to COVID-19 vaccines and medicines. In addition, it may have harmful effects going forward, when it comes to fighting future pandemics and overall, on the incentives for innovation. Vaccine research and production is generally not profitable and IP incentives are key to maintaining research in this area, in particular for the benefit for many lower-income countries where infectious diseases remain a significant problem. We will not repeat today all the arguments that we have put forward on multiple occasions, and in that regard, we ask the Secretariat to add all the EU statements made in informal TRIPS Council meetings to this statement, so that all these arguments are properly recorded.

33. Today we would like to recall the most important shortcomings of the proposed waiver. First of all, as already mentioned, the waiver focuses on intellectual property while the real bottlenecks lay elsewhere. In other words, the waiver has a wrong target. Second, it would operate against what should be our priority now, that is, to enhance transfer of technology. As mentioned, we are dealing with a highly complex manufacturing process, there is no other way to go about this manufacturing than knowing the exact recipe. This is crucial to be able to produce vaccines that are both effective and safe. The part of the recipe that is revealed in patent applications, which by the way have not even been published yet with regard to the relevant products, is far from sufficient to start a manufacturing process. A real collaboration needs to take place between the vaccine developer and the manufacturer. We have examples of multiple such ongoing collaborations, exceeding anything we know from the past. All these collaborations are based on one and the same framework, the protection provided by intellectual property. This platform provides for guarantees, a safe framework, and in this way helps in building trust between various actors. It is clear what happens when this platform is taken away – the framework falls apart and the relationships built on trust are broken.

34. The waiver proponents never answered the question as to how an action that undermines the existing collaborations, and the transfer of technology can be at all beneficial under the current circumstances. We all agree that we need to enhance transfer of technology to increase the manufacturing capacity for vaccines and medicines, also taking into account the preparedness for future pandemics. But this is a process that needs to be built on voluntary collaboration and trust, it is not by lifting intellectual property and inviting disclosures of information, that would constitute

breaches under agreements entered into between vaccine developers and various manufacturers, that such collaboration and trust are built. This is the wrong and very short-sighted approach that will not bring any benefit but introduce confusion and a lack of legal certainty. We need to create conditions that will invite the transfer of technology, strengthening manufacturing capacities and resilience of the health systems of lower- and middle-income countries, creating conditions for investment, including via adequate regulatory frameworks, in order to attract the private sector where their technology is crucial.

35. In that regard we would like to give an example of the Team Europe Initiative, an integrated and comprehensive support package that will tackle barriers to manufacturing and access to health products and technologies in Africa from all angles. This initiative encompasses three dimensions: supply side, demand side and enabling environment of the health system. On the supply side the initiative will incentivise and de-risk investment into local pharmaceutical and biotech companies. The Team Europe Initiative will support technology transfer and develop a number of regional manufacturing hubs in alignment with the African Union and the Africa Centre for Disease Control and Preventions which recently launched the Partnerships for African Vaccine Manufacturing. On the demand side the Initiative will work with African leaders and communities to tackle the fragmentation of local markets and help consolidate demand, facilitate market integration and the use of locally produced goods. The Initiative will substantially strengthen pharmaceutical and health systems, thus creating an enabling environment for sustainability. It will contribute to developing human resources by investing in skills and education, by increasing Africa research capacities and by enhancing scientific cooperation between the two continents. This Initiative will also address the problem of falsified products and boost confidence in local goods by strengthening regulatory frameworks. The European Commission is also willing to support digital solutions, for example, to trading vaccines and medicines across the supply chain. The Team Europe support and funding for vaccine production is also under way in a number of countries in Africa.

36. To improve the vaccine supply we are also working with industry to optimise the use of our existing capacity while building more capability. This will allow us to address the needs of EU citizens as well assist supply to third countries and low-and middle-income economies. We are doing that through the Taskforce for Industrial Scale-up of COVID-19 vaccine production, set up in February 2021. The Taskforce, operating under Commissioner Breton's responsibility, ramps up production capacity for vaccines in Europe and acts as a one-stop-shop for manufacturers in need of support. The Taskforce work includes mapping European vaccine production capacities throughout the supply chain, identifying, addressing and eliminating production bottlenecks in terms of capacity and supply chain issues, and promoting partnerships through matchmaking events for vaccine and therapeutics production.

37. The third shortcoming of the proposed waiver is the fact that it does not in any way specify what measures Members will be permitted to introduce as a result of the waiver. It is the normal practice with waivers that certain provisions are listed in order to allow specified measures. Here we are dealing with a situation where the TRIPS Agreement is lifted almost in its entirety and there is no clarification as to what measures can be taken in what manner. This causes enormous risks that we have pointed to in the previous meetings, ranging from invalidation of existing patents which could result in the impossibility of restoring protection even after the waiver expires, the denial of new patent applications which could result in product and processes losing the possibility of being patented in the future, invalidation of voluntary agreements licensing patents, and therefore a chilling effect on collaborations by removing incentives of the developers of the original products to provide know-how and technology to manufacturers of biosimilars and so on. In short, a great legal uncertainty with potentially long-lasting negative effects as regards production, distribution and access to vaccines and medicines.

38. We are ready to continue to discuss, to present our arguments in more detail, but also given the important shortcomings of the waiver proposal, the EU made an alternative proposal to this Council, the objective of which is to ensure that IP is an enabler for the use of the available and adequate manufacturing capacity as regards COVID-19 vaccines and medicines. We will say more about this proposal under the next agenda point and would like to encourage further engagement of Members. We are looking forward to advancing on this proposal and finding a common ground that would allow us to ensure that IP plays an enabling role in enhancing access to COVID-19 vaccines and medicines.

European Union's statement at the informal meeting held on 17 June 2021

39. The European Union would like to thank you for convening small-group consultations on the manner in which to take the text-based process forward. We have presented our position on the modalities of this process in the course of the small-group consultations. We would like to recall the main points and reiterate our position on the matter.

40. As stated at the previous meeting of the TRIPS Council, the European Union is ready to constructively engage in the text-based substantive process to find a way forward in this discussion on the role of intellectual property in enhancing access to affordable COVID-19 vaccines and therapeutics, and to proceed with concrete and pragmatic short- and medium-term solutions to enhance universal access to COVID-19 vaccines and therapeutics at affordable prices.

41. This discussion is part of a comprehensive approach to the crisis presented by the European Union in a communication on "Urgent trade policy responses to the COVID-19 crisis", document WT/GC/231, calling for a multilateral and comprehensive response by trade-related measures to the COVID-19 pandemic. We would like to emphasise that it is the view of the European Union that only a multi-pronged approach addressing the identified bottlenecks such as limited manufacturing capacity and access to raw materials can bring about a real change.

42. We are ready to immediately start a discussion based on the proposal set out in our communication on "Urgent trade policy responses to the COVID-19 crisis – intellectual property", document IP/C/W/680, submitted to this Council on 4 June, and intend to follow up in the coming days with a more elaborated text. We would like to thank you, Chair, for planning for a date for presenting our proposal.

43. At the same time, as mentioned at the previous meeting, the EU is ready to continue discussing the revised waiver proposal though we are not convinced that the broad waiver proposed by a number of WTO Members is the right response to the pandemic.

44. This is why the EU wants to include in this discussion our different and more targeted approach. We hope that we will be able to convince Members that our approach, including the components that will be addressed in the General Council, represents the best way to respond to the crisis in the short term in an effective and pragmatic manner.

45. We would like to recall that our proposal is based on the discussions that we have had in this Council over the last couple of months. In the course of these discussions, we have been examining various ways in which intellectual property can help in enhancing access to affordable COVID-19 vaccines and therapeutics. One of the results of these discussions is that a number of WTO Members identified aspects related to the use of compulsory licensing that, in their view, limit the use of this tool. The EU proposal aims to address these aspects, provide more legal certainty and enhance the effectiveness of the compulsory licensing system.

46. We note that our proposal has been welcomed by a number of delegations as a constructive contribution to the ongoing discussion. The revised proposal on the waiver and the EU proposal represent different approaches to the problem of the availability of COVID-19 vaccines and therapeutics and are based on different premises. We are of the opinion that it is key that Members can benefit from having a possibility of discussing these two approaches alongside one another and we request that our proposal is treated and discussed on an equal footing with the revised proposal on the waiver.

47. We also note that in the previous meeting the Chair recognised that there are still divergent views both on the underlying assumptions of the revised waiver proposal and on the specifics. There is no agreement among Members that the waiver can achieve our common goal, i.e. enhancing access to affordable COVID-19 vaccines and therapeutics.

48. In order to take account of all these considerations, to provide for an opportunity to discuss all pertinent issues and to facilitate the examination of both the revised proposal on the waiver and the EU proposal, we request a theme-based approach for our process that we would like to reiterate here for consideration of all Members. This approach would be based around the following themes:

Scope – under which we would examine

a. Provisions of the TRIPS Agreement covered:

   i. which provisions are affected and why – this for us is the first priority for setting the basis for our discussion; and

   ii. we would also compare waiving entire sections of the TRIPS Agreement to the targeted approach proposed by the EU.

Effects short-, medium- and long-term – under which we would examine effects of each proposal

a. on vaccine/medicine production;

b. on transfer of technology;

c. on legal certainty as to which IP rights continue to apply - effects on the current and future cross-licensing; and

d. on ongoing partnerships and concluded agreements.

Products – under which we would discuss the products covered by each proposal including issues such as

a. How the link with COVID is determined; and

b. Definition of a pharmaceutical product in the Annex to the TRIPS Agreement.

Duration – under which we would examine for each proposal

a. End date

b. Restoration, where applicable, (by type of IP right)

c. Compatibility with the WTO rules

Implementation in national law – under which we would discuss

a. Which measures are needed domestically to implement each of the proposals

b. How will these measures relate to the current legislation on compulsory licensing?

c. Effects on procedures of national IP offices

Links of the proposals with other international obligations

49. Of course, the sub-points are not exhaustive but are meant to indicate the aspects that we find the most pertinent for our discussion.

50. As regards the proposed calendar of meetings, we agree to the proposed schedule of weekly TRIPS Council informal sessions. We are also ready to discuss the use of small groups and will also engage bilaterally with Members to present our proposal.

51. As regards the proposed meetings in a small group starting next week, we would have preferred it to be scheduled after our proposal is presented on 24 June and ask for this request to be considered, but should that not be possible, we request that our proposal is discussed in this small group meeting on an equal footing with the revised proposal on the waiver.

52. We would like to thank you, Chair, for your efforts to find a pragmatic manner in which to organise the process before us and we remain committed to constructively engaging with all Members to find a pragmatic, inclusive and effective way forward.

European Union's statement at the informal meeting held on 6 July 2021

53. Chair, thank you for your efforts in advancing our discussions. We would also like to welcome Deputy-Director General Gonzalez and thank her for devoting her time and attention to this important matter. Enhancing equitable access to COVID-19 vaccines is the priority for the European Union and this is our objective in this discussion.

54. The European Union appreciated the possibility provided by the small group meeting to explain in more detail the EU proposal and to discuss the revised waiver proposal. We would like to thank all the delegations that engaged in the discussions and hope that the input provided by the European Union has been helpful in taking this discussion forward.

55. The European Union remains fully committed to this process and to finding the best way forward to ensure that the intellectual property system plays an enabling role in the context of deploying existing capacity or creating new capacity for the production of COVID-19 vaccines and medicines while keeping intact the necessary incentives that the intellectual property system provides to researchers of new vaccines and medicines to fight against the current and future variants of the virus that causes COVID-19. We will continue to engage constructively and are open to discussing all approaches that contribute to enhancing access to affordable COVID-19 vaccines and medicines and can bring results in an urgent manner.

56. Even though the discussions on the duration and implementation and especially on the implementation have not been finalised in our meeting of yesterday, the European Union would like to use this opportunity to recall some of the most pertinent, in our view, points that have been raised and which, in our view, deserve further discussion at the next small-group meeting.

57. Starting with the EU proposal for a General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, document IP/C/W/681, the EU has provided explanations on the duration and implementation of the EU proposal:

a. As regards the duration, the EU proposal clarifies certain requirements of the compulsory licensing system for the circumstances of a pandemic, therefore these clarifications will apply not only in the times of this pandemic but also in other such cases – as we said previously, this is of course without prejudice to other situations of 'national or extreme urgency' that Members may decide on in accordance with the TRIPS Agreement.

b. As regards the implementation, we would like to recall that we believe that one of the advantages of the EU proposal is that it can be adopted swiftly; the proposal clarifies certain provisions in Articles 31 and 31*bis* and the Annex of the TRIPS Agreement. As we do not aim to amend these articles, we will not require lengthy debates and procedures. The scope of these provisions will remain the same but agreeing on a declaration will remove legal uncertainty about their application and support those WTO Members who wish to use them. No implementation at national level will be required. This is how we can advance quickly and have immediate results on the ground.

On the duration aspect of the revised proposal on the waiver

58. We believe that any discussion about the duration of a measure needs to be preceded by a reflection on the impacts on the various stakeholders affected by the measure. In that respect, the discussion around the duration of the measures to enhance equitable access to COVID-19 vaccines and medicines also needs to be preceded by a reflection on the impacts in the short-, mid- and long-term, both in terms of benefits and negative impacts.

59. First, we need to make sure that the measure proposed is effective to achieve our common objective. This is a condition to accept any measure that could have negative impacts on various stakeholders or on incentives to innovate and research as well as on public health.

60. Second, only if the measure is effective, we need to make sure that the negative impacts of the measure are as limited as possible, both in terms of scope and duration, and that the benefits offset these negative impacts.

61. In the case of the EU proposal, we remain convinced that the clarification on the use of compulsory licensing under the TRIPS Agreement is effective to enhance equitable access to COVID-19 vaccines and medicines, together with other trade-related measures that are part of the comprehensive approach that the EU has proposed. Moreover, the duration is limited to what is necessary ("in the circumstances of a pandemic") in order to reduce the negative impacts of compulsory licensing on patent holders e.g. waiving the requirement to negotiate with the patent holder before issuing a compulsory licensing may result in missing opportunities of agreeing on voluntary licences – however this fast-track procedure is applied in the specific circumstances of a health emergency and not as norm, therefore the negative impacts of our proposal remain limited, as they keep intact the necessary incentives to continue research and innovation on vaccines and medicines against COVID-19 and other diseases.

62. With respect to the waiver proposed in document IP/C/W/669/Rev.1, we maintain our fundamental concerns about the lack of effectiveness of this measure to achieve our common goal of enhancing equitable access to COVID-19 vaccines and medicines. Moreover, we believe that a discussion on the duration of the potential waiver can only take place once the effects of the proposal in the short-, mid- and long-term are analysed and discussed, in particular:

a. the impacts on transfer of technology required to produce the existing vaccines against COVID-19;

b. the impacts on research and innovation of new vaccines and medicines against the existing and future variants of COVID-19 or against future pandemics; and

c. the impacts on public health (especially in the mid- and long-term if the incentives to innovation are removed).

63. We have had some exchanges on some of these issues yesterday but not in an exhaustive manner and we think it is important that we continue discussing these topics in the next session of the small-group meeting.

64. For example, the proponents of the waiver indicated that the waiver would enhance collaborations among vaccine developers and manufacturers and therefore would also enhance technology transfer. We question how the measure that takes away the platform on which collaboration and technology transfer can occur and introduces legal uncertainty as to the licensing agreements could have this effect. We would like to ask the proponents of the waiver to elaborate on this aspect of their proposal. Transfer of technology, as we know, is absolutely essential in our efforts to ramp up production and therefore understanding how exactly in practice the waiver would affect this transfer is key for assessing the effectiveness of the measure. We understand that this and similar questions will be discussed in the next sessions of the small-group meetings.

65. Without prejudice to the discussion on the effects of the measure and the links with the duration, we also note that the provision on the duration of the waiver is proposed in a manner that does not indicate the date on which the waiver would be terminated. Following three years and subject to exceptional circumstances ceasing to exist, the General Council would determine the date of termination of the waiver. As explained at yesterday's meeting by the waiver proponents, the General Council may or may not decide on the termination in such circumstances. This would indicate that the waiver could stay in force for an undefined period of time after the exceptional circumstances, which are presented as those justifying the waiver, cease to exist.

On the implementation of the revised waiver proposal

66. The proposed waiver does not contain any indications of the mechanisms of implementation at the national level, in contrast with, for instance, the provisions of the Annex to the TRIPS Agreement applying Art. 31*bis*.

67. The proposed waiver is currently being discussed as though it would be directly applicable to all Members and produce immediate effects. The assumption seems to be that if the waiver is adopted and Members avail themselves of it, the relevant IP rights will be suspended, without any further action being required. But this is not the case. Each waiver of the provisions of the TRIPS Agreement requires national implementation in national systems which are aligned with the TRIPS Agreement requirements – which is the case for most of our systems. The broader and less targeted the waiver,

the more complex implementation is required. The discussions we had yesterday confirm that the need for the national implementation would mean that whatever effects the proponents count on, would not materialise in the short term at all.

68. First, a national legal infrastructure would in many cases need to be created by the Members to enact measures permitted under the waiver, and in particular, to:

a. determine which IP rights would be deemed to fall under the ambit of the waiver; and

b. create a legal instrument and procedures to effect the suspensions and circumscribe their scope to the purposes provided in § 1 of the waiver.

69. In that regard we asked the proponents to explain how they see the waiver being implemented and how long this would take. Other delegations indicated that, considering that the corresponding domestic procedures often take time and may be complex, it is questionable how the waiver would provide a quick solution for the Members.

70. Further, the waiver provides no framework to establish clarity and transparency regarding the status of individual IP rights within the respective WTO Members – this creates a risk of additional legal uncertainty and further damage to the incentive function of the patent system as pointed out by a number of delegations in the course of yesterday's meeting.

71. The waiver provides no description of measures to be adopted by Members under the waiver. No measures are indicated or prescribed. There are no set boundaries to the measures which can be taken. The proponents explain that the 'waiver is permissive' and that 'the choice of measures is left to the Members'.

72. The lack of defined measures is, in our view, highly problematic and results in high risk as regards the effects of the waiver. The lack of any boundaries means that Members would be free to take any measures they deem appropriate without any accountability or scrutiny, and regardless of the impact of the waiver on incentives for innovation.

73. While the positive effects of the waiver are not proven and clearly questioned by many delegations, its effect in the short-term is likely impossible due to the need for the national implementation, the lack of defined measures and the permissiveness of the waiver proclaimed by the proponents is creating risks of harmful effects that would continue beyond the time of application of the waiver. It is not only about what procedure is used by Members – based on emergency prerogatives of the state or other – it is, beyond all, about the substance of these measures and their effects.

74. The first one concerns invalidation of existing patents: In the absence of TRIPS obligations to protect patents, Members may choose to invalidate existing patents on COVID-19 related products or processes. This would result in curtailing the patent protection without any compensation or the possibility of restoration of the right. Importantly, this could impact not only inventions that are specific to COVID-19, but also "dual-use" inventions that are relevant to both COVID-19 and other existing and future diseases. This protection would be impossible to restore once the invention would be in the public domain.

75. The second one concerns the possibility of rejecting pending patent applications: In the absence of TRIPS obligations to protect patents, Members may choose to provide that pending applications for new patents for all COVID-19-related technologies or for all products and processes relevant to the manufacture of vaccines, medicines and medical devices can be rejected. This would mean that new inventions related to these products and processes will not have patent protection and can be freely copied. In such a case such products/processes could not be patented going forward as, once known, they would lose their novelty characteristic which is one of the conditions of patent protection. In this respect, the explanations provided yesterday seem to assume that this condition of novelty could be ignored after the expiry of the waiver, but the TRIPS Agreement requires novelty to grant patents, as the novelty requirement is essential for the patent system to work properly.

76. In that regard we would like to discuss how proponents of the waiver suggest to guarantee that no measures may be taken with regard to patents or patent applications (the same goes for other registered rights) which will continue to produce effects once the waiver has terminated?

77. The other set of effects that need to be analysed are the effects on voluntary licence agreements and open licensing schemes: If existing patents are invalidated, this may in consequence also result in invalidation of the voluntary agreements licensing those patents, depending on how the new rules are implemented, under the terms of the contract and the applicable contract law. This would mean that the licensees would be free of licence conditions in their use of the invention. This would clearly undermine the ongoing collaborations and efforts to enhance production of COVID-19 vaccines.

78. As regards the collaborations based on voluntary agreements, compulsory licences or open licensing schemes, the question is – why would a waiver apply to these situations where obviously there is no barrier to access? Generally, where licences have been granted or the willingness to license has been expressed, does this not constitute evidence that the IP right in question is not a barrier to access for health products? Should the consequence be that such an IP right does not fall within the ambit of the waiver?

79. There were a number of other questions raised by various delegations including on safeguards for the holders of undisclosed information – in cases where such information enters the public domain, how exactly the proponents of the waiver suggest to protect the interests of such holders in the time after the waiver expires. It seems that if protection of undisclosed information is once disclosed, such information loses protection permanently, even after the waiver ceases to apply. This is another example of why negative impacts on holders of undisclosed information need to be carefully assessed.

80. We would also have additional questions about the implementation of the waiver that we hope to discuss today or during the meeting on 9 July.

81. We understand that the intention of the proponents of the waiver is to remove intellectual property protection from COVID-19 vaccines, medicines and medical goods for the purposes of making them public goods, so that they can be made accessible more widely to the vulnerable populations. This should entail, in practice, that the use of these inventions has a humanitarian and not a commercial objective. However, whereas the waiver takes away the obligation to remunerate the holders of intellectual property rights, we do not find any mechanism in the proposed waiver to ensure that the access to products covered by the waiver would be ensured in line with the stated objective of the waiver and not for the economic benefit of manufacturers relying on the waiver. In contrast, the EU proposal explicitly provides for a mechanism aiming to keep patent holders' remuneration in line with the non-for-profit manufacture and supply of vaccines and medicines. Therefore, we would like to ask the proponents of the waiver for an explanation: Will it be acceptable that entities benefitting from the waiver reap profits on the manufacture and distribution of health products during the pandemic, when such authorisation to use the invention has been granted under exceptional circumstances in the interest of public health? If not, how do they propose to avoid it in practice?

82. As is clear from the text of the waiver, the suspension of the IP rights should be solely for the purposes set out in § 1. Any further uses unrelated to the prevention, treatment or containment of Covid-19 shall not be covered by the waiver, and IP rights will deploy their full effects in this regard. At the same time, as discussed in the course of previous week, the waiver covers many products which are not limited to treating COVID-19 – how are proponents suggesting to guarantee that the permitted use of the invention under the waiver does not encompass use for other purposes or diseases or simply nullifies patents that are relevant for other areas?

83. The discussions we have had so far, rather than dispelling our concerns about the effects of the proposed waiver, confirm the merit of these concerns. We look forward to further discussions as a number of questions are still unanswered. For instance, the proposed duration, seems to us to be based on a certain assumption rather than evidence and underestimates the negative effects of the waiver on the system that has allowed researchers and innovation to develop various vaccines in an unprecedented time. On implementation, it seems to us that the assumption that the waiver does not require lengthy and complex implementation underestimates the challenges of implementing the waiver proposal in practice. Moreover, the approach according to which the choice of measures to

implement the waiver is left entirely to Members, without any boundaries that would take account of necessity and proportionality raises concerns on the long-term effects of the waiver not only on the IP system but on its disruptive effects for access to COVID-19 vaccines and medicines.

84. The EU is looking forward to further discussions on these points and is always ready to respond to any questions on the EU proposal.

85. As was mentioned by a number of delegations, the EU believes that Members should focus on solutions which are targeted, pragmatic and that can bring results in the short-term. We invite Members to discussions on the EU proposal, which in our view fulfils these requirements. As indicated in the previous meetings, the EU is also ready to discuss other aspects of compulsory licensing system that would merit clarification to enhance efforts to scale up the production of COVID-19 vaccines, therapeutics and diagnostics. Finally, we would like to emphasise that the IP-related discussion is only a part of the multi-pronged approach proposed by the EU. We call on all Members to engage in discussions on all elements of this approach as only this way we will be able to adequately respond to the current crisis.

European Union's statement at the informal meeting held on 14 July 2021

86. Chair, we would like to thank you for your continuous efforts in advancing our discussions. Enhancing equitable access to COVID-19 vaccines and medicines is a priority for the European Union and this is our objective in this discussion. The European Union appreciated the possibility provided by the small-group meeting of 9 July to explain in more detail the EU proposal and to discuss the revised waiver proposal.

87. The European Union remains fully committed to this process and to finding the best way forward to ensure that the intellectual property system continues to contribute to enhancing equitable access to COVID-19 vaccines and medicines. We remain convinced that the current intellectual property system can play an enabling role in deploying existing capacity or creating new capacity for the production of COVID-19 vaccines and medicines while keeping intact the necessary incentives for innovation. We will continue to engage constructively and are open to discuss all approaches that contribute to enhancing access to affordable COVID-19 vaccines and medicines and can bring results in an urgent manner. The discussions on implementation during our last two meetings have been helpful to understand the positions of various delegations, in particular of those who have put forward text-based proposals.

1.9 United Kingdom

88. The United Kingdom welcomes the text of the oral status report and is content for it to be delivered at the upcoming General Council. We believe this report is factual, objective, and accurately reflects developments made by this Council since the General Council was last updated in May, and we thank other delegations for their engagement.

89. The United Kingdom would like to extend our gratitude to you and the Secretariat for successfully organising several informal TRIPS Council sessions and small-group consultations, to help Members advance discussions on substantive topics in a transparent manner. Our delegation has engaged in good faith throughout this process, asking questions conducive to healthy discussion, and has found the exchange of views from Members useful. However, as reflected in the status report, this Council has been finding it difficult to move towards consensus. We once again reiterate our long-held view that a discussion on fundamental areas of disagreement would help guide discussions towards pragmatic solutions. It is only by developing a common understanding of these underlying principles, that we will be able to meaningfully move forward in this process.

90. We will continue to actively engage in all discussions and review the merits of any proposal submitted to the TRIPS Council. Responding to the question of vaccine equity necessitates a multifaceted response underpinned by pragmatic action, including voluntary licensing and technology transfer agreements for vaccines, support for COVAX, and solutions for production bottlenecks and supply chain issues. We will continue to support action in this regard, and we look forward to our future discussions.

1.10 China

91. We appreciate your leadership and great efforts in organising the text-based process for the past couple of weeks. We fully support your oral report to the General Council which we believe is a balanced and objective report and also a factual reflection of the *status quo* of our discussions so far. The days and weeks since have witnessed Members active and constructive discussions both in small group consultations and informal session on some important and specific issues in the waiver proposal focusing on the product scope, the scope of the IP rights, duration of the waiver, implementation-related considerations and regulatory data measures. Members have also touched upon some of the elements in the European Union proposal. These rounds of intensive discussions have provided opportunities for Members to clarify each other's positions and concerns and further understand the key issues in the proposal which has laid a sound foundation for our future work.

92. However, we are also aware that Members are still divided over some key elements in the waiver proposal, most notably the role of IP waiver in ramping up the production of vaccines and the scope and duration of the waiver as well. We realize that time is not on our side. If we do expect a good harvest in this regard before MC12 we may need to consider the possible landing zone as early as possible. The recent spread of delta variants has put developing countries with low vaccination rates in even greater danger. It is an urgent call for the international community to work together to expand the COVID vaccines manufacturing capacity and to ensure the fair and equitable access to COVID vaccines for developing countries.

93. At the APEC informal economic leaders meeting on 16 July, Chinese President Xi Jinping said that China has overcome the challenges of his own mass vaccination programme and provided more than 500 million doses of vaccines to other developing countries. In another package, international aid worth USD 3 billion will be delivered over the next three years to support COVID-19 response and economic and social recovery in other developing countries. It is notable that the President Xi reiterates China's support on the proposal of waiving intellectual property rights on COVID-19 vaccines and expects an early decision in the WTO.

94. Having said that, China will continue to actively engage in all forms of discussion at the TRIPS Council with other Members aiming to reach a balanced and effective solution from the perspective of IP, so as to promote the accessibility and affordability of vaccines for developing countries in the near future.

1.11 Cuba

95. We would like to congratulate you Chair on the way in which you have conducted our debates and for your efforts on these topics. Also, we acknowledge the work of all the colleagues that have been involved in informal discussions and other activities in relation to this topic. COVID-19 has led to a crisis with serious effects at a global level. Its implication goes well beyond the health sector and affects all sectors. The global system is complex, cases are still increasing, and the unfair and unequal distribution of vaccines is hampering our efforts to put an end to this epidemic. In this context, the WTO has been discussing the need to increase the capacities of our trading system to deal with the emergency in terms of public health. In this crucial time for humanity, it is absolutely vital that we find formulae to provide solutions that are comprehensive to all the aspects relating to comprehensive vaccinations in developing countries. We need to lift current restrictions on imports of vaccinations, for example, as well as medical products indispensable for the production of vaccines. Often it is only companies that are based in large, industrialized countries that produce these vaccines. It also means lifting the coercive measures that are unilateral and that are set up against developing countries which affect the access and distribution of vaccines.

96. It is undeniable that a large majority of developing countries have no vaccine production capacity and even if patents were to be facilitated, they do not have the necessary resources, technological, human or other resources necessary. We need firm commitments on behalf of industrialised countries for the capacity-building, funding and transfer of technology to developing countries. No less important are the health networks in various territories with storage and transport capacity and sufficient health personnel to carry out mass vaccination campaigns as swiftly as possible. Either way, most developing countries lack all of this and we need to work on building them or strengthening them whatever the case may be. We know that there is still much to be discussed given the impact of these topics and the timeframe we need greater analysis and more in-depth

analysis. We must overlook no aspect, we must carry out comprehensive analyses to ensure a global solution to the global problem ensuring affordability and access to vaccines, equipment and other inputs. We need to work on a consensus-based approach with our organization and the binding nature of its commitments and agreements. We reaffirm the need to work on immunizing against COVID-19 and ensuring a swift, equitable access to vaccines, equipment.

97. To come back to this pandemic, Cuba will continue in this vein to work on bilateral agreements, south-south cooperation, triangular cooperation, or cooperation through international organizations. We will support, as we have done since the very beginning of the pandemic in dozens of countries any campaign of vaccination and will assist in training health staff. The United States Government attitude against Cuba is only leading to a more difficult situation in our country. This is also having an impact on citizens of many other nations including US citizens. In the previous years, the economic situation of our country has significantly worsened given the measures taken by the United States, with over 300 measures having been taken during the presidency of President Trump and President Biden is leaving them intact. The Government of the United States identified the pandemic virus as an opportunity to strengthen these measures for political reasons and use the strongest measures possible to act against Cuba. This has been deliberate, cruel, and opportunistic. They have made the most of a pandemic to try and strangle our economy. In Cuba there were disturbances, protests on 11 July, they were very limited, and they were caused by communication that had been prepared a long time ago from the outside of the country. It is unfortunate that the United States Government is directly involved in this and is very much responsible for the incidents that happened on that day. Their goal is to create disturbance and instability, making the most of the difficulties that we are facing due to the pandemic. In the context of the measures taken by the United States and by President Trump there is a lot of fake news and misinformation against Cuba, we have proof of this. I denounce the measure taken by the US against Cuba and the terror carried out against it.

1.12 Switzerland

98. At the outset, let me clarify that our statement covers both, agenda items 1 and 2.

99. My delegation would like to thank you, Chair for your efforts in this process and for the consultations you held to find consensus on the status report to the General Council. It is important that this report reflects correctly and comprehensively the discussions the Council has held in the various formats on all the proposals made by Members, in an objective and factual manner. This includes, of course, in addition to the waiver request, also the proposal from the EU in document IP/C/W/681.

100. As you reported to this Council and will to the General Council, Chair, Members have intensified work over past weeks and have held substantive discussions on the proposals on the table. Switzerland remains committed to engage in the Council's discussions and the need to consider all the proposals when we resume that work.

101. My delegation requests the Secretariat to include its statements from the informal meetings since the Council met formally the last time in the minutes of this Council. At last week's meeting, my delegation noted the many questions posed by Members to the proponents and their TRIPS waiver proposal. These concerned in particular questions in relation to the national implementation and the impact and negative effects such a waiver risks to have on the ongoing international efforts to scale up the manufacturing of COVID-19 vaccines. The discussions show that there is still no consensus that a waiver is the adequate approach to achieve our shared goal of making global and equitable access to COVID-19 vaccines and therapeutics happen in the shortest time possible. Nor have we been presented with evidence that the TRIPS Agreement would indeed be a barrier to access. On the contrary, we see, in many examples, that it works as an enabler.

102. My delegation referred previously to the more than 300 voluntary agreements and partnerships that so far have been established internationally and are working currently on scaling up manufacturing of COVID-19 vaccines or work on the development of vaccines adapted to the new variants and respective health technologies. And new ones are announced almost every day. These partnerships are based on the international regulatory framework in place, of which the WTO TRIPS Agreement is a key component.

103. The case example of Lonza illustrates this, a Swiss pharmaceutical and biotech company with considerable experience and existing solutions facility, covering the complete biopharmaceutical lifecycle, ranging from preclinical to commercial stages, from drug substance to the final drug product:

104. The US vaccines developer Moderna and Lonza announced in May 2020 a ten-year agreement to support the manufacturing of Moderna's COVID-19 vaccine. Under this Agreement, Lonza provides drug substance manufacturing capacity for Moderna's mRNA COVID-19 vaccine. On the basis of their cooperation agreement, the two partners established a close collaboration:

a. They exchanged skilled personnel which are the holders of respective experience and knowhow, transferred technology and materials for the manufacturing of the product, handling instructions, protocols of production standards, other documentation necessary to maintain the properties of such materials for the performance of their service.

b. They established a Joint steering committee in charge of overseeing, reviewing, approving and coordinating the activities of the Parties under their cooperation agreement.

c. A joint manufacturing team was set up to oversee the services under each stage of production.

d. Licensing and confidentiality agreements were prepared in relation to trade secrets and manufacturing know-how to be exchanged.

e. Setting up such a complex manufacturing capacity of this scale would normally take up to two years till production is operational. Thanks to their close collaboration, sharing of knowhow and the focus they set to respond to the urgency of the pandemic, the two partners managed to start the first of three production lines after eight months' time. Not of the entire vaccine, of course, but as mentioned of the drug manufacturing substance. Moderna works with many more partners to produce and get the finished and filled vaccines ready for inoculation.

f. At the end April of this year, Moderna and Lonza announced that they intend to double the manufacturing capacity of Lonza, hoping to get three additional production lines going by spring 2022.

g. A major and urgent concern for Lonza remains finding sufficient qualified specialist staff, from vaccines researchers to other expert employees to implement this project and adhere to the set time schedule for establishing and scaling up its manufacturing capacity. This is particularly challenging today, in the time of the pandemic, where in the field of vaccines science the market for qualified research and other experts is almost dried up, and this at the international level. In this state of emergency, the Swiss Federal Government started to dispatch temporarily qualified experts from its own federal and from university staff to support the ramping up of Lonza's manufacturing capacity. Lonza itself contacted other Swiss companies to see whether they could loan specialists to step on a temporary basis.

105. We can take away a few lessons from this case example:

a. The close cooperation between Moderna, the vaccine developers, and Lonza, the qualified manufacturer, was quintessential for the scale-up of manufacturing to succeed. And to succeed within a timeline to matter for the fight against this pandemic.

b. Voluntary collaboration, exchange of expert personnel, transfer of their know-how and technology were key ingredients of their success.

c. Even with partners willing to collaborate, to contribute, exchange and share - it took time to get this up and running. This cannot be done at the push of a button.

d. Many operational challenges need to master: recruitment of the required number of qualified specialists, access to needed raw materials and getting the right supply chains in

place to secure the manufacturing process from sourcing raw materials to fill and finish the vaccines.

e. Last but certainly not least: protection of their trade secrets and manufacturing know-how were a given for both partners to enter into a partnership. For this, the two partners relied on the well-established and trusted international regulatory framework, part of which is the TRIPS Agreement. Had there been no international regulatory IP framework or had TRIPS been suspended, this international partnership, just one of many examples, would not have come about.

106. Against this backdrop, my delegation reiterates its concern that the proposed TRIPS waiver would jeopardize the partnerships and collaborations such as the one between Lonza and Moderna currently engaged in the manufacturing of COVID-19 vaccines, adapting them to new virus variants or the development of novel therapeutics against the Sars Cov2 virus. It also risks preventing the establishment of new partnerships and would thus have a counterproductive impact on our achieving, as soon as possible, the goal of broad and equitable access to COVID-19 vaccines.

107. We agree, that, at this juncture, in many countries we still face a severe shortage of vaccines, equitable access to it, and a lack of efficient vaccination strategies to inoculate populations. In this regard, we reiterate that a holistic approach is needed, that notably addresses trade measures and the real bottlenecks affecting access to COVID-19 vaccines and relevant health technologies. The WTO has an important role to play, and we welcome the trade policy actions identified by more than 50 of its Members on 15 July 2021 in the communication "COVID-19 and beyond: Trade and Health".

108. In addition, to ensure more equitable access to vaccines in the immediate term, countries disposing of sufficient doses must now share surplus vaccines quickly. Vaccine's production and sharing in cooperation with WHO's COVAX must be oriented with high priority to the needs of those countries with the most acute shortage.

109. Governments also need to boost local and regional vaccines production to be better prepared for future pandemics, including in Africa. But this is not a goal that can be achieved at once. Nor through a TRIPS waiver. This goal must be pursued in the medium and long term. Cooperation, capacity-building and manufacturing partnerships will be a prerequisite for this to happen successfully - the TRIPS regulatory framework will contribute again as an enabler. We took note with interest of the new initiative of WHO to establish a vaccine technology transfer hub mechanism. Switzerland has already been in touch with the person responsible at WHO to pledge our support.

110. On the further discussions and work of the TRIPS Council after the recess, Switzerland remains committed to contribute actively and constructively with the aim to find adequate solutions that can truly support us in achieving our shared goal that unites this Council.

Switzerland's statement at the informal meeting held on 17 June 2021

111. In order to respond efficiently to the COVID-19 pandemic, many measures are needed. These range from the support and facilitation of partnerships between innovative companies and qualified manufacturers with adequate production capacity, to removing export restrictions and minimizing barriers to trade. This is why a holistic approach is best suited to harness the contribution of trade to an effective response to fight the pandemic. In this regard, Switzerland would like to recall that the "Trade and Health" initiative by the Ottawa Group, and supported by other Members, provides pragmatic proposals on these issues. Switzerland actively supports this initiative and encourages all WTO Members to consider it positively.

112. My delegation reiterates its openness to examine all proposed measures by WTO Members which contribute - effectively - towards the goal of expanding the production of COVID-19 vaccines and health technologies and facilitates prompt and equitable access to them. Regarding the way forward, we would like to thank you Chair for holding small group consultations on this matter on 16 June as well as on 11 June.

113. In light of the various ideas on the table and the different perceptions of the best way forward, Switzerland believes that all the proposals and potential future proposals, which are all working towards the same goal, have to be discussed on an equal footing in this process. This means, irrespective of their current form, at the same time and with equal intensity.

114. Chair, we would like to thank you for your suggested calendar of meetings. This calendar, which contains indicatives dates, is very intensive, but we are ready to engage on this. We understand that in the stocktaking meeting on 30 June, Members will have an opportunity to review this schedule and whether the rhythm and thematic structure of meetings seems appropriate. We also welcome the approach to have dedicated meetings to discuss specific topics. As mentioned by the United Kingdom, which remarks on calendar we fully support, we need a pragmatic, solution-oriented and problem-based approach. To that effect, we need to look at specific topics and how the individual proposals would address them. Effectiveness, short, medium and long-term effects or national implementation are also important elements to discuss.

115. In order to ensure that all proposals can be treated on an equal footing, we would like to express our support to the European Union's suggestion to hold the first small group meeting only after the EU was given an opportunity to present its proposal on the 24 June. We are currently analysing proposals in documents IP/C/W/669/Rev.1 and IP/C/W/680 and would welcome to be able to benefit from sufficient time to allow in-depth study of these proposals. We agree to discuss all proposals that have the objective of ramping-up production and ensuring access, *inter alia* proposal document IP/C/W/669/Rev.1, including the draft text. Nevertheless, this is without prejudice to the Swiss position as to the TRIPS waiver proposal as such. Indeed, as we have clearly stated in our previous statements, we have not been convinced and do not believe that IP is a barrier to global access and that the suspension of the TRIPS Agreement would be an effective measure to ensure a global, equitable, affordable and timely access. Doing so could have counterproductive effects for reaching our common goal, fighting this and futures pandemics.

116. Switzerland will continue to actively contribute to the ongoing efforts at the WTO in order to reach our common goal of quickly scaling up global manufacturing capacity for equitable access to COVID-19 vaccines and other medical technologies.

Switzerland's statement at the informal meeting held on 24 June 2021

117. My delegation would like to thank you for organizing this open-ended informal meeting. As this Council is dedicated to proposal document IP/C/W/681, we will not repeat today our well-known position and refer on that point to our previous statements. We would like to thank the European Union for presenting its new proposal document IP/C/W/681. As this document was circulated four days ago, we are currently analysing it in capital.

118. Allow us, Chair, to make some preliminary comments and ask the distinguished delegation of the EU a question. Switzerland appreciates that proposal document IP/C/W/681 is part of a broader holistic approach reflected in the EU proposal WT/GC/231 on urgent trade policy responses to the COVID-19 crisis. We fully share the EU's views that the holistic approach is the right way in order to reach our common goal of expanding the production of COVID-19 vaccines and health technologies and facilitates prompt and equitable access to them. This approach is necessary not only to facilitate trade and address export restrictive measures, but also to enhance harmonious and trust-based collaborations as well as mutual exchange of know-how and technology.

119. Thanks to a holistic approach and to efforts based on the tools provided for under the multilateral framework we believe that manufacturing capacity will ramp up. As already stated, Switzerland fully acknowledges that compulsory licences are a flexibility that Members can use under Article 31 of the TRIPS Agreement, as also confirmed in the separate Doha Declaration on the TRIPS Agreement and Public Health. Under Article 31, a compulsory licence can be issued promptly and in the case of an emergency, like the COVID-19 pandemic, even without prior negotiations with the right holder.

120. We encourage Members facing practical challenges when making use of compulsory licences to bring this quickly to the attention of the TRIPS Council. Switzerland remains open to discuss solutions to concrete challenges. In our view, clarifying the application of existing provisions of the TRIPS Agreement concerning certain aspects of compulsory licensing, in the circumstances of a pandemic as suggested in proposal document IP/C/W/681, is a constructive approach. We believe that solutions should and can be found building on existing multilateral IP rules.

121. We welcome the fact that proposal document IP/C/W/681 underlines the need to provide and preserve appropriate incentives for investments in research and development of COVID-19 vaccines. We also share the view expressed in the communication that legal certainty on the flexibilities

provided for in the TRIPS Agreement is essential when making use of compulsory licences in the context of a pandemic. Our delegation would be interested to know if diagnostics are also covered by the proposal since they are not explicitly mentioned. As already stated several times, Switzerland believes that all existing and future proposals on these matters should be discussed on an equal footing. We look forward to discussing in an open-minded and inclusive way all proposals – including the present one – on 28 June at the small group consultation on IP rights.

Switzerland's statement at the informal meeting held on 30 June 2021

122. Our delegation would like to thank you for convening this important meeting, which gives Members the opportunity to take stock of the discussions, review the process's schedule, pace and thematic structure, as well as discuss the next steps. Allow us, Chair, firstly to reiterate that Switzerland is fully convinced that the IP system is part of the solution to fight the pandemic. IP rights are namely key for existing and forthcoming collaborations and partnerships between various stakeholders because they offer safe environment for know-how and technology transfer.

123. In a timesaving manner, we will not repeat our position and refer to all our previous statements made at the TRIPS Council. However, we would like to recall that there is no silver bullet to address the challenges we face in the current pandemic: Only a holistic approach can bring us closer to our common goal of increasing global manufacturing capacity for equitable and affordable access to COVID-19 health technologies. In the context of a holistic approach, we stand ready to discuss IP and in particular possible solutions to practical challenges that Members would face. We believe that Members need to adopt a pragmatic, targeted solution-oriented and problem-based approach, and that solutions can and should be found within the rules-based multilateral IP system.

124. Currently, two proposals – respectively documents IP/C/W/681 and IP/C/W/669/Rev.1 – are on the table, proposing different approaches in order to reach our common goal. There is currently no consensus among Members as to which approach should be pursued. We are convinced that it is therefore necessary to continue discussing all proposals on an equal footing. We appreciated the holding of the two small group consultations related to the scope of products and IP rights. Indeed, they gave Members the opportunity to discuss proposals documents IP/C/W/681 and IP/C/W/669/Rev.1 in a constructive, interactive and inclusive way.

125. In these meetings my delegation was in particular interested to understand better why existing TRIPS flexibilities are not sufficient to adequately address potential problems arising and how the approach suggested in document IP/C/W/669/Rev.1 would achieve the objective of ramping up manufacturing, in particular with regards to the question how a suspension of the protection of trade secrets would encourage technology transfer. We certainly agree with proponents of document IP/C/W/669/Rev.1 on the importance of know-how and technology transfer, but still fail to understand how this would be facilitated with a suspension of the protection of trade secrets.

126. We believe that it is our collective responsibility as Members of the WTO and as Parties to the TRIPS Agreement to search for solutions based on existing multilateral IP rules, rather than simply suspending these rules. In this regard, we reiterate our call to Members facing practical challenges when making use of TRIPS flexibilities such as compulsory licences to bring this quickly to the attention of the TRIPS Council.

127. Considering the number of open questions, Switzerland believes that it would be important to continue these discussions, with the aim to better understand the challenges concretely faced and identify the best way forward to achieve our collective goal. During the last small group meeting, Members touched upon the issue of implementation several times. We would therefore propose that the next small group consultation focuses on how the proposals would be implemented in domestic law, as this is a key aspect which has not been sufficiently addressed.

128. Furthermore, topics such as systemic implications, short, medium and long-term effects also seem very pertinent to us. We also support the suggestion that came up in the meeting on 28 June to have a dedicated small group consultation on technology transfer. Regarding the way forward in July and in order to manage time carefully, we suggest keeping the same rhythm of meetings as described in your communication dated 16 June. We are of the view that one small group consultation per week on a specific topic allows Members to adequately prepare for them and provides predictability. In this regard, we would also appreciate if you could indicate in a communication the dates for the small group consultations to be held in July.

129. As indicated in your communication dated 16 June, Chair, we have noted that you have the intention to convene three TRIPS Councils in the coming month: on 6, 14 and 20 July. These open-ended meetings would allow Members to take stock of the discussions and to prepare the status report for the General Council meeting of 27 and 28 July. Our delegation would appreciate to get more clarity on the structure on these open-ended TRIPS Councils. As envisaged in your communication Chair, we support the idea of holding one of the three meetings mentioned above as a formal meeting, in order to adopt the status report to the General Council. Let me reiterate, Chair, that Switzerland remains fully committed to engage actively in order to find with all Members a pragmatic solution to reach our common goal.

Switzerland's statement at the informal meeting held on 6 July 2021

130. My delegation would like to thank you for convening this open-ended meeting. We would like to start our statement by making an announcement: we are pleased to inform Members that the Swiss Federal Council decided, on 30 June, to transfer 4 million of vaccines doses to the COVAX Facility. To us, the COVAX facility is a key international initiative to reach the goal of equal and equitable access to COVID-19 vaccines. Indeed, it brings together Members, international organizations and other public and private stakeholders as partners to work together towards the goal of global access to COVID-19 vaccines.

131. Partnerships are key to fight this pandemic, also with regard to ramping up production. The IP system also brings together various stakeholders as partners to continue research and development of COVID-19 health technologies to fight the current pandemic. IP is thus part of the solution and is not a barrier. Therefore, and as mentioned in our previous statements at the TRIPS Council, we are convinced that Members should address the pandemic in a holistic and sustainable manner and within the rules-based multilateral IP system in order to overcome this crisis quickly.

132. As for the small group consultations on 22 and 28 June, we observed on 5 July that the consultation enabled Members to discuss proposals documents IP/C/W/681 and IP/C/W/669/Rev.1 in a constructive, interactive and inclusive way. The day before, we were especially interested to obtain more information on how a waiver would concretely be implemented. Unfortunately, many of our questions remain unanswered. For instance, we still fail to understand how a waiver would be a quick solution for all Members, if Members wishing to implement it would need to amend their domestic legislations. We also do not understand how waiving obligations of the TRIPS Agreement would be consistent with other international obligations. Finally, we also fail to see how predictability and transparency would be ensured with regard to the implementation of the waiver.

133. Regarding the duration of the effects of a waiver, we still do not understand how confidential information, which would be disclosed during the application of a waiver, would be protected after its end. Indeed, the conditions of Article 39 § 2 of the TRIPS Agreement would not been fulfilled anymore; that means that once disclosed, such confidential information would lose protection forever. Related to this, let me add one follow-up question to the discussion on 5 July: If our understanding is correct, safeguards could be built in to ensure confidentiality under the waiver? How would this work and what would then be the reason to suspend the legal certainty and confidentiality we have now with TRIPS Agreement in the first place?

134. While these small group discussions have been helpful in deepening our exchanges also with a view on the status report for the July General Council, Members views on the issues such as scope, duration or implementation are still diverging and it seems that we did not come closer to reaching consensus so far. Switzerland is ready to continue these discussions and will engage constructively.

135. Regarding the schedule, Chair, we understand that your intention is to convene another consultation on 9 July. We reiterate what we have explained at the TRIPS Council on 30 June and hope that you will consider it: namely that to us, one small group consultation per week on a specific topic is appropriate to allow Members to prepare adequately. We believe that having more than one consultation per week would weaken the quality of our discussions and take us away from our common goal.

136. With respect to the meeting on 9 July, we are ready to engage with the understanding that we will continue our discussion on implementation, as we have not had enough time on 5 July to discuss this topic. In order to structure our discussions in line with a pragmatic, targeted solution-oriented and problem-based approach, we propose to discuss topics such as systemic

implications and short, medium and long-term effects at the small group consultations. We also reiterate our support to the suggestion made by Brazil to have a dedicated consultation on transfer of technologies and know-how.

137. We thank the proponents of proposal document IP/C/W/669/Rev.1 for reaching out bilaterally to discuss the way forward. In that meeting, Switzerland indicated its willingness to engage in this text-based process by continuing discussions on all proposals that have the objective of ramping-up production and ensuring access under the Chair-led process. This is without prejudice to the Swiss position as to the TRIPS waiver proposal as such. We also reiterated our view on the importance of voluntary cooperation in particular with a view to enable the crucial transfer of technologies and know-how for the complex production of vaccines. A Swiss manufacturer is producing drug substance. We therefore have first-hand experience on how important the collaboration between IP holder and manufacturer is. In this respect, we fail to understand how this cooperation could still work, not to mention be even better, without the legal certainty granted by the existing multilateral IP framework.

138. Switzerland remains ready to discuss with all Members how we can ensure a global and prompt access to COVID-19 health technologies with the aim to better understand the challenges concretely faced and identify the best way forward based on existing multilateral rules to achieve our common objective.

Switzerland's statement at the open-ended informal meeting held on 14 July 2021

139. My delegation would like to thank you for convening this open-ended informal meeting to inform the Council about your recent consultation and to consider next steps.

140. Switzerland constructively engages in these consultations and the Council's discussion of the proposals made by Members, based on proposed draft texts. We reiterate that this is without prejudice to Switzerland's position - that a waiver such as the one proposed in document IP/C/W/669/Rev.1 is not a useful means to achieve our shared goal of ramping up manufacturing capacity for COVID-19 vaccines to enable global and equitable access as quickly as possible and encourage the development of new health technologies against COVID-19.

141. My delegation would like to thank you, Chair, for allocating time in the most recent small group consultations to discuss questions and concerns raised by Members in relation to the potential implementation of the proposed waiver. Switzerland and other delegations questioned claims that a waiver would – or even could – be swiftly implemented by Members. Members are bound by international IP treaties other than the WTO TRIPS Agreement. These treaties are outside the realm of the WTO and would not be subject to such a TRIPS waiver. Then, there is the national dimension: the domestic regulatory framework would need to be amended which cannot be achieved simply or swiftly.

142. While possible safeguards that could be built in a waiver have been mentioned by proponents of proposal in document IP/C/W/669/Rev.1, our questions and concerns on this important issue have so far remained unanswered. Why would the legal certainty we now have with TRIPS then be given up in the first place? Members in the consultations reiterated their concerns with respect to the legal uncertainty resulting from the suspension of large parts of the TRIPS Agreement. This would throw into jeopardy more than 300 voluntary agreements and partnerships that engage so far internationally in ramping up manufacturing of COVID-19 vaccines and in developing respective health technologies. It would also have a chilling effect on the establishment of new such partnerships.

143. An implementation of the waiver in a permissive way, such as advocated by the proponents of proposal in document IP/C/W/669/Rev.1, does not mitigate these concerns. Indeed, a situation where every Member decides whether, how and to what extent it would apply such a waiver would result in even more uncertainty. The various stakeholders would have no idea under what conditions to operate transnationally – as opposed to the current situation where the minimum standards of the TRIPS Agreement provided a safe point of reference and necessary guidance.

144. A number of delegations raised questions and reiterated concerns on the short-/mid-/long-term effects of the proposed waiver. We disagree with the claim that a waiver

would have no negative effects and we believe that the Council should continue its consideration on the potential effects of such a waiver in relation to all three-time dimensions.

145. At the Council's informal meeting the previous week, my delegation mentioned the case of a Swiss manufacturer engaged in the fight against the current pandemic. We would like to provide more detailed information. The Swiss company Lonza provides drug substance manufacturing capacity to the US company Moderna for its COVID-19 vaccine. Lonza and Moderna announced in May 2020 a ten-year strategic collaboration agreement to support the manufacturing of Moderna's COVID-19 vaccine. With this collaboration agreement between them, it took the two companies eight more months of close collaboration, intense cooperation, innumerable contacts and exchange of skilled personnel as well as the sharing of know-how and transfer of technology before production of drug substance could start at Lonza's site in Visp.

146. On the basis of this successful cooperation, Moderna and Lonza announced last April their intention to double production by building three additional production lines. Lonza hopes that with the close support of Moderna to have these new lines in operation in the course of spring of 2022. This target date is only feasible thanks to Lonza's existing solutions facility, which covers the complete biopharmaceutical lifecycle (ranging from preclinical to commercial stages, from drug substance to drug product).

147. A major and urgent concern in this context is to find the necessary qualified specialist staff, from vaccines researchers to other expert employees to implement this project and adhere to the set time schedule. This is particularly challenging today, in times of the pandemic, where in the field of vaccines science the market for qualified research and other experts is close to dry out, and this at an international level. In this state of emergency, the Swiss Federal Government started to dispatch temporarily qualified employees from its own federal and university staff to support the ramping up of Lonza's manufacturing capacity.

148. This example demonstrates how quintessential the close collaboration between vaccine developers and qualified manufacturers is, how the success of their partnership depends on voluntary transfer of technologies and know-how to become operational in a reasonable and useful timeframe in order to be still relevant for fighting this pandemic together. It also highlights that a range of other complex challenges related more to operational matters need to be mastered also successfully. And yes, it also demonstrates that this is still demanding work in progress.

149. Against the backdrop of this case example, my delegation is clearly of the view that the proposed TRIPS waiver would put into jeopardy existing transnational partnerships and collaborations engaged in the manufacturing of new vaccines and the development of novel therapeutics. It also risks to prevent the establishment of new partnerships as the existing international regulatory framework, important part of which is the WTO's TRIPS Agreement, could no longer provide the required regulatory basis.

150. Turning to the status report to the General Council of 27 and 28 July: We agree that the two previous status reports can serve as its basis. We have discussed in various formats how best to achieve our common objective and the role of IP for the past weeks. While we had intensive consultations, including text-based discussions on documents IP/C/W/669/Rev.1 and IP/C/W/681, Members' views on the best approach to achieve our common goal are still diverging. There is no consensus on the approach to take or on the solutions contained in documents IP/C/W/669/Rev.1 and IP/C/W/681. Clearly, the status report must refer to all proposals (including document IP/C/W/681) on the table that were subject of the recent consultations and the Council's discussions, and that in the absence of a consensus, the Council will continue its discussions.

1.13 Brazil

151. We want to thank you for your report and for your stewardship in this process. The intense schedule of consultations and informal open-ended meetings held in the past week have helped us delve deeper in the technical aspects of both the waiver and the European Union proposals. As many delegations and you, Chair, have pointed out, there are other aspects to explore and some others to revisit. Brazil wants meaningful, timely and comprehensive solutions that empower all Members in their response to the challenges we are currently facing. In that spirit, we have been engaging in a constructive manner regarding all proposals on the table and are open also to discuss any other

idea put forward by Members. We urge all to approach these negotiations with the necessary mix of flexibility, urgency and pragmatism.

152. We hope that discussions to follow will continue to show the same frank spirit of engagement. We have been carefully listening to the different voices in this debate. Some Members do not feel sufficiently reassured of their margin of manoeuvre within the IP system to take measures to boost production of life-saving drugs and vaccines to fight the pandemic. If it is not sufficiently clarified that flexibilities in all domains of IP rights can and should be used to protect public health, we should provide that assurance to Members. Discussions have also shed light on certain areas of the Agreement that could be amenable to improvement. Simplifying packaging requirements and enhancing the scope of products covered by the Article 31*bis* could be a way forward to empower Members in the use of flexibilities for this and future pandemics.

153. All in all, we are convinced there is a landing zone for these discussions, and we are committed to working with Members to find common ground and to finalizing this negotiation with an important legacy for IP and Public Health. As we move forward in our discussions and as previously suggested by my delegation, we would like to see a more in-depth discussion on transfer of technology and know-how. It is Brazil's priority to augment the productive capacity of developing countries in the pharmaceutical and health sectors. To that end, it is important that we continue to explore ways to disseminate crucial technology and know-how. While ramping-up production, we must also deconcentrate it.

154. We welcome Director-General's Dr Ngozi Okonjo-Iweala initiative to hold, together with the Director-General of the WHO, Tedros Adhanom, the High-Level Dialogue on "Expanding COVID-19 Vaccine Manufacturing to Promote Equitable Access". We hope these and future discussions, within the DG's "third way approach", might provide an enhanced understanding of the progress made and the prospects for further expansion of productive capacity in developing countries.

155. We welcome current efforts from the WTO, WHO and WIPO to enhance their trilateral cooperation and invite them to continue to explore innovative ways to support Members, each in their respective areas of expertise, to attain our common goal of ensuring fair and equitable access to medicines, vaccines and other health products worldwide.

1.14 Indonesia

156. Indonesia would like to join others in thanking you Chair for convening this meeting and for your leadership during the course of many discussions of the waiver proposal. The discussions have been very insightful and it made us even more convinced on the immediate necessity of having the TRIPS waiver. In this opportunity we would also like to reiterate our support for the Chair's report to the General Council. The report captures factual information objectively. Regrettably, Indonesia would also like to state its profound disappointment to the WTO Members for not being able to reach consensus on this very important issue despite the situation we are facing right now. The TRIPS waiver should not be considered as only a possible deliverable for MC12, but it is something that we should pursue and conclude immediately.

157. However, we also appreciate the constructive engagement by all Members during the course of the negotiations guided skilfully by you, Chair. Furthermore, Indonesia supports the statement made by other co-sponsors in this regard. The waiver is crucial in addressing one of the key barriers to the global access of health products and health technologies for the prevention, containment, and treatment of the COVID-19 pandemic. The COVID-19 pandemic is still continuing and even in many parts of the world, including in my country, is still getting worse due to the mutation of the virus. As of today, we have reached 244,000 new cases during the last seven days. Our situation is not because we have not made efforts to obtain enough vaccines for people, we have used bilateral as well as multilateral avenues in this regard, but still we have not obtained enough vaccines for our 300 million people because there are not enough vaccines available. Our situation is also not because we do not have the industry to produce vaccine, but it is more due to the barriers regarding the access to the supply of vaccine raw materials, IP obstacles as well as transfer of technology barriers.

158. There are not many voluntary licensing agreements in developing countries, and it is making things very difficult for developing countries to produce its own vaccine. The situation is reflected from the WHO Emergency Use Listing Procedure (EUL) on COVID-19 vaccines; from five vaccines

which have been given EUL, only one is applied in a developing country, the rest are applied in high-income countries. The fact is that there are 70 manufacturers in middle- and low-income countries having the capabilities to produce vaccines, but they do not have the access to such voluntary licensing. COVAX, as a multilateral system, have only been able to distribute around 90 million doses of COVID-19 vaccines during the past six months, while the global need of vaccines is around 11 billion doses. It is inevitable that we immediately pursue and conclude a TRIPS waiver to address such IP obstacles.

159. We share the view of our colleagues from South Africa that IP rights are not absolute, they are subject to public interest, and such interest in such public interest exists now. The TRIPS waiver is the Members' way to uphold public interest and the livelihood of so many. We believe that the TRIPS waiver addresses many concerns of Members and it is not reasonable that it provides a minimum condition in our efforts for ramping up the conditions for diagnostic, therapeutics and vaccines for the prevention, containment and treatment of the COVID-19 pandemic. The TRIPS waiver proposal now has a clear scope and duration. The scope is now limited to health products and technologies necessary for the prevention, containment and treatment of COVID-19 pandemic as per the WHO list of priority medical devices. Of course, we are committed to continuing negotiation with a view to arriving at an agreement on the TRIPS waiver decision that could be acceptable noting that the waiver proposal is targeted, time-bound and proportionate.

160. We believe that the waiver offered by the proposal will be one key solution in addressing the COVID-19 global pandemic, especially in helping global access of vaccines and medical products especially for the developing and least developed countries and will leave a legacy which all WTO Members could be proud of one day.

1.15 Chinese Taipei

161. I would like to start by thanking you, Chair, on behalf of my delegation, for the efforts you have made to convene this meeting in order that we can address the important and difficult issues we are all facing today and will continue to encounter if no multilateral action can be found.

162. We also want to thank you for the status report you issued early last week, and to express our support for the suggested actions contained therein. The report, which is both neutral and fact-based, in our view provides an accurate summary of the discussion as it stands at the moment. We would also like to thank all the Members that have tabled their proposals and engaged in constructive discussions.

163. I am sure we all agree that the extraordinary circumstances caused by the COVID-19 pandemic require a rapid, effective and coordinated response. The ultimate goal of this particular multilateral approach should be to expand the production and supply of vaccines and other medical products, so as to address the critical shortages in a timely and efficient manner. We sincerely hope and trust that WTO Members, working together, will be able to find a practical and mutually agreed solution to achieve this common goal as soon as possible.

1.16 Saudi Arabia, Kingdom of

164. First of all, the Kingdom of Saudi Arabia offers its condolences to all families who lost their loved ones all over the world. We recall our previous statements and emphasize that the situation is extremely serious. People are dying and getting hospitalized, and there is no time to lose. What we are facing now is urgent need to take action. We urge all Members to cooperate and show the necessary flexibility to provide timely and secure access to safe and affordable vaccines for all. Globalisation teaches us many lessons, and one important lesson is that no one is safe until everyone is safe.

1.17 Japan

165. The delegation of Japan appreciates the efforts made by the Chair and the Secretariat to convene this TRIPS Council meeting and to make and finalize the draft oral status report. We support the draft reflecting and based on discussions in previous meetings

166. In order to overcome COVID-19, it is important to promote equitable access to vaccines throughout the world. Japan co-hosted the COVAX AMC Summit and contributed to securing the funds which exceeded the target amount of USD 8.3 billion. Also, Japan announced a financial contribution of USD 800 million in addition to existing contribution of USD 200 million. In addition to financial contribution to COVAX, Japan announced that it will provide around 30 million doses of vaccines manufactured in Japan to various countries and regions, including through the COVAX Facility. Japan also will make steady progress in establishing cold chains, as "Last One Mile Support" to ensure vaccination down to the last person. Japan will continue to work towards securing equitable access to safe, effective and quality-assured vaccines through various supports, responding to the needs of worldwide countries, including developing countries, in cooperation with relevant countries and international organizations.

167. Japan will constructively discuss various issues and measures with Members in order to expand the production of safe and effective vaccines and ensure globally fair and equitable distribution toward an early convergence. From this perspective, any ideas and proposals, which aim at improving the IP system as a means to overcome COVID-19, should be considered. However, these ideas or proposals should be effective in achieving these goals. We have a variety of issues to consider, such as 'scope' or 'duration'. However, we would like to stress that any uncertainty or delay of achieving these goals should not be caused by 'implementation' of any proposals.

168. We appreciate the proposal from European Union for the purpose of legal certainty of the compulsory licence system. The delegation of Japan notes its interest in the EU's proposal, and will continue to consider the proposal with WTO Members.

169. The small-group consultations and informal open-ended meetings were helpful in sharing Members' opinions. However, consideration has not yet been completed from a technical perspective. We appreciate again the efforts made by the Chair and the Secretariat to convene these meetings. Japan will continue to exchange views on the waiver proposal and the EU proposal closely with WTO Members, and at the same time, Japan remains committed to tackling various problems caused by COVID-19, together with the international community.

1.18 Paraguay

170. My delegation would like to thank you for your efforts in guiding this process, and for the draft report to the General Council which we support. Similarly, we would like to thank the proponents of the waiver as well as the European Union for their impeccable work in presenting and defending their various proposals. The discussions of the last few weeks have been extremely useful to clarify different aspects of the various approaches. To be brief, we shall make a one single statement on both items 1 and 2 of the agenda together.

171. Paraguay has followed the debate very closely and with great interest and is open to discussing in a constructive manner all the proposals that have a comprehensive approach, the main goal of which is to increase the production of vaccines as well as guaranteeing equitable access and distribution in the short term.

172. In the case of our country we repeat, as we have done in the past, the fact that we do not have any local vaccine production capacity and we depend on imports. Paraguay will consider positively any consensual solution that includes additional elements such as greater transparency on contracts, measures on facilitation to trade, elimination of restrictions to exports, cooperation in terms of transport and logistics, facilities to import for those countries which use any of the two approaches, including through the COVAX facility mechanisms which we believe could improve the equitable distribution between regions. This is why my delegation reiterates its interest in achieving a joint objective which consists in saving lives and hopes to be able to continue discussing other aspects in future sessions of the Council such as the example issue of technology transfer and know-how, exchange of relevant data and increasing local production capacity.

1.19 Korea, Republic of

173. Thank you Chair for the status report. We appreciate your continued efforts to give this process transparency. Korea finds the status report objectively reflecting the actual discussion at the TRIPS Council since the last status report. At the TRIPS Council, both the TRIPS waiver proposal and

the European Union proposal delegations exchanged views and sought clarification through consultation in various formats. As indicated in the report it seems obvious that, given the divergent views expressed by Members, this Council needs to continue its deliberations on these two proposals, and others, if any.

174. As reiterated several times previously, we believe that any discussions on IP-related issues at the TRIPS Council should serve as a process leading up to the broader package of the WTO overall response to the need for increased production and equitable distribution of vaccines. Korea hopes that Members will continue to discuss this and other proposals in an open and constructive manner and my delegation will also actively engage with others with a view to helping build consensus.

1.20 Singapore

175. Let me begin by expressing Singapore's appreciation for your able stewardship of the discussions this far. Singapore supports your oral status report to the General Council which is objective and factual. In the interest of time, Singapore also delivers one intervention addressing both agenda items 1 and 2.

176. Singapore would like to thank the proponents of the TRIPS waiver proposal and the European Union's proposal for your detailed explanations and clarifications over the course of the various meetings. The discussions you have had on the proposals have been valuable, and have given us much to reflect on. First, we must bear in mind right from the start that all of us have a shared objective of increasing vaccine production and enhancing equitable vaccine distribution. We have heard in past meetings in statements about the high rate of COVID-19 infections and death, especially in developing countries and LDCs. We are faced with a crisis that requires an urgent response and Singapore believes the equitable and universal access to COVID-19 vaccines is essential to contain the pandemic and for global economic recovery.

177. We must keep an open mind in exploring all possible pathways for us to achieve this shared objective. Technically, this crisis demands a holistic approach, and we must identify and use all available tools at our disposal. As such, it is important that the TRIPS Council continues its consideration of all proposals in achieving this objective. We note that there have been questions and concerns raised on the proposals which have yet to be addressed, such as on the implementation timelines or the operationalisation of the proposals. Singapore looks forward to sharing answers to these in subsequent meetings.

178. We must exercise greater flexibility if we want to achieve an acceptable outcome. Fundamental differences persist as to whether IP is indeed a barrier to increasing the production and distribution of vaccines and other medical supplies or whether the clarification of the existing TRIPS Articles is necessary. In order to achieve an outcome by MC12, Members must continue to engage constructively to address these differences and reach an agreement on a mutually acceptable way forward. Singapore reiterates our commitment to contribute constructively to the discussions on all proposals.

1.21 Venezuela, Bolivarian Republic of

179. Thank you Chair, we welcome your efforts and think that the draft report is a correct assessment of the situation. We join those who have complained about the slow progress made despite our meetings It is unfortunate that we are in a third wave with delta variant, with suffering of the poorest, most vulnerable countries with no more than 20% vaccination whereas industrialized countries have almost vaccinated their entire population. In a pandemic, in a context marked by limited capacity of production this far into the pandemic, it is unfortunate that we are still at this stage with no prospect of moving forward to enable us to save lives. We, lastly, would like to join what was said by the distinguished Ambassador of Cuba about the restrictions on imports on vaccines which should also look at the validity of measures that are unilateral and affect access to vaccines. This is necessary on behalf of industrialized countries to ensure universal access to vaccines.

1.22 New Zealand

180. New Zealand is very happy to endorse the status report that was circulated, for which we provide our thanks for all the hard work that has been put into it. New Zealand has been pleased

with the level of detailed engagement which has taken place recently through the combination of the Chair's consultations and the formal and informal meetings of the TRIPS Council. The elements of the waiver proposal have been thoroughly discussed and a wide range of perspectives have been canvassed. Discussions of this detail was key, allowing us to reach a common understanding of the means by which we can achieve our common objective, providing timely and secure access to high-quality, safe, efficacious, and affordable vaccines and medicines for all.

181. While the upscale of manufacturing is happening at pace, more must be done on the manufacture and in particular the distribution side to enable us to meet our common goal. New Zealand continues to support the conclusion of a waiver in relation to vaccines. This will form a key part of the overall WTO response to the pandemic in the pursuit of our common objectives. While further discussion is needed on the detail on product scope, coverage of disciplines, duration and the practicality of implementation, we are much further along the path than we were a month ago. It is our hope that we will be able to reach agreement in the coming months. The COVID-19 pandemic continues to create tragedy, hardship and loss for millions around the world. This Council, with the will of the Members, can contribute to the easing of those hardships.

1.23 Turkey

182. We would like to join other colleagues in expressing our support to your status report and our appreciation for your leadership and efforts. My statement will cover both proposals on the Council's agenda today.

183. We very much value discussions at the WTO on how to respond and contribute to the global fight against the COVID-19 pandemic. We observe that Members continue to be divided between two different approaches for delivering a swift response to possible IP-related issues. While a large group of Members are supporting a wide-ranging waiver on TRIPS Agreement for efforts to tackle the pandemic, others propose facilitation of the use of existing flexibilities provided in Articles 31 and 31*bis* of the TRIPS Agreement. We also take note of the divergent views among Members with respect to the advantages of these two different approaches and the concerns expressed about them.

184. We are of the view that both approaches proposed by the Members have their own merits and they are not necessarily alternatives to each other. We believe that we should continue our deliberations on both proposals, namely, the proposed waiver and the facilitation of the existing flexibilities, for reaching a meaningful and effective outcome to address the IP-related issues in the fight against the pandemic. For this purpose, we invite all Members, including the proponents of the proposals, to engage constructively in discussions for addressing the concerns raised about the existing proposals, and bridging the gap between Members.

185. While we believe that the proposed waiver may provide Members with important policy-space on IP-related issues during the fight against the pandemic, the product scope and the termination of the waiver still need further clarifications. We think that an intensified and focused text-based discussion may bring a common-ground on those matters.

186. On the other hand, we would like to thank the European Union for its preliminary answers to our questions on its proposal during the informal deliberations of the Council. While we continue to reflect on these answers, we still believe that further clarifications are needed on this proposal with regard to the extension it brings on the existing flexibilities in Articles 31 and 31*bis* of the TRIPS Agreement. Turkey is ready to engage in discussions with all Members to reach a meaningful, relevant and timely answer to the possible IP-issues in the fight against the pandemic.

1.24 United States of America

187. I would like to say that we appreciate the efforts of India, South Africa and the other waiver proponents, as well as the European Union in putting forward proposals. We are grateful for the Chair's work in facilitating various small-group, informal and formal meetings of the TRIPS Council membership to engage on these proposals. The United States believes that it is important that all formal proposals be given due consideration by the TRIPS Council and we welcome additional proposals from other Members. We continue to urge Members to focus on proposals that are pragmatic and that gain consensus from the TRIPS Council in a timely manner. With respect to the

proposed report by the Chair to the General Council on this agenda item, we support the proposed language as it provides a factual description of the process and status since the last report.

1.25 India

188. At the outset my delegation would like to thank you for your endeavours in taking this process forward. We would also thank Members who have unequivocally supported the waiver proposal. The past year-and-a-half has been unprecedented in the history of this Organization with regards to where we have reached on the wavier and our continuous engagement on the proposal, and more so because of the waning enthusiasm to finalise it. Since the previous formal TRIPS Council meeting on 8 and 9 June 2021, we have had several rounds of small-group meetings and informal TRIPS Council meetings to take stock of the progress made. These meetings gave the opportunity to Members to discuss in detail key elements of the waiver proposal like the scope of products as well as the scope of IP, implementation issues, the duration for which the waiver would be in place and other relevant elements.

189. I also take this opportunity to inform Members on the outreach undertaken by the proponents of the waiver proposal. In continuation of our outreach to Members on this proposal in the previous two weeks, proponents have engaged bilaterally with several Members and have explained in detail the reason and rationale behind the proposal, with an aim to respond to all their concerns. In these discussions we have proposed to a few Members to engage bilaterally on the text and iron out the differences in a focused manner. However, there seems to be little enthusiasm among these Members to engage bilaterally on detailed text negotiation. Generally, we have seen Members have been receptive of such bilaterals during fisheries negotiations. The lack of enthusiasm substantiates our fear that a few Members have agreed for the text-based negotiations, but not with an intent of concluding it. Most of the questions and concerns raised by these Members with regards to the waiver text were repetitive and had already been answered in detail, and those responses are contained in the documents IP/C/W/670, IP/C/W/672, IP/C/W/673 and IP/C/W/674. The co-sponsors have engaged positively and responded to these questions at the small-group meetings. However, such beating around the bush has only led to losing precious time that also means losing lives. Clearly, and sadly indeed, the delaying tactics of these few Members has worked, and that entails that we will not be able to deliver the outcome by end of July.

190. For the sake of time, my delegation will not repeat the detailed responses and statements made in the small group and open-ended meetings, and provide these as my written statement to the Secretariat to be incorporated in the minutes of the present formal meeting.

191. As the challenges posed by the pandemic are still unfolding, we would still need to work towards collaborative efforts to combat COVID-19. In this regard, while discussions are moving forward on various proposals seeking to combat the crisis and enhance preparedness for future pandemics, it is our firm belief that the TRIPS waiver proposal remains at the core of our response and preparedness. It is also important that we agree on the waiver as it aims at relieving the supply side constraints. The waiver entails enhancing the production and the supply of vaccines and other COVID-related products. This is addressing the root cause of most problems with respect to distribution, access and affordability. The past ten months have been spent discussing the waiver, we have lost three million more people with new variants adding to the uncertainties surmounting us.

192. Only 2% of the least developed countries that represent 14% of the world population and 23% of developing countries that represent 70% of the world population have received at least a single shot as of June 2021, compared to 46% of the developed world. With less than 1% of vaccines administered in low-income nations, increasingly we see that a two-track pandemic is developing, with richer countries having access, while poorer nations being left behind. Each nation's fate is entwined with that of the other, while developed country Members have outpaced developing and LDCs in vaccinations, and have also secured supplies for future doses, such a differential approach will not help us in ending the pandemic, as the virus does not differentiate and discriminate in affecting people.

193. Despite Members agreeing to the collective goal of saving lives and the consequent need of augmenting production of vaccines, therapeutics and diagnostics needed to combat COVID-19, we see a lack of urgency and enthusiasm by a few Members to reach a conclusive decision on the waiver.

Time is of the essence. We should not miss the opportunity of finalising the waiver. The extraordinary circumstances of the pandemic demand more than a moderate collective response, and everyone in a position to contribute must do so. Members have agreed to pursue different approaches simultaneously in this regard, and without prejudice to each other. The co-sponsors of the waiver proposal have reiterated that they welcome all proposals. However, this understanding from the co-sponsors have been construed differently. What we intend to say is that each proposal should be considered on its own merit and follow its own course, and agreeing on the waiver does not mean that we cannot agree on anything else or vice versa.

194. We have also clearly stated in several meetings earlier that the two proposals cannot be clubbed together as they follow different procedures and legal approaches and with this understanding, we have engaged in discussions on the European Union proposal in good faith, but this has not been reciprocated. We have never said that there could only be one approach which could deliver. No single mechanism will be able to provide a perfect solution for this crisis.

195. There have been questions with regards to the uncertainty that the waiver may bring. On the contrary, we understand that in fact the waiver would provide more companies with the freedom to operate and to produce more without the fear of infringing on other parties' rights and the threat of litigation. From what has been reiterated often by a few Members, that they do not see the waiver as a response to the crisis, this argument compels us to think that perhaps we do not share the urgency, severity and need for quick solutions to put an end to the pandemic. The waiver is necessary at this time as the existing flexibilities in the TRIPS Agreement have not proved to be sufficient in the context of the pandemic. Additionally, the insufficient voluntary mechanism and engagement by pharmaceutical companies to scale up manufacturing makes the waiver an important policy response for radically increasing manufacturing capacity and thus ensuring sufficient supplies and facilitating pathways to achieve equitable access.

196. The waiver will be a critical ingredient of the multi-pronged approach to combat the pandemic. The proponents have argued previously on many occasions how flexibilities provided in the TRIPS Agreement are inadequate in responding to the pandemic of this magnitude. The limited policy space provided by the TRIPS Agreement flexibility to address monopoly actions through the issuing of compulsory licences would not be a feasible option in a pandemic. Beyond patents, other IP rights including trade secrets, industrial designs, copyrights etc. also pose barriers. Compulsory licensing does not address the barriers posed by these rights. In fact, these limitations posed by compulsory licensing can be addressed by the waiver. The waiver, once approved and applied, would provide countries with an effective and expeditious way to remove IP barriers that scuttle the use of latent capacities.

197. Lastly, it is imperative of us that we logically and meaningfully conclude what we started. It is important that the waiver proposal is taken forward constructively and finalised expeditiously. The discussions that were held in the small-group meetings on the draft of the oral report of the Chair to the General Council do not reflect our position. Such a report to the General Council by a subsidiary body, mandated by Article 9.3 should contain only deliberations with respect to the waiver and other discussions on the TRIPS Council on other proposals could be reflected separately. However, in the spirit of compromise this was agreed to have a report to the General Council and also to help move the process forward. It is our view that any other discussions on other proposals should be looked at separately and are not mutually exclusive or clubbed together with the waiver proposal.

198. While we have been painstakingly creating this rules-based system, it is to our dismay that the rules here get selectively interpreted and run contrary to our understanding of the rule of law. These derogations would not help in our efforts of restoring the credibility of this Organization in the midst of the pandemic. This cannot be achieved without delivering on the solutions that would help scale up production of life-saving vaccines, therapeutics and diagnostics and ensure access for all.

India's statement at the small-group meeting held on 22 June 2021

199. Let me begin by thanking Members for their continuous engagement on this critical issue, I also thank the Chair for his tireless efforts and guidance in bringing this together to this point where today we begin substantive discussions on the text, we have come a long way in these nine months, wherein we have engaged and discussed the waiver proposal thoroughly and have now achieved concurrence on a range of crucial issues that are pertinent in formulating the solutions to the pandemic. We have acknowledged the existence of supply side problems and therefore the need for

expanding manufacturing, we have recognised that there is idle and latent capacity that needs to be harnessed, we agree that different aspects of IP and IP-related barriers are impeding the availability and accessibility of vaccines and other products required for prevention, treatment and containment of COVID-19, we are also looking at the limitations of existing TRIPS flexibilities in a pandemic situation especially the need to improve upon compulsory licences. This summarises our work so far and would be the basis to continue discussions on the text with a view to finalise it before the next General Council.

200. Chair as the proponents of the proposal and as suggested by you Chair in the previous informal meeting, we will begin by discussing the scope. The scope comprises of two elements i.e. the scope of products covered by the waiver and the scope of different aspects of IP, it would be prudent to focus the discussions today on scope of the products.

201. Let me take this opportunity to briefly reiterate and explain the rationale behind the proposed Scope. The operative paragraph 1 of revised waiver text in document IP/C/W/669/Rev 1. has been revised to add specificity to the decision text in response to the concern that the original decision text was too broad. Hence the revised text addresses this concern by focusing the language in the paragraph on "health products and technologies" as the prevention, treatment or containment of COVID-19 involves a range of products, their materials or components, as well as their methods and means of manufacture.

202. The TRIPS waiver proposal is motivated by the need for swift ramping up of manufacturing, to address alleviate the supply side concerns for timely availability, accessibility and affordability of the required products to prevent, treat and contain COVID-19.

203. Hence, the starting point in determining the scope of health products and technologies to be covered by the text is to determine what is needed to prevent, treat, or contain COVID-19. Any strategy that does not address these three elements simultaneously would fall short of yielding any positive results.

204. We have learnt from experiences of the past year and a half that it is critical to scale up production and access to personal protective equipment (PPE), masks, testing kits, ventilators, diagnostics, therapeutics apart from vaccines to prevent the spread and to treat the disease and prevent deaths. These resources have been in acute shortage in many countries leading to limited accessibility. It became clear that the prevention, containment and treatment of COVID-19 involves a range of health products and technologies. It is clear that vaccines are necessary but not sufficient to respond to the pandemic in the short term

205. The scope of products is also reflected in the national COVID-19 response strategies, of many countries that acknowledge the need to ensure equitable access to critical COVID-19 PPE, tests, therapeutics, and vaccines. For example, one of the therapeutic strategy states "vaccines will not eliminate the disease overnight and therapeutics will still be needed for patients in hospitals and at home, including people suffering from 'long COVID' (the long-term effects of COVID-19 infection). For these reasons, therapeutics will continue to play a significant role in the response to COVID-19.

206. In a similar vein another Member recognizes antiviral medicines as part of the whole-of-government strategy. What these statements reveal is that therapeutics are expected to play a role in addressing the response gaps in the pandemic. WHO's consultations on COVID-19 therapeutics reveals that a range of therapeutics will be required including "drug combinations targeting specific aspects of infection, as well as suites of treatments targeting different disease processes (such as antivirals, immunomodulators and anti-coagulants)"[1]. Thus, one cannot ignore therapeutics, diagnostics or other health technologies relevant and required to combat COVID-19.

207. Equally critical are diagnostics, as the ACT-A strategy recognizes that "Testing is a critical element in the armoury of tools needed to defeat COVID-19. Without it, the spread of the virus cannot be tracked or contained, patients cannot access the care they need, the efficacy of vaccines cannot be assessed, nor the emergence of new variants detected. Major gaps in testing are still putting lives at risk and threatening progress to end the pandemic. There is an urgent need to scale up testing and ensure immediate, equitable access to diagnostic tools in every country across the

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

world. In high-income countries there are 603 tests per 100 thousand of population compared to about 100 tests in middle income countries and about five tests in low-income countries.[2] We stress that the disparity in testing is hindering efforts to control the pandemic. No country can afford to adopt only one intervention in this pandemic. Vaccination and test and treat strategies are needed alongside other interventions.

208. In this context, it is justified that the revised text extends to "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19." Having said that Chair, we would like to hear from delegations their views on the scope of products proposed by the co-sponsors in the revised decision text.

India's statement at the small-group meeting held on 28 June 2021

209. On 22 June, discussions were held on the scope of products and the co-sponsors provided justification for the scope of products proposed in the revised decision text. Today the discussion would be focussed on the scope of IP with regards to these products. Therefore, the proposal calls for a waiver of the application, implementation, and enforcement of TRIPS provisions on copyright (Section 1), industrial designs (Section 4), patents (Section 5) and protection of undisclosed information (Section 7).

210. These categories of intellectual property are relevant to the production, supply, and access to COVID-19 health products and technologies. We also point out that Paragraph 3 of the revised text makes explicit that the waiver will not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.

211. The proponents have made several submissions highlighting the relevance of addressing existing and potential IP issues in copyright, industrial designs, patents, and protection of undisclosed information.

212. Let me also reiterate here that the proponents at no point have argued against the Intellectual Property rights in fact most of us have robust domestic frameworks protecting Intellectual property rights. We must bear in mind that the proposal calls for a limited period waiver from these four sections and is an exceptional measure for exceptional circumstances like these.

Patents

213. The patent landscape usually varies from product to product and country by country. In the case of COVID-19, the patent landscape remains quite uncertain as many patent applications are yet to be published.

214. In the case of mRNA vaccines there is a complex web of patent holdings. While larger companies involved in product development may have a patent portfolio, the patents portfolio to the underlying technology is held by numerous other academic labs or small biotech companies. This reveals the complex patent landscape that exists with respect to mRNA technology.

215. In the case of therapeutics, in document IP/C/W/670 the co-sponsors have presented a preliminary patent landscape that offers a non-exhaustive snapshot of the patent filing and granting status on five selected therapeutics candidates. However, many more therapeutics are being investigated and evaluated for efficacy against COVID-19. Some of the therapeutics under investigation are presently off-patent but as its use is explored for COVID-19 treatment, the filing of new patent applications extending to secondary uses of these therapeutics is expected. A similar situation exists with respect to other health products and technologies as well.

Trade Secret Protection

216. In addition to patents trade secret protection is another hurdle to access various health products and technologies. With respect to vaccines and bio-therapeutics, the manufacturing methods and techniques (know-how) tend to be protected by trade secrets. This includes dossiers

[2] http://www.finddx.org/covid-19/test-tracker/

to obtain regulatory approval that will usually include robust information regarding the manufacturing process, formulation and dosage, method of delivery, storage conditions, indicated uses along with safety and efficacy information. Hence the importance of addressing protection of undisclosed information under Article 39 of TRIPS.

217. Lifting trade secret protection is essential to expanding and diversifying global production. For instance, by waiving trade secret protection, and as a start facilitating the sharing of regulatory dossiers especially with potential manufacturers, existing production capacity especially in developing countries can be mobilised. And as demonstrated sufficiently now most recently by the event hosted on the 14 April where interaction with several pharmaceutical companies did show that several unused capacities do exist in several developing countries.

218. The slow roll out of vaccination in developing countries is testament to the fact that the current system of production and supply is not working to deliver equitable access. Numerous examples have been reported of the industry turning down offers of help from other drug makers, including those from developing countries, to boost global manufacturing and supply. There have been and continue to be similar experiences in developing countries and least developed countries. We have also provided other examples in paragraph 43 of document IP/C/W/672 and paragraph 65 in document IP/C/W/673.

219. These numerous examples show how in a pandemic we cannot rely solely on *ad hoc*, non-transparent and unaccountable voluntary mechanisms. The existing mechanisms are not delivering and artificially constraining supply, at the expense of prolonging the pandemic, lives and live hoods around the world. A pandemic by nature of its spread, severity and uncertainty needs global collaboration and extraordinary measures.

220. We need supply now and at least in the near future and we need supply at affordable prices. With developed country Members prebooking future supply for boosters and additional rounds of vaccination, we urgently need to ramp up manufacturing and this requires the lifting of trade secret protection. Expanding manufacturing of health products is crucial not only for this pandemic but also for future pandemics. The waiver, if granted, would provide potential manufacturers the freedom to operate and achieve economies of scale, thereby incentivizing production and supply of therapeutics and vaccines.

Copyright and Industrial Designs

221. Copyright and Industrial Designs are also categories of IP that may hinder production and supply. Copyright issues may also arise in other situations such as with respect to software in medical devices, compilation of data and algorithms, product information documents or product labelling, diagnostic kits, and digital technologies, etc.

222. In document IP/C/W/673, the co-sponsors responded in detail from paragraph 54 to 63 on the industrial design and copyright challenges faced by Members in procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines. In the same document the co-sponsors illustrated the case where a hospital ran out of ventilator valves and had 3D-printed replacement valves at a much lower cost, but it was stymied by threats of IP infringement.

223. These instances elucidate that complex intellectual property issues are involved in the manufacture and supply of needed health technologies and their parts, and these issues go beyond patents.

224. The proponents and the co-sponsors of the waiver have these four elements in scope of IP as we believe that rather than entering discussions on the nitty-gritties of the relevance of each section we must work towards the final objective that is to ramp up production and save lives. We must list out all possible elements of IP that may be a barrier in achieving our final goal.

225. Finally, would like to draw attention to the fact that we often tend to overlook the lessons learned from the HIV/AIDS crisis where an absence of IP landscape did enable augmenting production of life saving generic drugs, thereby enhancing both accessibility and affordability of ARVs and FDCs which helped saved millions of lives. The current pandemic is far worse, severe and unprecedented, the waiver would be an enabler to boost the production of vaccines, therapeutics

and other health products needed to combat the virus. Increased production coupled with robust competition; we see a substantial reduction in prices. Here would give an example of a study that shows that for products with a single generic producer, the generic Average Manufacture Price is 39% lower than the brand AMP before generic competition, with two competitors, that generic prices are 54% lower with four competitors the generic prices are 79% less than the brand drug price before generic entry and with six or more competitors, generic prices show price reductions of more than 95% compared to brand prices.

226. Thus, the waiver would aid in ramping up production, fill the supply side gaps, and this augmented supply would ensure both accessibility and affordability. We are of the view that a waiver once implemented will provide greater certainty to manufacturers by providing them freedom to operate, and for governments to collaborate to increase supply options. Waiver being sought for a limited period and that too only from some specific TRIPS provisions in such testing times does not increase uncertainty for the IP system. This is not an ideological debate on the IP regime per say. Instead, it shows that in exceptional circumstances, the IP system can be flexible and accommodating and one that can be manoeuvred to suitably address the unprecedented challenges posed by the pandemic. We have heard from some Members in the recent meetings that they do not see waiver as a part of the solution, and do not see how IP is a barrier even for vaccines production. Had that been the case why have these Members agreed to engage in the text-based negotiations on the waiver proposal which was clear from the previous formal meeting held on 8-9 June 2021. Was this the case such Members should be more forthcoming during the discussions on whether to start the text-based negotiations or not. Or is it an attempt to filibuster the entire process? And hopefully if that is not the case, we would urge Members to engage constructively and in good faith on the waiver text under consideration with an aim to finalise it.

227. It will be presumptuous to think that the co-proponents do not believe in IPR, some Members have argued that they do not see waiver of IP resulting in augmenting manufacturing or as a measure easing supply side constraints, or having impact outside voluntary licensing mechanisms , on the other hand they firmly believe and argue that this proposal will cause significant damage to commercial interests of IP rights holders so both arguments cannot be true at the same time, we cannot have the cake and eat it too. And if the proposal seriously damages the commercial interests of a few private entities by ramping up production then we are on our way to achieve our objective. And if the waiver fails to succeed as some Members say there will be no harm to commercial interests and this could be another tool in the WTO policy toolkit.

228. We have agreed to work on a multipronged approach to tackle the crisis and finalising the waiver is a step forward towards our end goal of saving lives. Thus, discussions must be continued in a constructive and focussed manner on the waiver text towards achieving this. Other proposals will be considered separately and not in tandem with the waiver proposal.

229. These elaborate explanations provide the basis of including in the revised decision text the relevant parts of the TRIPS Agreement within the scope of IP, that should be waived to ramp up production and supply.

India's statement at the informal meeting held on 30 June 2021

230. Chair, I thank you for your summary of the discussions that took place in the small group meetings held on 22 and 28 June 2021. There were several questions posed and answers provided both on the scope of products as well as on the scope of IP. While all Members have committed to engage in text-based negotiations it is disappointing to note that some Members are not willing to contribute to the waiver text with an aim to finalize it.

231. In the past nine months we all have invested our time and energy in discussing the waiver proposal in various formats formal informal at the TRIPS Council, in small group meetings as well as in bilateral engagements. All Members have concurred that there is a dire need to enhance the production of health products including vaccines, diagnostics, and therapeutics to ensure timely and equitable access. All Members have further agreed that various ways can be pursued simultaneously and without prejudice to each other. Furthermore, Members including the proponents and co-sponsors of the waiver proposal have said that they welcome all proposals, and it is only fair to say that each proposal should be considered on its own merit and as to what it brings on the table as a part of the solution. The waiver has been a standalone agenda item and cannot be clubbed together with any other proposal, the waiver proposal will follow a different procedural course under

Article IX.3 of the Marrakesh Agreement. Its therefore not clear as to how the waiver and the European Union proposal stand on equal footing.

232. From what has been reiterated often by some Members that they do not see waiver as a response to the crisis, well more than half of the membership does see waiver as a legitimate policy option that could be used to offset the supply side constraints. This argument compels us to think that perhaps we are not on the same boat and the urgency, severity, and the need for quick solution in the form of waiver would depend on the vantage point of the Member, whether you are the one who has secured access to vaccines, therapeutics medicines or you are part of the scramble.

233. On the EU proposal, notwithstanding the fact that compulsory licences and other TRIPS flexibilities are important, but the limited policy space provided by the TRIPS Agreement flexibilities to address egregious monopoly actions through issue of compulsory licences has not until now proved to be a feasible and expeditious option in a pandemic of this scale and magnitude.

234. Invoking compulsory licences across a wide range of medical products, that too on a "case by case" or "product by product" basis is a cumbersome and time-consuming process, severely limiting their effectiveness, in the context of products and technologies required for fighting the virus. Beyond patents, other IP rights, including trade secrets, industrial designs, copyrights, etc. also pose barriers. Compulsory Licensing does not address the barriers posed by these rights. The understanding and implementation of TRIPS flexibilities in IPRs other than patents are limited making their use to address the supply side constraints for products required for dealing with ongoing pandemic not a viable option.

235. Additionally, the medical technologies required for COVID-19 response are surrounded by a thicket of patents and other intellectual property rights. Practically, operating within the current system means that each country is obligated to use its stretched human resources to identify which of the patents and other IPRs are relevant and thus should become the object of a compulsory licence. The accompanying delays in such a process are unacceptable in an emergency like this.

236. Furthermore, Article 31*bis* which allows export to countries with insufficient or no manufacturing capacity, is subject to extremely cumbersome and lengthy procedures, rendering it meaningless and impractical to use especially in a pandemic where each delay costs several lives. Simply put, there are currently no provisions in TRIPS Agreement to allow countries to act more expeditiously in a global crisis to use Article 31 compulsory licensing to export without limitation on quantity and other additional procedural requirements. In fact, these limitations posed by the compulsory licences can be easily addressed by the waiver. Moreover, the EU proposal does not bring any value add to the existing flexibilities rather a fundamental flexibility enjoyed by WTO Members to determine any grounds for compulsory licensing as explicitly affirmed by Doha Declaration, the proposal however as an unintended consequence asks for an agreement to be reached to allow WTO Members to use the pandemic as a ground for issuing compulsory licensing thereby reducing the existing flexibility enjoyed by all WTO Members.

237. I stated in an earlier discussion Chair, that if a particular prescription is not effective in treating a disease then, it is only logical and prudent to find a new prescription, we do not continue following the old prescription.

238. Chair, lastly, it is imperative upon us that we logically and meaningfully conclude what we started, it is important that the waiver proposal is taken forward constructively and finalized expeditiously. We look forward to intensive discussions on other elements of the waiver text including the implementation issues and duration in the upcoming TRIPS Council meetings.

239. The credibility of this organization will not be successfully reinstated if it overlooks vital policy options like the waiver that acts as an enabler, a policy option among the many options being discussed, for Members to use as per their own needs and circumstances. We owe this not just to ourselves but to our future generations as well.

240. Members have often said this crisis is unprecedented, we need extraordinary measures, we need concerted multilateral efforts, saving lives is a priority, no one is safe until everyone is safe well the time to act on this is now. Now is the time Chair for us to walk the talk.

India's statement at the small-group meeting held on 5 July 2021

241. The WHO COVID-19 dashboard of 4 July 2021 shows that there have been over 184 million confirmed cases of COVID-19, including 3.9 million deaths, reported to WHO. As of 1 July 2021, a total of 2.95 billion vaccine doses have been administered. 75% of these doses, however, have been administered in the developed country Members. Only about 1% of people in low-income countries have received at least one dose. Until June not more than 3 billion vaccines have been produced, it is difficult to fathom how without taking exceptional measures, like agreeing to the waiver proposal, will we be able to reach an output of even 10 billion doses by the end of the current year. Again, we often forget that it's not just the availability of supply but also the vast inequity both in accessibility and affordability of these supplies.

242. Previously as well, in several discussions the proponents of the waiver proposal have presented their understanding and rationale behind the proposed implementation and duration of the waiver. We are grappling with a novel pathogen, and this novelty brings with it many uncertainties. There are emerging variants and mutations and while we are better off in our understanding of the virus than the previous year still many unknowns remain with respect to the duration of immunity provided by the vaccines, effectiveness of these vaccines against new variants, whether or not there will be a need for a booster dose, or the requirement for an annual vaccination.

243. All these elements such as the duration of immunity conferred, need for booster doses, effectiveness of vaccines against new variants, and the need of vaccines for children will determine the scale of manufacturing needed and supply that will be needed to control the pandemic, and this is just for the vaccines. Production for therapeutics, diagnostics and other COVID 19 related health products will also need to be ramped up in order to diagnose and treat people as subsequent waves continue infecting people across the globe.

244. Therefore, with regards the time or duration of the waiver the revision text states that the waiver shall be in force for at least three years from the date of this decision. And the uncertainties and reasons that we just cited along with the concerns raised by Members in earlier meetings on the original text, the proponents have proposed this, this also clearly captures the temporary nature of the waiver. Furthermore, the General Council shall determine the date of termination of the waiver, once the exceptional circumstances justifying the waiver cease to exist.

245. What needs to be guiding us while deciding on the timeline therefore is that the duration also has to be practical for manufacturing to be feasible and viable. The complexities and uncertainties related to the pandemic suggest the need for a practical and flexible duration. Hence it is proposed that the General Council assesses the existence of the exceptional circumstances justifying the waiver after a minimum period to determine the date of termination. The proposed language is based on Article IX (4) of the WTO Agreement. Importantly, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement, the waiver shall be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates.

246. Now coming to the implementation of the waiver, we have reiterated that the waiver is not a prescriptive tool, it's an enabler. National implementation of the waiver depends on a country's political and/or constitutional arrangement. There is no one size fits all approach to national implementation. However, once the waiver proposal is approved, emergency, disaster management legislations or any other relevant legislative methodology may be relied upon to provide for executive action to operationalise the waiver at the national level. Many governments have/are already using executive action to put in place lockdowns, quarantine, and other measures to curb the spread of present pandemic.

247. As we have mentioned, at several meetings earlier on this issue the national implementation should be left to national governments as each operates within its own legal system. We also believe that in many cases implementation may be done through executive action, relying on existing national legislation or through use of emergency legislative provisions.

India's statement at the informal meeting held on 6 July 2021

248. Chair let me thank you for your efforts in taking this process forward, the past few meetings in the small group format were quite helpful in taking these discussions forward and inputs from Members does help in improving the text and arriving at a landing zone.

249. Chair before coming to the substantive part of the intervention, as suggested by you yesterday Chair, I take this opportunity to inform Members on the outreach undertaken by the proponents of the waiver Proposal. In continuation of our outreach to Members on this proposal in the last two weeks proponents have engaged bilaterally with several Members and have explained in detail the reason, rationale behind the proposal, with an aim to respond to all concerns raised. In these discussions we proposed to some Members to engage bilaterally on the text and iron out the differences in a focused manner, however, there seems to be little enthusiasm among these Members to engage bilaterally to discuss the text. Generally, Members have been receptive of such bilateral during fisheries negotiations, chair this lack of enthusiasm substantiates our fear that some Members have agreed for TBN but not with an intent of concluding it.

250. Chair in the short time span when we have begun 13 million people have got further infected, and 430 thousand more lives have been lost. In total so far there have been over 184 million confirmed cases of COVID-19, including 3.9 million deaths, reported to WHO as per the WHO COVID-19 dashboard of 4th July 2021. Chair, time is of the essence we do not want to miss the opportunity of finalizing the waiver in July and get going on finding modalities for ramping up production for COVID-19 related health products.

251. As of 1 July 2021, a total of 2.95 billion vaccine doses have been administered. 75% of these doses, however, have been administered in the developed country Members. Only about 1% of people in low-income countries have received at least one dose. Until June not more than 3 billion vaccines have been produced, it is difficult to fathom how without taking exceptional measures, like agreeing to the waiver proposal, will we be able to reach an output of even 10 billion doses by the end of the current year. Again, we often forget that it is not just the availability of supply but also the vast inequity both in accessibility and affordability of these supplies.

252. Previously as well, in several discussions the proponents of the waiver proposal have presented their understanding and rationale behind the proposed implementation and duration of the waiver. We are grappling with a novel pathogen, still many unknowns remain with respect to the duration of immunity provided by the vaccines, whether there will be a need for a booster dose, or the requirement for an annual vaccination also there are varying reports on how long it will take to roll out vaccination globally to ensure immunity. Demand in developed country Members for booster doses and vaccines for teens and children will further impact supply in developing countries. And even more importantly, vaccines will not only be needed in 2021 but also beyond. Some developed country Members have already reserved vaccines right up to 2025.

253. Among all these uncertainties one thing is certain and clear to us that wherever vaccination rates are higher the severity of the disease in the form of hospitalization and mortality is lower. Augmenting the manufacturing of vaccines as of now seems to be the only way to save lives and therefore we should aim for producing 14 billion doses by the end of 2021.

254. Chair, apart from vaccines production for therapeutics, diagnostics and other COVID-19 related health products will also need to be ramped up to diagnose and treat people as subsequent waves continue infecting people across the globe. The pandemic has already gone on for 1.5 years and right now no end in sight with infections rising in most countries. While the pandemic continues unabated it would be unwise for us to have a short time frame for a TRIPS waiver.

255. What needs to be guiding us while deciding on the timeline therefore is that the duration of the waiver must be practical to scale up manufacturing a noticeably short time might not be feasible and viable for the intended purpose of ramping up manufacturing.

256. With these reasons in mind the proponents in the revision text have proposed that the waiver shall be in force for at least three years from the date of this decision. This also was in response to concerns raised by Members in earlier meetings on the original text, this duration also clearly captures the temporary nature of the waiver. The duration of three years is also reflective of the fact that co proponents at no point in time have intended for the waiver to be of an indefinite nature.

257. Further it is proposed that the General Council assesses the existence of the exceptional circumstances justifying the waiver after a minimum period to determine the date of termination. The proposed language is based on Article IX (4) of the WTO Agreement. Importantly, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement, the waiver shall be reviewed

by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates. And as was discussed in the small group meeting yesterday we are open to deliberate on these aspects further based on any suggestions.

258. Now coming to the implementation part of the waiver and responding to the concerns raised by Members with respect to lack of guidance or mechanism in the text on the domestic implementation of the waiver, we have reiterated that the waiver is not a prescriptive tool, it is an enabler and therefore national implementation of the waiver depends on a country's political and/or constitutional arrangement. There is no one size fits all approach to national implementation. However, once the waiver proposal is approved, emergency, disaster management legislations or any other relevant legislative methodology may be relied upon to provide for executive action to operationalise the waiver at the national level. Many governments have/are already using executive action to put in place lockdowns, quarantine, and other measures to curb the spread of present pandemic.

Rebuttal

259. TRIPS flexibilities have played a crucial role in promoting access to medicines. The use of such flexibilities and the waiver are not mutually exclusive. However, the global pandemic presents exceptional circumstances for the international community that demands an exceptional global solution. After all, countries all over the world have had to put in place extraordinary measures to contain COVID-19.

260. Compulsory licences are issued on a country by country, case by case and product by product basis, where every jurisdiction with patents would have to issue compulsory licence, practically making collaboration among countries for the development and manufacturing of medical products (where different components are sourced from different countries) onerous.

261. Further Article 31*bis* mechanism (that waives the condition in Article 31(f) that a compulsory licence should be predominantly for the supply of the domestic market) established to support countries with insufficient pharmaceutical manufacturing capacity has been found to be cumbersome like the mechanism includes procedures such specific labelling or marking of products; special packaging and/or special colouring/shaping of products. Moreover, the E.U proposal does not bring any value add to the existing flexibilities, it seeks to clarify something that is not in dispute on the contrary could limit existing flexibility.

262. Much has been said about "business as usual voluntary licensing" as the way out of this pandemic and yet more than a 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, and is artificially constraining global supply.

263. These "business as usual" approaches championed by some Members is not the global solution but really the root cause of why to date we have less than 1% of people in low-income countries that have received at least one dose.

264. The global needs are massive and can only be addressed with global sharing of technology, knowledge and related IP, which is what our waiver proposal seeks to achieve. We believe it would be naïve for any country to think that it can win over a virus, which knows no boundaries, by securing vaccinating their own population. By putting boundaries to and limit Members policy options in combating the virus that knows no boundary seems to be counterintuitive.

265. A recurring concern against the waiver proposal is the impact on the incentives for the development of diagnostics, therapeutics and vaccines. Generally, R&D in emerging infectious diseases (EIDs) has been driven by public investment. The narrow emphasis on maintaining intellectual property to increase resources for private pharmaceutical R&D, disregards the fact that rapid development of COVID-19 diagnostics, therapeutics and vaccines is the sum of public funding and global collaboration. The waiver is more than just a legal mechanism, it is a statement of intent by all countries that they accord highest value to protecting human lives rather than protecting private profits.

266. The TRIPS waiver is a necessary, proportionate, and temporary legal measure for clearing IP barriers paving the way for more companies to produce COVID-19 vaccines and other health products and technologies by providing them freedom to operate without the fear of infringement of IP rights or the threat of litigation.

267. Chair, to conclude we would say we all need to rise to the demands of this crisis and show to the world that WTO is still relevant and very much capable of responding to the global need of saving lives and livelihoods, at least during a health crisis like COVID-19. We have been open to the suggestions from Members on the text of the Proposal and look forward to subsequent discussions in small group meetings or other formats including further discussion on elements like undisclosed information, duration or any other aspects and look forward to a constructive discussion in small group meetings.

India's statement at the small-group meeting held on 9 July 2021

268. Chair let me begin by some comments on the implementation aspect of the waiver. Among WTO Members there is a diversity of legal systems, hence national implementation of waiver depends on a country's political and/or constitutional arrangement. Similarly, the parameters and conditions of implementation should be a national decision. Each country will need to decide what is needed nationally to curb COVID-19 and the parameters of implementation. One size does not fit all as the legal systems, needs and conditions varies from country to country. In fact, the IP systems instituted in Member countries differ from each other. Therefore, the proponents of the waiver have not prescribed definite set of rules or methods as far as national implementation of the waiver is concerned.

269. In order to expeditiously implement the TRIPS waiver each Member should decide what is the best approach in the context of their legal system and this need not involve an amendment of the intellectual property laws.

270. Some countries have invoked emergency provisions or enacted legislation to implement the wide range of measures required for effective response to the COVID19. Such legislation may also provide governments the discretion to implement measures with respect to existing laws or privileges and such provisions could be used for the implementation of the TRIPS waiver. In some country's emergency legislations has been utilised to make changes to intellectual property legislation.

271. Apart from the emergency powers the executive may also have certain powers under the Constitution to issue orders suspending or amending the legal provisions. For instance, I can give an example for India where if both houses of the parliament are not in session, to avoid delay in passing a legislation the executive can give effect to the waiver decision through an ordinance. Under Article 123 of the Constitution "the President is satisfied that circumstances exist which render it necessary for him to take immediate action, he may promulgate such Ordinances as the circumstances appear to him to require". The ordinance can then be tabled for the approval of both house of parliament within six months from the date of its promulgation and becomes law after the obtainment of the assent of the parliament. WTO Members may also have disaster management laws to organise an effective response to disasters including a pandemic. These laws may also contain provisions providing powers to the government to suspend the operation of legislations to take effective measures. There is also the option of amending national intellectual property legislations. Such an amendment need not be a time-consuming exercise. In this pandemic we have seen governments fast tracking enactment of legislation and taking extraordinary measures for controlling the pandemic.

272. Since the outbreak of the pandemic, almost every country has implemented or is still implementing lockdown in some form or other to contain the spread of COVID-19. That does not mean that authorities of these countries were against the fundamental rights of "freedom of movement" of their citizens. Governments worldwide have also introduced fiscal packages to the tune of trillions of US dollars to help the recovery of ailing economies. That does not mean that they have deviated from their stated objective of fiscal consolidation towards fiscal profligacy. In the same light, the temporary waiver from certain provisions of TRIPS Agreement does not mean that the co-sponsors are against the Intellectual Property Rights but are arguing only for a temporary departure therefrom to ensure enhanced manufacture, timely supply and enhanced accessibility as well as affordability of health products essential for prevention, treatment and control of COVID-19.

The global community has resorted to exceptional measures in the exceptional circumstances of pandemic, and the waiver should be seen in a similar vein. The proposed waiver requires a one-time implementation and, for the duration of the waiver, will remove legal barriers, create freedom to operate facilitating collaboration at the regional and global levels, allow economies of scale to be achieved, motivating further manufacturing, and consequently lower prices. With a waiver, the administrative and procedural delays and conditions linked to Article 31 and 31*bis* will be avoided, meaning that countries will have full freedom to collaborate, manufacture and supply the required products.

273. Some arguments from Members portray that it is the IP system and the incentives that accrue from this system that has driven all innovation and R&D. However, it cannot be denied that it was 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. We respect the intellectual property rights and their value as incentives for innovation, but for the COVID-19 pandemic research and innovation has mostly been spearheaded by massive public funding, expedited regulatory approvals, and global collaboration. While millions of lives have already been lost, and no respite is in sight, where the only thing certain is the uncertainty, we cannot just rely on endeavours and voluntary mechanisms of a handful of private companies to secure an end to this pandemic. The proponents have always argued that the waiver is not standing in the way of any other solution or way that we could pursue, it is one of the many ammunitions in the policy arsenal of Members that can be deployed to fight the virus. The waiver is a collective response to a collective crisis; this should not be viewed as a zero-sum game.

Duration

274. Let me quickly reiterate our understanding and rationale behind the proposed duration of the waiver. We are combating a novel virus. There are emerging variants and mutations that lead to uncertainty with respect to the duration of immunity provided by the vaccines, the effectiveness of these vaccines against these new variants, whether or not there will be a need for a booster dose, or the requirement for an annual vaccination, the need and efficacy of vaccines for children and teens, and the duration of immunity conferred by them. All these factors determine the scale of manufacturing needed and supply that will be needed to control the pandemic, and this is just for the vaccines. Production for therapeutics, diagnostics and other COVID 19 related health products will also need to be ramped up in order to diagnose and treat people as subsequent waves continue infecting people across the globe.

275. Therefore, with regards to the time or duration of the waiver the revision text states that the waiver shall be in force for at least three years from the date of this decision.

276. While deciding on the timeline or the duration one has to keep in sight that this duration is practical, feasible and viable for scaling up manufacturing, however, as said in last small group meeting as well proponents are open to constructive suggestions on the duration and would rather have Members provide an alternative to this formulation than raising similar question on the duration.

India's statement at the informal meeting held on 14 July 2021

277. Chair, thank you for your opening remarks summarizing the discussions that took place in the small group meetings. Also Chair I take this opportunity to thank you for your efforts in organizing and taking forward these discussions. Since the previous formal TRIPS Council meeting on the 8-9th June 2021 we have had several rounds of small group meetings and informal Council meetings to take stock of the progress made. These meetings gave further opportunity to Members to discuss in details key elements of the waiver proposal like the scope of products as well as on the scope of IP, implementation issues, the duration for which the waiver would be in place and other elements.

278. I thank South Africa for their comprehensive summary on these discussions that were held in these small group meetings. It is helpful for the information of the larger membership participating today.

279. Chair, briefly, as you suggested we would inform on our outreach with Members. Chair, in the last few weeks the proponents have continued their outreach to Members and have engaged

bilaterally with several Members explaining in detail the reason, rationale, and our understanding behind the proposal, and have responded to the many concerns raised. In these discussions we proposed to some Members to engage bilaterally on the text and iron out the differences in a focused manner, however, there seems to be little enthusiasm among these Members to engage bilaterally to discuss the text. Generally, Members have been receptive of such bilaterals during fisheries negotiations. Chair, this lack of enthusiasm substantiates our fear that some Members while agreeing for text-based negotiations in 8-9 June TRIPS Council meeting, have shown lack of interest when the actual process started thus not allowing a text-based negotiation.

280. The Pandemic will not wait for MC12. Its spread will continue unabated negatively impacting lives and livelihoods. Also the virus will not take a break or pause while we go for our summer break and come back to the issue of scaling up manufacturing and ensuring equitable access in September after whiling away our time in July and taking a break in August. As responsible Members we have responsibility to conclude this if we all agreed to start it and reach a minimal understanding on the text by July end.

281. Chair, in the past nine months that we spent discussing the waiver we have lost 3 million more people, with new variants adding to the uncertainties surmounting us, only 2% of least developed countries (that represent 14% of the world population) and 23% of developing countries (that represent 70% of the world population) have received at least one shot as of 23 June 2021 compared to 46% of developed world receiving a shot. This huge disparity and gap in accessibility and affordability of vaccines must be a driving force for us to deliver an outcome in the form of waiver.

282. Despite Members agreeing to the collective goal of saving lives and the consequent need for augmenting production of vaccines, therapeutics and diagnostics needed to combat COVID-19 we see lack of urgency and enthusiasm in some Members to reach a conclusive decision on the waiver. Chair, time is of the essence we should not miss the opportunity of finalizing the waiver in July and get going on finding modalities for ramping up production for COVID-19 related health products.

283. Each nations' interests are entwined with that of the other, while developed country Members have outpaced developing and LDCs in vaccinations and have also secured supplies for future doses such differential approach will not yield results of ending the pandemic, as the virus will not differentiate and discriminate in affecting people.

284. The extraordinary circumstances of the pandemic demand more than a minimal or even moderate collective response and everyone in a position to contribute must do so. Members have agreed to pursue different approaches simultaneously in this regard and without prejudice to each other. The co-sponsors of the waiver proposal have reiterated that they welcome all proposals, and that each proposal should be considered on its own merit and follow its own course. And we have engaged in discussions on the E.U proposal as well in good faith. We have never said that there could be only one approach which could deliver, no single mechanism will be able to provide a perfect solution for this crisis. There have been questions with regards the uncertainty that waiver may bring on the contrary Chair we understand that in fact the waiver would provide more companies with freedom to operate to produce more without the fear of infringing another party's rights and the threat of litigation.

285. While Members have been undertaking extraordinary measures domestically in the form of lockdowns, quarantine and restricting movement of its people thereby essentially curtailing their fundamental human rights, for the larger and greater good. We have seen there has been no problem in the implementation of such extreme measures. Similarly, the economic stimulus packages that many Members have provided to their domestic industries without a prerequisite of this stimulus not being used to target exports which can potentially distort global trade. All these extraordinary measures were taken, and no questions were raised as to their compatibility with WTO agreements or Members' international obligations. The waiver should also be viewed in a similar vein as a temporary and extraordinary measure.

286. From what has been reiterated often by some Members that they do not see the waiver as a response to the crisis. This argument compels us to think that perhaps we do not share the urgency, severity, and the need for quick solution to put an end to the pandemic. The waiver is necessary at this time as the existing flexibilities in the TRIPS Agreement have not proved to be sufficient in the context of the pandemic. Additionally, the insufficient voluntary mechanisms and engagements by

pharmaceutical companies to scale up manufacturing makes the waiver much needed for radically increasing manufacturing capacity and thus ensuring sufficient supplies and facilitating pathways to achieve equitable access. The waiver will be a critical ingredient of the multi-pronged approach to combat the pandemic.

287. The EU proposal talks only about compulsory licence under Article 31 and Article 31*bis* of the TRIPS Agreement. These Articles are confined to the issue of patents. Hence, the proposal by the EU attempts to address only patent barriers and not intellectual property barriers in general in responding to the pandemic. Issues such as trade secret, copyright, industrial designs, etc which are equally important barriers are out of the purview of this proposal. The proposals by the EU are confusing and repeat what is already addressed under Article 31, Article 31*bis* and the Doha declaration on public health. Importantly, the proposal by the EU contains only 'may obligations' which makes these proposals even more redundant in addressing the COVID-19 pandemic. The EU proposal even fails to address the problems with current Compulsory Licensing procedures under the TRIPS Agreement such as requirement under Article 31*bis* for mandatory differential packaging and colouring of products under the compulsory licences. Also, requirements of notification of quantities and other details under Annex of the TRIPS Agreement which delays the process of exporting compulsory licences products instead of simplifying it are important. What the proposal covers is a reiteration of existing provisions of TRIPS Agreement. We wish to know how these reiterations of existing provisions result in ensuring augmentation of production of vaccines, therapeutics and diagnostics for the treatment, prevention and containment of the pandemic, how will these secure access to vaccines for developing countries and the LDCs. Additionally, we would like to know what will be the legal enforceability of this declaration, since it does not change the existing Agreement, how will Members use this declaration to procure more vaccines, therapeutics, PPEs, masks etc for their population.

288. The proponents of the waiver proposal have argued previously on many occasions how flexibilities provided in the TRIPS Agreement are inadequate in responding to a pandemic of this magnitude. The limited policy space provided by the TRIPS Agreement flexibilities to address monopoly actions through issue of compulsory licences would not be a feasible option in a pandemic. Beyond patents, other IP rights, including trade secrets, industrial designs, copyrights, etc. also pose barriers. Compulsory Licensing does not address the barriers posed by these rights. In fact, these limitations posed by the compulsory licences can be easily addressed by the waiver. The waiver once approved and applied would provide countries with an effective and expeditious way to remove key IP barriers that scuttle the use of existing idle capacities.

289. Chair, lastly, it's imperative upon us that we logically and meaningfully conclude what we started, it is important that the waiver proposal is taken forward constructively and finalized expeditiously. The report to the General Council should convey both the importance and urgency to conclude the discussions and finalize the waiver. Any other discussions on other proposals should be looked at parallelly and not as mutually exclusive to the waiver proposal.

290. We talk of restoring the credibility of this organization, but this cannot be achieved without delivering on the solutions that would help scale up production of life saving vaccines, therapeutics and diagnostics and ensure access for all.

2 DRAFT GENERAL COUNCIL DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH IN THE CIRCUMSTANCES OF A PANDEMIC

2.1 European Union

291. Thank you for providing the European Union with this opportunity to follow up on the discussions on our proposal as submitted to the Council in document IP/C/W/681. The European Union would first like to recall that our proposal is part of a wider comprehensive approach to the COVID-19 crisis, an approach that is based on the use of trade-related measures at the disposal of the WTO to address the real bottlenecks that affect the production and distribution of COVID-19 vaccines and medicines. The European Union set out this approach in the communication on "Urgent Trade Policy Responses to the COVID-19 Crisis", document WT/GC/231 which we submitted to the WTO General Council on 4 June 2021. In that communication the intellectual property component is one element of the solution, as explained in a dedicated communication on

"Urgent Trade Policy Responses to the COVID-19 Crisis – Intellectual Property" document IP/C/680, which the European Union submitted to the Council for TRIPS on 4 June 2021.

292. As set out in that communication, the intellectual property component focuses on the clarifications and facilitation of TRIPS Agreement flexibilities relating to compulsory licences. The European Union believes that our discussion in the TRIPS Council should concentrate on how the IP system can contribute towards increasing the manufacturing capacity and equitable access to vaccines around the world.

293. When we discussed the role, that intellectual property plays to solve the COVID-19 crisis, we should not underestimate the role that it has already played and will continue to play. The current system has provided the necessary incentives for vaccine developers to research and invest in the existing vaccines that exist against COVID-19. The world has obtained not only one, but several vaccines against COVID-19 in an unprecedented time. Researchers count on the IP incentives. We still need more effective vaccines, not only for the existing variants but also for the future ones. Therefore, we must make the most of the existing IP system, while maintaining incentives that have proven effective. With our proposal for a General Council declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic, the EU would like to find a pragmatic approach on the role of the intellectual property in enhancing access to affordable COVID-19 vaccines and medicines with concrete short- and medium-term solutions that can have quick results on the ground.

294. We agree that intellectual property rights do not and should not stand in the way of deploying existing capacity or creating new capacity or of ensuring that access to COVID-19 vaccines and medicines is equitable. The EU believes that it is possible to achieve this objective while at the same time maintaining the protection required for incentivising technology transfer and investment in innovation so that we can fight against new strains of COVID-19 and any future diseases. In our view, this can be done by using the compulsory licensing system that the TRIPS Agreement provides for and the use of which is supported by the Doha Declaration on the TRIPS Agreement and Public Health. This system provides for an IP solution to a situation when there is a producer having the ability to produce the particular product but does not have a licence from the patent holder to proceed with the production. The system can be used for domestic needs, this is the case where the country grants a compulsory licence to a manufacturer established in its territory, and the product will be predominately sold within the same country, but more importantly, under the current circumstances, it can also be used for exports. In situations where the product cannot be produced domestically at all or in sufficient quantities due to lack of capacity and where the producer having the ability to produce and willing to produce the product is located in a country where a patent is in force on that product and needs a compulsory licence in that country to produce for export.

295. When it comes to the potential IP-related obstacles, this system can work effectively, also in times of a pandemic. It actually has elements inbuilt specifically for the circumstances of an emergency and a pandemic is clearly such a circumstance. In the discussions in the Council we have heard Members assert that this is not the case. These assertions were based on seeing the system as too complex. This is precisely where the EU proposal comes in. We believe that the compulsory licensing system provides for tools that can be used in the times of the pandemic. It also provides enough legislative space to apply the system in a swift manner. The EU proposal is meant to clear any doubts that persist about the use of the system and to indicate ways in which the system can be used in a manner that is full adapted to the challenges of the pandemic. The EU proposal is based on a number of clarifications that have as their objective to facilitate and increase the effectiveness of the use of the system. We have proposed clarifications on the elements that we find most relevant for the situation of the pandemic and these are the fast-track procedure, the support for manufacturers wishing to supply to low and middle-income countries at discounted prices, and a simple single notification of the exporting country.

296. We have provided details on these three elements in our interventions in the informal meetings of this Council. We would like to ask the Secretariat to add all these interventions to the current statement for completeness of the information.

297. In our view, clarifications on the proposed aspects would provide the necessary legal certainty to Members that have the possibility of using the existing capacity or increasing their capacity to produce COVID-19 vaccines and medicines. They would also promote production and supply of those

products to low-and middle-income countries at affordable prices including via the COVAX facility and this should be our priority right now.

298. In summary, the declaration to be adopted by the General Council would be based on the following premises:

a. First, it keeps entire necessary incentives that the intellectual property system provides to fight against the current and future variants of the virus that causes COVID-19.

b. Second, it builds upon the existing flexibilities in the TRIPS Agreement and content of the Doha Declaration.

c. Third, it provides legal certainty on those areas related to compulsory licencing that WTO Members have identified as discouraging them from using this possibility due to risk of being in being in breach of their obligations under the TRIPS Agreement.

d. Fourth, it contributes to our global efforts to ensure equitable access to COVID-19 in low-and middle-income countries through the COVAX facility.

e. Fifth, it addresses not only the ongoing COVID-19 crisis, but also future pandemics.

299. Finally, a declaration is a pragmatic solution that can be adopted swiftly. We need to act urgently. As the proposal does not amend Articles 31 and 31*bis* and the Annex of the TRIPS Agreement, we will not require lengthy procedures. In addition, the clarification that we propose can also be applied in a national legislation swiftly, with none or minimal changes to the current system as it uses the space and the flexibility provided by the system. This means that the declaration could have immediate or almost immediate results on the ground.

300. We would like to recall that our proposal emerges from the discussions that we have had in the Council over the last months. In the course of those discussions, we examined various ways in which intellectual property can help in enhancing access to affordable COVID-19 vaccines and medicines. One of the results of these discussions is that a number of WTO Members identified aspects related to the use of compulsory licensing that in their view limit their use of this tool.

301. We thank all Members for their engagement on our proposal and for their contributions, questions, and thoughts on it so far. We have discussed our proposal in open-ended informal meetings of the TRIPS Council as well as in all small group meetings that the Chair has organised. We have received valuable feedback and we are pleased to see the interest of various delegations in continuing and exploring this approach. We have also heard suggestions from Members on other aspects of the compulsory licensing system that would, in their view, deserve further examination and eventually be included among the elements to be clarified, for example, issues related to labelling and packaging, as well as broader notification issues.

302. We are currently analysing these proposals and are ready to discuss these issues in more detail. We remain also open to discussing which other requirements concerning compulsory licensing can be clarified to facilitate the use of the system. We look forward to our continued discussion on these matters. We are confident that all WTO Members can agree with the clarifications contained in our proposal as well as those that it might be appropriate to add. It is necessary and timely, and it can have immediate impact on the ground and apply also for future situations of a similar kind. Therefore, we believe that, with the commitment of all WTO Members, we should be able to find convergency rapidly on how to clarify and facilitate the use of the compulsory licensing system.

European Union's statement at the informal meeting held on 24 June 2021

303. Chair, thank you for providing us with this opportunity to present our proposal as submitted to this Council in document IP/C/W/681. We continue to be committed to achieving our common goal: to continue ramping up production, to share COVID-19 vaccines more widely and faster and to ensure equitable access to low- and middle-income countries. Equity for us does not only mean access but also access at affordable prices.

304. We already see incredible progress in the total global production of COVID-19 vaccines with more than 10 billion doses to be produced by the end of 2021. For comparison, the total global output of all vaccines before COVID-19 was only 5 billion doses. However, further ramping up the production and, most importantly, ensuring equitable distribution of COVID-19 vaccines remain essential in the fight against time in this pandemic.

305. Setting up and ramping up the production of vaccines is a highly complex process which requires adequate facilities, trained personnel, raw materials and other inputs. It is a complex issue that cannot be solved by one simple solution. The overall strategy is not within the WTO only either. The World Health Organization, other organizations, institutions and initiatives – such as the COVAX Facility – are working on these solutions. In the WTO, the Members must collectively find ways to address the current delays and shortages in vaccine production to the extent that is possible in the WTO framework.

306. Following the intense discussions in this Council as well as in other fora and events organised by the Director General of the WTO, Dr Ngozi Okonjo-Iweala, it is our assessment that limited manufacturing capacity and restricted access to raw materials and other inputs are the main bottlenecks as regards the production and distribution of COVID-19 vaccines. In addition, having the required know-how is key due to the complexity of the production process of these vaccines.

307. In order to deal with these bottlenecks with the use of trade-related measures at our disposal at the WTO, the EU believes a multi-pronged approach is needed. This is why, on 4 June, the European Union submitted to the WTO General Council a Communication on "Urgent trade policy responses to the COVID-19 crisis", document WT/GC/231, calling for a multilateral and comprehensive response by trade-related measures to the COVID-19 pandemic.

308. In that communication, the EU proposes that WTO Members agree as soon as possible on a global trade initiative for equitable access to COVID-19 vaccines and therapeutics encompassing the following three components: 1) trade facilitation and disciplines on export restrictions; 2) concrete actions to expand production and ensure supply of vaccines at affordable prices to low and middle income countries during the pandemic and; 3) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory licences.

309. While the EU considers that the General Council should be the forum to address all three components in a comprehensive manner, the third component on intellectual property is in the remit of the Council for TRIPS. For this reason, on 4 June 2021 the EU also submitted a dedicated communication on "Urgent trade policy responses to the COVID-19 crisis – intellectual property", document IP/C/W/680, to the Council for TRIPS.

310. Further to that communication, on Monday the EU submitted to the TRIPS Council our proposal for a General Council declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic (document IP/C/W/681). We are pleased to present this proposal today. The proposal submitted to the TRIPS Council is part of a broad, comprehensive proposal of the EU on the urgent response to the COVID-19 crisis.

311. We believe that our discussion in the TRIPS Council should concentrate on how the IP system can contribute towards increasing the manufacturing capacity and the equitable access to vaccines around the world. When we discuss the role that intellectual property plays to solve the COVID-19 crisis we should not underestimate the role that it has already played and will continue to play. The current system has provided the necessary incentives for vaccine developers to research and invest in the existing vaccines and medicines against COVID-19. The world has obtained and had access to not only one, but several vaccines against COVID-19 in an unprecedented time, less than one year. Researchers count on the IP incentives to continue developing vaccines against COVID-19. We still need more effective vaccines, not only for the existing variants, but also for future ones. Therefore, we must make the most of the existing IP system while maintaining incentives that have proven effective.

312. With this proposal the EU would like to find a way forward in the discussion on the role of intellectual property in enhancing access to affordable COVID-19 vaccines and medicines, with concrete short- and medium-term solutions.

313. Firstly, we would like to recall that in addition to ensuring the uninterrupted flow of raw materials and inputs for the vaccine production, the key issue for increasing access to COVID-19 vaccines is to enhance the transfer of COVID-19 vaccine technology. Contrary to simple chemical medicines that are relatively easy to replicate, COVID-19 vaccines involve a complex biological process which requires the relevant know-how.

314. Voluntary licences are the most effective instrument to facilitate the sharing of know-how. Intellectual property framework provides a platform that incentivises collaboration and transfer of know-how. It is thanks to the intellectual property system that knowledge and technology are disseminated. It is our view that the question as to which measures incentivise transfer of technology and which have the opposite effect, is one of the key questions in this debate.

315. This is why we would like to reiterate our view on this matter: in the context of the novel vaccine production, collaboration and licensing are key for the transfer of know-how. It may be a very different situation for simpler pharmaceutical products. In the current case, the authorisation to use a patent is only one side of the coin, but it is not enough. The patent holder, that is, the inventor of the vaccine, also needs to share its know-how with the manufacturer; and only a voluntary licence provides the ideal framework for this transfer of know-how. This is one of the key premises of our proposal. Setting up the manufacturing infrastructure to produce vaccines not only requires this know-how, but also time and resources. And this is also why Europe committed EUR 1 billion to create, with our African partners and our industrial partners, manufacturing hubs in different regions in Africa. These solutions must go hand in hand.

316. We agree that intellectual property rights should not stand in the way of deploying existing capacity or creating new capacity or of ensuring that access to COVID-19 vaccines and medicines is equitable. The EU believes that it is possible to achieve this objective while at the same time maintaining the protection required for incentivising technology transfer and investment in innovation, so that we can fight against new strains of COVID-19 and any future diseases.

317. The Doha Declaration on the TRIPS Agreement and Public Health affirms that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. It further affirms the flexibilities contained in the TRIPS Agreement, including specific flexibilities related to compulsory licences. The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also states that each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency which includes public health crises.

318. We would like to contribute to the discussion we are having in this Council with a targeted approach. We hope that we will be able to convince Members that our approach, including the key components that will be addressed in the General Council, represents the best way to respond to the crisis in a short term in an effective and pragmatic manner.

319. We would like to recall that our proposal is based on the discussions that we have had in this Council over the last months. In the course of these discussions, we have been examining various ways in which intellectual property can help in enhancing access to affordable COVID-19 vaccines and medicines. One of the results of these discussions is that a number of WTO Members identified aspects related to the use of compulsory licensing that, in their view, limit the use of this tool. The EU proposal is a response to these comments.

320. We propose a declaration to be adopted by the General Council that would be based on the following premises:

a. First, it keeps intact the necessary incentives that the intellectual property system provides to researchers on new vaccines and medicines to fight against the current and future variants of the virus that causes COVID-19.

b. Second, it builds upon existing flexibilities under the TRIPS Agreement and reaffirms the content of the Doha Declaration.

c. Third, it provides legal certainty on those areas related to compulsory licensing that WTO Members have identified as discouraging them from using this possibility due to risk of being in breach of their obligations under the TRIPS Agreement.

d. Fourth, it contributes our global efforts to ensure equitable access to COVID-19 vaccines and medicines in low- and middle-income countries thorough the COVAX Facility.

e. Finally, it addresses not only the ongoing COVID-19 crisis but also future pandemics.

321. Consequently, in order to address comments raised in the context of our discussions, provide more legal certainty and enhance the effectiveness of the system, the EU considers that all WTO Members should be ready to agree on the following clarifications of the compulsory licensing system set out in Articles 31 and 31*bis* and in the Annex of the TRIPS Agreement:

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

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

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

322. Clarifications on these aspects would, in our view, provide the necessary legal certainty to Members that have the possibility of using the existing capacity or increasing their capacity to produce COVID-19 vaccines and medicines. They would also promote production and supply of those products to low- and medium-income countries at affordable prices, including via the COVAX Facility. And this should be our priority right now.

323. We would like to recall that an additional value added of our proposal is that it can be adopted swiftly. The proposal clarifies certain provisions in Articles 31 and 31*bis* and the Annex of the TRIPS Agreement. As we do not aim to amend these articles, we will not require lengthy debates and procedures. The scope of these provisions will remain the same, but agreeing on a declaration will remove legal uncertainty about their application and support those WTO Members who wish to use them.

324. The first element is to clarify that in a circumstance of a pandemic, governments can proceed quickly and they do not have to engage in the negotiations with patent holders, which normally is the longest part of the procedure. Some WTO Members raised doubts as to whether this 'fast-track' procedure can be used only in the case of compulsory licences for domestic use or also with regard to the, crucial now, licences for exports. We want to make it absolutely clear that this possibility applies also to licences for exports. Therefore, we propose to clarify that WTO Members may waive the requirement of making efforts to obtain authorisation from the right holder, provided for in Article 31(b) of the TRIPS Agreement, for the purposes of issuing a compulsory licence not only for domestic use, under Article 31, but also for exports, under Article 31*bis*.

325. The second element concerns remuneration for patent holders. This is a crucial element of a compulsory licence and we need to promote those manufacturers that are ready to produce at affordable prices for low- and middle-income countries and to provide supplies to COVAX. This means different levels of discounted prices, e.g., supplies at cost or at lower prices to low- and middle-income countries. The clarification would provide legal certainty that in such cases manufacturers will be supported by governments setting the remuneration for patent holders reflecting these discounted prices, in order to ensure that the remuneration does not become a blocking factor in enhancing production. Therefore, we propose to clarify that WTO Members may provide, for the purposes of determining the remuneration to be paid to the right holder under a compulsory licence for domestic use (Article 31.h) or for exports (Article 31*bis* paragraph 2), that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.

326. The third element deals with an often-raised, procedural problem of country-to-country application of compulsory licence. We want to make sure that a willing manufacturer can easily export to all eligible countries, including via COVAX, under a single simple procedure. Therefore, we propose to clarify that the notification procedure in paragraph 2.c) of the Annex to the TRIPS Agreement allows WTO Members to submit a single notification that includes the list of all countries to which the vaccines and medicines are to be supplied. We also propose to clarify that this notification is valid not only when the exporting Member exports the vaccines directly, but also when it does so through the COVAX Facility. COVAX is already supplying vaccines to many countries of the world, many of which are eligible importing Members under the Annex to the TRIPS Agreement. Therefore, we propose that WTO Members agree that, where a WTO Member provides COVAX with vaccines produced under a compulsory licence, it is understood that COVAX distributes those vaccines to the eligible importing Members included in the notification submitted by the exporting Member.

327. We are talking about a substantial reinforcement of the TRIPS flexibilities and of the legal certainty required for their use. It is our objective to bring all sides of the discussion closer together on this approach and find solutions quickly while also fully engaging on other aspects of our comprehensive proposal which are key, in our view, to make a real difference on the ground. We invite all Members to consider our proposal and engage on this approach. We are of course open to discuss which other requirements concerning compulsory licensing can be clarified to facilitate the use of the system.

328. We are confident that all WTO Members can agree that the clarifications contained in our proposal are necessary and timely and can have an immediate impact on the ground and apply also for future situations of the similar kind. Therefore, we believe that, with the commitment of all WTO Members, we should be able to rapidly find convergence on how to clarify and facilitate the use of the compulsory licensing system.

European Union's statement at the informal meeting held on 30 June 2021

329. The European Union much appreciated the possibility provided by the small group meetings to explain in more detail the EU proposal and to discuss the revised waiver proposal. We would like to thank all the delegations that engaged in the discussions and hope that the input provided by the European Union has been helpful in taking this discussion forward.

330. The European Union remains fully committed to this process and to finding the best way forward to ensure that the intellectual property system plays an enabling role in the context of deploying existing capacity or creating new capacity for the production of COVID-19 vaccines and medicines while keeping intact the necessary incentives that the intellectual property system provides to researchers of new vaccines and medicines to fight against the current and future variants of the virus that causes COVID-19. We will continue to engage constructively and are open to discuss all approaches that contribute to enhancing access to affordable COVID-19 vaccines and medicines and can bring results in an urgent manner.

331. The European Union would like to use this opportunity to recall some of the most pertinent, in our view, points that have been raised in the discussion in small groups on the scope of products and provisions covered.

332. Starting with the EU proposal for a General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, document IP/C/W/681, the EU have provided explanations on the scope of its proposal.

333. As regards the scope of products covered by the EU proposal, we have explained that:

a. The EU proposal emerges from the discussions that WTO Members have had in the TRIPS Council since the COVID-19 started.

b. Those discussions have focused on how intellectual property can contribute to ensuring global equitable access to COVID-19 vaccines and medicines.

c. We are aware that WTO Members use different terms to refer to the products we aim to cover e.g., pharmaceuticals, medicines, treatments, therapeutics, diagnostics, etc. We

also understand that intellectual property law does not usually address definitions of terms such as medicines.

d. It is important to recall that our proposal concerns Articles 31 and 31*bis* of the TRIPS Agreement and therefore the product scope as applicable to these articles applies also in the context of our proposal. In the case of Article 31 of TRIPS there are no limitations to the scope – all products that are patented are covered. Article 31*bis* is more specific, as it applies to pharmaceutical products, which are defined as "patented products, or products manufactured through a patented process, of the pharmaceutical sector".

e. Therefore, the EU proposal covers all patented products as far as the application of Article 31 is concerned and all pharmaceutical products as far as Article 31*bis* is concerned. The pharmaceutical products under Article 31*bis* cover vaccines, therapeutics, diagnostics and active ingredients and therefore these products, which are key for tackling the COVID-19 crisis, are covered by the EU proposal. When we speak about 'medicines' in the EU proposal as regards the facilitation of compulsory licences, diagnostics as well as therapeutics fall under that term.

334. As regards the provisions covered by the EU proposal, the EU has explained that:

a. The EU proposal to the WTO is a comprehensive proposal as it addresses trade issues related to the actual bottlenecks that affect the speed of manufacturing and the fair supply of vaccines and medicines in the current pandemic. The component on compulsory licensing as proposed for discussion at the TRIPS Council is thus only one element of this comprehensive approach. We consider that intellectual property plays an important role as an enabler that contributes to our overall objective of ramping up production of COVID- 19 vaccines and medicines. However, it is not and should not be a barrier to achieve this objective. We have been clear that in a global emergency like this pandemic, if voluntary licensing fails, compulsory licensing is a legitimate tool to scale up production. This is why we propose to clarify and simplify the use of compulsory licensing in times of a pandemic.

b. If we examine how intellectual property can enable the production of vaccines or medicines, the focus is primarily on patents. We believe that a debate on the entire intellectual property system is not necessary and will only delay our urgent action. Moreover, the intellectual property framework is already a system of checks and balances. There are relevant exceptions that can be used with regard to every intellectual property right, be it copyright, design or protection of undisclosed data.

c. For example, as regards trade secrets, it is important to note that the TRIPS Agreement only protects trade secrets against disclosure, acquisition or use in a manner contrary to honest commercial practices. Trade secrets do not have to be protected in situations concerning disclosure, acquisition or use which is consistent with honest commercial practices. This provides for space for governments to provide exceptions e.g. in a health emergency situation. The EU Directive on trade secrets provides for an exception 'for the purpose of protecting a legitimate interest recognised by Union or national law'.

d. As regards regulatory data, we agree that the national provisions on compulsory licensing need to be effective and should therefore allow manufacturers of generics to produce them. Regulatory data protection should not be an obstacle to achieve this objective. Article 39 paragraph 3 of the TRIPS Agreement allows exceptions 'where necessary to protect the public'. The EU uses this exception in its implementation of Article 31*bis* of the TRIPS Agreement.

e. Moreover, we must be realistic as to what the proposed lifting of the Members' obligations under the TRIPS Agreement can achieve. For example, in the long-discussed case of trade secrets, waiving Article 39 of the TRIPS Agreement does not grant access to companies' confidential information, only removes certain minimum remedies against a misappropriation of that information. There seems to be a misunderstanding about this fact as some Members indicated possibilities of governments to requisition and repurpose

trade secrets. We would like to emphasise that such measures which may be provided under national law of some Members fall outside of the realm of intellectual property.

335. Without prejudice to our position on the revised waiver proposal, and in particular the fact that we do not believe that it would have the effect of increasing production and enhancing access to COVID-19 vaccines and medicines, in the course of the small group meetings, we have raised a number of concerns with regard to this proposal:

a. As regards the product scope, it was observed that the link between the accessibility of the broad list of products and intellectual property is not clear. There is no evidence that it is IP that is at the origin of the shortages of these products. The fact that a product is protected by an IP right, such as patent, is not in itself an indication that there is an IP obstacle that limits its accessibility.

b. Moreover, if an IP would stand in the way of accessibility, it is not clear why the existing flexibilities provided in the TRIPS Agreement, and in particular compulsory licensing, could not be used.

c. In addition to the possibility of relying on exceptions which can also be used for public purposes, in accordance with the trilateral study by WHO, WTO and WIPO on Promoting Access to Medical Technologies and Innovation, numerous private sector companies have taken access-oriented actions that include: (i) committing to non-exclusive and royalty-free licensing or issuing non-enforcement declarations of patent rights in some or all jurisdictions; (ii) publishing scientific data on a free-to-use basis; (iii) publishing technical specifications of vital equipment (e.g. ventilators); and (iv) sharing knowledge to enable others to manufacture and use such technologies. In addition, among other voluntary actions in support of R&D that have been observed are the permission to use text and data mining and machine-learning technologies and to freely access and reuse COVID-19 related scientific literature protected by copyright and the making available of standards protected by copyright. For example, as part of the Open Covid Pledge, a number of private companies and universities are granting free access to patented technologies and protected designs related to diagnosing, preventing, containing and treating COVID-19.

d. There are questions as to the establishment of the link between a product and the prevention, treatment or containment of COVID-19. While certain products, such as vaccines or certain therapies, have been developed and are approved as COVID-19 products, there are also products that have at the same time different uses, this concerns also 'materials and components' covered by the revised waiver proposal.

e. As regards the provisions covered, the EU questions the approach under which the entire sections of the TRIPS Agreement are subject to the waiver. This includes for example provisions on compliance with the Berne Convention, exceptions and limitations to various rights, inventions excluded from patentability, conditions on patent applications or provisions on compulsory licensing. Again, the link between these provisions and the objective of the waiver is not clear. This approach points rather to a suspension of the TRIPS Agreement than a waiver that should be limited to what is justified and necessary in view of its stated objective.

f. We should not lose sight of our common aim, i.e. enhancing global access to affordable COVID-19-related medical products and addressing global production constraints and supply shortages. The EU believes that this objective must inform our discussions. We have previously expressed concerns as to the impact of the proposed waiver on what is the core element for expanding the current production of vaccines, i.e. transfer of technology.

g. As already mentioned, Articles 39 paragraphs 1 and 2 of the TRIPS Agreement provide only for remedies in case of breach of confidence or other dishonest commercial practices. Waiving these paragraphs does not in any way compel the holder of the trade secret, in this case the technology and the know-how, to reveal it. To the contrary, lifting the

protection granted by these provisions takes away the platform on which such transfer can occur with full legal certainty.

h. Intellectual property rules provide the legal framework for cooperation between companies by licensing contracts and partnership agreements. Therefore, IP rights do not obstruct production but are an enabler to enhance production. The most efficient way of knowledge sharing is a cooperation on a voluntary basis, that enables a quick exchange of know-how needed besides the patent itself.

i. As regards Article 39 paragraph 3 on regulatory data, it is not clear to us what would prevent Members to use undisclosed data by regulatory agencies where necessary to protect the public as provided by this Article.

j. There are further questions regarding the implementation of the waiver, e.g. its impact on pending patent applications that would need to be discussed and closely analysed. The same concerns medium- and long-term consequences of the waiver. For example it is important to note that health products and technologies developed during the waiver period would, in all likelihood, not be eligible for patent protection even after the termination of the waiver, because they would no longer fulfil the patentability requirement of novelty. Finally, there are also questions as regards effects of the waiver on international obligations of WTO Members under international agreements in the area of intellectual property. We are looking forward to further discussions on these points and will of course present these aspects also in the context of the EU proposal.

336. As was mentioned by a number of delegations, the EU believes that Members should focus on solutions which are targeted, pragmatic and that can bring results in the short-term. We invite Members to discussions on the EU proposal which in our view fulfils these requirements. As indicated during the last week's meeting, the EU is also ready to discuss other aspects of the compulsory licensing system that would merit clarification to enhance efforts to scale up the production of COVID-19 vaccines, therapeutics and diagnostics.

337. Finally, we would like to emphasise that the IP-related discussion is only a part of the multi-faceted approach proposed by the EU. We call on all Members to engage in discussions on all elements of this approach as only this way we will be able to adequately respond to the current crisis.

European Union's statement at the informal meeting held on 14 July 2021

338. For the European Union, the discussions the previous week allowed us to explain in detail the advantages of the EU proposal from the perspective of implementation. We have looked at it from two key angles. First, from a procedural angle, the EU proposal for a General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, document IP/C/W/681 can be adopted swiftly. Moreover, the clarifications on the use of the existing flexibilities on compulsory licensing would normally not require implementation by WTO Members to have immediate results - they would remove any legal uncertainty on a number of aspects that WTO Members have identified during the last months as unclear.

339. Second, the other key angle when we discussed implementation is the substantive angle. The EU proposal for a General Council Declaration is targeted and addresses the key aspects of the compulsory licensing system that can be clarified or facilitated to make sure that we make the most of the system during this and future pandemics. Even if the list of these aspects is extended in the course of the negotiations, it will remain targeted and easily applicable. Moreover, if any WTO Member actually needs to incorporate these clarifications into its national regime, the implementation would be simple due to the targeted approach of the proposal.

340. As regards the implementation of the revised waiver proposal:

341. The discussions during the last two meetings showed, in our view, that the implementation of the waiver would be a very complex exercise and would involve important risks. To begin with, a waiver does not have direct application in the national systems of WTO Members. All WTO Members that have implemented the TRIPS Agreement in their national law would need to adopt national law to implement the waiver. This is already an important difference between the waiver and the EU

proposal. It is true that, as the proponents have explained, WTO Members having fast-track legislative procedures in place could use them to implement the waiver at national level. However, if we take into account the second implementation angle we have mentioned, i.e. the substantive angle, further hurdles and concerns appear.

342. First, as already mentioned in the previous meeting, the proposed waiver does not contain any indication as regards the measures that can be applied by the Members. In other words – it is not clear what the Members can do on the basis of the waiver and how they can do it.

343. Second, clearly the broader and less targeted the waiver, the more complex implementation is required. This means national rules:

a. to determine which IP rights would fall under the ambit of the waiver, under which conditions and with which effects in the short, mid- and long-term; and

b. to create a legal instrument and procedures to effect the suspensions and circumscribe their scope to the purposes provided in § 1 of the waiver.

344. The proponents have explained that the waiver provides no description of measures to be adopted by Members under the waiver. No measures are indicated or prescribed. These means that, from the substantive angle, there are no set boundaries to the measures that Members can implement. The proponents explain that the 'waiver is permissive' and that 'the choice of measures is left to the Members'.

345. The lack of defined measures is, in our view, highly problematic and results in high risk as regards the effects of the waiver. The lack of any boundaries means that Members would be free to take any measures they deem appropriate without any accountability or scrutiny, and regardless of the impact of the waiver on incentives for innovation. We would like to emphasise here that we are talking about the substance of the measures, not their form – the fact that there can be emergency measures or measures taken in a different procedure does not change the fact that the substance of the measures is unknown.

346. The proponents have explained that they expect that WTO Members will not use the waiver to its full extent, as they should use it in a targeted manner. The waiver is, in their view, a tool that would give freedom to Members to adopt measures in their own way. This does not in any way remove the discussed concerns, including those related to:

a. the invalidation of existing patents, including in the long term, once the waiver ceases to apply;

b. the possibility of rejecting pending patent applications and its effects on the loss of novelty of the products and processes relevant to the manufacture of vaccines, medicines and medical devices;

c. the effects of the waiver on existing and future voluntary licence agreements and open licensing schemes;

d. the effects of the waiver on trade secrets, which, if disclosed due to the waiver, would lose their secret character and therefore any protection, even after the waiver ceases to apply – in that regard we also noted certain comments pointing to using the waiver as a vehicle for forcing rather than enhancing technology transfer – this increases our concerns about this approach;

e. how to ensure that the waiver is used exclusively for the announced intention and not for commercial purposes;

f. how to ensure that a COVID-19 related waiver does not affect IP rights that are related to other purposes or diseases or are relevant for other areas;

g. the application of the waiver to enforcement procedures – it is not at all clear what the waiver would mean for the application of rules such as that the procedures must be fair and equitable, that court decisions must be reasoned and in writing, etc..

347. Chair, the discussions we had last week showed, in our view, that a reply based on mere permissiveness or reliance on Members' freedom to implement the waiver does not provide an answer to these and other questions posed by Members.

348. At the very end of the meeting the previous week, we also started a discussion on regulatory data protection. We did not have much time to discuss this issue, so we look forward to continuing our dialogue on this point in the future. The main area to explore, in our view, is the flexibility provided by Article 39(3). But as the discussion has not really taken place in the small group meeting, we will not comment on these matters at this stage – we have presented our preliminary comments on other occasions.

349. Chair, we, as other WTO Members, remain unconvinced about the benefits and concerned about the effects of the proposed waiver. On implementation, the discussion we have had so far shows that the assumption that the waiver does not require lengthy and complex implementation underestimates the challenges of implementing the waiver proposal in practice. Moreover, the approach according to which the choice of measures to implement the waiver is left entirely to Members, without any boundaries that would take account of necessity and proportionality raises concerns on the long-term effects of the waiver not only on the IP system but also as regards access to COVID-19 vaccines and medicines. On regulatory data protection, subject to further discussions, it seems to us that the existing flexibilities under the TRIPS Agreement do not justify a waiver in the circumstances of a pandemic.

350. We would like to thank again all the delegations that engaged on the EU proposal. We have noted the main two additional angles as regards requirements in Article 31*bis* – one concerning the labelling requirements and one the statements on the lack of manufacturing capacity. We would like to invite Members to present views on these two issues. We are all aware of the justification of the labelling requirement – which is an anti-diversion measure. It seems to us that in the case of exports to multiple countries there is no need of distinguishing labels depending on the importing country. We would be interested to know whether this is also the understanding of the other Members. It would be important to understand which aspect of the labelling requirement is viewed as cumbersome so that we can advance on our discussion. The same goes for the requirement to indicate the insufficient manufacturing capacity – we would be very interested to hear the views of Members on this requirement. This would also help us present in more detail a case study as suggested by the United Kingdom.

351. We are also discussing bilaterally with various delegations to explain our proposal in more detail and will continue these efforts.

352. Chair, we had important and good exchanges with Members on the EU proposal in the context of the text-based process. In view of these exchanges and the great potential of finding solutions on the basis of the EU approach, we would like to ask you to reflect this fact in the report to the General Council. It is, in our view, vital for the next steps that the General Council has the full view of the discussions that are taking place in the TRIPS Council and all proposals that are on the table.

353. As was mentioned by a number of delegations, the EU believes that Members should focus on solutions which are targeted, pragmatic and that can bring results in the short-term. In this context, we invite Members to discussions on the EU proposal. As indicated in the previous meetings, the EU is also ready to discuss all aspects of compulsory licensing system that would merit clarification to enhance efforts to scale up the production of COVID-19 vaccines, therapeutics and diagnostics.

354. Finally, we would like to emphasise that the IP-related discussion is only a part of the multi-pronged approach proposed by the EU. We call on all Members to engage in discussions on all elements of this approach as only this way we will be able to adequately respond to the current crisis.

2.2 Switzerland

355. [Switzerland made a single statement under agenda items 1 and 2. See the statement recorded under agenda item 1]

2.3 Paraguay

356. [Paraguay made a single statement under agenda items 1 and 2. See the statement recorded under agenda item 1]

2.4 Singapore

357. [Singapore made a single statement under agenda items 1 and 2. See the statement recorded under agenda item 1]

2.5 Turkey

358. [Turkey made a single statement under agenda items 1 and 2. See the statement recorded under agenda item 1]

2.6 Chad on behalf of the LDC Group

359. On behalf of the LDC Group allow me to thank the European Union for this statement that was just submitted under agenda item 2. Document IP/C/W/681 includes a draft declaration which provides for three clarifications in the framework of this pandemic regarding the mechanism of the compulsory licence, Article 31 of the TRIPS Agreement. As we see it, the objectives of these three suggestions that were voiced in this draft declaration are useful and we embrace them, we see them in a very positive light. To be more specific first of all, as we see it, it is judicious to facilitate the possibility to waive the obligation under Art. 31 (b) before actually moving to compulsory licensing agreements, and also to providing that, where vaccines are provided at affordable prices to low-and medium-income countries, the renumeration required from the manufacturers should reflect these prices, and to simplify and streamline the notification requirements for the exporting Members. That is the current state of play of our thinking with regard to the statements by the European Union and the LDC Group still is assessing these statements-. Bilateral consultations will be provided for and our Group will fine-tune these various concerns and then refer these to the delegation of the European Union.

2.7 South Africa

360. At the outset I want to thank the European Union for its introduction. I think we are on record in many of the meetings indicating that we believe that the response proposed by the European Union is essentially insufficient. We also note that the proposal is underpinned by an assumption that the laudable and unprecedented progress made in developing COVID-19 vaccines was incentivised by IPRs. While recognizing the role of IP to research and development, we also have to recognize other factors incentivising the rapid development of COVID-19 vaccines would also apply in this case. We believe that a common desire to ameliorate and eliminate an existential threat to the human race in terms of its health and economic wellbeing is part of that driving force. Also, large-scale public investment in research and development amounting to billions of dollars have also contributed.

361. We would be the first country to acknowledge and appreciate the role that intellectual property can play in stimulating innovation and as we have said in previous statements our IP Policy of 2018 is testament to this particular aspect. However, we believe that it is important to focus on the facts of the matter. In our view, an urgent multilateral response to the pandemic requires acceleration and diversification of production of health products and technologies, especially in low- and medium-income countries. We see that Africa lags far behind in the global distribution and access. A continent of 1.2 billion people imports 99% of its vaccines. This is unsustainable and something that would have to change. It is therefore critical that we use all the policy tools available to us to achieve this stated purpose to address barriers to production and diversification of production across the world. From this perspective we believe that the TRIPS waiver is a credible response by Members that should engage in good faith to achieve this objective, and that objective would be to save lives.

362. Substantively, we have raised various issues, and I will quickly go through some of these points. We believe that the proposal which envisages a declaration by the General Council provides clarification in relation to the rights of Members that are already clear. Where Members have to use compulsory licences, in reality, all the clarifications that have been advanced by the European Union are already abundantly clear and this can be ascertained by a simple reading of the text of TRIPS Article 31*bis*, and the Doha Declaration on TRIPS and Public Health has already given us a very clear picture of the right of Members to use compulsory licences. So from that perspective the EU proposal seeks to provide a clarification at the level of the General Council to essentially seek clarification on so-called national emergency and other circumstances of extreme urgency within the meaning of Article 31.b of the TRIPS Agreement.

363. This was never in question. We believe that in addition, the highest decision-making body of the WTO clarified in 2001 that for the purposes of Article 31.b, "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency". Another concern that we have raised in the deliberations that we have had relates to the clarification that the EU is advancing, which seems to limit the flexibilities provided to WTO Members under Article 31 and 31*bis* of TRIPS. During a pandemic, compulsory licences can be issued for purposes of public non-commercial use as well as to remedy anti-competitive practices, in which event there is also no need to obtain authorization from the right holder.

364. A serious concern with EU's proposal is that it implies that an authoritative interpretation by the WTO is required before an event can qualify as a "national emergency or other circumstances of extreme urgency". But this is not the case as - clearly - paragraph 5.c of the Doha Declaration has already provided this particular clarification.

365. In relation to remuneration, we have also raised the issue that Article 31.h of TRIPS allocates and states that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The TRIPS Agreement already provides full freedom in terms of the level of "adequate remuneration" to be paid to the patent holder under a compulsory licence. From that perspective, under Article 31.j of the TRIPS Agreement, the right holder has the right to appeal such a decision concerning remuneration, if the holder is not satisfied. This has also been clarified by work conducted by the Secretariat that the decision to set the level of remuneration is that of the national authorities that are competent to make such a decision.

366. The EU's text also implies that remuneration reflecting the generic price is only allowed in situations of "addressing the pandemic at affordable prices for low- and middle-income countries" and for "vaccine or medicine" although the flexibility to determine adequate remuneration in Article 31 is applicable to all WTO Members in all circumstances even beyond pandemics.

367. Furthermore, we would want to say, in short, it is unclear what the EU proposal adds to the status quo from a substantive perspective. If anything, it appears that the EU proposal seeks to limit the existing TRIPS flexibilities. Another point that we would very quickly like to raise is that the EU proposal treats compulsory licensing of products as a panacea for all IP-related barriers. In reality, this is not the case. As proponents of the TRIPS waiver, we have outlined in detail why compulsory licensing of patented products are inappropriate to comprehensively and expeditiously deal with COVID-19 in our documents IP/C/W672 and IP/C/W/673, so I will not repeat those particular aspects but merely indicate that compulsory licences as a response to the pandemic may not be able to deliver the results that we are seeking.

368. We do believe there is a need to simplify the compulsory licensing system, however we do not see how the EU proposal achieves this objective, other than maintaining the status quo. We take good note of the intervention by Brazil that looks at issues such as packaging as a further simplification, and we believe that this could be useful as an addition to our discussions. From that perspective we think that the EU proposal does not go far enough and certainly, as we have stressed, the EU proposal in its current form cannot be seen as an alternative to the waiver proposal, since it addresses only very limited issues and so from that perspective, we think that a further discussion could unlock an expansion of the ideas that have been introduced by the European Union.

369. I guess, as we have reiterated, the proposal is certainly limited to compulsory licensing of patents. As the waiver proponents have said, it does not address intellectual property beyond these

concerns and so we think that issues around the protection of undisclosed information, copyright, industrial designs and so forth are also important responses to deal with the situation that we face with COVID-19. On the other hand, as we have reiterated, the waiver proposal comprehensively deals in a holistic manner with all the matters in relation to COVID-19 technologies and intellectual property. It is also not clear how the EU proposal will facilitate the transfer of technology and know-how. We also note the call by several Members, including the delegation of Brazil, to have a further discussion on this particular issue. The communication also fails to address the major underlying concern with respect to compulsory licensing-that is the "case-by-case" or "product-by-product" approach which is limiting during the pandemic, and that this approach means that additional tools are needed to overcome IP barriers.

370. At the start of this discussion on the TRIPS waiver in October 2020, we heard some developed country Members referring to C-TAP and COVAX as tools that will deliver equitable access in due course. We have always been open to alternative approaches and we have welcomed these as alternatives to what we are proposing, but to date these tools have not delivered as much as they had promised. We have seen many pharmaceutical companies rejecting CTAP and we have witnessed a growing inequality and insufficient supply to COVAX which as of 19 July 2021 had only shipped 129 million doses, 6.5% of the 2 billion doses which will be due by the end of 2021. From that perspective it is very clear that we need additional capacity, we need more producers to come online to produce vaccines for everyone including for the developing world. We have heard voluntary licences is the way to go, but the experience during this time has indicated that these are extremely limiting. We have heard various delegations including the delegation of Indonesia indicating that many producers in the developing world requesting licences have been rebuffed and clearly under these circumstances compulsory licences are not delivering the results that we need.

2.8 European Union

371. I just wanted to very quickly thank for the comments, both from the LDC Group and from South Africa. As regard to the LDC Group we understand that our proposal is being analysed and we can look forward to some comments and to some proposals and that is very good news. And we are very much looking forward to this discussion. In the same way, regarding comments from South Africa, I think that one strand of these comments is about the fact that in the view of South Africa, the European Union proposal does not go far enough, it has only very limited issues included as the delegate said, and that there can be some further expansion of these ideas. That again is very good news to us. We are looking forward to this discussion, I think that if there is something missing, if there are issues that should be addressed or clarified in the view of South Africa, we want to reiterate our openness to such discussion. We have always emphasized that the list of issues that we proposed in our proposal to be clarified is not exhaustive, and therefore we are open to discussions on other issues and other clarifications, so we would like to really look, if need be, issue by issue, requirement by requirement, to see where there are problems, where there is complexity, where these are cumbersome in view of delegations, and to see what we can do to facilitate the use of the system.

372. I think we had a very broad discussion here and we are struggling as regards the way forward, and finding a common ground, but we have to start somewhere. I think we all agreed that patents is the most relevant part. What we would suggest is to start the discussion with regards to patents, let's have a discussion with regards to requirement by requirement and looking at what could be clarified, what could be facilitated. I would just like to emphasise that the European Union is very ready to have this discussion and with look forward to furthering discussions.

2.9 India

373. I also thank the European Union delegation for introducing their proposal. I take this opportunity to raise certain questions and seek clarifications and explanations from the EU on their proposal. It is indeed heartening to see that the proponents recognise the pandemic to be a global and economic crisis that calls for urgent multilateral action which is key to respond to this crisis swiftly. It would be useful if EU could clarify what it envisages as the urgent multilateral action and what would be the timeline for such an action. We are glad to see that the main objective of this proposal as reflected in the preamble is to ensure fair and equitable distribution of vaccines and medicines to fight against the COVID-19 pandemic and that requires concerted efforts to increase manufacturing capacity and investment as well as supplies at an affordable cost.

374. It also mentions in a number of places the need for accelerating the production of vaccines and medicines and their equitable global distribution. We wish to know and understand how this is envisaged in the proposal to achieve equitable distribution of this accelerated production of vaccines and medicines, especially with the concern over rampant pre-ordering of vaccines by developed country Members, how will this increased output be equitably distributed.

375. The proposal stresses the need for legal certainty on the flexibilities provided by the TRIPS Agreement and that the established procedures to use compulsory licences for those purposes be as efficient and streamlined as possible. It proposes to facilitate the determination of the renumeration to be paid under compulsory licences in the circumstances of the pandemic in order to support manufacturers ready to produce pharmaceutical products including vaccines or medicines at affordable prices for low- and middle-income countries. It is reassuring that at this critical time the proposal then delivers to reaffirm existing rights emanating from the Doha Declaration on the TRIPS Agreement and Public Health and the TRIPS provisions itself. It would be helpful if the EU could share some experiences in this regard. The proposal desires to facilitate the use of WTO notification procedures on compulsory licensing and I would like to state here that it is these cumbersome preconditions that render the mechanism impractical in a pandemic situation and these need to be revisited.

376. We have heard from a delegation in this meeting itself regarding their first-hand account of the difficulties being faced in utilising the compulsory licensing system, especially in the context of a pandemic, and we hear that the proponents still continue to support their proposal. However, while the majority of Members of the waiver proposal are calling for a waiver, it has not been given a chance to prove itself.

377. Another pertinent question here would be whether, since its proposal deals with explanation on the compulsory licensing, the EU is monitoring existing requests on compulsory licensing being filed by Members.

378. Now let me touch upon the three points mentioned in the operative part of the proposal. Point A clarifies that a pandemic is a national emergency or other circumstance of extreme urgency, that is the meaning of Article 31.b. We are not clear what elicited such clarification from the EU, since this was never in dispute and a pandemic by its definition is a global emergency and that does qualify as a national emergency. Additionally, Article 5.c of the Doha Declaration on the TRIPS Agreement and Public Health clearly states that each Member can determine as to what constitutes a national emergency. Further the second point reads that a Member can set a remuneration that reflects the price charged by the manufacturer of the vaccine for medicine produced under the compulsory licence. However, Article 31.h already provides for Members' freedom to set the level of adequate remuneration. Point C of the proposal says that the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied. What these points covered is a reiteration of existing provisions of the TRIPS Agreement. Importantly the proposal contains only 'may' obligations which makes these proposals even more redundant in addressing the current COVID-19 pandemic. Would the EU elucidate how these reiterations of the existing provisions result in ensuring production of vaccines, therapeutics and diagnostics for the treatment, prevention and containment of the pandemic and how they will secure access to vaccines for the developing countries and the LDCs?

379. Finally, we also want to know and understand what the legal enforceability of this declaration will be since it does not bring in any change to the existing agreement. How will Members use this declaration to procure more vaccines, therapeutics, PPE kits, masks etc. for their population? The proponents of the waiver proposal have argued on many occasions how flexibilities provided in the TRIPS Agreement are inadequate in responding to a pandemic of this magnitude. The limited policy space provided by the TRIPS Agreement flexibilities to address monopoly actions through issue of compulsory licences would not be a feasible option in a pandemic. Invoking compulsory licences across a wide range of medical products, on a case-by-case or product-by-product basis is a cumbersome and time-consuming process, severely limiting its effectiveness in the context of products and technologies required for fighting the virus. Beyond patents, other IP rights including trade secrets, industrial designs, copyrights etc. also pose barriers, and the current proposal is silent on those issues. Compulsory licence does not address these barriers posed by these rights.

380. What is pertinent to note here is that the discussion on improving on existing TRIPS flexibilities as well as the 2001 Doha Declaration on TRIPS and Public Health is crucial and relevant. However,

we would also only be deceiving ourselves by believing that a mere reiteration of existing flexibilities, with more stringent interpretations, would make them practical, less cumbersome and effective, and provide a timely solution to the pandemic.

India's statement at the informal meeting held on 24 June 2021

381. I thank you Chair for organising this meeting and I also thank the EU for introducing their proposal.

382. I take this opportunity to raise some questions and seek clarifications and explanations from the proponents. It is indeed heartening to note that the proponents recognise the pandemic to be a global health and economic crisis that calls for urgent multilateral action which is key to respond to this crisis swiftly. It would be useful if European Union could clarify what it envisages as urgent multilateral action and what would be the timeline for such action?

383. Further it reads that pandemic affects all countries and therefore requires concerted global efforts to ensure that all people in all countries have access to safe and effective vaccines and medicines as soon as possible. Here again would want to know what is meant by concerted effort and what is the understanding of the term 'as soon as possible' as it lacks specificity.

384. We are glad to see that the main objective of this proposal as reflected in the text is to ensure fair and equitable distribution of vaccines and medicines to fight against COVID-19 and that requires concerted efforts to increase manufacturing capacity and investment, as well as supplies at an affordable cost. The text does mention in a number of places the need for accelerating the production of vaccines and medicines and their equitable global distribution.

385. So while the proposal aims for fair and equitable distribution of vaccines and medicines it does not recognize that access to diagnostics and therapeutics is equally critical to save lives. Does the proposal aim to increase existing manufacturing capacity of the few players and, if so, could they provide evidence as to how increased manufacturing capacity will yield affordable supplies? And especially, with rampant pre-ordering of vaccines by developed country Members, how will the increased output be equitably distributed?

386. The proposal also talks of the need to provide and preserve appropriate incentives for investments in research and development of COVID-19 vaccines and medicines, particularly in view of the continuing emergence of new variants of the virus. What would be an appropriate incentive for R&D? Will it not be prudent to prioritise vaccination of people across the globe, as more unvaccinated people would only help the virus incubate and mutate into new variants defeating the purpose of these concerted efforts?

387. The proposal stresses the need for legal certainty on the flexibilities provided by the TRIPS Agreement and that the established procedures to use compulsory licences for those purposes be as efficient and streamlined as possible. to facilitate the determination of the remuneration to be paid under a compulsory licence in the circumstances of a pandemic, in order to support manufacturers ready to produce pharmaceutical products, including vaccines or medicines, at affordable prices for low- and middle-income countries. It is reassuring that at this critical time EU proposal endeavours to reaffirm our existing rights emanating from the Doha Declaration on the TRIPS Agreement and Public Health and the TRIPS provisions itself. The proposal desires to facilitate the use of WTO notification procedures on compulsory licensing, let me state here that it is these cumbersome preconditions that render the compulsory licensing mechanism impractical in a pandemic situation and these need to be revisited.

388. Now let me touch upon the three points mentioned in the operative part of the proposal point a clarifies that pandemic is a national emergency or other circumstances of extreme urgency withing the meaning of Article 31.b. We don't know what elicited such clarification from E.U since this was never in dispute and pandemic by its definition is global so a global emergency does qualify as a national emergency. Additionally, Article 5.c of the Doha Declaration on TRIPS Agreement and Public Health clearly states that each Member can determine as to what constitutes a national emergency.

389. Further, the second point reads that Members can set a remuneration that reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.

However, Article 31.h of TRIPS already provides Members freedom to set the level of adequate remuneration.

390. Point c of the proposal says that the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied. What these points covered is a reiteration of existing provisions of TRIPS Agreement. Could the EU elucidate how these reiterations of existing provisions result in ensuring augmentation of production of vaccines, therapeutics and diagnostics for the treatment, prevention and containment of the pandemic, how will these secure access to vaccines for developing countries and the LDCs.

391. Finally, we would like to hear as to what will be the legal enforceability of this declaration, since it does not change the existing Agreement, how will Members use this declaration to procure more vaccines, therapeutics, PPEs, masks etc. for their population?

392. The proponents of the Waiver proposal have argued previously on many occasions how flexibilities provided in the TRIPS Agreement are inadequate in responding to a pandemic of this magnitude. The limited policy space provided by the TRIPS Agreement flexibilities to address monopoly actions through issue of compulsory licences would not be a feasible option in a pandemic. Invoking compulsory licences across a wide range of medical products, that too on a "case by case" or "product by product" basis is a cumbersome and time-consuming process, severely limiting their effectiveness, in the context of products and technologies required for fighting the virus. Beyond patents, other IP rights, including trade secrets, industrial designs, copyrights, etc. also pose barriers. Compulsory licence does not address the barriers posed by these rights. In fact these limitations posed by the compulsory licensing can be easily addressed by the Waiver. The waiver once approved and applied would provide countries with an effective and expeditious way to remove key IP barriers that scuttle the use of existing idle capacities.

393. What is pertinent to note, Chair, is that this discussion on improving upon the existing TRIPS flexibilities as well as the 2001 Doha Declaration on TRIPS and Public Health is crucial and relevant, however, we would only be deceiving ourselves by believing that a mere reiteration of existing flexibilities would make them practical, less cumbersome and effective and provide a timely solution to the pandemic.

2.10 European Union

394. I would like to give some first responses to questions from India. I think we have discussed a lot of these issues already in the context of small groups and informal meetings and of course we are ready to discuss again and in more detail. First of all, about the multilateral action and multifaceted action, that was the question of India. What is part of this proposal, so here I would like to reiterate the engagement of the EU in both the Trade and Health Initiative that was presented by the Ottawa Group that deals with a number of trade-related policy responses to the COVID-19 crisis, and also a specific communication on urgent trade policy responses to COVID-19 crisis, document WT/GC/231, that we have submitted to the WTO General Council on 4 June 2021. The approach proposed in these documents is basically to explain that we need a number of trade-related measures that deal with identifying bottlenecks. It is to tackle export restrictions, to look at supply chains, to look at trade facilitation measures, that we need to have also a proper cooperation with industry and see how we can support collaborations between industry, and this is where the Director-General of the WTO, Dr Ngozi Okonjo-Iweala, has organised a number of events as to how to strengthen these collaborations and how to strengthen this matchmaking.

395. The third component of this approach is the intellectual property component where the logic of our proposal is, that IP should be an enabler when it comes to increasing capacity and using the current adequate capacity. It is all of these components together that work towards accelerating the production of vaccines and medicines. None of these elements alone can do it and certainly not the element on intellectual property, whether it is compulsory licensing or the waiver, cannot achieve it. What we need, as we have presented in our intervention, we need discussions, we need investments, we need to create conditions, we need to see which facilities can be used, we need to see what additions to these facilities have to be made. Switzerland gave a very good example of what had to be done to ensure there is skilled personnel, there is a question of access to raw materials, so all of this has to come together in order to accelerate production of vaccines and medicines, and as South Africa was saying today, I think that there are clearly things that can be done in the short

term and things that can be done in the medium- and long term. And clearly, as the delegate from South Africa was referring to, the fact of the dependence of certain regions like Africa on imports of pharmaceuticals - I think the delegate referred to 99% of imports - is not a situation that can be accepted going forward. And this is also why the European Union is engaging on supporting what I think was included very clearly in our intervention today, on the creation of manufacturing hubs in Africa and also strengthening the resilience of health systems. So, to answer the question, all of this comes together to produce a set, because it is not by one click or one decision or one change, especially in the area which has nothing to do with the bottlenecks which are identified, that we can bring any change.

396. All of this is also done in such a way as to maintain incentives and not break the current collaboration – not taking away incentives for transfer of technology and know-how, I think that is a crucial part of the EU proposal. Our proposal is proposed in such a way to ensure when IP is an obstacle, so when the licence is an obstacle, then the compulsory licences system can be used and can respond to this obstacle. At the same time, we are not proposing an approach that undermines the current collaborations, that result in a chilling effect on collaboration going forward, and basically backfires and puts into question all our efforts and objectives that we have.

397. When it comes to questions about particular clarifications, I think I have referred to this already, when replying to the honourable delegate from South Africa, we are not reiterating what is in the TRIPS Agreement or the Doha Declaration, we are giving additional precision, an additional comfort regarding these three issues in the circumstances of the pandemic. It does not have a limiting effect of course, as we have explained many times. The intention is not to provide clarification in a way that limits Members in the use of these flexibilities, on the contrary, it is to provide additional comfort, to provide legal certainty to make the system as effective as possible. We heard now from India and we hear from a number of delegations that it is does not go far enough, that it is inadequate, that there can be other issues. India mentioned notification procedures. There were also references to packaging and labelling requirements. Well, I would say, let's discuss it. Please let us know what else is missing, because moving away, and leaving the discussion at the level of 'it is inadequate and cannot work because it does not go far enough' is not helping to go forward. Let's discuss requirement by requirement, what else is needed, we are very open to do that.

398. The European Union has been saying this from the beginning, we have come up with our proposal on what we think is most relevant but we are absolutely open to discussing, and this already came in a very useful manner last week from the delegation of Turkey, for which we are very grateful. As I explained in our intervention today, we are analysing very closely this proposal. So let's discuss it, let's not just say it is inadequate, let's not just say it doesn't go far enough. Please put issues forward so that we can look into this. All of this is open to discussion, we discussed legal enforceability, for the time being I can say it is the same as the Doha Declaration. We see how the Doha Declaration has been agreed and what kind of impact it has had and continues to have, and we think that our declaration as proposed can have a very similar impact and can be extremely useful for the times of a pandemic. I will stop here, but the most important, from my point of view, is the invitation to share. We are not limiting our approach to the proposal to what we are putting on paper. We are open to discussing all requirements and looking at all issues and we think that we need to move forward in the discussion, we need to advance, we cannot as has been said many times by the proponents of the waiver, we cannot go in circles. Let's try to find some areas of convergence, let's try to start with something smaller, something relevant, something on which we can build convergence and communication between us – and obviously patents is the area which is most relevant here. So let's start with this, rather than discuss and not find any solutions, let's start with something that can bring solutions in the short term and make a real difference. That is what we would like to invite all Members to do.

3 OTHER BUSINESS

3.1 World Intellectual Property Organization

399. The global pandemic continues to wreak havoc on the lives and livelihoods of people across the globe. While the threat is coming under control in some countries, many others continue to suffer the full force of the pandemic. Winning the battle against COVID-19 is the world's most pressing and immediate challenge. Finding ways to secure global vaccine production to overcome

global vaccine shortages is central to that endeavour. Let us not forget that no one is safe until we are all safe.

400. Human ingenuity offers great hope. Over the last year, we have witnessed the fastest development and deployment of vaccines in history. The anticipated ramp up in COVID-19 vaccine production over the coming months promises to bring total production to some 11 billion doses by year-end. While this is very good news, there is still much to do to ensure that these life-saving vaccines reach all communities in every part of the world.

401. Beyond overcoming the pandemic, we also need to come together to support countries as they lay the foundations for a post-COVID recovery. Harnessing the innovative and creative capacities of our people and building a balanced and effective global IP ecosystem to support these efforts, will be key to building back better. While the important discussions in this forum are proceeding, WIPO is committed to taking measures to support our common goal of equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies. But the challenge ahead is complex and multi-faceted and requires concerted action across agencies.

402. This is why we are very pleased that the trilateral cooperation with the WHO and WTO has been stepped up. Last month, the Directors-General of WIPO, WHO and WTO met to map out further collaboration to tackle the COVID-19 pandemic and other pressing challenges at the intersection of public health, IP and trade. The teams from all three agencies have since been working hard to concretize these aspirations. We have agreed to organize a series of capacity-building workshops to enhance the flow of updated information on current pandemic-related development and responses to achieve equitable access to COVID-19 health technologies. Scheduled for September, the first workshop will focus on technology transfer and licensing.

403. We further agreed to implement a joint gateway for tripartite technical assistance to support countries in assessing, prioritizing, and responding to unmet needs for COVID-19 vaccines, medicines and related technologies. Work on this is still ongoing and further details will be shared in due course.

404. While the Trilateral work is proceeding apace, solely at the WIPO front, the previous week Director General Daren Tang announced a package of COVID-19 services and measures to support Members as they overcome the pandemic and rebuild. The package covers five areas in which WIPO has significant experience and expertise, namely, Policy and Legislative Assistance; Technical Assistance and Capacity Building; Innovation Support and Technology Transfer; and IP Dispute Resolution and Knowledge Resources. Full details can be found on our website and via WIPO's COVID-19 Related Services and Support page.

405. The package complements other long-standing WIPO pandemic-response measures, such as the COVID-19 Policy Tracker and our work in support of an enabling environment for tech transfer and licensing. In fact, today, we are holding a workshop on The Role of Knowledge Transfer Policies, which is the first in a series of seminars focused on Innovation in the Time of COVID-19.

406. WIPO has been a longstanding observer at the proceedings of this august Council, and we are following the important deliberations of WTO Member governments on COVID-19 related proposals in the TRIPS Council very closely. And we stand ready to provide legal and technical assistance in line with Article 67 of the TRIPS Agreement, and Article 4 of the WIPO-WTO Agreement.

407. We look forward to working with our key partners around the globe to support collective efforts to bring the COVID-19 pandemic to an end and to build back in a more inclusive and sustainable way. WIPO also wishes to thank you, Chair, for your tireless efforts in building consensus to achieve these shared goals.

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