Informal TRIPS Council, 3 December 2020

Statement of the European Union

- We all share one objective: to rapidly develop safe and effective therapeutics and vaccines, to manufacture them in required quantities as soon as possible and to distribute them equitably across the world.

- Following the recent announcements on the results of clinical trials of some candidates for vaccines, we may be getting closer to overcoming the first major challenge, *i.e.* the development of a vaccine. Further vaccines and therapies may follow in the near future.

- But this does not mean that the challenges that we face are not enormous. The manufacturing at huge scale, the distribution of vaccines, their storage and even their administering will test our financial capacity, our logistical skills and perhaps, most of all, our global collaboration and solidarity in the face of this crisis.

- Although it is primarily a sphere of health policy, trade policy can support the vaccine delivery by keeping markets open to essential healthcare products, avoiding export restrictions and adopting trade facilitation measures. In this regard we have referred to in our previous interventions to the so-called "Trade and Health Initiative" that the EU and other like-minded WTO partners have submitted to the WTO.

- As also previously stated, the EU response to the crisis is based on the two main tracks:

    - public-private cooperation with pharmaceutical industry that has the expertise and the means to develop and manufacture a vaccine, and

    - a cooperation at a global level that would not only accelerate the development and manufacture of vaccines, but also guarantee rapid, fair and equitable access to them for people in all countries.

- Those who researched the vaccines for years, developed them in record time and have all the know-how are best placed to produce the vaccines in required quantities including by licensing technology and know-how to other manufacturers that have the

capacity to produce them without compromising their efficacy and safety. The EU's investment in advance purchasing agreements contributes to expanding production capacities and to securing large quantities of raw materials.

- We see that the expansion of production is already taking place with AstraZeneca's licensing to the Serum Institute of India and we expect that other companies will also expand their manufacturing capacities by granting licences. We call on these companies to use the licensing mechanisms to the maximum to support the rapid manufacturing of the vaccines.

- The COVAX Facility is the mechanism by which we expect the high-income countries to finance the vaccines and the deployment of vaccines for low- and middle-income countries. Here the key issue is to address the remaining global financing needs as underlined in the recent G20 Riyadh Leaders Declaration.

- The public funding and support is contributing significantly to the development of the future treatments and vaccines against COVID-19.

- However, it is the researchers and the industry with their know-how, previous and current investment that will be delivering these new vaccines, including the running of clinical trials in parallel with investing in production capacity to be able to produce millions, or even billions, of doses of a successful vaccine.

- We note that public financing of research and development of the innovative treatments and vaccines can be subject to certain conditions. For example, the European Commission has published a Manifesto for EU COVID-19 research to encourage recipients of EU funding to make research results accessible to all. Recent Horizon 2020 COVID-19 calls have also included a temporary obligation to license results on a non-exclusive basis and on fair and reasonable conditions.

- We would like to thank the delegations of South Africa and India for the information provided in the course of the consultations and for the document no. IP/C/W/670 from South Africa which we have carefully studied. It presents the patent landscape of various anti-viral and other medicines. As the existence of these patents as such does not amount to a barrier, we would be interested to know more about the cases concerning these medicines. We note also

the examples of shortages in supply that occurred at the early stages of the pandemic. We understand that these were resolved rather quickly but are of course open to hear more.

- Without doubt, making sure that there is a continued supply of medicines and technologies related to COVID-19 is a difficult task. However, fragile and underfunded healthcare and procurement systems, spikes in demand and lack of manufacturing capacity are much more likely to have an impact on the access to those medicines and technologies than intellectual property.

- Having said that, in case intellectual property should become an issue in the context of this access, the international intellectual property system already provides solutions. We spoke of this before. Patent or any other intellectual property protection, such as the protection of test and clinical trial data, is not absolute. Intellectual property is a system of checks and balances. The TRIPS Agreement provides for the necessary flexibilities such as a possibility to grant compulsory licences – these are provided specifically for emergencies such as this pandemic. And can be used if the companies do not heed the calls for manufacturing at scale including with the use of adequate licensing. We want to emphasise this point. This includes fast-track procedures where no negotiations with the patent holder are required and the possibility of granting licences for export to countries with no or insufficient manufacturing capacity. Only simple notifications are required to put the latter one into effect. It is also possible to dispatch notifications with regard to many products at the same time. We are ready to discuss ways of facilitating the use of these flexibilities.

- In view of the above, we continue to have important questions on the rationale and the potential benefit of the waiver, especially when compared to the licensing solution with the safety valve of compulsory licensing. Our main concern is the impact such a waiver cam have on the ongoing and future private-public partnerships as well as the global effort undertaken via the COVAX Facility.

- In that regard, and in order to facilitate a consensual, constructive and evidence-based discussion, we fully support the approach presented in the document submitted by the delegations of Australia, Canada, Chile and Mexico and the questions put forward in this document as highly pertinent for our discussion.

- In addition to the questions posed by these delegations, in the spirit of open discussion and to foster further exchanges, while appreciating comments already provided, we would like to invite the proponents to:
    - explain in more detail how concretely the waiver could operate with regard to the vaccine production, including the transfer of the required technology and know-how,
    - how it would affect the existing licensing mechanisms e.g. the AstraZeneca licence and the COVAX Facility more generally,
    - what would the domestic implementation of the waiver entail and why would it be easier to carry out than introducing fast-track procedures for compulsory licensing on the basis of the existing system?,
    - how the "temporary" nature of the waiver would work, with regards to unregistered rights as copyright and with regard to patents and designs - should they not be granted if in application stage? If they are already granted, does the waiver mean that they cannot be enforced? When the application of the waiver is over, how do the owners recuperate their rights?
- We agree that the report to the General Council should be succinct and factual. We thank the Chair for the draft of this report. We will respond with any potential comments by the deadline.
- I would like to emphasise that the EU is ready to engage in a dialogue with other WTO members on all areas that would be helpful in fighting the pandemic, including on intellectual property, e.g. what can be done to facilitate the implementation of the TRIPS Agreement flexibilities that have been provided for specifically to address problems in the area of public health.