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Council for Trade-Related Aspects of Intellectual Property Rights

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

## COMMUNICATION FROM THE EUROPEAN UNION TO THE COUNCIL FOR TRIPS

- 1. On 4 June 2021 the European Union submitted to the Council for TRIPS a communication on "Urgent trade policy responses to the COVID-19 crisis: intellectual property" (document IP/C/W/680).
- 2. Following that communication, the European Union requests that the Council for TRIPS recommend to the General Council the adoption of the annexed declaration text.

#### **ANNEX**

### **DRAFT DECLARATION TEXT**

# DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH IN THE CIRCUMSTANCES OF A PANDEMIC

The General Council,

Reaffirming the content of the General Council Declaration 'A Trade Policy Response to the COVID-19 Pandemic and to Enhance Resilience Against Future Pandemics', which this Declaration aims to complement,

Recognizing that the COVID-19 pandemic continues to be a global health and economic crisis that affects all WTO Members and that urgent multilateral action is key to respond to this crisis swiftly,

Recognizing that pandemics affect all countries and therefore require concerted global efforts to ensure that all people in all countries have access to safe and effective vaccines and medicines as soon as possible,

Recognizing that our main objective is to ensure fair and equitable distribution of vaccines and medicines to fight against COVID-19 and that this objective requires concerted efforts to increase manufacturing capacity and investment, as well as supplies at an affordable cost,

Recognizing that the WTO must step up its efforts to ensure that the rules-based global trading system plays its role in response to the COVID-19 crisis,

Recognizing 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,

*Recognizing* that the response to the COVID-19 crisis needs to be comprehensive and include, but not be limited to, ensuring that the intellectual property system supports efforts to enhance production and supply of vaccines and medicines,

Recognizing that pandemics pose specific challenges for developing and least-developed countries,

Recognizing that, in the circumstances of a pandemic, an urgent multilateral response requires accelerating the production of vaccines and medicines and their equitable global distribution,

*Emphasizing* that, where Members need to use compulsory licensing for those purposes, legal certainty on the flexibilities provided for in the Agreement on Trade-Related Aspects of Intellectual Property Rights ('the TRIPS Agreement') is essential,

Recognizing that, in the circumstances of a pandemic, it is also essential to support the production and supply of vaccines and medicines at affordable prices to low- and middle-income country Members, including through international joint initiatives that aim to ensure equitable access of vaccines or medicines, such as the COVAX Facility for the COVID-19 pandemic, and through concerted efforts of voluntary technology transfer,

*Stressing* the need to ensure that the established procedures to use compulsory licences for those purposes be as efficient and streamlined as possible,

Desiring to clarify that a pandemic constitutes a national emergency or a circumstance of extreme urgency for the purposes of issuing a compulsory licence, including for export, under the TRIPS Agreement, to support a swift use of the compulsory licensing system in the times of a pandemic,

Desiring 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,

*Desiring* to facilitate the use of the WTO notification procedures on compulsory licensing for exporting or importing purposes, including in the context of international joint initiatives that aim to ensure equitable access of the vaccines or medicines covered by a compulsory licence.

#### Declares that:

We, the WTO Members, reaffirm the content of the Doha Declaration on the TRIPS Agreement and Public Health.

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to vaccines and medicines for all.

In this connection, we reaffirm the right of WTO Members to use the provisions in the TRIPS Agreement, which provide flexibility for this purpose, including those relating to compulsory licensing in Articles 31 and 31*bis*.

### We agree that:

- a. A pandemic is 'a national emergency or other circumstances of extreme urgency' within the meaning of Article 31(b) of the TRIPS Agreement. For the purposes of issuing a compulsory licence pursuant to Articles 31 and 31bis of the TRIPS Agreement, a Member may waive the requirement of making efforts to obtain authorization from the right holder, provided for in Article 31(b).
- b. In the circumstances of a pandemic and to support manufacturers ready to produce vaccines or medicines addressing the pandemic at affordable prices for low- and middle-income countries, a Member may provide, for the purposes of determining the remuneration to be paid to the right holder pursuant to Article 31(h) and paragraph 2 of Article 31bis of the TRIPS Agreement, that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.
- c. In the circumstances of a pandemic, for the purposes of Article 31bis and paragraph 2.c) of the Annex to the TRIPS Agreement, the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member directly or through indirect means, including international joint initiatives that aim to ensure equitable access to the vaccines or medicines1 covered by the compulsory licence. It shall be presumed that such joint initiatives supply those vaccines and medicines to eligible importing Members within the meaning of paragraph 1.b) of the Annex to the TRIPS Agreement.

 $<sup>^{1}</sup>$  It is understood that, in the circumstances of the COVID-19 pandemic, COVAX is an international joint initiative within the meaning of this paragraph.