

COMMUNICATION FROM THE EUROPEAN UNION TO THE COUNCIL FOR TRIPS

URGENT TRADE POLICY RESPONSES TO THE COVID-19 CRISIS: Intellectual property

Brussels, 4 June 2021

1. The COVID-19 pandemic continues to be a global health and economic crisis affecting all WTO Members. Concerted global efforts are required to ensure that all people in all countries have access to safe and effective COVID-19 vaccines and therapeutics as soon as possible. The WTO must step up its efforts to ensure that the rules-based global trading system plays its role in response to the crisis.
2. On 4 June the European Union submitted to the WTO General Council a Communication on "Urgent trade policy responses to the COVID-19 crisis". The Communication underlines that the EU strongly supports a multilateral and comprehensive response to the COVID-19 pandemic. The most urgent challenge now is to ensure a rapid and equitable roll out of vaccines and therapeutics globally, as this is the only way to control the virus effectively.
3. The Communication underlines that the rules-based global trading system can contribute to expanding the production of and equitable access to COVID-19 vaccines and therapeutics swiftly. Since last year, together with a growing number of WTO members, the EU has been calling for a multilateral Trade and Health initiative. The EU has also been engaged in discussions on the proposal for a temporary waiver of intellectual property rights for COVID-19 health products, and has strongly supported the WTO's Director General in her initiative to consider practical ways to enhance production capacity and cooperation with the private sector.
4. 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) expansion of production, including through pledges by vaccine producers and developers and; 3) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory licences.
5. 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, the EU is presenting the specific elements related to intellectual property to the Council for TRIPS.
6. The rapid development of several safe and effective COVID-19 vaccines has shown the value of intellectual property, in terms of the necessary incentives and rewards to research and innovation. With the support of public financing, pharmaceutical and biotechnology companies throughout the globe have built on their expertise and invested resources to find solutions against COVID-19. With several successful vaccines available, research into alternative vaccines and new treatments against COVID-19 continues. In that context, the role of intellectual property will continue to be essential. However, the role of intellectual property is not limited to incentivising the development of vaccines and treatments. Intellectual property should also play an important role in enabling equitable access to COVID-19 vaccines and therapeutics.

7. In less than a year, the global production of COVID-19 vaccines has gone from 0 to 2 billion doses produced by end of May 2021. It is estimated that more than 10 billion doses of COVID-19 vaccines will be produced by the end of 2021. However, the urgency of the public health crisis requires not only the acceleration of the production of vaccines but also their equitable global distribution.

8. The 2001 Doha Declaration on the TRIPS Agreement and Public Health clarifies the links between the TRIPS Agreement, its flexibilities and public health. It 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. Under paragraph 1 of Article 66 of the TRIPS Agreement and following further extensions of the period provided therein, the least developed country Members are exempted from the obligations under the TRIPS Agreement except Articles 3, 4 and 5 until July 2021. The extension of this period is currently under discussion by the Council for TRIPS. The least developed country Members are also specifically exempted from obligations under Sections 5 (Patents) and 7 (Protection of undisclosed information) of Part II of the TRIPS Agreement with respect to pharmaceutical products until 2033.

9. The discussions in the Council for TRIPS since the start of the COVID-19 pandemic have identified aspects related to the use of compulsory licensing that, in the view of a number of WTO Members, limit the use of this tool. In order to address these aspects, 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:

- (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 therapeutics 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.

10. Point (a) refers to *Article 31(b)* of the TRIPS Agreement, which provides that a compulsory licence may be granted if "the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have been unsuccessful for a reasonable period of time". *Article 31(b)* further provides that "this requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". The EU proposes to clarify that the circumstances of a pandemic fulfil the requirement of a national emergency and therefore the requirement to demonstrate the efforts to negotiate for a certain period of time can be waived. Waiving this requirement ensures that any WTO member can proceed quickly to issue a compulsory licence. Finally, *paragraph 5 of Article 31bis* on compulsory licence granted for export purposes provides that it is without prejudice to any provisions of the TRIPS Agreement, other than paragraphs (f) (predominantly for the supply of the domestic market) and (h) (adequate remuneration) of Article 31 of the TRIPS Agreement. Therefore, the EU

proposes to clarify that the waiving of the requirement to negotiate with the right holder applies also in the circumstances of Article 31bis.

11. Point (b) concerns a clarification of *Article 31(h)* on the adequate remuneration to be paid to the right holder. Article 31(h) provides "that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation". *Paragraph 2 of Article 31bis* specifies this rule for circumstances of export to countries that lack manufacturing capacity. It provides that in a situation of a compulsory licence for export purposes the adequate remuneration is to be determined taking into account the economic value of the licence to the importing member. The EU proposes to clarify that in the circumstances of a pandemic, WTO Members can set the remuneration to the right holder at a level that reflects the price charged by the manufacturer of the vaccine or therapeutic under a compulsory licence. This would support production and supplies of vaccines and therapeutics at affordable prices to low and middle-income countries. This should also include the case of supplies to the COVAX Facility, which is the main global initiative to ensure equitable and fair access to safe and effective vaccines in the short term.

12. Under point (c), the EU proposes to tackle a procedural aspect of Article 31bis and the *Annex to the TRIPS Agreement*. Under the procedure established in the Annex, each eligible importing Member makes a notification to the TRIPS Council that specifies in particular the names and quantities of the product needed. At the same time, the exporting Member must also notify the Council for TRIPS of the grant of the licence, including any conditions attached to it. The exporting Member must include the information of the licensee, the product and the quantities, the duration of the licence and the "country(ies) to which the product(s) is (are) to be supplied". The EU proposes that in the circumstances of a pandemic, the WTO Members agree that the exporting Member may provide in one single notification a list of all countries to which vaccines and therapeutics are to be supplied directly or through the COVAX Facility. The objective is to ensure that with a single notification providing the elements required under Article 31bis for transparency purposes, the export can go ahead.

13. The EU considers that these elements are most urgent to ensure the full and effective application of the TRIPS flexibilities in relation to compulsory licences. However, the EU is also ready to engage on other points regarding the facilitation of the use of compulsory licensing as provided for in the TRIPS Agreement. In addition, the EU is ready to consider which actions and what support the Council for TRIPS and each WTO Member individually can provide to other WTO Members to facilitate the use of these flexibilities in practice. The EU would also propose to recall the technical support offered by the secretariat of WTO to all WTO Members that seek to use the systems of Articles 31 and 31bis.

14. Global equitable access to safe and effective COVID-19 vaccines and therapeutics is a common objective of all WTO Members. As a matter of urgency, the production of COVID-19 vaccines must be ramped up as soon as possible and their equitable and global distribution at affordable prices must be ensured. It is therefore urgent for the WTO to take multilateral action on a contribution by the trading system towards an expansion of production and equitable access to COVID-19 vaccines and therapeutics. The EU considers that the proposal for a comprehensive WTO initiative for equitable access to COVID-19 vaccines and therapeutics encompassing the three main components, including but not limited to intellectual property, should facilitate finding a common solution among WTO Members and bring about a concrete urgent response to the COVID-19 crisis.