



## **STATEMENT BY THE SOUTH CENTRE ON THE WTO DOHA MINISTERIAL DECLARATION ON TRIPS AND PUBLIC HEALTH ON ITS TWENTIETH ANNIVERSARY**

Twenty years ago, developing countries succeeded in obtaining the adoption of a landmark ministerial declaration in the World Trade Organization (WTO) to mitigate the impact of the obligations imposed on them by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) on access to medicines.

The Declaration on the TRIPS Agreement and Public Health ('the Declaration') was adopted on 14<sup>th</sup> November 2001 by the 4<sup>th</sup> WTO Ministerial Conference at Doha, Qatar, after complex negotiations. It was a response to government-backed actions by pharmaceutical companies aimed at limiting the policy space left by that Agreement to pursue legitimate public health objectives. The African Group played a key role in the process leading to the adoption of the Declaration which, in the context of an unbalanced international system, represented a distinct achievement for all developing countries.

The Declaration applies to any health problems or epidemics and to all intellectual property rights (IPRs) that are within the scope of the TRIPS Agreement. It not only reaffirms the right of WTO Members to use the TRIPS flexibilities to the fullest extent possible, but it also requires those Members to restrain from any action that may hinder them.

Despite the continuing challenges that WTO Members have faced, the Declaration has contributed to advance the use of the policy space and specific mechanisms available in the TRIPS Agreement to promote public health, commonly referred to as "flexibilities". It has influenced legislation and national court decisions. The express reference to the Declaration in treaty provisions has also given normative weight to the principles of the Declaration in many free trade agreements.

The Declaration also contributed to mainstreaming the concept of TRIPS flexibilities in WTO jurisprudence. As recognized by the WTO panel in *Australia-Tobacco Plain Packaging*, the Declaration is much more than a political statement. It is a 'subsequent agreement' to the TRIPS Agreement under the principles of international law. Consequently, a pro-public health interpretation of the Agreement's provisions is not only tenable but also mandated. WTO Members can confidently adopt pro-public health perspectives while designing, implementing and interpreting IPR laws.

Important - but in some cases still insufficient - efforts have been made by countries to make use of TRIPS flexibilities to the fullest extent in order to further public health objectives. In line with the Doha Declaration, national IPR legislations should at

minimum include rigorous standards for the examination of pharmaceutical patents and thereby avoid the proliferation of patents on minor or trivial developments. There should also be specific provisions for compulsory licensing on nationally determined grounds for issuance with simplified procedures; provisions for parallel importation based on an international exhaustion principle; early working ('Bolar') exceptions; and full use of the transition period for Least Developed Countries (LDCs).

Paragraph 6 of the Doha Declaration recognized that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing as allowed by the TRIPS Agreement, and instructed the Council for TRIPS to find an 'expeditious solution' to this problem. While the Paragraph 6 system -initially adopted as a waiver and later incorporated as Article 31*bis* of the TRIPS Agreement- sought a 'solution' to the problems faced by developing countries and LDCs in accessing affordable medicines under patent, in actual practice it has not contributed to solve such problem. The lack of effective use of the system is not due to lack of need of use, but to the cumbersome conditions imposed. In the context of the Covid-19 pandemic, the value of the system has been further put into question, as it has not worked to support countries with no domestic manufacturing capacity in dire need for access to vaccines. There is a need to undertake a profound assessment of the special compulsory licensing system under Article 31 *bis*. An effective solution to the problem identified in Paragraph 6 of the Doha Declaration must still be found.

Paragraph 7 of the Declaration reaffirmed "the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2". This is another area in which the objectives of the Declaration have not been achieved, as transfer of technology to LDCs is still clearly insufficient. Further action is also necessary to effectively implement the obligations under Article 66.2 of the TRIPS Agreement.

In the context of the Covid-19 pandemic, the importance of enabling national legislation to use the TRIPS flexibilities has become ever more evident. The need to act fast and collectively justifies, however, the temporary suspension (waiver) of the TRIPS Agreement's obligations as currently proposed by a large number of the WTO Members.

In line with the objectives of the Declaration, WTO Members should assess and identify the challenges for the full use of the TRIPS flexibilities to promote public health, with the aim of designing new supplementary tools to that end. The international community should never allow again the inequity in access to life saving pharmaceuticals that has characterized the response to the Covid-19 pandemic.

**An assessment of the Doha Declaration on its 20<sup>th</sup> Anniversary is provided in South Centre Policy Brief No. 107, "The Doha Declaration on TRIPS and Public Health on its Twentieth Anniversary". A series of analyses on the Declaration in response to a call for contributions by the South Centre on occasion of this anniversary will be published in the coming months.**