

## **South Centre Statement on the Amendment to the WTO TRIPS Agreement to Ease Access to Affordable Medicine**

**27 January 2016**

An amendment to the TRIPS Agreement that aims to facilitate the access to affordable medicines has entered into force upon approval by two thirds of the WTO Members. The amendment reflects the recognition by WTO Members of the need for the continued enhancement of global intellectual property rules to allow Members to systematically take measures to protect public health.

The amendment is the result of a negotiated solution among WTO Members, known as the Paragraph 6 system. It modifies elements of intellectual property rules under the WTO TRIPS Agreement that constrained the ability of Members to make available affordable medicines. The use of a compulsory license (allowing production or importation of a patented medicine without the agreement of the patent holder) was legally restricted to be predominantly for the domestic market. The amendment establishes new rules allowing Members to export/import limited quantities of patented medicines under certain circumstances.

During the negotiations of the Paragraph 6 system, in the context of the Doha Declaration on TRIPS and Public Health, the aspiration was to develop a system to enhance access to patented medicines at affordable prices. So far this aspiration has not materialized. To date there is only one recorded instance of the use of the system (export of an HIV/AIDS medicine from Canada to Rwanda). The reasons for the lack of use of the system have not been assessed yet in the WTO context.

The interest in the use of the Paragraph 6 system as a means to supply affordable medicines to developing countries is likely to rise. With the number of essential medicines, including biologics, under patent protection expected to increase countries without manufacturing capacity should explore all means available to increase affordable access to medicines for their people. With the amendment in place, eligible exporting and importing countries may growingly seek to use the system. This will require the adoption at the national or regional level, both by potential exporting and importing countries, of streamlined, easy to follow rules and procedures that ensure legal certainty and an effective operation of the system.

The United Nations Secretary General's High Level Panel on Access to Medicines has highlighted the importance of designing legislation that allows for quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and recommended WTO Members to revise the paragraph 6 system in order

to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license.

The South Centre stresses the continued importance for Least-Developed Countries (LDCs) to make full use of the special status they enjoy in not being required to adopt rules on patent protection and most other rules of the TRIPS Agreement, in order to build their technological capabilities and reduce obstacles to affordable access to medicines. The LDCs would not need, in this case, to make use of the system.

Increased action, readiness, collaboration and assistance among governments, international organizations and public and private sector entities, will be needed, both to test the effectiveness of the Paragraph 6 system and to support LDCs to build an adequate technological base.

Efforts should be made by governments and the WTO, in cooperation with other international organizations including WIPO and WHO, to encourage entities, private and/or public, to come on board with good will to help make the system operational. Close attention will need to be paid to the design of national implementing legislations and the feedback from potential user entities of the system on any hurdles they may face that diminish interest in its use. The evaluation of the system must continue in the TRIPS Council.

The South Centre shall willingly provide assistance to countries in examining national implementing legislations, and providing information to potential interested parties. Templates for facilitated implementation and meeting of conditions required under the system may be provided. Countries that are already suffering significant burdens from the lack of access to medicines should not have to face additional technical and financial burdens to make use of the system.

As a contribution to advancing the analysis of the Paragraph 6 system, the South Centre organized a side event to the TRIPS Council on 8 November 2016. (See <https://www.southcentre.int/sc-side-event-paragraph-6-of-the-doha-declaration-on-trips-and-public-health-an-effective-solution-8-november-2016/>.)

The South Centre is committed to continue to assist its Member States and other developing countries to participate in the evolution of the multilateral trade and intellectual property system that allows policy space to promote public health.