WORLD TRADE ORGANIZATION

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General Council

PROTOCOL AMENDING THE TRIPS AGREEMENT: EXPECTED BENEFITS OF THE PARAGRAPH 6 SYSTEM OF SPECIAL LICENCES FOR EXPORT OF MEDICINES[1]

AIDE MÉMOIRE[2]

Key points

- A 2005 General Council Decision affirmed WTO Members' unanimous agreement to amend the TRIPS Agreement to create a permanent legal pathway for access to affordable medicines to countries with limited or no production capacity, delivering on the Ministerial mandate of paragraph 6 in the Doha Declaration on the TRIPS Agreement and Public Health.

- The "Paragraph 6" System (the System) is currently available in the form of a waiver, but Members called for the legal certainty of a permanent amendment to the TRIPS Agreement that would put the System on par with other public health-related TRIPS flexibilities.

- **Entry into force** of the Protocol Amending the TRIPS Agreement would:

    - give practical effect to Members' resolve to provide a new TRIPS public health flexibility for the benefit of those Members most reliant on trade to fulfil their needs for medicine;

    - provide legal certainty that will strengthen its future potential to facilitate export of needed medicines and give this additional flexibility the same status as all other TRIPS public health flexibilities;

    - provide a more secure and sustained legal basis for both potential exporters and importers to adopt legislation and establish the means needed to implement the System; and

    - respond to encouragement from the multilateral system to complete the process of acceptance of the amendment.

- **Benefits of the System** are naturally focused on those Members which lack production capacity and are especially reliant on imports of medicines:

    - The potential need to import medicines produced under a compulsory license in another country – the specific procurement scenario that the System addresses – would generally arise when newer generations of medicines become more likely to be covered by patents in traditional lower-cost producing countries, or in the event of a global pandemic.

[1] This was circulated at the General Council meeting of 20 February 2015 under Agenda Item 3 – Protocol Amending the TRIPS Agreement: Update on Status – Statement by the Director-General – Aide Mémoire as RD/GC/3. At that meeting, it was agreed that the aide memoire be circulated as a formal General Council document.

[2] This aide mémoire has been prepared by the WTO Secretariat on its own responsibility. It responds to requests from a number of WTO Members, most recently reiterated at a meeting of the African Group with the WTO Director-General on 9 February 2015, for a succinct outline of potential benefits from the Paragraph 6 System. This note provides a general, non-technical explanation for background purposes only, and should not be viewed as a legal interpretation.

- The bulk of the world's exporters of medicines are now covered by laws implementing the system, meaning that potential beneficiaries have a wide range of potential suppliers, if needed, under the System; entry into force may trigger further legislation and implementation by potential exporters.

- To enhance potential future benefits of the System, the Secretariat can provide tailored and practical technical assistance on request to support Members in making more regular use of the System to notify their expected medicine needs, to build it into drug procurement programmes, and to tap into the System's intended potential to harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.

What is the System for?

1. The "Paragraph 6" System of special export licences for medicines takes its name from the provision that mandates its creation in the Doha Declaration on the TRIPS Agreement and Public Health. The System provides an additional TRIPS flexibility in the form of an additional legal avenue for access to medicines that a Member may use when it is reliant on international trade for access to a needed pharmaceutical – in particular, as the Doha Declaration phrased it in its paragraph 6, when a country has "insufficient or no manufacturing capacities in the pharmaceutical sector" and therefore confronts difficulties "in making effective use of compulsory licensing"[3], when this is the preferred means of access.

2. To overcome this limitation, the System creates a new form of compulsory licence, tailored specifically for export of medicines to countries in need. When they have been issued by Members, compulsory licences have been used to service the domestic market, in line with a TRIPS Agreement requirement that compulsory licences should in general be authorized "predominantly for the supply of the domestic market". The System enables a compulsory licence to be issued by an exporting Member specifically to meet the needs of an importing country – in a sense, a "trade-related" compulsory licence, to be available when this is the best option for a country in need of specific medicines.

What is its status?

3. The System was first established as a waiver by the General Council on 30 August 2003.[4] Especially at the urging of the African Group, the waiver decision provided for work to commence on a formal amendment. On 6 December 2005 the General Council unanimously decided to amend the TRIPS Agreement through a Protocol of amendment.[5] For the Protocol to enter into legal force, and thus permanently to amend the TRIPS Agreement, two thirds of the membership must formally confirm their acceptance, following through the existing political consensus (Annex 2 lists the Members which accepted the Protocol).

4. In the Council for TRIPS, and directly through outreach to Members, the Secretariat has given guidance on the straightforward steps required to notify acceptance. This has included making available a model instrument of acceptance (Annex 1) and guidance on how to accept the Protocol.[6]

5. The Secretariat has also clarified that acceptance signals willingness for this option to be available to all Members if they choose to use it, but does not compel the Member accepting the Protocol actually to implement the measure on the domestic plane. Many Members have accepted the Protocol of Amendment without having implemented any domestic legislation.

[3] WTO document WT/MIN(01)/DEC/2.
[4] WTO document WT/L/540 and Corr.1 and Statement read out by the Chairman of the General Council, WT/GC/M/82, paras. 29 to 31.
[5] WTO document WT/L/641 and Statement read out by the Chairman of the General Council, WT/GC/M/100, paras. 29 to 32.
[6] Available at http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

What are the benefits of entry into force of the Protocol Amending the TRIPS Agreement?

6. Beyond the general benefits that the System offers, there are some specific advantages from taking the step of incorporating the System into the TRIPS Agreement on a permanent basis by making the Amendment enter into force.

- Entry into force will put beyond doubt the permanent status of this pro-public-health TRIPS flexibility, and will set it on the same legal footing as all other TRIPS flexibilities that are relevant for access to medicines and thus for public health. Some Members have suggested that uncertainty over the ramifications of using the System may deter its use; permanent legal status will provide the surest foundation for its future use and will concretely contribute to confidence that it is a legitimate tool for access to medicines when required.

- For the WTO, it would complete the process initiated by the Doha Declaration on the TRIPS Agreement and Public Health aimed at improving coherence between TRIPS and public health objectives, and it would set the seal on a significant contribution to international law in the form of the first amendment to the multilateral trade agreements.

- This step would also respond concretely to widespread calls within the multilateral system – notably from the UN General Assembly, ECOSOC, the WHO and UNAIDS - for the amendment to enter into force or for the system to be implemented effectively, for example:

    - The Ministerial Declaration of the 2009 High-Level Segment of the UN Economic and Social Council expressly called for a broad and timely acceptance of the TRIPS amendment;

    - Resolution 65/277 of the UN General Assembly, the Political Declaration on HIV/AIDS: Intensifying our Efforts to Eliminate HIV/AIDS similarly called for early acceptance.

What are the benefits from the use of the System?

7. This section reviews in very general terms the potential benefits Members may derive from use of the System. The System is an optional tool for use at a Member's own discretion either to import or export medicines. It exists to eliminate a particular legal obstacle that Ministers identified at Doha that limited authorised exports under a compulsory licence. Hence it offers benefits when that obstacle would otherwise be encountered – in the specific procurement scenario when a Member or group of Members determines that the best means of access to a particular medicine would be achieved through production and export under a compulsory licence by a supplier in another country.

8. The past decade has seen considerable diversification in methods and sources for ensuring access to medicines. Trends in patenting medicines are also changing and diversifying, including in traditional low-cost exporters of medicines. It is accordingly difficult to predict exactly when and for what specific medicines this new pathway for access will be the optimal choice in coming years for the Members concerned. However, the 2013 WHO-WIPO-WTO Trilateral Study on *Promoting Access to Medical Technologies and Innovation*[7] noted that the System "could be more widely used in the future, for example, following the introduction of the product patent regime in key potential exporting countries, or in the case of a pandemic or some other health security event where effective treatments may be patented in all major supplier countries".

9. The following specific factors may contribute to deriving benefits from the System in future medicine procurement programmes:

- Patent protection for newer generations of medicines is more likely to apply in traditional low-cost suppliers of medicines, meaning that alternative means of procurement such as is provided by the System are more likely to be called upon for access to medicines by lower income countries.

[7] Available at http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

- A significant proportion of WTO Members with major manufacturing and export capacity in the pharmaceutical sector have progressively adopted specific legislation implementing the System into domestic law, and others may be encouraged to do so after the amendment enters into force.[8] This means that the framework will be increasingly built and expanded for companies to supply generic medicines under the System.

- Triggering the use of the System simply entails a Member or a group of Members communicating the expected quantities of medicines that are needed; model notifications have been made available by the WTO Secretariat on a dedicated webpage[9] to facilitate this simple and straightforward step. Notification of such needs will enable suppliers to respond – either using the System, if this provides the best means of supply, or outside the System if this proves preferable for the Member or Members in need. The impact of the System in facilitating supplier response would be increased if notifications were made early and routinely in the procurement process.

- Recognizing the benefit of harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, the System provides for a mechanism of regional distribution of medicines. The more recent movement towards regional procurement of medicines and greater regulatory harmonization offers important prospects for the System to work, alongside other tools, to facilitate cost-effective regional procurement and dissemination of medicines.

10. The *WHO-WIPO-WTO Trilateral Study* includes a more extensive discussion of the factors affecting use and potential benefits from the System, as well as an Annex outlining its practical use.

11. The WTO Secretariat can provide technical assistance in relation to the System, including on the following specific steps to enhance its use: (i) national procurement programmes of beneficiary Members notifying expected needs of medicines to the Council for TRIPS early in the procurement process; (ii) procurement programmes factoring the System into their planning at an early stage; and (iii) facilitating regionally coordinated procurement programmes to tap into the System's intended potential to harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.

[8] An overview of implementing legislation that has been notified to the WTO is available at http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

[9] http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm.

ANNEX 1

MODEL INSTRUMENT OF ACCEPTANCE

INSTRUMENT OF ACCEPTANCE OF THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Whereas the Protocol Amending the TRIPS Agreement ("the Protocol") was done at Geneva on 6 December 2005 (WT/L/641);

And whereas pursuant to paragraph 3 of the Protocol, on 26 November 2013 the WTO General Council extended the period for acceptance of the Protocol to 31 December 2015 (WT/L/899);

And whereas, in accordance with its paragraph 4, the Protocol shall enter into force in accordance with Article X:3 of the Marrakesh Agreement Establishing the World Trade Organization;

Now therefore, I, [name of signatory], [*where applicable:* head of state, head of government or minister of foreign affairs] of [Member], do hereby formally declare that [Member] accepts the aforementioned Protocol and expresses its consent to be bound by it.

In witness whereof, I [name and title of signatory] have signed this Instrument of Acceptance, at [place] on this [day] of [month] in the year 2015.

[Signature, title and seal]

ANNEX 2

WTO MEMBERS WHICH HAVE ACCEPTED THE PROTOCOL AMENDING THE TRIPS AGREEMENT

This Annex reproduces the list of WTO Members which have accepted the Protocol Amending the TRIPS Agreement since its adoption by the General Council on 6 December 2005 (WT/L/641), as well as the respective dates of acceptance[1]:

- Albania (28 January 2009)
- Argentina (20 October 2011)
- Australia (12 September 2007)
- Bahrain, Kingdom of (4 August 2009)
- Bangladesh (15 March 2011)
- Botswana (18 June 2014)
- Brazil (13 November 2008)
- Cambodia (1 November 2011)
- Canada (16 June 2009)
- Central African Republic (13 January 2014)
- Chile (26 July 2013)
- China (28 November 2007)
- Colombia (7 August 2009)
- Costa Rica (8 December 2011)
- Croatia (6 December 2010)
- Dominican Republic (23 May 2013)
- Egypt (18 April 2008)
- El Salvador (19 September 2006)
- European Union with its 27 Member States on the date of acceptance (30 November 2007)
- Honduras (16 December 2011)
- Hong Kong, China (27 November 2007)
- India (26 March 2007)
- Indonesia (20 October 2011)
- Israel (10 August 2007)
- Japan (31 August 2007)
- Jordan (6 August 2008)
- Korea, Republic of (24 January 2007)
- Macau, China (16 June 2009)
- Mauritius (16 April 2008)
- Mexico (23 May 2008)
- Mongolia (17 September 2010)
- Montenegro (9 September 2013)
- Morocco (2 December 2008)
- New Zealand (21 October 2011)
- Nicaragua (25 January 2010)
- Norway (5 February 2007)
- Pakistan (8 February 2010)
- Panama (24 November 2011)
- Philippines (30 March 2007)
- Rwanda (12 December 2011)
- Saudi Arabia, Kingdom of (29 May 2012)
- Senegal (18 January 2011)
- Singapore (28 September 2007)
- Switzerland (13 September 2006)
- Chinese Taipei (31 July 2012)
- The former Yugoslav Republic of Macedonia (16 March 2010)
- Togo (13 March 2012)
- Trinidad and Tobago (19 September 2013)
- Turkey (14 May 2014)
- Uganda (12 July 2010)

[1] A regularly updated list of WTO Members which have accepted the Protocol is available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

- United States of America (17 December 2005)
- Uruguay (31 July 2014)
- Zambia (10 August 2009)

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