

# HOW TO ACCEPT THE PROTOCOL AMENDING THE TRIPS AGREEMENT

## Background information for Members on procedures

### **Introduction**

The **Protocol Amending the TRIPS Agreement** (WTO document [WT/L/641](#)), adopted by the WTO General Council in 2005, is the first treaty amendment agreed by WTO Members since the WTO Agreement came into force in 1995. It confirms a decision by Members in 2003 to establish the Paragraph 6 System (WTO document [WT/L/540](#) and [Corr.1](#)), which provides additional flexibilities so as to facilitate access to medicines under TRIPS.

Many delegations have sought practical information on procedures for acceptance of the Protocol. Similar questions often also arise in capacity building activities on TRIPS and public health.

This note responds to some frequently asked questions about the acceptance procedure, and provides a model instrument of acceptance. In view of the interest expressed during the annual review of the operation of the Paragraph 6 System in the TRIPS Council meeting on 26–27 October 2010, the WTO Secretariat has prepared this background information in order to help Members draw up their instruments of acceptance of the Protocol.

Interested delegations can also contact the Legal Affairs Division or the Intellectual Property Division if they have any questions.

### **Frequently asked questions**

*How should the protocol be accepted?*

In accordance with Article X:7 of the WTO Agreement, each Member accepting the Protocol shall deposit an “instrument of acceptance” with the Director General.

*What must be stated in the instrument of acceptance?*

There is no established form for an instrument of acceptance of the Protocol; each Member will have its own practice for accepting international treaties and treaty amendments. However, in line with international practice, the instrument of acceptance must give clear and unambiguous expression to the relevant Member’s intention and consent to be bound by the Protocol.

In particular, the instrument of acceptance must:

- clearly identify the Protocol by its title and by the place and date of its adoption, i.e. “the Protocol Amending the TRIPS Agreement, done at Geneva on 6 December 2005” or, alternatively, reproduce the Protocol;
- state that the Member concerned formally accepts the Protocol;
- state the date and the place of issuance of the instrument of acceptance;
- be signed; and
- state the name and title of the person signing the instrument.

*Who may sign the instrument of acceptance?*

Recognized practice is for the instrument of acceptance to be issued and signed by the head of state, the head of government, or the minister for foreign affairs (the “Big Three”). Alternatively, the instrument may be signed by another official, such as the permanent representative to the WTO, on the condition that he or she produces documentation to the effect that one of the “Big Three” has authorized him or her to do so.

Unsigned instruments in the form of *notes verbales*, even bearing the seal of the ministry or of the presidency, are therefore not sufficient for accepting the Protocol.

*When must the instrument of acceptance be deposited?*

For an instrument of acceptance to be valid, it must be deposited within the period of acceptance. The original acceptance period ran until 1 December 2007, as set out in paragraph 2 of the 6 December 2005 General Council decision and in paragraph 3 of the Protocol. These same provisions, however, allow for the possibility of extending the acceptance period.

The General Council has extended the acceptance period three times, in 2007, 2009 and 2011. The current deadline for depositing acceptances is 31 December 2013. Therefore, as of today, for an instrument of acceptance to be valid, it would need to be deposited by that date.

*Can a Member accept the Protocol without implementing the Paragraph 6 System?*

Accepting the Protocol is clearly distinct from implementing the Paragraph 6 System in Members’ domestic legal frameworks. In other words, the Protocol can be accepted independently from adopting domestic implementing legislation.

Accepting the Protocol is a legal act whereby a Member expresses its consent to be bound by the Protocol on the international plane, or, in other words, its consent that all WTO Members are *entitled* — that is permitted, not required — to use the Paragraph 6 System, which is incorporated in the TRIPS Agreement through the agreed amendment. This process of acceptance needs to follow both the relevant Member’s own constitutional requirements, and the content requirements outlined above. Should a WTO Member wish to take advantage itself of the additional flexibilities provided in the Protocol, it may need to put it in place through implementing laws or regulations following its normal domestic legislative and regulatory processes.

The legal act of acceptance of all WTO Members’ *entitlement* to use the System is not dependent upon and is therefore distinct from a Member’s domestic implementation of the System in the accepting Member in the event it decides *itself* to take advantage of the System.

Therefore these two processes are entirely separate: Members can choose to deal with them either at the same time or separately. A Member can choose to deposit an instrument of acceptance of the Protocol without having adopted domestic legislation implementing the Paragraph 6 System, because it only wishes to commit itself to accepting that additional *flexibilities* for all WTO Members shall become an integral part of the TRIPS Agreement.

For the time being, the flexibilities are available under the waivers provided in the 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WTO document [WT/L/540](#) and [Corr.1](#)). The waivers remain in force until the amendment to the TRIPS Agreement takes effect for a Member. Therefore, a Member may also choose to put in place domestic implementing legislation before depositing its instrument of acceptance.

**Model instrument of acceptance**

for the Protocol Amending the TRIPS Agreement, done at Geneva on 6 December 2005

[Member]

**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;

And *Whereas* pursuant to paragraph 3 of the Protocol, on 30 November 2011 the WTO General Council extended the period for acceptance of the Protocol to 31 December 2013;

And *Whereas*, in accordance with its paragraph 4, the Protocol shall enter into force in accordance with Article X:3 of the WTO Agreement;

*Now Therefore*, I, [name of signatory], [head of state, head of government or minister of foreign affairs] of [Member], do hereby formally declare that the Government of [Member] accepts the Protocol Amending the TRIPS Agreement.

In *Witness Whereof*, I [name and title including Member] have signed this Instrument of Acceptance on this [day] of [month] in the year [year].

[Signature, title and seal]