

MODEL NOTIFICATIONS FOR USE OF THE PARAGRAPH 6 SYSTEM

This Annex provides a brief overview of the notifications involved in using the Paragraph 6 System, and provides model notifications to illustrate its practical operation.

What is the Paragraph 6 System?

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, as the agreement then stood.

Paragraph 6 addressed a specific procurement scenario for access to medicines:

- Countries with insufficient or no manufacturing capacities are naturally reliant on imports from foreign suppliers.
- When medicines are produced under a compulsory licence in another country, TRIPS in effect limited the proportion that could be exported.
- TRIPS therefore posed a potential barrier, if a country lacked its own production capacity and wished to import medicines from another country where a patent was in force and where a compulsory licence was needed for production. (Although such a barrier would not arise, in any case, if the imported medicines were produced either under a compulsory licence predominantly for the domestic market of the exporting country, or under a compulsory licence issued to remedy anticompetitive practices).

The “Paragraph 6 System” is the name commonly given to the system set up by the WTO to address this problem (see [background](#)). It was established by the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 (“2003 Decision”, WTO document [WT/L/540 and Corr.1](#)). WTO Members have since decided by consensus to incorporate the system in an amendment to the TRIPS Agreement ([WTO document WT/L/641](#)), although the amendment — while politically agreed — has yet to enter into legal effect.

What notifications are required to use the Paragraph 6 System?

The Paragraph 6 System includes three types of notification:

1. Importing Member’s one-off general notification of intention to use the Paragraph 6 System (not required for LDC Members);
2. Importing Member’s specific notification of its need to import pharmaceutical products under the Paragraph 6 System; and
3. Exporting Member’s notification of grant of a compulsory licence for export.

Who can sign a notification?

Notifications can be signed by any authorized government official, including a Minister, a Permanent Secretary, Ambassador to the WTO, senior official or other authorized person. They do not need to be signed by the Head of State, Head of Government, Foreign Minister or a person with Full Powers, unlike Instruments of Acceptance of the Protocol Amending the TRIPS Agreement (see [explanation](#)).

Where to send notifications?

Notifications are sent to the WTO Council for TRIPS through the WTO Secretariat. They can be sent by post (see models for postal address) or fax to +41 22 739 5790, with a copy by email to crn@wto.org with a copy to ipd@wto.org. The WTO Secretariat will circulate the notification to other Members of the Council for TRIPS and the Chairperson will bring it to the attention at the next meeting. The notifications will be circulated as formal WTO documents in series IP/N/8, 9 or 10 and will also be made available publicly by the WTO Secretariat [here](#).

Do notifications need to be approved by the TRIPS Council?

No. It is explicitly provided that notifications do not need to be approved by a WTO body in order for a Member to use the System.

Where to find out more?

Each model notification is set out on a right hand page below, with explanatory notes on the corresponding left hand page. The notes include some references to the requirements of the Paragraph 6 System to allow users to cross-check. These refer to the WTO General Council Decision, although corresponding provisions of the Protocol Amending the TRIPS Agreement of 2005 will apply once the Protocol enters into force for those Members that have accepted it.

What is the status of these model notifications?

These models notifications are provided for illustrative purposes only and without prejudice to WTO Members' rights and obligations under the WTO agreements.

Web links used here:

Background on TRIPS and health: www.wto.org/tripshealth

Document WT/L/540 and Corr.1: www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

Document WT/L/641: www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

Document WT/GC/M/82: docsonline.wto.org/DDFDocuments/t/WT/GC/M82.doc

Accepting the TRIPS amendment: www.wto.org/english/tratop_e/trips_e/accept_e.htm

Dedicated webpage for notifications: www.wto.org/english/tratop_e/trips_e/public_health_e.htm

Par.6 of the 2003 Decision: www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#6

Par.1(b) of the 2003 Decision: www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#1

Par.2(a) and 2(c) of 2003 Decision: www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#2

Annex of 2003 Decision: www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#a

NOTES TO MODEL 1

This one-off notification confirms in general that a Member intends to use the Paragraph 6 System as an importer.

Who needs to make the importing Member's general notification?

- LDCs are automatically entitled to use the Paragraph 6 System as importing Members and need not make a general notification of intent to use it.
- Developed country Members cannot use the Paragraph 6 System to import medicines, so cannot make this or any other importing Member's notification.
- Others — developing country Members who wish to use the Paragraph 6 System to import medicines need only make this general notification once.

When to notify?

A WTO Member can make this notification at any time prior to its first concrete use of the System as an importer, or at the same time as it first notifies specific needs under the system (see Model 2). No notification is needed to import pharmaceutical products from another Member party to a regional trade agreement under the regional mechanism (see [paragraph 6 of the 2003 Decision — WTO document WT/L/540 and Corr.1](#)).

Making this general notification doesn't commit a Member actually to use the system — it simply confirms a broad intent potentially to use it in the future.

Who has said they intend to use the System only in a limited way?

Eligible Members are entitled to notify their intent to use the system 'in whole or in a limited way.' When the System was set up, several Members stated that they would only use it in situations of national emergency or other circumstances of extreme urgency: these are Hong Kong, China; Israel; Republic of Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey; and United Arab Emirates. There is no obligation to notify this or any other kind of limitation, and so it is only shown as 'OPTION' in the model notification.

Reference for this notification

See [paragraph 1\(b\) of the 2003 Decision \(WTO document WT/L/540 and Corr.1\)](#).

MODEL 1: IMPORTING MEMBER'S GENERAL NOTIFICATION OF INTENT TO USE

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

Dear Sir or Madam,

General notification of intention to use the Paragraph 6 System as an importing Member

[Name of WTO Member] intends to use the system set out in the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 as an importing Member.

OPTIONAL: [This notification only applies to use of the system in the case of a national emergency or other circumstances of extreme urgency.] OR [This notification only applies to use of the system in the following limited way:]

Yours faithfully,

[Name, position and signature
of authorized government official]

NOTES TO MODEL 2

This is the importing Member's specific notification of its need to import pharmaceutical products under the Paragraph 6 System.

Who needs to make the importing Member's specific notification?

A notification must be made by or on behalf of an importing Member each time it uses the Paragraph 6 System to import pharmaceutical products. No notification is needed when pharmaceutical products are imported from another Member party to the regional trade agreement under the regional mechanism (see [paragraph 6 of the 2003 Decision — WTO document WT/L/540 and Corr.1](#)).

Point 1: the pharmaceutical product(s)

The importing Member has to notify the names and expected quantities of the pharmaceutical product needed. The expected quantity can, for example, be a number of doses or packs (e.g. "5 million doses of medicine X"). The importing Member does not need to state the name of a supplier, nor the expected timeframe of supply and use.

Point 2: manufacturing capacity

LDCs are assumed to lack manufacturing capacity and do not need to state anything about it. Other importing Members need to confirm that they have established that they have insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the [Annex to the Decision](#). A Chairman's statement read out when the System was adopted mentioned that it was understood that notifications would include information on how the Member had established this point ([WTO document WT/GC/M/82](#), paragraph 29).

Point 3: patent protection in the importing Member

Where there is no patent for the pharmaceutical product(s) in the importing Member, there is strictly no need to mention the absence of any patent, but it may be helpful to state this expressly, so that it is clear that it has not been overlooked. Where there is a patent for the product(s) in the importing Member, the notification must address the issue of compulsory licensing. Alternatively, LDCs may refer to their transitional period under the TRIPS Agreement (currently due to expire on 1 January 2016 for patent protection and enforcement with respect to pharmaceutical products).

Joint notifications

A notification can cover more than one importing Member. A regional economic community that satisfies the conditions in paragraph 6 of the WTO General Council Decision can also make a notification on behalf of its member States, with their consent. Joint notifications should confirm that the Members that they cover have consented.

Reference for this notification

See [paragraph 2\(a\) of the 2003 Decision \(WTO document WT/L/540 and Corr.1\)](#).

MODEL 2: IMPORTING MEMBER'S SPECIFIC NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND
Email: crn@wto.org; ipd@wto.org

[Date]

Dear Sir or Madam,

Notification of need to import pharmaceutical products under the Paragraph 6 System

1. [Name of Member] needs [names and expected quantities of pharmaceutical product(s)].
2. *EITHER*: [Name of Member] has no manufacturing capacities in the pharmaceutical sector. *[Information on how this was established.]*

OR: [Name of Member] has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for this (or these) pharmaceutical product(s). *[Information on how this was established.]*

3. *OPTIONAL, IF NO PATENTS IN FORCE*: *[The pharmaceutical product(s) is (are) not protected by patent in the territory of [name of Member]].*

IF PATENT(S) IN FORCE:

EITHER: [Name of Member] has authorized (or intends to authorize) use of the subject matter of the patent or patents in force for the pharmaceutical product(s) without the consent of the patent owner in accordance with the provisions of Article 31 of the TRIPS Agreement and the provisions of the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003.

OR (for LDC Members): Having regard to the transitional period for LDC Members in Article 66.1 of the TRIPS Agreement, as extended for pharmaceutical products in line with Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, [name of LDC Member] will not enforce any patents in force for this (or these) pharmaceutical product(s).

Yours faithfully,

[Name, position and signature
of authorized government official]

NOTES TO MODEL 3

This is the exporting Member's notification of the grant of a compulsory licence for export.

Who needs to make an exporting Member's notification?

Any Member that exports under the Paragraph 6 System must make this notification for every compulsory licence that it issues under the System prior to export. A notification is not required to export pharmaceutical products under the regional mechanism ([paragraph 6 of the 2003 Decision — WTO document WT/L/540 and Corr.1](#)). If the medicines to be exported only form part of production under a compulsory licence that is issued predominantly for the domestic market, then there is no need to use the Paragraph 6 System at all, and consequently no notification is needed.

Can the exporting Member attach a copy of the compulsory licence(s) instead?

Yes, as long as all the information listed in the model notification is included in the attachment. Other information, such as the patent number(s), can also be included.

Must the licensee set up its own website?

No. The licensee may post the required information on its own website or, with the assistance of the WTO Secretariat, on the page of the WTO website dedicated to the Paragraph 6 System.

Reference for this notification

See [paragraph 2\(c\) of the 2003 Decision \(WTO document WT/L/540 and Corr.1\)](#).

MODEL 3: EXPORTING MEMBER'S NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

Dear Sir or Madam,

Notification of compulsory licence to export under the Paragraph 6 System

[Name of exporting Member] has granted [a licence] [licences] to use the subject matter of a patent or patents solely for the purposes of production of [a pharmaceutical product] [pharmaceutical products] and [its][their] export under the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. The details of the [licence] [licences] granted are as follows:

- Name and address of the licensee(s): []
- Product(s) for which the licence(s) has/have been granted: []
- Quantity(ies) for which the licence(s) has/have been granted: []
- Country(ies) to which the product(s) is/are to be supplied: []
- Duration of the licence(s): []
- *OPTIONAL [Any other licence conditions not set out above] [Other information, such as the patent number(s)]*

The licensee will post information before shipment on the quantities being supplied to each destination and the distinguishing features of the product(s) on the following website: []

Yours faithfully,

[Name, position and signature
of authorized government official]