

## **GUÍA ILUSTRATIVA PARA LAS NOTIFICACIONES EN EL MARCO DEL SISTEMA PREVISTO EN EL PÁRRAFO 6**

En el párrafo 6 de la Declaración de Doha relativa al Acuerdo sobre los ADPIC y la salud pública se reconocía que los Miembros de la OMC cuyas capacidades de fabricación en el sector farmacéutico fueran insuficientes o inexistentes podrían tropezar con dificultades para hacer un uso efectivo de las licencias obligatorias con arreglo al Acuerdo sobre los ADPIC, tal como estaba formulado entonces.

**(de momento solamente en inglés)**

### **BACKGROUND**

- *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.*

### **PARAGRAPH 6 SYSTEM**

*The "Paragraph 6 System" is the name commonly given to the system set up by the WTO to address this problem by creating a new form of compulsory licence specifically for the export of medicines. The use of this special compulsory licence requires formal notification to the WTO. There are three types of notification:*

- 1.Importing Member's one-off general notification of intention to use the Paragraph 6 System (not required for least-developed country members);*
- 2.Importing Member's specific notification of the details of the needed pharmaceutical products and other details required under the Paragraph 6 System;*
- 3.Exporting Member's notification of grant of a compulsory licence for export and conditions attached to it.*

### **NOTIFICATIONS**

*Notifications can be signed by any authorized government official. They are made for transparency purposes, and do not need to be approved by a WTO body in order for a member to use the System.*

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](mailto:crn@wto.org) with a copy to [ipd@wto.org](mailto: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.

The following model notifications are provided for illustrative purposes only as an aid to technical assistance, and are prepared without prejudice to WTO members' rights and obligations under the WTO agreements. As illustrative guides only to what is to be notified, they do not have any legal or procedural status.

**Modelos ilustrativos para las notificaciones en el marco del sistema del párrafo**

Modelo 1: notificación de la intención general de utilizar el sistema	Modelo 2: notificación de la necesidad de importar	Modelo 3: notificación de una licencia de exportación
<p style="text-align: center; font-size: small;">MODEL 1: IMPORTING MEMBER'S GENERAL NOTIFICATION OF INTENT TO USE</p> <p style="text-align: center; font-size: x-small;">[Government letterhead]</p> <p style="text-align: center; font-size: x-small;">Council for TRIPS World Trade Organization c/o Central Registry of Notifications 114 rue de Lausanne CH-1211 Geneva 21 SWITZERLAND Email: <a href="mailto:crn@wto.org">crn@wto.org</a> <a href="mailto:ipd@wto.org">ipd@wto.org</a></p> <p style="text-align: center; font-size: x-small;">[Date]</p> <p style="text-align: center; font-size: x-small;"><b>General notification of intention to use the Paragraph 6 System as an importing Member</b></p> <p style="font-size: x-small;">[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.</p> <p style="font-size: x-small;">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: ...)</p> <p style="text-align: right; font-size: x-small;">[Name, position and signature of authorized government official]</p>	<p style="text-align: center; font-size: small;">MODEL 2: IMPORTING MEMBER'S SPECIFIC NOTIFICATION</p> <p style="text-align: center; font-size: x-small;">[Government letterhead]</p> <p style="text-align: center; font-size: x-small;">Council for TRIPS World Trade Organization c/o Central Registry of Notifications 114 rue de Lausanne CH-1211 Geneva 21 SWITZERLAND Email: <a href="mailto:crn@wto.org">crn@wto.org</a> <a href="mailto:ipd@wto.org">ipd@wto.org</a></p> <p style="text-align: center; font-size: x-small;">[Date]</p> <p style="text-align: center; font-size: x-small;"><b>Notification of need to import pharmaceutical products under the Paragraph 6 System</b></p> <p>1. [Name of Member] needs (name and expected quantities of pharmaceutical product(s)).</p> <p>2. <b>ATTORNEY:</b> [Name of Member] has no manufacturing capacities in the pharmaceutical sector. [Information on how this was established.]</p> <p>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.]</p> <p>3. <b>OPTIONAL: IF ASO PATENTS IN FORCE:</b> (The pharmaceutical product(s) is/are not protected by patent in the territory of [Name of Member].)</p> <p><b>IF PATENTS IN FORCE:</b></p> <p><b>ATTORNEY:</b> [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.</p> <p>OR (for LDC Members): Having regard to the transitional period for LDC Members in Article 66.1 of the TRIPS Agreement, as amended 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).</p> <p style="text-align: right; font-size: x-small;">[Name, position and signature of authorized government official]</p>	<p style="text-align: center; font-size: small;">MODEL 3: EXPORTING MEMBER'S NOTIFICATION</p> <p style="text-align: center; font-size: x-small;">[Government letterhead]</p> <p style="text-align: center; font-size: x-small;">Council for TRIPS World Trade Organization c/o Central Registry of Notifications 114 rue de Lausanne CH-1211 Geneva 21 SWITZERLAND Email: <a href="mailto:crn@wto.org">crn@wto.org</a> <a href="mailto:ipd@wto.org">ipd@wto.org</a></p> <p style="text-align: center; font-size: x-small;">[Date]</p> <p style="text-align: center; font-size: x-small;"><b>Notification of compulsory licence to export under the Paragraph 6 System</b></p> <p>[Name of exporting Member] has granted (s/he/has) (s/he/has) to use the subject matter of a patent or patents solely for the purposes of production of (s) pharmaceutical product(s) (pharmaceutical product) and (s/he/has) 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 (s/he/has) (s/he/has) granted are as follows:</p> <ul style="list-style-type: none"> <li>• Name and address of the licensee(s): [ ]</li> <li>• Product(s) for which the licensee(s) has/have been granted: [ ]</li> <li>• Quantity(ies) for which the licensee(s) has/have been granted: [ ]</li> <li>• Country(ies) to which the product(s) is/are to be supplied: [ ]</li> <li>• Duration of the licensee(s): [ ]</li> <li>• OPTIONAL: (Any other licence conditions not set out above) (Other information, such as the patent number(s)).</li> </ul> <p style="font-size: x-small;">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: [ ]</p> <p style="text-align: right; font-size: x-small;">[Name, position and signature of authorized government official]</p>

## WEB LINKS FOR FURTHER BACKGROUND

Background on TRIPS and health [www.wto.org/tripshealth](http://www.wto.org/tripshealth)  
 Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (Document [WT/L/540](#) and [Corr.1](#))  
 Amendment of the TRIPS Agreement (Document [WT/L/641](#))  
 Minutes of General Council meetings in [WT/GC/M/82](#) and [WT/GC/M/100](#)  
 Accepting the TRIPS amendment

[http://www.wto.org/english/tratop\\_e/trips\\_e/accept\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/accept_e.htm)

Dedicated webpage for notifications

[http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm)

Par.6 of the 2003 Decision

[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm#6](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#6)

Par.1(b) of the 2003 Decision

[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm#1](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#1)

Par.2(a) and 2(c) of 2003 Decision

[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm#2](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#2)

Annex of 2003 Decision

[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm#a](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#a)

---