



TRIPS: SPECIAL COMPULSORY LICENCES FOR EXPORT OF MEDICINES

GUIDE TO NOTIFICATIONS

The model notifications herein have been prepared under the Secretariat's own responsibility and without prejudice to positions of Members and to their rights and obligations under the WTO. They are provided for illustrative purposes only as an aid to technical assistance and do not have any legal or procedural status.

1 INTRODUCTION

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:

- 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, the TRIPS Agreement 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 and export.

The mechanism set up by the WTO to address this problem, often referred to as the "Paragraph 6 System" (the System), created a new form of trade-related compulsory licence specifically for the export of medicines (see further information at: https://www.wto.org/english/tratop_e/trips_e/pharm_patent_e.htm). The use of this special compulsory licence requires formal notifications to the WTO both by the importing and exporting Member.

2 NOTIFICATIONS

2.1 What to Notify

There are three types of notifications:

- importing Member's one-off general notification of its intention to use the System (not required for least-developed country Members);
- importing Member's specific notification of the details of the needed pharmaceutical products and other details required under the System;
- exporting Member's notification of grant of a compulsory licence for export and conditions attached to it.

2.2 How to Notify

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), fax to +41 22 739 5790 or 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 Council's 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.

Since the entry into force of the TRIPS Amendment in January 2017, Members that have accepted the Amendment operate on the basis of the amended TRIPS Agreement. Other Members who have yet to accept the Protocol Amending the TRIPS Agreement continue to operate on the basis of the Decision of 2003.

Annex 1 to this Guide contains model notifications that may be used by Members operating on the basis of the amended TRIPS Agreement (Article 31*bis* and the Annex and Appendix to the TRIPS Agreement).

Annex 2 to this Guide contains model notifications that may be used by Members operating on the basis of the Decision of 2003.

3 INFORMATION RESOURCES

Web version of the Illustrative Guide and the model notifications: https://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm

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

Factsheet on the TRIPS amendment: https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_e.htm

Decision of the General Council of 30 August 2003 (WT/L/540 and Corr.1): https://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm

Chairman's statement read out when the System was set up, WTO document WT/GC/M/82, available at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S001.aspx

TRIPS Agreement (as amended on 23 January 2017): https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm

Chairman's statement read out when the Protocol Amending the TRIPS Agreement was adopted, WTO document WT/GC/M/100, available at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S001.aspx

ANNEX 1

MODEL NOTIFICATIONS FOR MEMBERS OPERATING ON THE BASIS OF THE AMENDED TRIPS AGREEMENT (ARTICLE 31*BIS* AND THE ANNEX AND APPENDIX TO THE TRIPS AGREEMENT)

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

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?

- X** Least-developed countries are automatically entitled to use the System as importing Members and need not make a general notification of intent to use it.
- X** Developed country Members are committed not to use the System to import medicines, so cannot make this or any other importing Member's notification.
- ✓ Others — developing country Members who wish to use the 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 3 of Article 31*bis* of the amended TRIPS Agreement).

Making this general notification does not 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 Protocol Amending the TRIPS Agreement was adopted, several Members confirmed 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 (see the Chairman's statement read out when the Protocol Amending the TRIPS Agreement was adopted (WTO document WT/GC/M/100, paragraph 29)).

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 Annex to the amended TRIPS Agreement.

[Government letterhead]

Council for TRIPS
World Trade Organization
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154 rue de Lausanne
CH-1211 Geneva 21
Switzerland

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

[Date]

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 Article 31*bis* of the TRIPS Agreement, and the Annex and the Appendix to it, 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: IMPORTING MEMBER'S SPECIFIC NOTIFICATION

This is the importing Member's specific notification of the details of the needed pharmaceutical products and other details required 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 System to import pharmaceutical products. No notification is needed when pharmaceutical products are imported from another Member party to a regional trade agreement under the regional mechanism (see paragraph 3 of Article 31*bis* of the amended TRIPS Agreement).

Making this notification does not commit a Member actually to procure medicines under the System — it simply flags a Member's needs which may ultimately be satisfied through other supply sources.

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

Least-developed countries (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 Appendix to the Annex of the amended TRIPS Agreement. The Chairman's statement read out when the Protocol Amending the TRIPS Agreement was adopted mentioned that it was understood that notifications would include information on how the Member had established this point (see WTO document WT/GC/M/100, 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, which was last extended until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier (Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, adopted by the TRIPS Council on 6 November 2015).

Joint notifications

In general, a notification can cover more than one importing Member.

A regional organization that satisfies the conditions in paragraph 3 of Article 31*bis* of the TRIPS Agreement can also make a notification on behalf of its Members, with their consent. Joint notifications should confirm that the Members that they cover have consented (see footnote 4 of the Annex to the amended TRIPS Agreement).

Reference for this notification: see paragraph 2(a) of the Annex to the amended TRIPS Agreement.

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[Date]

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

Dear Sir or Madam,

[Name of Member] needs [names and expected quantities of pharmaceutical product(s)].

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.]

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 Articles 31 and 31bis of the TRIPS Agreement.

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 and the related Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement on 6 November 2015 (IP/C/73), [name of LDC Member] will not grant patents / 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: EXPORTING MEMBER'S NOTIFICATION

This is the exporting Member's notification of the grant of a compulsory licence for export, including the conditions attached to it, as required under the Paragraph 6 System.

Who needs to make an exporting Member's notification?

Any Member that exports under the 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 (see paragraph 3 of Article 31*bis* of the amended TRIPS Agreement).

If the medicines to be exported form part of production under a compulsory licence that is issued predominantly for the supply of the domestic market, then there is no need to use the 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 System.

Reference for this notification: see paragraph 2(c) of the Annex to the amended TRIPS Agreement.

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[Date]

Notification of compulsory licence to export under the Paragraph 6 System

Dear Sir or Madam,

[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 Article 31*bis* of the TRIPS Agreement, and the Annex and the Appendix to it. 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: []] [on the WTO website dedicated to the Paragraph 6 System].

Yours faithfully,

[Name, position and signature
of authorized government official]

ANNEX 2

MODEL NOTIFICATIONS FOR MEMBERS OPERATING ON THE BASIS OF THE DECISION OF 2003

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

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?

X Least-developed countries are automatically entitled to use the System as importing Members and need not make a general notification of intent to use it.

X Developed country Members are committed not to use the System to import medicines, so cannot make this or any other importing Member's notification.

✓ Others — developing country Members who wish to use the 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 does not 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 confirmed 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 (see Chairman's statement read out when the System was set up (WTO document WT/GC/M/82, paragraph 29)).

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).

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[Date]

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]

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Point 2: manufacturing capacity

Least-developed countries (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 (see 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, which was last extended until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier (Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, adopted by the TRIPS Council on 6 November 2015).

Joint notifications

In general, a notification can cover more than one importing Member.

A regional organization that satisfies the conditions in Paragraph 6 of the WTO General Council Decision can also make a notification on behalf of its Members, with their consent. Joint notifications should confirm that the Members that they cover have consented (see footnote 4 to the Decision of 2003).

Reference for this notification: see paragraph 2(a) of the 2003 Decision (WTO document WT/L/540 and Corr.1.)

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[Date]

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

Dear Sir or Madam,

[Name of Member] needs [names and expected quantities of pharmaceutical product(s)].

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.]

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 and the related Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement on 6 November 2015 (IP/C/73), [name of LDC Member] will not grant patents / 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: EXPORTING MEMBER'S NOTIFICATION

This is the exporting Member's notification of the grant of a compulsory licence for export, including the conditions attached to it, as required under the Paragraph 6 System.

Who needs to make an exporting Member's notification?

Any Member that exports under the 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 (see paragraph 6 of the 2003 Decision — WTO document WT/L/540 and Corr.1).

If the medicines to be exported form part of production under a compulsory licence that is issued predominantly for the supply of the domestic market, then there is no need to use the 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 System.

Reference for this notification: see paragraph 2(c) of the 2003 Decision (WTO document WT/L/540 and Corr.1).

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

[Date]

Notification of compulsory licence to export under the Paragraph 6 System

Dear Sir or Madam,

[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: []] [on the WTO website dedicated to the Paragraph 6 System].

Yours faithfully,

[Name, position and signature
of authorized government official]