

[Government letterhead]

Council for TRIPS
World Trade Organization
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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 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 6 of the 2003 Decision — WTO document WT/L/540 and Corr.1).

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 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.)