# WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

# Declaration on the TRIPS agreement and public health

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize 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. We instruct the Council for TRIPS to find an

expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

# AIPPI

## INTERNATIONAL ASSOCIATION FOR THE PROTETION OF INTELLECTUAL PROPERTY

## SPECIAL COMMITTEE Q94

---

# QUESTIONNAIRE NO. 4

## on the

# IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

---

## GENERAL REMARKS AND INSTRUCTIONS

I. The terms of reference of the Special Committee Q94 is to monitor developments in regard to the TRIPS Agreement, and to determine the extent of compliance with the provisions of TRIPS by the national laws of national groups of AIPPI.

II. This is the fourth questionnaire circulated by Committee Q94 to national groups. It follows on and is closely related to the third questionnaire of October 2002 in regard to the Doha Health Declaration. Committee Q94 records its appreciation for the participation of national groups to provide the requested information by completing the questionnaire and returning it to the AIPPI General Secretariat.

III. It would be most helpful if national groups could return the completed questionnaire by ……. 2004.

IV. If there are any questions with regard to the questionnaire, please contact:

(i) Chairman of Q94: Mr Ivan Hjertman
email: ivan.hjertman@telia.com
fax: +46 8 510 105 27

(ii) Co-Chair of Q94: Ms Esmé du Plessis
email: edp@adamsadams.co.za
fax: +27 12 362 6440

## PURPOSE OF THE QUESTIONNAIRE

The purpose of the questionnaire is to determine the extent to which the compulsory licensing model set out in the WTO General Council decision of 30 August 2003 has been implemented in WTO member countries, including by way of legislative amendments, statements of intention, granting of concessions, or other initiatives.

To assist national groups with their responses, a copy of the WTO decision is attached as Annexure A, as well as a copy of the Statement by the Chairperson of the General Council, marked Annexure B.

1. **QUESTION 1**

**Steps to implement the WTO decision**

In the preamble to the WTO General Council decision, reference is made to the instruction of the Ministerial Conference in Doha, 2001 that an expeditious solution is to be found for the difficulties in some WTO member countries in regard to access to pharmaceutical products.

1.1 Are you aware of any actual or impending legislative amendments in your country, including,

- statements of intention to introduce amendments,
- consultation processes with a view to legislative amendments,
- proposals for new or amended legislation
- already enacted legislation

with a view to implementing any or all of the features of the WTO Council decision?

☐ Yes ☐ No

If yes, please provide details such as

- Government Act, Regulation, Proclamation or Bill no.
- Proposal or Policy Paper details
- Website information for text
- Other details

_____
_____
_____
_____

1.2 Has your country made any changes to your laws to provide for importation licences in respect of pharmaceutical products? If so, please provide details.

☐ Yes ☐ No

- Act / Regulation / Proclamation no.
- Website information for text
- Other details

_____
_____
_____
_____

1.3 Has your country made any changes to your laws to provide for exportation licences in respect of pharmaceutical products? If so, please provide details.

☐ Yes ☐ No

- Act / Regulation / Proclamation no.
- Website information for text
- Other details

_____
_____
_____
_____

2. **QUESTION 2**

**Identification of 'eligible importing countries'**

Clause 2(a) of the WTO decision requires 'eligible importing Member' countries to make a notification to the TRIPS Council recording certain information. (Note: the countries specified in Note 3 of the decision have already indicated that they will not use the compulsory licensing system as importing countries).

2.1 Are you aware -

Whether your own country has filed a notification as an 'eligible importing Member country', and if so, when?

☐ Yes ☐ No

Date:

2.2 Whether any other country/countries have filed such a notification, and if so, which countries?
Countries and dates:
_____
_____
_____
_____
_____

2.3 If your answer to 2.1 is Yes, are you aware of any compulsory licences granted in your country for the importation of pharmaceutical products, and if so, do you have any details as regard licensor, licensee, products covered, etc?
☐ Yes ☐ No
Details:
_____
_____
_____
_____
_____

3. **QUESTION 3**
**Granting, notification and information of export licences**
Clause 2(b) of the WTO decision deals with compulsory licences granted in 'exporting Member' countries for the exportation of pharmaceutical products in terms of the waiver of TRIPS Art 31(f).

3.1 Are you aware of any compulsory licences which have been granted in your country for the exportation of pharmaceutical products to eligible importing member countries? If so, please provide details of which you are aware, such as licensor, licensee, products covered, etc.
☐ Yes ☐ No
Details:
_____
_____
_____
_____
_____

3.2 Clause 2(c) of the WTO decision requires notification to the TRIPS Council by an exporting member country of the grant of any such compulsory licences. Are you aware of such a notification having been made, and if so, when?

☐ Yes ☐ No

Date(s):

3.3 Clause 2(b) requires a licensee under such a compulsory licence to post certain information on a website. Are you aware of any such website? and if so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

4. **QUESTION 4**

**Prevention of re-exportation/diversion of imported products**

Clauses 4 and 5 of the WTO decision deal with the need to prevent re-exportation of products imported into eligible importing countries under the licensing system.

Are you aware –

4.1 Whether special measures (in laws or otherwise) have been introduced in your country to prevent re-exportation of products? If so, please provide details, such as Government Act, Proclamation, export restriction, etc

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

4.2 Whether any technical or financial cooperation or assistance has been provided to developing or least-developed countries to prevent trade diversion and re-exploitation? If so, please provide details, such as type of assistance, receiving country, etc.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

5. **QUESTION 5**

**Waiver of TRIPS Art 31(f): domestic market supply**

Clause 6 provides for the waiver of TRIPS Art 31(f), ie the restriction to use predominantly for the supply of the domestic market, in respect of developing and least-developed member countries which are parties to a regional trade agreement, to permit exportation to other parties of the regional trade agreement of products imported or manufactured under compulsory licences.

Are you aware –

5.1 In the event that your country falls within the provisions of Clause 6, whether use has been made of the exportation provisions of Clause 6? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

5.2 In the event of exportation from your country in terms of a compulsory licence to a country/countries falling within the provisions of Clause 6, whether use has been made of the exportation provisions of Clause 6? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

6. **QUESTION 6**

**Technology transfer and capacity building**

Clause 7 provides for the promotion of technology transfer and capacity building in the pharmaceutical sector by using the compulsory licensing system of the WTO decision.

Are you aware of any such technology transfer or capacity building initiatives, in your own country or elsewhere? If so, please provide details.

☐ Yes ☐ No

Details:

_____
_____
_____
_____
_____

**ANNEXURE A**

GENERAL COUNCIL

WT/L/540
1 September 2003

# Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

## Decision of the General Council of 30 August 2003 *

The General Council,

**Having regard** to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

**Conducting** the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

**Noting** the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

**Recognizing**, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

**Noting** that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

**Decides** as follows:

**1.** For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

**2.** The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed (5);
(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has 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 this Decision; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
(iii) before shipment begins, the licensee shall post on a website (7) the following information:
- the quantities being supplied to each destination as referred to in indent (i) above;
and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

**3.** Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

**4.** In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

**5.** Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

**6.** With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

**7.** Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

**8.** The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

**9.** This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under

a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

**10.** Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

**11.** This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

## ANNEX (ad paragraph 2(a)(ii))

### Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

## NOTES

1. This subparagraph is without prejudice to subparagraph 1(b). back to text

2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision. back to text

3. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. back to text

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties. back to text

5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision. back to text

6. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement. back to text

7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision. back to text

8. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision. back to text

9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision. back to text

**ANNEXURE B**

# WTO NEWS: 2003 NEWS ITEMS

30 August 2003
**INTELLECTUAL PROPERTY**
The General Council Chairperson's statement

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.
- Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

**APPENDIX C**

# AIPPI Q94

## Questionnaire No. 4
### IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

## SCHEDULE OF RESPONSES RECEIVED

| National / Regional Group | Responses received |
|---|---|
| Argentina | 18.11.2004 |
| Australia | 07.12.2004 |
| Austria | |
| Belarus | |
| Belgium | |
| Bolivia | |
| Brazil | 08.11.2004 |
| Bulgaria | 25.11.2004 |
| Canada | 11.11.2004 |
| Chile | |
| China | Sept. 04 |
| Colombia | |
| Croatia | |
| Czech Republic | 08.11.2004 |
| Denmark | 08.11.2004 |
| Ecuador | |
| Egypt | 28.10.2004 |
| Estonia | 11.11.2004 (no answer) |
| Finland | 08.11.2004 |
| France | 10.11.2004 |
| Georgia | |
| Germany | |
| Greece | 03.11.2004 |
| Hungary | 26.11.2004 |
| Iceland | |
| India | |
| Indonesia | 08.11.2004 |
| Ireland | |
| Israel | 09.11.2004 |
| Italy | 09.11.2004 |
| Japan | 05.11.2004 |
| Latvia | 12.11.2004 (no answer) |
| Lithuania | 23.11.2004 (no answer) |
| Luxembourg | |
| Malaysia | 20.12.2004 |

**APPENDIX C**

| | |
|---|---|
| Mexico | 08.11.2004 |
| The Netherlands | |
| New Zealand | 07.11.2004 |
| Nigeria | |
| Norway | 29.10.2004 |
| Panama | |
| Paraguay | 05.11.2004 |
| Peru | |
| Philippines | |
| Poland | 26.11.2004 |
| Portugal | |
| Republic of Korea | 06.12.2004 |
| Romania | 26.11.2004 |
| Russia | 24.11.2004 |
| Serbia and Montenegro | |
| Singapore | |
| Slovak Republic | |
| Slovenia | |
| South Africa | 26.11.2004 |
| Spain | 03.11.2004 |
| Sweden | 05.11.2004 |
| Switzerland | 23.09.2004 |
| Thailand | |
| Ukraine | |
| United Kingdom | 09.11.2004 |
| United States of America | 20.12.2004 |
| Venezuela | |
| Arab Regional Group | |
| | |
| **TOTAL 65** | **32**<br>**(35)** |

**Information as at: February 2005** **Initial deadline: November 8, 2004**

**Reminder: November 10, 2004**

# AIPPI Q94

## Questionnaire No. 4
### IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

## ANALYSIS OF ANSWERS

| Question | Information received | No steps / No information |
|---|---|---|
| | | |
| **Question 1** | | |
| 1.1 | 13 | 19 |
| 1.2 | 2 | 30 |
| 1.3 | 3 | 29 |
| | | |
| **Question 2** | | |
| 2.1 | 2 | 30 |
| 2.2 | 3 | 29 |
| 2.3 | 1 | 31 |
| | | |
| **Question 3** | | |
| 3.1 | 1 | 31 |
| 3.2 | | 32 |
| 3.3 | 1 | 31 |
| | | |
| **Question 4** | | |
| 4.1 | 5 | 27 |
| 4.2 | 1 | 31 |
| | | |
| **Question 5** | | |
| 5.1 | | 32 |
| 5.2 | | 32 |
| | | |
| **Question 6** | 3 | 29 |
| | | |

**APPENDIX E**

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2004) 737

Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

(1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could

face difficulties in making effective use of compulsory licensing.

(2) On 30 August 2003 the General Council of the WTO adopted the Decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter "the Decision". Subject to conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement, to address the needs of WTO Members with insufficient manufacturing capacity.

(3) Given the Community's active role in the adoption of the Decision, its commitment made at the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

(4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all Member States and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to this Regulation.

(5) This Regulation is intended to be part of the wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines.

(6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. It should not be used with the primary purpose of addressing other objectives, and in particular objectives of a purely commercial nature.

(7) Products manufactured pursuant to this Regulation should reach those who need them and should not be diverted from those for whom they were intended. Compulsory licences issued under this Regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which these products will be exported.

(8) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence and which a person attempts to re-import into the territory of the Community.

(9) To avoid facilitating overproduction and possible diversion of products, competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant,

(10) Since the objectives of the action to be taken, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be

sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

[1] OJ C, p.
[2] OJ C, p.
[3] OJ C, p.

HAVE ADOPTED THIS REGULATION:

*Article 1*

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible WTO members affected by public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 5 and subject to the conditions set out in Articles 5 – 8.

*Article 2*

For the purposes of this Regulation, the following definitions shall apply:

(1) "pharmaceutical product" means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council[4], active ingredients and diagnostic kits;

(2) "right holder" means the holder of any patent or SPC in relation to which a compulsory licence has been applied for under this Regulation; in cases where more than one right holder is involved, for the purposes of this Regulation the singular term should be read as plural;

(3) "importing WTO member" means the name of the WTO member to which the pharmaceutical product is to be exported;

*Article 3*

**APPENDIX E**

The competent authorities in the Member States for granting compulsory licences under this Regulation shall be those which have competence for the granting of compulsory licences under national patent law, unless the Member State concerned determines otherwise.

Member States shall notify the Commission of the competent authorities designated for the purposes of this Regulation.

Notifications shall be published in the *Official Journal of the European Union*.

*Article 4*

The following are eligible importing WTO members:

(a) any least-developed country member of WTO

(b) any other member of WTO that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing WTO member.

[4] OJ L 311, 28.11.2001, p. 67

*Article 5*

1. Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

2. If the person applying for a compulsory licence is submitting applications to competent authorities in more than one Member State for the same product, he shall indicate that in each application, together with details of the quantities and importing WTO members concerned.

3. The application pursuant to paragraph 1 shall set out the following:

(a) the name and contact details of the applicant and of any agent or representative the applicant has appointed to act for him before the competent authority;

(b) the name of the pharmaceutical product or products the applicant intends to manufacture and sell for export under the compulsory licence, including

any additional information needed to ensure the precise identification of the product or products in question;

(c) identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought;

(d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

(e) the importing WTO member or members;

(f) evidence of prior negotiation with the right holder pursuant to Article 7;

(g) evidence of a specific request to the applicant from authorised representatives of the importing WTO member and indicating quantity of product required.

4. The competent authority may prescribe additional formal or administrative requirements for efficient processing of the application.

*Article 6*

1. The competent authority shall verify that each importing WTO member cited in the application has made a notification to the WTO pursuant to the Decision of 30 August 2003 of the General Council of the WTO on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter "the Decision" in respect of each of the products covered by the application that:

(a) specifies the names and expected quantities of the product(s) needed;

(b) unless the importing WTO member is a least-developed country, confirms that the importing WTO member has established that it either has no manufacturing capacities in the pharmaceutical sector or has examined its manufacturing capacity in that sector and found that, excluding any capacity owned or controlled by the right holder, it is currently insufficient for meeting its needs;

(c) confirms that where a pharmaceutical product is patented in the territory of the importing WTO member, that WTO member has granted or intends to grant a compulsory licence for import of the product concerned in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.

2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to the WTO by the importing WTO

member(s), and that, taking into account other compulsory licences ordered in the Community, the total amount of product authorised to be produced for any importing WTO member does not significantly exceed the amount notified to the WTO by that member.

*Article 7*

The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

The determination of a reasonable period of time shall take into account whether the importing WTO member has declared a situation of national emergency or other circumstances of extreme urgency.

*Article 8*

1. The licence granted shall be non-exclusive and non-assignable. It shall contain the specific conditions set out in paragraphs 2 to 8 to be fulfilled by the licensee.

2. The amount of patented product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing WTO member or members cited in the application.

3. The licence shall be strictly limited to the acts of manufacturing the product in question and selling for export to the WTO member or members cited in the application. No product made under the compulsory licence shall be offered for sale or put on the market in any country other than the WTO member(s) cited in the application.

4. Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the right holder through special packaging. The packaging and any associated literature shall bear an indication that the product is subject of a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and sale in the importing WTO member or members concerned. Unless the applicant proves that such distinction is not feasible or has a significant impact on price, special colouring or shaping of the products themselves shall also be required.

5. Before shipment to the importing WTO member or members cited in the application, the licensee shall post on a website the following information:

(a) the quantities being supplied under the licence and the WTO members to which they are supplied

(b) the distinguishing features of the product or products concerned.

The website address shall be communicated to the competent authority.

6. If the product(s) covered by the compulsory licence are patented in the importing WTO members cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import and sale of the products.

7. The licensee shall keep complete and accurate books and records of all quantities of product manufactured and of all dealings therein. The licensee shall make these books and records available on request to an independent person agreed by the parties, or otherwise appointed by the competent authority, for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met.

8. The licensee shall be required to provide proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation or putting on the market certified by an authority of the importing WTO member, and shall retain such records for at least three years. Upon request these proofs must be supplied to the competent authority.

9. The licensee shall be responsible for the payment of adequate remuneration to the right holder as determined by the competent authority taking into account the economic value of the use that has been authorised under the licence to the importing WTO member(s) concerned.

*Article 9*

The competent authority shall refuse an application if any of the conditions set out in Article 5 (3) and (4) and Articles 6, 7 and 8 is not met. Before refusing an application, the competent authority shall give the applicant an opportunity to rectify the situation and to be heard.

*Article 10*

1. When a compulsory licence has been granted the competent authority shall notify the Commission of the grant of the licence, and of the specific conditions attached to it.

   The information provided shall include the following details of the licence:

   (a) the name and address of the licensee;

   (b) the product or products concerned;

   (c) the quantity to be supplied;

   (d) the country or countries to which the product or products are to be exported;

   (e) the duration of the licence;

   (f) the address of the website referred to in Article 8 (5).

2. The Commission shall forward the information referred to in paragraph 1 to the Council for TRIPS.

*Article 11*

1. It is prohibited to import into the Community products subject of a compulsory licence under this Regulation for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse.

2. Paragraph 1 shall not apply in the case of re-export to the importing WTO member cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing WTO member.

*Article 12*

**APPENDIX E**

1. Where there is reason to suspect that, contrary to Article 11(1), products subject of a compulsory licence under this Regulation are being imported into the Community, customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the relevant national authority on the character of the merchandise. The period of suspension or detention shall not exceed 10 working days unless special circumstances apply, in which case the period may be extended by a maximum of 10 working days. Upon expiry of that period, the products shall be released, provided that all customs formalities have been complied with.

2. The relevant national authority and the manufacturer or exporter of the products concerned shall be informed without delay of the suspended release or detention of the products and shall receive all information available with respect to the products concerned. Due account shall be taken of national provisions on the protection of personal data, commercial and industrial secrecy and professional and administrative confidentiality. The importer, and where appropriate, the exporter, shall be given ample opportunity to supply the relevant national authority with the information which it deems appropriate regarding the products.

3. The procedure of suspension or detention of the goods is carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

4. If the relevant national authority finds that products suspended for release or detained by customs authorities were intended for import into the Community contrary to the prohibition in Article 11 (1), that authority shall ensure that these products are seized and disposed of in accordance with national legislation. These procedures are carried out at the expense of the importer. If it is not possible to recover these expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

5. Where products suspended for release or detained by customs authorities subsequent to further control by the relevant national authority are found not to violate the prohibition in Article 11(1), the customs authority shall release the products to the consignee, provided that all customs formalities have been complied with.

6. The relevant national authority shall inform the Commission of any decisions on seizure or destruction which are adopted pursuant to this Regulation.

*Article 13*

7. Articles 11 and 12 shall not apply to goods of a non-commercial nature contained in travellers' personal luggage for personal use within the limits laid down in

respect of relief from customs duty.

*Article 14*

1. Subject to adequate protection of the legitimate interests of the licensee, a compulsory licence granted pursuant to this Regulation may be terminated by a decision of the competent authority or by one of the bodies referred to under Article 16 in either of the following cases:

   (a) if the conditions of the licence are not respected by the licensee;

   (b) if and when the circumstances which led to the grant of the licence cease to exist and are unlikely to recur.

   The competent authority shall have the authority to review, on its own initiative or upon reasoned request by the right holder or the licensee, whether either of those situations applies.

2. Termination of a licence granted under this Regulation shall be notified to the Commission who shall inform the WTO.

3. Within a reasonable time following termination of the licence the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need or otherwise as prescribed by the competent authority in consultation with the right holder.

*Article 15*

Appeals against any decision of the competent authority, and disputes concerning compliance with the conditions of the licence, shall be heard by the appropriate body responsible under national law.

*Article 16*

1. Where the application for a compulsory licence concerns a medicinal product authorised in accordance with Article 6 of Directive 2001/83/EC, the provisions of Article 24(4) and (5) and of Article 14(4) and (5)[5] of Regulation (EC) No 726/2004 of the European Parliament and the Council shall not apply.

   For the purpose of the application of this paragraph, and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required

to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or under Article 3 of Regulation (EC) No 726/2004.

2. Where the application for a compulsory licence concerns a medicinal product and the applicant for the compulsory licence is not the holder of a marketing authorisation valid within the Community for the product concerned, he may avail himself of the scientific opinion procedure provided for under Article 58 of Regulation (EC) No 726/2004 or any similar procedure provided under national law.

3. For the purposes of obtaining a scientific opinion under paragraph (2) and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or Article 3 of Regulation (EC) No 726/2004.

*Article 17*

Three years after the entry into force of this Regulation, the Commission shall present a report to the European Parliament, the Council, and the Economic and Social Committee on the operation of this Regulation and the contribution it has made to the implementation of the system established by the Decision.

[5] OJ L 136, 30.4.2004, p. 1.

*Article 18*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

*For the European Parliament For the Council*
*The President The President*