Policy rules on issuing compulsory licences pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995

The State Secretary for Economic Affairs, Having regard to the WTO Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and section 4:81 of the General Administrative Law Act,

Orders as follows:

Article 1

The following definitions shall apply for the purposes of these policy rules:

a. the Minister: the Minister of Economic Affairs;
b. the Act: the Kingdom Act on Patents of 1995;
c. pharmaceutical product: any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, including active ingredients for the manufacture of these products and the diagnostic kits to use the products;
d. compulsory licence: a licence as referred to in section 57, subsection 1 of the Patents Act 1995;
e. the WTO Decision: the Decision of the General Council of the World Trade Organisation (WTO) on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540);
f. importing state: one of the least developed countries, or a WTO Member that has made a notification as referred to in article 2, paragraph (a) (ii) of the WTO Decision;
g. group of states: a group of importing states, as well as organisations as referred to in article 6, paragraph (i) of the WTO Decision;
h. order: a written order for a pharmaceutical manufacturer to manufacture a specific amount of a pharmaceutical product.

Article 2

1. In the interests of solving public health problems in an importing state or group of states, the Minister shall, upon receiving an application that satisfies the requirements of articles 3 and 4 of these policy rules, issue a compulsory licence as referred to in section 57, subsection 1 of the Patents Act 1995 for the pharmaceutical product that is needed to address the public health problems in question.

2. The compulsory licence shall at a minimum state the type and amount of the pharmaceutical product to which the compulsory licence issued for the purposes of the order applies.

3. The compulsory licence shall relate only to pharmaceutical products intended for the national market or markets of the importing state or group of states.

Article 3

1. The pharmaceutical manufacturer shall submit an application to the Minister for the issue of a compulsory licence.

2. The application shall be accompanied by an order addressed to the pharmaceutical manufacturer from an importing state, a group of states or a non-governmental organisation acting for one or more importing states.

3. If the pharmaceutical product to which the compulsory licence relates is intended for one of the least developed countries that is not a WTO Member, the application shall be accompanied by a declaration from that country affirming:

a. that the country does not have sufficient capacity to manufacture the pharmaceutical product and
b. what measures the country is taking to prevent trade diversion.

4. To prevent trade diversion of the pharmaceutical products to other states than the importing state, the pharmaceutical manufacturer shall take measures with regard to the packaging, colouring and/or shaping of the pharmaceutical products, provided these measures are feasible and do not have a significant impact on the price.

5. In its application, the pharmaceutical manufacturer shall state what measures, as referred to in paragraph 4, it has taken.

6. The compulsory licence shall contain the condition that, prior to shipping the pharmaceutical products to the importing state or group of states, the licensee shall post, on either its own website or the WTO webpage dedicated to that purpose, the measures that it has taken and the quantity and the characteristics, as referred to in paragraph 4, of the pharmaceutical products being shipped.

Article 4

If the order is placed by a WTO Member that is not one of the least developed countries, the application shall not be considered unless that Member meets the conditions referred to in article 2, paragraph (a) (ii) of the WTO Decision.

Article 5

Taking into account the economic value of the order to the importing state, the Minister shall determine adequate remuneration to be paid by the licensee to the patent holder as compensation for the compulsory licence.

Article 6

A decision by the Minister on issuing a licence, as referred to in article 2, shall state whether the lodging of an objection or an application for review will suspend implementation of the decision.

Article 7

These policy rules shall enter into force on the second day after the date of the Government Gazette in which they appear.

These policy rules will be published in the Government Gazette with the explanatory notes.

The Hague, 17 December 2004

The State Secretary for Economic Affairs

EXPLANATORY NOTES

I. GENERAL

These policy rules execute the Decision of the General Council of the World Trade Organisation (WTO) on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) ("the WTO Decision"). The WTO Decision makes it possible to issue compulsory licences for the export of pharmaceutical products to states where public health problems are grave if those states do not have sufficient capacity to manufacture those pharmaceutical products themselves.

It was decided that the WTO Decision would be implemented by means of policy rules explaining the nature of the Minister of Economic Affairs' general authority to issue compulsory licences pursuant to section 57, subsection 1 of the Patents Act 1995. These policy rules are subject to articles 4:81 to 4:84 of the General Administrative Law Act.

Some countries cannot solve their public health problems because they do not have the capacity to manufacture pharmaceutical products. For various reasons, it can

also be difficult to purchase these pharmaceutical products. For instance, they may be covered by one or more patents. As a result, the price may be too high for developing countries to buy sufficient quantities from either the patent holder or a licensee. In addition, the patent holder's available manufacturing capacities may be insufficient to meet the demand.

Manufacturers of generic pharmaceutical products may not market cheaper copies of patented products unless the patent has expired or a licence for that purpose has been issued to them. If the patent holder will not voluntarily issue such a licence, the Minister of Economic Affairs ("the Minister") may issue a compulsory licence pursuant to section 57, subsection 1 of the Patents Act 1995.That subsection empowers him to issue compulsory licences if, in his opinion, it is in the public interest to do so.

The Minister must exercise this authority in accordance with article 31 of the TRIPS Convention, which contains conditions for the issue of such compulsory licences. Article 31, paragraph (f) of the TRIPS Convention states that compulsory licences shall be authorised predominantly in order to supply patented products to a domestic market. Article 31, paragraph (h) states that the patent holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation. The value of the licence that is considered is that in the patent holder's country, which is often higher than that in the importing country. The obligations set out in article 31, paragraphs (f) and (h) make it impossible to issue compulsory licences with the aim of increasing the availability of sufficient affordable pharmaceutical products for developing countries that do not have the capacity to manufacture generic versions. The WTO Decision attempts to bring this situation to an end by stipulating that, if a compulsory licence is issued in line with its provisions, article 31, paragraphs (f) and (h) of the TRIPS Convention shall not apply. Accordingly, the reference to the public interest in section 57, subsection 1 of the Patents Act 1995 may be interpreted as including the addressing of a public health problem in another WTO Member or in one of the least developed countries.

The WTO Decision creates a system for issuing compulsory licences aimed at solving the public health problem. The only purpose for which importing states or groups of states may use the imported pharmaceutical products is to address their own public health problems. The policy rules are intended to help alleviate public health problems in countries that may import cheap pharmaceutical products on the basis of the WTO decision on this matter of 30 August 2003. The solution offered by this arrangement may not be used improperly in pursuit of industrial or commercial ends.

The WTO Decision also allows WTO Members that are not among the least developed countries to apply to import generic pharmaceutical products if they have made a notification as referred to in article 2, paragraph (a) (ii). However, a

number of Members have declared that they will not make use of the system as importing Members; this includes all the EU member states, Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland and the United States.

The WTO Decision provides for waivers of the obligations set out in article 31, paragraphs (f) and (h) of the TRIPS Convention in the interest of public health in WTO Members. These waivers do not formally apply to non-WTO Members. However, it was decided that the policy rules would also be made applicable to non-WTO Members that are among the least developed countries, because they too face major public health problems and have insufficient manufacturing capacities.

On application by a pharmaceutical manufacturer who has received an order from an importing state or group of states, a compulsory licence is issued by the exporting state if the conditions for issue have been met.

These policy rules were drafted prior to the presentation of the European Commission Regulation on this topic, which is now in preparation and will be presented to the Council by the Commission to promote uniform national implementation throughout the European Union. At such time as this Regulation enters into force, Dutch legislation will be amended to conform with it as needed.

II. INDIVIDUAL ARTICLES

Article 1

Paragraph (c) adopts the definition of 'pharmaceutical product' from the WTO Decision, in which the term covers not only medicines but also the diagnostic kits needed to use the medicines.

Article 2

Compulsory licenses exhaustively specify the scope of the waiver granted; they are intended solely for the manufacture of the pharmaceutical products mentioned in the application. The scope of the compulsory licence must be commensurate with the public health problems to be solved.

Under section 57, subsection 1 of the Patents Act 1995, the Minister must make certain that the patent holder is unwilling to issue a voluntary licence before issuing a compulsory licence. In urgent cases, the section in question allows the Minister to refrain from investigating whether the patent holder is willing to issue a licence voluntarily.

In forming a view on the existence of a public health problem, the Minister will follow the notification arrangements set out in the WTO Decision or, with regard

to least developed countries that are not WTO Members, the arrangements described in article 3, paragraph 3 of these policy rules.

The foregoing does not affect the Minister's obligation under section 4:84 of the General Administrative Law Act to ascertain, when giving a decision, whether this decision may have an impact on one or more interested parties that due to exceptional circumstances would be out of proportion to the aims of these policy rules.

Article 3

The pharmaceutical products manufactured under the compulsory licence may only be used as part of the solution to the public health problems of the importing country. It is therefore important for the pharmaceutical products not to be re-exported from the importing country. The pharmaceutical manufacturer submits an application to the Minister of Economic Affairs. These applications are subject to the General Administrative Law Act, especially sections 4:2 and 4:3. Under these sections and these policy rules, the applicant is required to state at a minimum the name and quantity of the pharmaceutical product that it wishes to manufacture and the patent by which the product is covered. If an application is not accompanied by one of the documents referred to in article 3, paragraph 2, such as the order, section 4:5 of the General Administrative Law Act shall apply, which requires the administrative authority to give the applicant the opportunity to supplement its application within a period set by the administrative authority*.

A pharmaceutical manufacturer who applies for a compulsory licence must state in the application what measures it will take to prevent trade diversion of the pharmaceutical products that it manufactures and exports under the compulsory licence. At a minimum, it must state what measures it will take with regard to the packaging, colouring or shaping of the pharmaceutical products. If the manufacturer does not intend to take these measures because they are not feasible or have a significant impact on the price, it must explain why this is the case.

If it comes to light that the pharmaceutical manufacturer is misusing the compulsory licence and hence is partly or wholly responsible for the trade diversion of the pharmaceutical products that it manufactured and exported, criminal charges may be brought against it.

Article 4

If a country wishes to make use of the system established by the WTO Decision, it must make a notification to the Council for TRIPS. If the importing Member is not among the least developed countries, the compulsory licence will only be issued if that Member has notified the WTO, through the proper procedure, that it intends to use the system.

If such notification has been made, it will be assumed that the Member using the system established by the WTO Decision meets the applicable conditions.

Article 5

Under normal circumstances, the remuneration that the licensee pays to the patent holder must be commensurate with the economic value of the authorisation in ordinary trade. In the present case, the remuneration will be based on the value of the pharmaceutical products in the importing country. If price and income levels are lower in that country than in the Netherlands, that fact will play a leading role in the calculation of the remuneration owed. As a result, the pharmaceutical products should be affordable to everyone in the importing country.

Article 6

Section 57, subsection 1 of the Patents Act 1995 stipulates that objections against and applications for review of a decision to issue a compulsory licence shall suspend implementation of the decision, unless that would be inappropriate in view of the urgency of the case. Such cases are likely to be regarded as urgent, given the gravity of the public health problems in the countries for which the pharmaceutical products to be exported are intended. For that reason, the Minister will always state in his decision whether or not he will allow objections and applications for review to suspend implementation.

The State Secretary for Economic Affairs