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Committee on Development

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DRAFT OPINION

of the Committee on Development

for the Committee on International Trade

on the 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 (COM(2004)0737 – C6-0168/2004 – 2004/0258(COD))

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SHORT JUSTIFICATION

The Doha WTO Ministerial in 2001 produced a landmark agreement, The Doha Declaration on TRIPS and Public Health, which clearly defined the primacy of public health in relation to intellectual property rights. The EC draft Regulation aims to provide the detail on the measures needed to implement the subsequent WTO General Council Decision of August 30th 2003 within the European Union. The relevant paragraph in the Doha Declaration recognises that WTO members with insufficient, or no manufacturing capacity, in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement.

Historically, pharmaceutical companies and governments have argued that the high cost of research and development dictates that there should be strong patent protection, likely to provide incentives for that investment. TRIPS, in theory, exists to reward innovation but, as things stand, the system lacks a mechanism likely to ensure that, in particular, the diseases of the poor and developing country's health priorities are addressed. The reality is that only 10% of global research in development are actually directed towards illnesses that account for 90% of the world wide disease burden. Millions of people in developing countries are dying every year because the only drugs available to treat tropical diseases are either old, toxic or ineffective.

The draft EC Regulation is intended to establish the conditions under which compulsory licenses for export can be granted. However, the test of the current Regulation is whether it actually has the potential to maximise developing country access to low-priced, essential medicines through making full use of the flexibilities which clearly are in the WTO text.

Although there has been an acknowledgement by a number of commentators that there are positive elements in the regulation, some concerns remain. Indeed, the European Generic Medicines Association has concluded that, "the procedures are complicated, the terms under which new producers must operate are very restrictive and the various measures proposed are ambiguous."

The process, therefore, should be simplified in order to encourage European suppliers to operate under the system. Clearly, there needs to be safeguards which ensure that generic pharmaceutical products do not find their way into the European market. Since, however, trade in pharmaceutical products is subject to stringent national regulations, the risk of diversion is not high. Indeed, the Commission itself has noted that there has been no evidence of the re-importation of medicines from the poorest developing countries into the EU. Therefore, these provisions should not and need not impose unnecessary restrictions. The fact that the Dutch legislation is less restrictive is an indication that it should be possible to take more advantage of the opportunities which exist in the WTO text to address those public health objectives, which are at the heart of the Doha Declaration. Regrettably, the Regulation consistently applies conditions which are not featured in the WTO Decision and which could potentially discourage suppliers. Serious consideration should now be given to the need for some relaxation of what is an over zealous interpretation of the WTO Decision.

The draft Regulation also includes a requirement which does not feature in the WTO Decision. This appears to exclude the right of NGOs and international institutions such as the

UN to import medicines under the rules of the regulation under the system, and, indeed, fails to take into account the critical role NGOs play in the supply of healthcare services and treatment. In addition, it takes no account of the NGOs role in, for instance, disasters or conflicts, where governments, for whatever reason, cannot be present. Again, we should note that the Dutch regulation includes a clear reference to the role of NGOs.

Also, unlike the EC Regulation, the Canadian, Norwegian and Dutch Regulations all include clear reference to non-WTO members - 40 of which are least developed countries.

In addition, the EC regulation imposes restrictions which are more severe than those included in the TRIPS agreement. Voluntary licences do not need to be negotiated in declared situations of national emergency or other circumstances of extreme urgency. The EC regulation in fact does not apply these exceptions, and is therefore applying so-called "TRIPS plus" conditions.

This Regulation should therefore not be seen as the last word and it should be understood that a further review and assessment will be necessary. It does, in fact, call for an annual report on the implementation of its recommendations. It should also be noted that the WTO Decision allows for such an annual review. We also require greater clarity on provisions for further action. Indeed, any future amendment of TRIPS in order to incorporate the WTO Decision would, it seems, require an immediate review of the EC Regulation and its operation should be monitored at regular intervals.

Issues related to the transfer of technology to developing countries, as well as the need for capacity building in the production of pharmaceuticals, are a serious omission from the draft Regulation. These elements are clear objectives of the WTO Decision. There needs to be a clear understanding that the research and development of medicines is a global, public good and, therefore, requires global action including sustainable and long-term financing, including through the Seventh Framework Programme.

The European Parliament's study by Carlos Correa (Directorate General External Policies) estimates that the impact of the Draft Regulation on developing country health problems "will probably be modest". It is therefore a matter of some concern that its ability to meet the Doha vision of how we "promote access to medicines for all" could remain elusive. Clearly much remains to be done - both in terms of adequate funding and ensuring flexible intellectual property frameworks.

AMENDMENTS

The Committee on Development calls on the Committee on International Trade, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
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.***	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 ***countries.***

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 2
Article 2, paragraph 3

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

Justification

All subsequent references to "WTO members" should be corrected accordingly in keeping with amendment 1.

Amendment 3
Article 4

[1] Not yet published in OJ.

The following are eligible importing WTO members:	***deleted***
(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.	

Amendment 4
Article 4, paragraph 1 (new)

1. Any country may import pharmaceutical products under this Regulation, with the exception of WTO members that have made a declaration to the WTO that they will not use the system as importing members;

Amendment 5
Article 4, paragraph 2 (new)

2. United Nations organisations , other international health organisations and non-governmental organisations may import pharmaceutical products under this Regulation, in the event of public health problems in a given country.

Justification

The proposed regulation appears to exclude the right of NGOs to import medicines under the rules of the regulation under the system, and, indeed, fails to take into account the critical role NGOs and UN bodies play in the supply of healthcare services and treatment. In addition, it takes no account of the NGOs role in, for instance, disasters or conflicts, where governments, for whatever reason, cannot be present.

Amendment 6

Article 5, paragraph 2

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.***	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***.***

Justification

The determination of the needed quantities by the importing country adds unnecessary complication, since needs may change as circumstances evolve.

Amendment 7
Article 5, paragraph 3, point (c)

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

Justification

Identification of patents is not required by the WTO Decision and, in fact, it may be difficult and costly to determine which patents cover a given pharmaceutical product.

Amendment 8
Article 5, paragraph 3, point (b a) (new)

	(ba) the importing countries or organisations as referred to in Article 4;

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 9
Article 5, paragraph 3, point (c a) (new)

	(ca) evidence of a notification to the TRIPS Council of the name and expected quantities of the product required;

Amendment 10
Article 5, paragraph 3, point (d)

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

Justification

The determination of the needed quantities by the importing country adds unnecessary complication, since needs may change as circumstances evolve.

Amendment 11
Article 5, paragraph 3, point (e)

(e) the importing WTO member or members;	***deleted***

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 12
Article 5, paragraph 3, point (f)

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

Justification

The WTO Decision provides for certain circumstances in which prior negotiation can be waived. The possibility of applying fast-track procedures is of particular importance given the risk of patentees not engaging in negotiations in good faith.

Amendment 13
Article 5, paragraph 3, point (g)

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

Justification

This requirement is absent from the WTO Decision and adds unnecessary complication.

Amendment 14
Article 5, paragraph 4

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

Justification

This requirement is absent from the WTO Decision and adds unnecessary complication.

Amendment 15
Article 6, paragraph 1, introductory part

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:	1. The competent authority shall verify that each ***country*** 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:

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 16
Article 6, paragraph 1, point (b)

(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;	(b) unless the importing ***country*** is a least-developed country, confirms that the importing ***country*** has established that it either has no manufacturing capacities in the pharmaceutical sector ***in relation to a particular product or products*** 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 ***for that product or products***;

Justification

A general declaration of no or insufficient manufacturing capacity is a more stringent standard than the one established in the WTO decision.

Amendment 17
Article 6, paragraph 1, point (c)

(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.	(c) ***unless the importing country is a least developed country*** confirms that where a pharmaceutical product is patented in the territory of the importing ***country***, that ***country*** 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.

Justification

Exemption for least developing countries

Amendment 18
Article 6, paragraph 2

2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to	2. The competent authority shall verify that the ***expected*** 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***.	the WTO by the importing ***country or countries***, and that, taking into account other compulsory licences ordered in the Community, the total amount of product authorised to be produced for any importing ***country*** does not significantly exceed the amount notified to the WTO by that ***country***.

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 19
Article 7, paragraph 1

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 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 ***30 days***.

Amendment 20
Article 7, paragraph 2

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.	***Prior negotiations shall not be required in situations of national emergency, other circumstances of extreme urgency, public non-commercial use or anti-competitive practices.***

Justification

The WTO Decision provides for certain circumstances in which prior negotiation can be waived. The possibility of applying fast-track procedures is of particular importance given the risk of patentees not engaging in negotiations in good faith.

Amendment 21
Article 8, paragraph 1

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.	1. The licence granted shall be non-exclusive and non-assignable. It shall contain the specific conditions set out in paragraphs 2 to ***6*** to be fulfilled by the licensee.

Amendment 22
Article 8, paragraph 2

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

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 23
Article 8, paragraph 3

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.	3.***(a)*** The licence shall be strictly limited to ***all acts necessary to import, produce and sell the relevant pharmaceutical product to the country or countries*** 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 ***country or countries*** cited in the application.

Justification

The wording of the proposed legislation is ambiguous and could prevent the importation of active pharmaceutical ingredients, thereby threatening to seriously undermine the system.

Amendment 24
Article 8, paragraph 3, point (b) (new)

	(b) By way of exception, imported products may be re-exported by an eligible country to other members of a regional trade agreement of which the importing country is also a member, provided that at least half of the then current membership is made up of countries then on the United Nations list of least developed countries. It is understood that this will not prejudice the territorial nature of the patent rights in question.

Justification

This article is provided for under the WTO decision - in order to promote economies of scale.

Amendment 25
Article 8, paragraph 4, introductory part

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.	***deleted***

Justification

This requirement is absent from the WTO Decision and adds unnecessary complication.

Amendment 26
Article 8, paragraph 5

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

Amendment 27
Article 8, paragraph 5, point (a)

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

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 28
Article 8, paragraph 6

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.	6. If the product(s) covered by the compulsory licence are patented in the importing ***country*** 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.

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 29
Article 8, paragraph 7

7. The licensee shall keep complete and accurate books and records of all quantities of product manufactured and of all	***deleted***

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*.*

Justification

This requirement is absent from the WTO Decision and adds unnecessary complication.

Amendment 30
Article 8, paragraph 8

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.	***deleted***

Justification

This requirement is absent from the WTO Decision and adds unnecessary complication.

Amendment 31
Article 8, paragraph 9

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.	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 ***country or countries*** concerned.

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this

must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 32
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.	The competent authority shall refuse an application if any of the conditions set out in Article 5 (3) and Articles 6 ***and*** 7 is not met. Before refusing an application, the competent authority shall give the applicant an opportunity to rectify the situation and to be heard.

Amendment 33
Article 11, paragraph 2

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***.	2. Paragraph 1 shall not apply in the case of re-export to the importing ***country*** 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 ***country***.

Justification

The proposed regulation would exclude non-WTO members from the provisions, including 40 LDCs. If we are achieving the Doha objective of promoting access to medicines for all, this must include these 40 poorest countries. Nothing in the WTO Decision prevents such an extension as is demonstrated by the legislation presented in Norway, Canada and the Netherlands.

Amendment 34
Article 14, paragraph 1, point (b)

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

Justification

This is a TRIPS-plus condition and ignores the right of importing countries to determine when

the continuation of a compulsory licence is no longer justified.

Amendment 35
Article 15, paragraph 1 a (new)

An appeal against a decision to grant a compulsory licence shall not suspend the execution of the licence.

Justification

The possibility of blocking the supply of medicines for long periods of time will lead to uncertainty for prospective suppliers and may further reduce the interest of potential suppliers in operating under the system.

Amendment 36
Article 16 a (new)

Article 16a

The Commission shall establish a fund in order to provide direct support in the form of grants to companies and institutions for the transfer of technology to developing countries.

Justification

The draft Regulation also lacks instruments to promote the transfer of technology and capacity building in pharmaceuticals in developing countries and LDCs, despite that this is one of the objectives of the WTO Decision.

Amendment 37
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 European 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.

The Commission shall carefully monitor the operation of this Regulation and each year shall present a ***Report*** to the European Parliament, the Council, and the European Economic and Social Committee on the contribution it has made to the implementation of the system established by the Decision.
A full review of this Regulation shall take place immediately after the amendment of

TRIPS and thereafter every three years.

Justification

Constant monitoring and review of the regulation are important in order to ensure the good functioning of the system, which will be subject to review.