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***I
REPORT

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))

Committee on International Trade

Rapporteur: Johan Van Hecke

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2004)0737)[1],

– having regard to Article 251(2) and Articles 95 and 133 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0168/2004),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on International Trade and the opinions of the Committee on Development, the Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs (A6-0242/2005),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 6	
(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***.	(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. ***This Regulation aims to discourage litigation with regard to the established system***.

[1] Not yet published in OJ.

Justification

The draft Regulation does not provide any specific incentive that would encourage generic companies to produce under the system. It cannot be expected that commercial undertakings make the investments necessary to develop the chemistry, formulate, produce and distribute the required products on a non-profit basis. Pharmaceutical companies involved in these activities pursue commercial objectives in the same way as companies developing new drugs. Therefore, even minimal additional deterrent elements might eventually discourage the generic industry from using the system.

Amendment 2
Recital 6 a (new)

	(6a) Research and development in the field of health at a global level only partially answers health needs in poor countries. In order to address this situation, measures should be implemented as soon as possible, with a view to improving the technical capacity of those countries.

Justification

As research and development in the field of neglected diseases is not commercially viable, R&D is mainly geared towards the Western world, widening the inequality between developed and poor countries. It is important for the European Union to give a clear political signal.

The desirability of the transfer of technology to developing and least-developed countries is set out in the Decision of 30 August, but not incorporated in the regulation.

Amendment 3
Recital 7

(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.	(7) Products manufactured pursuant to this Regulation ***must*** reach ***only*** those who need them and should not be diverted from those for whom they were intended. ***The issuing of*** compulsory licences under this Regulation ***must*** 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.

Amendment 4

Recital 9

(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.	(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. ***Where they do not already exist, the data exchange networks necessary for this purpose should be created.***

Amendment 5
Recital 10 a (new)

	(10a) The Community recognises that the measures provided for in this Regulation are not sufficient to guarantee adequate access to generic medicines in developing countries and that it must take additional measures as a matter of urgency with a view to:
	- encouraging within the European Union the production of medicines and research to combat the major epidemics affecting developing countries; and
	- encouraging the transfer of technology, research, capacity strengthening, regional supply systems and help with registration, in order to facilitate and increase the production of pharmaceutical products by the developing countries themselves.

Justification

Although this is one of the objectives of the WTO decision, the proposal does not provide any concrete machinery for promoting the production of generic medicines in the EU, the transfer of technology and the production of pharmaceutical products by developing countries themselves in order to render them less dependent.

Amendment 6
Article 1, paragraph 1

This Regulation establishes a procedure for the grant of compulsory licences in relation	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***.	to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible ***importing countries***.
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.	

Justification

The phrase 'affected by public health problems' imposes an additional criterion of eligibility, which is neither required by the WTO Decision nor clarified in other parts of the draft Regulation. This should not be an independent criterion.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Given that problems of lack of affordable medicines are not limited to WTO member, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 7
Article 2, paragraph (3)

(3) "importing ***WTO member***" means the name of the WTO member to which the pharmaceutical product is to be exported;	(3) "importing ***country***" means the name of the WTO member***, of the developing country or of the least-developed country*** to which the pharmaceutical product is to be exported;

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 8
Article 4

The following are eligible importing ***WTO members***:	***1.*** The following are eligible importing ***countries***:
(a) any least-developed country ***member of WTO***	(a) any least-developed country
(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.	(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.
	(c) any developing country that is not a member of WTO and has made a notification to the Commission 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***.	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 ***country***.

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 9
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, together with details of the quantities and importing ***countries*** concerned.

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

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

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

Justification

These details must be supplied in the application for a compulsory licence, since otherwise, under Article 5a, the competent authority would be required to find them out, which would generally lead to a delay. The applicant already possesses these data from an earlier stage of negotiations. The amendment is thus in the interest of a speedy procedure.

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

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

Justification

The WTO General Council Decision of 30 August 2003 does not lay down such a provision concerning the information required to be supplied by the applicant in connection with an application for a compulsory licence (cf. paragraph 2(b)(ii) of the WTO General Council Decision).

Amendment 12
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 the patents subject to a compulsory licence is not required by the WTO Decision. The licence may be granted in relation to all relevant patents, as it is the practice in some countries. In fact, it may be difficult and costly to determine which patents cover a given pharmaceutical product, since a large number of patents (regarding active ingredients, formulations, polymorphs, salts, processes of manufacture, etc.) are usually obtained with respect to a single product. In addition, during the execution of the compulsory licence new patents may be granted in relation to the same product.

Finally, the applicant for a compulsory licence is under an obligation to provide evidence that he has negotiated with the holder of the patent(s) or supplementary protection certificate(s) in accordance with Article 7 of this proposal for a regulation.

This provision is redundant, and is likely to have the effect of preventing potential applicants from making use of this compulsory licensing system. It should therefore be deleted.

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

(d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;	(d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence***, in accordance with Article 8(2)***;

Justification

Cf. amendment to Article 8(2).

Amendment 14
Article 5, paragraph 3, point (e)

(e) the importing ***WTO member*** or ***members***;	e) the importing ***country*** or ***countries***;

Amendment 15
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 16
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	(g) evidence of a specific request from***:*** ***(i)*** authorised representatives of the importing ***country or countries;*** ***(ii) a non-governmental organisation acting with the formal approval of one or more importing countries;*** ***(iii) UN bodies or other international health organisations acting with the formal approval of one or more importing countries;*** and indicating the quantity of product required.

Justification

Countries should be able to file an application together and the system should offer the possibility to NGOs, organisations of the United Nations or other international health organisations to act for one or more importing countries in the search for a producer and to import the pharmaceutical products in the importing countries.

International tendering is the preferred way of purchasing medicines and other medical supplies and is also often required by bilateral donors. In developing countries, obtaining medicines through a public tendering-procedure, which tends to drive down the prices, is becoming common practice. Therefore, the words "to the applicant" should be deleted.

Amendment 17
Article 5, paragraph 4

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

Justification

The draft Regulation allows the competent authority to 'prescribe additional formal or administrative requirements for efficient processing'. It is unclear what these requirements may be and why national authorities should be given such power if the purpose of the draft Regulation is to establish a uniform system throughout the EU.

Amendment 18
Article 5, paragraph 4 a (new)

	4a. The competent authority shall inform the right holder of the application for a compulsory licence within a period of 14 days. Before the grant of the compulsory licence, the competent authority shall give the right holder an opportunity to comment upon the application and to provide the competent authority with any relevant information regarding the application.

Justification

The right holder should be informed and able to comment his position. This could be particularly important if the rights holders interests have not been respected in the importing country.

Amendment 19
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 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", ***or*** ***- that each developing country or least-***

	developed country cited in the application which is not a WTO member has made a notification to the Commission according to this Regulation in respect of each of the products covered by the application that:

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 20
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 ***where necessary*** that the ***country*** has established that it ***had insufficient or*** no manufacturing capacities in the pharmaceutical sector ***in relation to a particular product or products in one of the ways set out in the Annex to the WTO decision of 30 August 2003***;

Justification

Takes over the wording of the WTO decision of 30 August 2003. It is important that the wording should be identical in order to prevent a situation where potential applicants have no recourse to the compulsory licensing system.

Amendment 21
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	(c) confirms that where a pharmaceutical product is patented in the territory of the importing ***country***, that ***importing 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.	provisions of the Decision. ***This is without prejudice to the flexibility that least-developed countries have under the Decision of the Council for TRIPS of 27 June 2002.***

Justification

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Given that problems of lack of affordable medicines are not limited to WTO member, the scope of the regulation should be extended to include also developing countries and least-developed countries.

According to the Decision of the Council for TRIPS of 27 June 2002, "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".

Amendment 22
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 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.	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) ***or to the Commission by an importing developing country or least-developed country which is not a WTO member***, 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 ***WTO*** member ***or to the Commission by that developing country or least-developed country which is not a WTO member***.

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members,

WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 23
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 and that such efforts have not been successful within ***a period of thirty days before submitting the application, except in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.***

Justification

Efforts by the applicant are required to obtain authorisation on "reasonable commercial terms and conditions". Although commercial interest will be present in the case of companies willing to supply required products, there might be cases in which the license for export may be used for non-profit purposes.

The 'reasonable period of time' for the prior negotiation with a patentee is not specified. The uncertainty left by this provision will possibly invite drawn-out negotiations and court proceedings to determine whether a reasonable period of time has elapsed before requesting a compulsory licence. This may constitute a significant disincentive to prospective users of the system. A concrete specification could have positive effects by providing more legal certainty.

Article 31(b) of the TRIPS Agreement authorises, under certain conditions, waiving the requirement to obtain prior authorisation from the holder of the patent(s) or supplementary certificate(s). The Community rules on compulsory licensing should not go beyond the provisions adopted and accepted at the WTO level; otherwise there is a risk that it will become impossible at the Community level and within the European Union to use the compulsory licensing system.

Amendment 24
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.

Justification

See amendments 32 and 33.

Amendment 25
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***; authorisation to produce any additional amount of the same patented product(s) manufactured under the licence shall be granted within 8 days by the competent authority on submission of an application stating the reasons for which additional production is necessary. Any additional amount of the same patented product(s) manufactured under the licence shall be notified to the competent authority, the Commission and the WTO***.

Justification

Only a simple procedure, not a new licensing procedure, should be required in respect of any increase in the amount of identical product(s).

Amendment 26
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. The licence shall be strictly limited to ***all*** acts ***necessary for the purposes of production and distribution of a pharmaceutical product and its*** export to the importing ***country or countries*** cited in the application ***or to a developing or least-developed country party to a regional trade agreement, at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, to the extent necessary to enable a pharmaceutical product produced or***

	imported under a compulsory licence in that country 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.

Justification

The draft Regulation limits the scope of the licence strictly to the acts of manufacturing and selling. The WTO Decision is broader, as it waives TRIPS Article 31(f) obligation 'to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export [...]'. The production of a pharmaceutical product may require the importation of active pharmaceutical ingredients (APIs). In fact, the EU pharmaceutical industry depends to a significant extent on APIs produced outside the EU and imported therein for the formulation of pharmaceutical products.

Paragraph 6 of the WTO Decision permits the re-exportation of products imported under the system to other members of a regional trade agreement at least half of the membership of which is made up of LDCs. In these cases, the countries to which re-exportation takes place need not to have been mentioned in the notification made by the importing country.

Amendment 27
Article 8, paragraph 4

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.***	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 ***and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price***. 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 ***distribution*** in the importing ***country*** or ***countries*** concerned. ***Details of the product characteristics shall be made available to the customs authorities of the Member States.***

Justification

The WTO Decision requires suppliers to distinguish their 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'. This means that differentiation can be satisfied through special packaging or special colouring/shaping, at the option of the supplier, provided it is feasible and does not have a significant impact on price. The draft Regulation makes special colouring or shaping mandatory 'unless the applicant proves that such distinction is not feasible or has a significant impact on price'. This provision clearly goes beyond the WTO Decision, as the supplier will be obliged to prove that changing colour or shape is not feasible or has a significant impact on price.

This will aid Customs officials in identifying infringing products.

Amendment 28
Article 8, paragraph 5, introductory part

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:

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 29
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 ***importing countries*** to which they are supplied;

Justification

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members,

WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries.

Amendment 30
Article 8, paragraph 5, subparagraph 4

The website address shall be communicated to the competent authority.	The website address shall be communicated to the competent authority***, the Commission and the right holder. The Commission shall post the address on its central website***.

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

In order to promote transparency and checks on the use of compulsory licences, it would be useful to notify the right holder of the website containing the information to be made public, and to post the address on the central Commission web page.

Amendment 31
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 ***countries*** cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import***,*** sale ***and/or distribution*** of the products.

Justification

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Given that problems of lack of affordable medicines are not limited to WTO member, the scope of the regulation should be extended to include also developing countries and least-developed countries.

The draft Regulation conditions exportation upon the prior granting of 'a compulsory licence for the import and sale' in the importing country. However, in many cases the products subject to the compulsory licence may not be sold but distributed free of charge (e.g. by public hospitals or NGOs).

Amendment 32
Article 8, paragraph 7

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.	***deleted***

Justification

This paragraph obliges suppliers to keep complete and accurate books and to permit access thereto to authorised persons. This condition is not imposed by the WTO Decision. Given the various measures provided for in the draft Regulation to avoid diversion, this additional obligation seems redundant and may further discourage prospective suppliers unwilling to have direct State control over their commercial operations. The patentee will always have the right to request the review of the compulsory licensee's books to check his operations under the license.

Amendment 33
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 paragraph requires the supplier to provide proof of exportation. This condition is not imposed by the WTO Decision. Given the various measures provided for in the draft Regulation to avoid diversion, this additional obligation seems redundant and may further

discourage prospective suppliers unwilling to have direct State control over their commercial operations. The patentee will always have the right to request the review of the compulsory licensee's books to check his operations under the license.

Amendment 34
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. ***In making this determination, the humanitarian and non-commercial reasons underlying the issue of the licence must be considered.*** ***The amount of the adequate remuneration shall be determined in accordance with guidelines to be established by the Commission.*** ***Member States shall communicate to the Commission within six months after the entry into force of this Regulation the royalty rates and the regulatory formula they will apply in the calculation of the adequate remuneration.***

Justification

The lack of guidance about the remuneration to be paid creates considerable uncertainty for prospective users of the system (both potential producer companies and importers of pharmaceutical products) and may give rise to litigation as to whether the determined remuneration is adequate.

In order to enhance the predictability of the determinations to be made at national level, the draft Regulation should include guidance on what factors must be considered in determining adequate remuneration.

Amendment 35
Article 9

The competent authority shall refuse an	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.	application if any of the conditions set out in Article 5 (3) 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.

Justification

Amendment consistent with the amendment to Article 5(4).

Amendment 36
Article 10, paragraph 1, point (e)

(e) the duration of the licence	(e) the duration of the licence ***and the conditions for its issue***;

Justification

In order to be consistent with Recital 7 which states that 'compulsory licences issued under this regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence'.

Amendment 37
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

Given that problems of lack of affordable medicines are not limited to WTO member countries, the mutual beneficiality of trade and development policy can not be ensured if the scope is limited to WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO members in extending the implementation of the Decision to non-WTO members. Therefore, the scope of the regulation should be extended to include also developing countries and least-developed countries

Amendment 38
Article 12, paragraph 1

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.	1. ***If***, contrary to Article 11(1), products subject of a compulsory licence under this Regulation are being imported into the Community, ***in breach of the provisions laid down in Article 5(3) and Articles 6, 7 and 8,*** customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the ***competent*** authority on the character of the merchandise. ***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 such importation is taking place.*** 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.

Justification

The text inserted makes clear when the competent authority can act and brings Article 12 into line with Article 14.

The wording in the proposal for a regulation is too vague. The grounds on which the release of products may be suspended should be the same as the conditions specified for the granting of a compulsory licence.

Amendment 39
Article 12, paragraph 2

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	2. The ***competent*** authority***, the right holder*** 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

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.	products concerned. Due account shall be taken of national provisions on the protection of personal data and commercial and industrial secrecy and professional and administrative confidentiality. The importer, and where appropriate, the exporter, shall be given ample opportunity to supply the ***competent*** authority with the information which it deems appropriate regarding the products.

Justification

This amendment brings the terminology into line with the remaining text of the regulation, which refers only to the competent authority.

The rights holder is an interested party as it is possible that diverted products may have already entered the market.

Amendment 40
Article 12, paragraph 2 a (new)

	2a. The right holder shall be informed without delay, by the competent authority of the Member State concerned, of the suspended release or detention of the products. He may supply that authority with any information which he deems appropriate regarding the products.

Justification

Enabling the right holder to supply the relevant information could be extremely helpful for the national authority responsible for monitoring infringements of the ban on reimporting products into the Community. Moreover, the right holder is directly damaged by any fraudulent use of the compulsory licence.

Amendment 41
Article 12, paragraph 3

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	***deleted***

national legislation, be recovered from any other person responsible for the attempted illicit importation.

(See amendment to Article 12(4) (new))

Justification

The provisions on payment of the expense occasioned by the - suspected or established - illegal importation of products have been transferred to paragraph 4a (new), so as to avoid the repetition of these provisions in paragraphs 3 and 4 of this Article.

Amendment 42
Article 12, paragraph 4

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.***	4. If ***it is confirmed*** 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), ***the competent*** authority shall ensure that these products are seized and disposed of in accordance with national legislation.

Justification

The wording in the proposal for a regulation is too vague. Products imported illegally into the European Union or one of its Member States may only be seized on the basis of confirmation of a breach of the provisions of this regulation.

The provisions on payment of the expense occasioned by the seizure of products have been deleted solely in order to avoid unnecessary repetition in relation to the (amended) provisions contained in paragraph 3 of this Article.

Amendment 43
Article 12, paragraph 4 a (new)

	4a The procedure of suspension or detention or seizure 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.

Justification

See amendment to Article 12(3). The words "or seizure" have been added.

Amendment 44
Article 12, paragraph 5

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.	***deleted***

Justification

The provisions contained in this paragraph are redundant, in the light of the provisions laid down in paragraph 1 of this Article.

Amendment 45
Article 12, paragraph 6

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

Justification

This amendment brings the terminology into line with the remaining text of the regulation, which refers only to the competent authority.

Amendment 46
Article 14, paragraph 1

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	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:***	decision of the competent authority or by one of the bodies referred to under Article 16 if the conditions of the licence are not respected by the licensee.
(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.	The competent authority shall have the authority to review, upon reasoned request by the ***right holder*** or the licensee, whether ***the conditions of the licence have been respected***. ***This review shall be based on the assessment made in the importing country.***

Justification

The possibility of terminating a compulsory licence means that a European government might substitute the government of the importing country in determining when a situation that justifies the application of the system subsists. The decision to declare a situation of national emergency or other circumstances of extreme urgency, as well as of establishing the lack or insufficiency of manufacturing capacity, is the competence of the importing country, and not that of the exporting country.

The Doha Declaration explicitly reinforced WTO Members' right to autonomously determine what constitutes a national emergency or other circumstances of extreme urgency. Therefore, a transfer of this judgement of emergency in the importing country to the authorities of the exporting country is not consistent with the Doha Declaration.

Amendment 47
Article 14, paragraph 3

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.	3. ***Following termination of the licence, the competent authority shall be entitled to establish a reasonable period of time within which*** 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.

Justification

Given that the competent authority is entitled to terminate a compulsory licence, it must also be able to determine the period of time within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected.

Amendment 48
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.	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. ***Appeals against a decision to grant a compulsory licence shall not have a suspensory effect in relation to the licence.***

Justification

The draft Regulation permits appeals against any decision by the competent authority. The system established by the draft Regulation will operate in a context of conflict or disagreement with the patentee, in a sector where litigation is extremely frequent. If the right to appeal is not appropriately regulated, the patentee may be able to obtain injunctive relief from the courts and block for a long time the supply of medicines. The possibility of obtaining this type of measures creates a high uncertainty for prospective suppliers and may further reduce the interest of potential suppliers to operate under the system. As established in many national regulations, an appeal by the patentee should not suspend the execution of the compulsory licence.

Amendment 49
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) of Regulation (EC) No 726/2004 of the European Parliament and the Council[1] shall not apply.***	1. Where the application for a compulsory licence concerns a medicinal product, the applicant may avail himself of ***a)*** the scientific opinion procedure as provided for under Article 58 of Regulation (EC) No 726/2004, or ***b)*** any similar ***procedures*** under national

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

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.	law***, such as scientific opinions or export certificates, intended exclusively for markets outside the Community.***
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**.**	***2. If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/ECshall not apply.***
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.	

Justification

The content of Article 16 is not entirely clear and needs to be reformulated.

Amendment 50
Article 16, paragraph 3 a (new)

	3a. Where the applicant for a compulsory license conducts studies and trials necessary to obtain a scientific opinion or other similar procedure provided for under

national law as referred to in paragraph 2 of this Article, this shall not constitute an infringement of the rights conferred by a patent (or supplementary protection certificate granted pursuant to Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products[1]).

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[1] OJ L 182, 2.7.1992, p. 1.

Justification

Licensees will wish to be confident that the acts preparatory to applying for a scientific opinion will not leave them open to litigation by patent holders.

Amendment 51
Article 16 a (new)

Article 16 a

The effect of a patent does not extend to the production, storage, use, including use for clinical trials, or sale of a patented innovation where these actions are carried out solely for the purpose of the granting of a compulsory licence within the meaning of this Regulation. This shall be without prejudice to Article 16.

Justification

The insertion of a 'Bolar provision' means that the studies and trials necessary for a pharmaceutical product to be authorised and the consequent practical requirements are not to be seen as an infringement of the patent. The absence of such a provision results in work on developing new generic products being done outside Europe, in countries which have such a provision. The consequence is that jobs are lost within the Community. Given that the development of generic products during the period covered by patent protection is allowed internationally in any case, the patent protection enjoyed by the right holder will not be abridged in practice. The insertion is in line with EU Directive 2004/27/EC, which also envisages the introduction of a 'Bolar provision'.

Amendment 52
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.	Three years after the entry into force of this Regulation, ***and every three years thereafter,*** 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. ***Where necessary, it shall present proposals for amendments to this Regulation.***
	The Commission shall also present to the European Parliament and the Council any necessary proposals for revising this Regulation when the TRIPS Agreement has been amended.

Justification

Publication of reports on implementation must be accompanied, where necessary, by proposals for amendments to Community provisions in order to address gaps found. Furthermore, the Commission must propose any amendments to this Regulation necessary in order to take account of amendments to the TRIPS Agreement. Consistency between the texts should be ensured.

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EXPLANATORY STATEMENT

1. Background

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was adopted in April 1994 as part of the results of the Uruguay Round of International Trade Negotiations. The TRIPS Agreement combines an extension of basic World Trade Organisation (WTO) law principles to the area of intellectual property (IP), an increase in minimum protection standards for IP, enforcement obligations and provisions relating to dispute settlement.

The significant costs associated with the introduction of higher IP protection standards in developing countries created much discussion on how the TRIPS Agreement could best be implemented in view of developmental concerns. The most ardently debated issue with regard to developing countries has been the question whether increased patent protection under the rules of the TRIPS Agreement impedes access to affordable medicines in poor countries.

At the Doha Ministerial Conference, the debate culminated in the landmark adoption of the "Doha Declaration on the TRIPS Agreement and Public Health". In the Doha Declaration, WTO Members stressed that the TRIPS 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."

The Doha Declaration mainly affirmed existing flexibilities in the TRIPS Agreement to achieve these goals. However, paragraph 6 of the Doha Declaration also recognised that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. It instructed the Council for TRIPS to find "an expeditious solution to this problem".

The Decision of the General Council of the WTO of 30 August 2003 spells out the circumstances under which countries without pharmaceutical manufacturing capacity can import generic versions of drugs still under patent. The Decision temporarily waives Members' obligations under TRIPS Article 31(f) by allowing them to export pharmaceuticals produced under compulsory licence, subject to a large number of conditions in both the exporting and importing country. In the Decision - the adoption of which was accompanied by a statement from the Chair of the General Council assuring that it would not be misused - Members agreed that the waiver would last until the TRIPS Agreement is permanently amended.

Until now, Members of the WTO Council for TRIPS were unable to reach consensus on how to formally amend Article 31 of the TRIPS Agreement in order to facilitate the export of drugs produced under compulsory license. The already-extended deadline to do this expired on 31 March 2005. Members will have to discuss how to proceed further.

2. The draft regulation

The draft regulation aims at uniformly implementing, within the European Union, the WTO Decision. The rapporteur welcomes the draft regulation as a positive step forward in the process of implementing the WTO-decision promoting public health in developing countries. However the rapporteur believes that the text should be further improved on the following points:

2.1 Eligible countries

As proposed, the draft Regulation would only benefit WTO member countries.

The draft Regulation should be an instrument reflecting the link between EU trade and development policies. Given that problems of lack of affordable medicines are not limited to WTO Member countries, the mutual beneficiality of trade and development policy can not be ensured if the potential beneficiary countries are limited to countries that are members of the WTO.

It makes no sense from a public health perspective to limit the application of the system to WTO members. Whether a country is a WTO member or not does not constitute a valid criterion for allowing or not exports of low priced drugs to address public health needs. Threats to public health do not recognise such arbitrary legal distinction. In addition, public health problems in a non-WTO member may have serious implications in WTO members.

While the WTO Decision was negotiated in the context of WTO and to benefit its members, WTO law does not restrict WTO Members in extending the implementation of the Decision to non-WTO Members. If the EU allows exports of pharmaceutical products under the draft Regulation to WTO members, there is no reason to discriminate against other countries, as long as the conditions set forth by the draft Regulation are complied with.

Therefore, the scope of the draft regulation should be extended to include also non-WTO Members - both developing countries and least-developed countries - as potential beneficiary countries.

2.2 Waiver of obligation to negotiate with the patent holder

Under article 31(b) of the TRIPS agreement, the obligation to obtain a voluntary license should be waived in situations of national emergency, other circumstances of extreme urgency and public non-commercial use. In developing countries “public non-commercial use” is the most important ground besides emergency-situations to buy pharmaceutical products in order to face public health problems. Therefore “public non-commercial use” should be included in the draft regulation as a ground for waiving the obligation.

2.3 Timeframe for the negotiation with the patent holder

The draft Regulation does not specify the ‘reasonable period of time’ for the prior negotiation with a patentee. The uncertainty left by this provision will possibly invite drawn-out negotiations and court proceedings to determine whether a reasonable period of time has elapsed before requesting a compulsory licence. This may create uncertainty and delays that may result in disincentives for generic producers to make use of the system.

2.4 Public tendering for pharmaceutical products

The draft Regulation seems to exclude the possibility of using tendering procedures to purchase the needed pharmaceutical products. However, international tendering is the preferred way of purchasing medicines and other medical supplies and is also often required by bilateral donors. In developing countries, obtaining medicines through a public tendering-procedure, which tends to drive down the prices, is becoming common practice.

2.5 Non-governmental procurement of medicines

Under the WTO Decision the importing country has to make a notification to the TRIPS Council, specifying the names and expected quantities of the products needed. However, this does not exclude that the importing country authorises another entity, such as the United Nations or an non-governmental organisation (NGO), to contract with a licensee in order to procure and distribute the medicines.

Under the Regulation the request can only come 'from authorised representatives' of the importing country. This requirement, absent in the WTO Decision, may be interpreted as excluding the importation under the system by NGOs, as well as from other organisations, such as the United Nations. Several NGOs, in particular, play an important role in the supply of health care services and treatment (e.g. for HIV/AIDS patients) in developing countries and LDCs, and work in areas struck by disasters, war or other circumstances where government authorities cannot reach people in need. Therefore the request from a NGO, acting with the authorisation of one or more importing countries, should also be eligible.

2.6 Re-exportation to members of a regional trade agreement

The draft Regulation seems to exclude the possibility of export within a regional trade agreement. Paragraph 6 of the WTO Decision permits the re-exportation of products imported under the system to other members of a regional trade agreement at least half of the membership of which is made up of LDCs.

2.7 Product differentiation

The WTO Decision requires suppliers to distinguish their 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'.

The draft Regulation makes special colouring or shaping mandatory 'unless the applicant proves that such distinction is not feasible or has a significant impact on price'. This provision clearly goes beyond the WTO Decision, as the supplier will be obliged to prove that changing colour or shape is not feasible or has a significant impact on price. The burden of proof is shifted, in a way that makes more difficult and less attractive for prospective suppliers to use the system. Differentiation of the formulation would imply longer periods for registration in the exporting and in the importing country, since proof of bioequivalence is dependent on substantial similarity in formulation and dosage. Moreover, such differentiation may lead to reduced adherence with a treatment regime.

2.8 Adequate remuneration

The draft Regulation, consistently with the WTO Decision, requires the compulsory licence to pay an adequate remuneration to the patentee "taking into account the economic value of the use that has been authorised under the licence to the importing WTO member(s) concerned". This provision does not provide any direction as to what constitutes adequate remuneration. The absence of predictability creates considerable uncertainty for prospective users of the system (both potential producer companies and importers of pharmaceutical products) and may give rise to litigation as to whether the determined remuneration is adequate.

The specification of what is to be considered “adequate remuneration” will also provide guidance on what would be considered a “reasonable royalty” to be agreed upon in negotiations on a voluntary licence between the patent holder and the generic producer.

In order to enhance the predictability of the remuneration, the Commission should establish guidelines.

2.9 Technology transfer and capacity building

The establishment of local manufacturing capacity is an important element in order to ensure that countries with insufficient or no manufacturing capacity in the pharmaceutical sector could make effective use of compulsory licensing. In the WTO Decision, WTO Members recognise the desirability of technology transfer and capacity building in the pharmaceutical sector. Therefore, the Regulation should specify that the Community recognises the necessity of promoting technology transfer and capacity building in the pharmaceutical sector in order to overcome the problem recognised in paragraph 6 of the Doha Declaration. It should further be specified that the Regulation encourages the use of the established system in a way that would promote such technology transfer and capacity building. Moreover, the Community should actively support the implementation of the WTO Decision in importing countries and the establishment of regional patent systems through its technical assistance activities.

13.6.2005

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))

Draftsman: Glenys Kinnock

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 licences 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 need 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***.	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.***
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.	
	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

[1] Not yet published in OJ.

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;	(3) "importing ***country***" means the name of the WTO member ***or developing country or least developed country*** to which the pharmaceutical product is to be exported;

Justification

Non-WTO-member LDCs should be able to make use of the system.

Amendment 3
Article 4, paragraph 1, introductory part

The following are eligible importing ***WTO members***:	The following are eligible importing ***countries***:

Amendment 4
Article 4, paragraph 1, point (a)

(a) any least-developed country ***member of WTO***	(a) any least-developed ***or developing country***

Justification

Non-WTO-member LDCs should be able to make use of the system.

Amendment 5
Article 4, paragraph 2

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

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, together with details of the quantities and importing ***countries*** concerned.

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

(e) the importing ***WTO member*** or ***members***;	e) the importing ***country*** or ***countries***;

Amendment 8
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 9
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.	(g) evidence of a specific request to the applicant from***:***
	i) authorised representatives of the importing ***country or countries;***

	ii) a non-governmental organisation acting with the formal approval of one or more importing countries;
	iii) organisations from the UN system or other international health organisations acting with the formal approval of one or more importing countries;
	and indicating quantity of product required.

Justification

Countries should be able to file an application together and the system should offer the possibility to NGOs, organisations of the United Nations or other international health organisations to act for one or more importing countries in the search for a producer and to import the pharmaceutical products in the importing countries.

Amendment 10
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 11
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 12
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 13
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) 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 14
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 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***.	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 ***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 15
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 16
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 17
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. ***Any additional amount of the same patented product(s) manufactured under the licence shall be subject to renewed notification to the competent authority and the WTO***.

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 18
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. 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 19
Article 8, paragraph 3 a (new)

	3a. 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 20
Article 8, paragraph 5, introductory part

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 21
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 22
Article 8, paragraph 6

6. If the product(s) covered by the compulsory licence are patented in the importing ***WTO members*** cited in the	6. If the product(s) covered by the compulsory licence are patented in the importing ***country*** cited in the application,

application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import and sale of the products.	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 23
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.	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 ***country***, and shall retain such records for at least three years. Upon request these proofs must be supplied to the competent authority.

Amendment 24
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 25
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 26
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.***	(b) if and when the ***terms of the licence are deliberately breached by the importing country, the importing countries or representatives of the importing country or countries as mentioned in Article 5(3)(g)(i) to (iii).***

Justification

The decision whether the circumstances have changed and the licence is no longer necessary, must be made by the importing country. The competent authority should however be able to act in case of improper use of the licence.

Amendment 27
Article 15, paragraph 1 a (new)

	An appeal against a decision to grant a compulsory licence shall not suspend operation 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 28
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, research, capacity building, regional supply systems and registration assistance, with a view to facilitating and bolstering the production of pharmaceutical products by the countries themselves.

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. Although this is one of the objectives of the WTO decision, the proposal makes no provision for any practical means of promoting technology transfer and the production of pharmaceutical products by developing countries themselves, with a view to reducing their dependence.

Amendment 29
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.

The Commission shall conduct a full review of this regulation immediately after the amendment of the TRIPS Agreement 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.

PROCEDURE

Title	Licences for pharmaceutical products intended for countries with public health problems
References	COM(2004)0737 – C6-0168/2004 – 2004/0258(COD)
Committee responsible	INTA
Committee asked for its opinion Date announced in plenary	DEVE 14.12.2004
Enhanced cooperation	No
Drafts(wo)man Date appointed	Glenys Kinnock 19.01.2005
Discussed in committee	13.3.2005
Date amendments adopted	24.5.2005
Result of final vote	for: 27 against: 0 abstentions: 0
Members present for the final vote	Margrete Auken, Alessandro Battilocchio, Danutė Budreikaitė, Nirj Deva, Michael Gahler, Jana Hybášková, Filip Andrzej Kaczmarek, Glenys Kinnock, Ģirts Valdis Kristovskis, Maria Martens, Miguel Angel Martínez Martínez, Gay Mitchell, Luisa Morgantini, Toomas Savi, Jürgen Schröder, Margrietus van den Berg, Anna Záborská, Feleknas Uca, Jan Zahradil
Substitutes present for the final vote	John Bowis, Linda McAvan, Manolis Mavrommatis, Karin Scheele, Britta Thomsen, Zbigniew Zaleski, Gabriele Zimmer
Substitutes under Rule 178(2) present for the final vote	Agustín Díaz de Mera García Consuegra

26.5.2005

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

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))

Draftswoman: Anja Weisgerber

SHORT JUSTIFICATION

The Committee on the Environment, Public Health and Food Safety welcomes the Commission proposal for a regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

The serious public health problems facing the world's least developed countries cannot be solved by issuing such compulsory licences, but they can at least be contained.

The Commission proposal represents a balanced attempt to reconcile the concerns of countries in need on the one side and the interests of patent holders which deserve to be protected on the other side.

Nevertheless, it is not only member countries of the WTO which face public health problems, and other little developed countries in the world must also be given access to affordable pharmaceutical products.

It must not be forgotten that the issuing of a compulsory licence represents a serious encroachment on the ownership rights of the patent holder. For this reason, patent holders should be involved in monitoring the application of the compulsory licensing system set up by this regulation to ensure that it is used in good faith. Access to the necessary information must be guaranteed.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety 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 Recital 6	
(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.	(6) ***The*** compulsory licensing system set up by this Regulation is intended to address public health problems, ***and must therefore be*** used in good faith. It ***must on no account*** be used with the purpose of addressing other objectives, and in particular objectives of a purely commercial nature.
Amendment 2 Recital 6 a (new)	
	(6a) Research and development in the field of health at the global level only partially answers health needs in poor countries. In order to address this situation, measures and action should be implemented as soon as possible, with a view to improving the technical capacity of those countries .
	Justification
	As research and development in the field of neglected diseases is not commercially viable, R&D is mainly geared towards the Western world, widening the inequality between developed and poor countries. It is important for the European Union to give a clear political signal.
	The desirability of the transfer of technology to developing and least-developed countries is set out in the Decision of 30 August, but not incorporated in the regulation.
Amendment 3	

[1] OJ C ... /Not yet published in OJ.

Recital 7

(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.	(7) Products manufactured pursuant to this Regulation ***must*** reach ***only*** those who need them and should not be diverted from those for whom they were intended. ***The issuing of*** compulsory licences under this Regulation ***must*** 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.

Amendment 4
Recital 9

(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.	(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. ***The data exchange networks necessary for this purpose should be created, where they do not already exist.***

Amendment 5
Article 1, paragraph 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.	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 ***and other countries in need*** affected by public health problems.

Justification

The insertion makes it clear that countries which are not members of the WTO are also to be considered as eligible countries.

Amendment 6
Article 1, paragraph 2

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.	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***, unless the right holder can prove that the compulsory licence is to be used with the purpose of addressing other objectives, and in particular objectives of a purely commercial nature***.

Justification

The text inserted offers licence issuers the possibility of taking on a comprehensive monitoring role and drawing attention at an early stage to a possible intention on the part of the licensee to misuse the licence.

Amendment 7
Article 2, point 3 a (new)

	(3a) "other country in need" means any of the least-developed countries in accordance with the official UN list of LDCs.

Justification

The insertion defines countries which are not members of the WTO but which should nevertheless be regarded as countries in need.

Amendment 8
Article 4, paragraph 1 a (new)

	Other countries in need which are not WTO members are also eligible provided that they:
	(a) are entitled to official development aid according to the Organisation for Economic Cooperation and Development and
	(b) declare a national emergency or other circumstances of extreme urgency and
	(c) specify the exact name and quantity of a

	particular product which they require in order to overcome the emergency.

Justification

The text inserted expands the group of eligible countries to include countries in need which are not WTO members in line with the international conditions valid at UN level. These countries should also be eligible, under certain supplementary conditions.

Amendment 9
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, together with details of the quantities and importing WTO members ***or other countries in need*** concerned.

Justification

Adjustment to the wording to reflect the expanded group of eligible countries.

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

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

Justification

The WTO General Council Decision of 30 August 2003 does not lay down such a provision concerning the information required to be supplied by the applicant in connection with an application for a compulsory licence (cf. paragraph 2(b)(ii) of the WTO General Council Decision).

Amendment 11
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

The WTO General Council Decision of 30 August 2003 does not lay down such a provision concerning the information required to be supplied by the applicant in connection with an application for a compulsory licence.

Furthermore, this identification procedure for patents or supplementary protection certificates could prove long and costly in view of the composition of the medicine to which an application for a compulsory licence relates.

Finally, the applicant for a compulsory licence is under an obligation to provide evidence that he has negotiated with the holder of the patent(s) or supplementary protection certificate(s) in accordance with Article 7 of this proposal for a regulation.

This provision is redundant, and is likely to have the effect of preventing potential applicants from making use of this compulsory licensing system. It should therefore be deleted.

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

(d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;	(d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence***, in accordance with Article 8(2)***;

Justification

Cf. the amendment to Article 8(2).

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

(e) the importing WTO member or	(e) the importing WTO member or members

members;	***or other country or countries in need***;

Justification

Adjustment to the wording to reflect the expanded group of eligible countries.

Amendment 14
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.	(g) evidence of a specific request from the importing WTO member ***or members or other country or countries in need*** and indicating quantity of product required.

Justification

Adjustment to the wording to reflect the expanded group of eligible countries.

Non-governmental and even international organisations should be allowed to participate in this system.

Amendment 15
Article 5, paragraph 4

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

Justification

On the one hand, the wording is too vague, and it is unclear what additional requirements might be specified by the competent authority of a Member State. On the other hand, such a requirement is contrary to the objective of this proposal to harmonise EU Member States' provisions. This paragraph should therefore be deleted.

Amendment 16
Article 5, paragraph 4 a (new)

	4a. The competent authority shall inform the right holder of the application for a compulsory licence within a period of 14 days.

Justification

The text inserted enables the right holder to participate in the compulsory licence system from the outset and thus strengthens the right holder's position.

Amendment 17
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 WTO member is a least-developed country, confirms***, if necessary,*** that the importing WTO 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 the Decision***;

Justification

This wording follows that contained in the WTO Decision of 30 August 2003. The form of wording should be identical in order to prevent a situation in which certain potential applicants cannot make use of the compulsory licensing system.

Amendment 18
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) confirms that where a pharmaceutical product is patented in the territory of the importing WTO member, ***other than a least-developed country,*** 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.

Justification

Least-developed countries that are WTO members are exempt from the obligations placed on developing countries that are members of that organisation, in accordance with the Decision of the Council for TRIPS of 27 June 2002 (IP/C/25, 1 July 2002).

Amendment 19
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 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.	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 exceed the amount notified to the WTO by that member.

Justification

The deletion removes a contradiction between this paragraph and Article 8(2). The products manufactured under a compulsory licence must not exceed the amount needed as notified to the WTO.

Amendment 20
Article 6, paragraph 2 a (new)

	2a. The competent authority shall ensure that paragraphs 1 and 2 are correspondingly applied to any other country in need so that these countries may submit an application for a compulsory licence under the same conditions as WTO members, as laid down in those paragraphs.

Justification

The amendment adjusts the wording to reflect the expanded group of eligible countries and makes it clear that other countries in need should on no account be granted compulsory

licences under different conditions from those applying to WTO members.

Amendment 21
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 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 period of ***30 days, except in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use pursuant to Article 31(b) of the TRIPS Agreement***.

Justification

Article 31(b) of the TRIPS Agreement authorises, under certain conditions, waiving the requirement to obtain prior authorisation from the holder of the patent(s) or supplementary certificate(s). The Community rules on compulsory licensing should not go beyond the provisions adopted and accepted at the WTO level; otherwise there is a risk that it will become impossible at the Community level and within the European Union to use the compulsory licensing system.

Amendment 22
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.	***deleted***

Justification

Inserting a clearly specified period removes the legal uncertainty associated with defining what constitutes a reasonable period. This is an appropriate time limit for negotiations with a view to authorisation from the right holder and avoids delays in the granting of a licence.

Amendment 23
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 WTO member or members ***or other country or countries in need*** cited in the application***. Any additional amount of the same patented product(s) manufactured under the licence shall be the subject of renewed notification to the competent authority and the WTO***.

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

Only a simple procedure, not a new licensing procedure, should be required in respect of any increase in the amount of identical product(s).

Amendment 24
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. The licence shall ***cover all of the stages necessary for the importation, manufacture and sale of the various ingredients of*** the product in question***, including active ingredients, in order to enable the product to be sold*** for export to the WTO member or members ***or other country or countries in need*** cited in the application. ***Re-export by the country that originally requested the product(s) shall be authorised in the case of parties to a regional trade agreement, pursuant to the provisions of paragraph 6 of the Decision***.

Justification

The wording of the original regulation does not allow for the importing of all of the ingredients needed to manufacture medicines covered by a compulsory licence. Without this more precise wording, the regulation is likely to be ineffective.

Furthermore, the WTO Decision authorises re-export to countries that are parties to a regional trade agreement.

This amendment adjusts the wording to reflect the expanded group of eligible countries.

Amendment 25
Article 8, paragraph 4

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.***	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 ***and/or special colouring or shaping of the products themselves, provided that such distinction is feasible and has no, or almost no, impact on price***. ***This applies to all the places where the product made under the licence is marketed.*** 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 ***distribution*** in the importing WTO member or members ***or other country or countries in need*** concerned.

Justification

The wording contained in the WTO Decision of 30 August 2003 (Article 2(b)(ii)) should be used. The wording proposed by the Commission is far more stringent and lays down additional requirements, which will limit the use of the compulsory licensing system.

Furthermore, the amendment proposed takes account of the fact that any significant change to the formulation and/or dose of a medicine could lead to a reduction in the effectiveness of, or even render ineffective, the medicine produced under a compulsory licence, contrary to the objective of dealing with an emergency health situation in the importing country or countries.

The word 'sale' should be replaced by 'distribution' in order to take account of public non-commercial use of the medicine under a compulsory licence.

In order to prevent trade diversion, it is advisable to differentiate clearly between products

made under the licence and products made by the right holder wherever they are marketed.

Amendment 26
Article 8, paragraph 5, subparagraph 1, introductory part

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 WTO member or members ***or other country or countries in need*** cited in the application, the licensee shall post on a website the following information:

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

In order to promote transparency and checks on the use of compulsory licences, it would be useful to notify the right holder of the website containing the information to be made public, and to post the address on the central Commission web page.

Amendment 27
Article 8, paragraph 5, subparagraph 1, 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 WTO members ***or other countries in need*** to which they are supplied

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

In order to promote transparency and checks on the use of compulsory licences, it would be useful to notify the right holder of the website containing the information to be made public, and to post the address on the central Commission web page.

Amendment 28
Article 8, paragraph 5, subparagraph 2

The website address shall be communicated to the competent authority.	The website address shall be communicated to the competent authority***, the Commission and the right holder. The Commission shall post the address on its central website***.

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

In order to promote transparency and checks on the use of compulsory licences, it would be useful to notify the right holder of the website containing the information to be made public, and to post the address on the central Commission web page.

Amendment 29
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 WTO members ***or other countries in need*** cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import and ***distribution*** of the products.

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

Amendment consistent with the amendment to Article 8(4).

Amendment 30
Article 8, paragraph 7

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.	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 ***the right holder and*** 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

In order to promote transparency and increase the possibilities for monitoring, it would be

useful to make the licensee's accounting records available to the firms and manufacturers holding the licence as well, on request and where necessary.

Amendment 31
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.	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 ***or other country in need***, and shall retain such records for at least three years. Upon request these proofs must be supplied to the competent authority. ***The right holder concerned shall also be granted access to the files on request, at the latest 14 days after the export has taken place.***

Justification

The group of LDCs has been enlarged beyond the circle of WTO members in line with Amendment 4. In order to improve checks on the manufacturing side as well, it would be useful to grant right holders access to the export and customs documents as well.

Amendment 32
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 WTO member(s) ***or country or countries in need*** concerned. ***When determining the amount, the competent authority shall also take account of the position occupied by the importing WTO member in the UN Human Development Index (HDI).***

Justification

The reference to adequate remuneration is excessively vague. The reference to the HDI index

will make it easier to predict the amount of remuneration and ensure greater legal certainty.

Amendment 33
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, 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.

Justification

Amendment consistent with the amendment to Article 5(4).

Amendment 34
Article 10, paragraph 1, subparagraph 2, point f a (new)

	(fa) the features described in Article 8(4) which distinguish the products made under the licence from those made by the right holder.

Justification

Notifying the distinguishing features to the Commission will increase transparency and help prevent trade diversion and reimporting.

Amendment 35
Article 10, paragraph 2 a (new)

	2a. For the purpose of data exchange between the competent authorities, right holders and applicants, the Commission shall set up a central website on which the requisite data shall be published.

Amendment 36
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 WTO member ***or other country in need*** 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 ***or other country in need***.

Justification

This amendment adjusts the wording to reflect the expanded group of eligible countries.

Amendment 37
Article 12, paragraph 1

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.	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 ***competent*** authority on the character of the merchandise. ***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 such action is suspected.*** 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.

Justification

The text inserted makes clear when the competent authority can act and brings Article 12 into line with Article 14.

Amendment 38
Article 12, paragraph 2

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.	2. The ***competent*** 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 ***competent*** authority with the information which it deems appropriate regarding the products.

Justification

This amendment brings the terminology into line with the remaining text of the regulation, which refers only to the competent authority.

Amendment 39
Article 12, paragraph 3

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.	***deleted***

Justification

The provisions on payment of the expense occasioned by the - suspected or established - illegal importation of products have been transferred to paragraph 4a (new), so as to avoid the repetition of these provisions in paragraphs 3 and 4 of this Article.

Amendment 40
Article 12, paragraph 4

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.***	4. If ***it is confirmed*** 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), ***the competent*** authority shall ensure that these products are seized and disposed of in accordance with national legislation.

Justification

The wording in the proposal for a regulation is too vague. Products imported illegally into the European Union or one of its Member States may only be seized on the basis of confirmation of a breach of the provisions of this regulation.

The provisions on payment of the expense occasioned by the seizure of products have been deleted solely in order to avoid unnecessary repetition in relation to the (amended) provisions contained in paragraph 3 of this Article.

Amendment 41
Article 12, paragraph 4 a (new)

	4a. The suspension or detention or seizure procedure for the products 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.

Justification

The provisions on payment of the expense occasioned by the - suspected or established - illegal importation of products have been transferred to paragraph 4a (new), so as to avoid the repetition of these provisions in paragraphs 3 and 4 of this Article.

Amendment 42
Article 12, paragraph 5

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.	5. Where products suspended for release or detained by customs authorities subsequent to further control by the ***competent*** 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.

Justification

This amendment brings the terminology into line with the remaining text of the regulation, which refers only to the competent authority.

Amendment 43
Article 12, paragraph 6

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

Justification

This amendment brings the terminology into line with the remaining text of the regulation, which refers only to the competent authority.

Amendment 44
Article 16, paragraph 1

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)	***deleted***

and (5) of Regulation (EC) No 726/2004 of the European Parliament and the Council[1] 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.

Justification

The Commission's draft regulation seeks to prescribe rules governing marketing approval in the European Union in the context of compulsory licences. This is not only superfluous given that medicines produced in this way are exclusively intended for the market of selected LDCs, which is at the core of the regulation, but also conflicts with the rules laid down in Regulation (EC) No 726/2004, Article 58 of which is echoed in paragraph 2.

Amendment 45
Article 16 a (new)

Article 16 a

The effect of a patent does not extend to the production, storage, use, including for clinical trials, or sale of a patented innovation where these actions are carried out solely for the purpose of the granting of a compulsory licence within the meaning of this Regulation. This shall be without prejudice to Article 16.

Justification

The insertion of a 'Bolar provision' means that the studies and trials necessary for a pharmaceutical product to be authorised and the consequent practical requirements are not to be seen as an infringement of the patent. The absence of such a provision results in work on developing new generic products being done outside Europe, in countries which have such a provision. The consequence is that jobs are lost within the Community. Given that the development of generic products during the period covered by patent protection is allowed internationally in any case, the patent protection enjoyed by the right holder will not be

abridged in practice. The insertion is in line with EU Directive 2004/27/EC, which also envisages the introduction of a 'Bolar provision'.

Amendment 46
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.	Three years after the entry into force of this Regulation, ***and thereafter every three years,*** 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. ***Where necessary, it shall present proposals for amendments to this Regulation.*** ***The Commission shall also present to the European Parliament and the Council any necessary proposals for revising this Regulation when the TRIPS Agreement has been amended.***

Justification

Publication of reports on implementation must be accompanied, where necessary, by proposals for amendments to Community provisions in order to address gaps found.

Furthermore, the Commission must propose any amendments to this Regulation necessary in order to take account of amendments to the TRIPS Agreement. Consistency between the texts should be ensured.

PROCEDURE

Title	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
References	COM(2004)0737 – C6-0168/2004 – 2004/0258(COD)
Committee responsible	INTA
Committee asked for its opinion Date announced in plenary	ENVI 14.12.2004
Enhanced cooperation	
Draftsman Date appointed	Anja Weisgerber 23.11.2004
Discussed in committee	20.4.2005 24.5.2005
Date amendments adopted	24.5.2005
Result of final vote	for: 45 against: 0 abstentions: 4
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Irena Belohorská, Johannes Blokland, John Bowis, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Avril Doyle, Mojca Drčar Murko, Jillian Evans, Anne Ferreira, Karl-Heinz Florenz, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Gyula Hegyi, Caroline Jackson, Dan Jørgensen, Christa Klaß, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Linda McAvan, Marios Matsakis, Riitta Myller, Péter Olajos, Dimitrios Papadimoulis, Vittorio Prodi, Guido Sacconi, Karin Scheele, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Jonas Sjöstedt, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber and Åsa Westlund.
Substitutes present for the final vote	Margrete Auken, María del Pilar Ayuso González, Giovanni Berlinguer, Jutta D. Haug, Erna Hennicot-Schoepges, Karsten Friedrich Hoppenstedt, and Robert Sturdy.
Substitutes under Rule 178(2) present for the final vote	Joachim Wuermeling

7.6.2005

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on International Trade

on the proposal for a European Parliament and Council regulation 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))

Draftsman: Giuseppe Gargani

SHORT JUSTIFICATION

The aim of the regulation proposed by the Commission is to enable manufacturers of generic pharmaceutical products to produce and sell patented pharmaceutical products intended for export to countries in need of such products which either have no manufacturing capacity, or are not self-sufficient, in the relevant sector.

The regulation aims to implement at Community level the WTO General Council decision of 30 August 2003 on the implementation of paragraph 6 of the Declaration on the TRIPs agreement and public health.

By waiving WTO members' obligations under Article 31(f) of the WTO agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS agreement), this decision allows WTO members to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

Uniform implementation of the decision within the Community is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all EU Member States, to avoid distortion of competition for operators in the EU single market and to apply uniform rules to prevent re-importation into the territory of the European Union of pharmaceutical products manufactured under compulsory licences.

The European Union, therefore, proposes to take a stand as one of the international players with the greatest commitment to ensuring that the citizens of the most disadvantaged countries have access to pharmaceutical products at lower prices.

In view of the objectives set forth by the Commission, your rapporteur can only warmly welcome this proposal for a regulation.

However, it should be remembered that the measures contained in the proposal in question constitute, objectively speaking, a reduction in the protection usually accorded to intellectual property rights through the TRIPS agreement.

Consequently, while fully supporting the principle of solidarity with the disadvantaged which underlies the proposal, it is perfectly reasonable to allow patent holders the opportunity to be involved in the procedure laid down for the granting of compulsory licences for the manufacture and sale of pharmaceuticals intended for export to WTO countries with public health problems.

The amendments tabled by your rapporteur aim, therefore, to protect the legitimate economic, industrial and commercial interests of pharmaceutical patent holders. This would be achieved by giving them the right to submit comments to the competent national authority in order to ensure, by providing for both parties to have a say in the proceedings, that the decision taken minimises any loss of rights in relation to intellectual property. Provision is made also for the right holder to be involved in any proceedings to ascertain whether there has been an infringement of the ban on re-importing into the European market pharmaceutical products manufactured under a compulsory licence.

Finally, your rapporteur has sought to avoid giving manufacturers of generic pharmaceuticals under compulsory licences an unfair competitive advantage. Article 16 of the proposal refers to two possible procedures which may be used to enable importing countries to control the quality of the pharmaceuticals exported: a marketing authorisation for the European market (under Article 6 of Directive 2001/83/EC) or the scientific opinion procedure (under Article 58 of Regulation (EC) No 726/2004). In both cases, provision is made for derogations from the usual data protection and caducity rules.

However, in the case of marketing authorisation, this procedure would allow the authorised person to enter the EU market on conditions in which he would not otherwise be allowed to do so. Even on the understanding that such authorisation was granted only for export purposes, it would have the effect of reducing legal certainty and creating an unfair advantage for manufacturers of generic pharmaceuticals who, at the end of the period laid down for the protection of data relating to the patented product, could obtain marketing authorisation for the EU market before they could otherwise expect to do so.

The solution proposed by your rapporteur, therefore, is to drop the marketing authorisation procedure, given that the scientific opinion procedure guarantees the possibility of controlling the quality of pharmaceutical products intended for export.

AMENDMENTS

The Committee on Legal Affairs 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 8, paragraph 5, subparagraph 2

The website address shall be communicated to the competent authority.	The website address shall be communicated to the competent authority ***and to the right holder***.

Justification

The other party concerned, i.e. the right holder, should have access to this information.

Amendment 2
Article 8 a (new)

	Article 8a
	1. Within a month of applying to the competent national authority for a compulsory licence, the applicant shall notify the right holder of that application.
	2. The notification shall be communicated to the competent authority by the applicant. If the applicant fails to notify the right holder, the procedure for granting the compulsory licence shall be suspended.
	3. The right holder may intervene in the procedure for granting the compulsory licence in order to:
	(a) submit his own comments concerning the existence of the evidence and the factual circumstances referred to in Article 7;
	(b) state his opinion on the terms and conditions governing the grant of the compulsory licence;
	(c) submit his own comments concerning compliance with the conditions laid down in Article 8 (2),(3),(6) and (9);
	(d) submit proposals and comments

[1] Not yet published in OJ.

concerning the requirements laid down in Article 8(4) on the labelling, marking and packaging of products manufactured under a compulsory licence.

Justification

Granting a compulsory licence involves a significant curtailment of intellectual property rights. For that reason, it is essential to have a system that allows both sides to be heard and enables the right holder to participate in the procedure brought before the competent national authority. This will enable him to protect his legitimate rights by submitting his own observations on the terms and conditions for the grant of the compulsory licence.

Amendment by Marie Panayotopoulos-Cassiotou

Amendment 3
Article 10, paragraph 1, point (e)

(e) the duration of the licence	(e) the duration of the licence ***and the conditions for the issue thereof***;

Justification

In order to be consistent with Recital 7 which states that 'compulsory licences issued under this regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence'.

Amendment 4
Article 12, paragraph 2 a (new)

2a. The right holder shall be informed without delay, by the competent authority of the Member State concerned, of the suspended release or detention of the products. He may supply that authority with any information which he deems appropriate regarding the products.

Justification

Enabling the right holder to supply the relevant information could be extremely helpful for the national authority responsible for monitoring infringements of the ban on reimporting products into the Community. Moreover, the right holder is directly damaged by any fraudulent use of the compulsory licence.

Amendment by Marie Panayotopoulos-Cassiotou

Amendment 5
Article 14, paragraph 3

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.	3. ***Following termination of the licence, the competent authority shall be entitled to establish a reasonable period of time within which*** 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.

Justification

Given that the competent authority is entitled to terminate a compulsory licence, it must also be able to determine the period of time within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected.

Amendment 6
Article 16, paragraph 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) of Regulation (EC) No 726/2004 of the European Parliament and the Council[1] shall not apply.	***deleted***
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.

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

Justification

The proposed provision aims to guarantee the quality of the products in question for the importing country. However, allowing derogations from the rules on data protection and caducity in connection with the market authorisation procedure could give an unfair competitive advantage to manufacturers of generic pharmaceuticals on the European market. By removing the reference to market authorisation, derogations would only be possible in connection with the scientific opinion procedure referred to in Article 58 of Regulation 726/2004/EC, which fully meets the purpose of ensuring the quality of products.

PROCEDURE

Title	Proposal for a European Parliament and Council regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
References	COM(2004)0737 – C6-0168/2004 – 2004/0258(COD)
Committee responsible	INTA
Committee asked for its opinion Date announced in plenary	JURI 27.1.2005
Enhanced cooperation	no
Draftsman Date appointed	Giuseppe Gargani 20.1.2005
Discussed in committee	6.6.2005
Date amendments adopted	6.6.2005
Result of final vote	for: 12 against: 7 abstentions: 0
Members present for the final vote	Maria Berger, Monica Frassoni, Giuseppe Gargani, Piia-Noora Kauppi, Kurt Lechner, Klaus-Heiner Lehne, Antonio López-Istúriz White, Antonio Masip Hidalgo, Aloyzas Sakalas, Francesco Enrico Speroni, Diana Wallis, Rainer Wieland, Nicola Zingaretti, Jaroslav Zvěřina, Tadeusz Zwiefka
Substitutes present for the final vote	Brian Crowley, Jean-Paul Gauzès, Evelin Lichtenberger, Manuel Medina Ortega, Marie Panayotopoulos-Cassiotou, József Szájer
Substitutes under Rule 178(2) present for the final vote	

PROCEDURE

Title	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
References	COM(2004)0737 – C6-0168/2004 – 2005/0258(COD)
Legal basis	Articles 251(2) , 95 EC and 133 EC
Basis in Rules of Procedure	Rule 51
Date submitted to Parliament	29.10.2004
Committee responsible Date announced in plenary	INTA 14.12.2004
Committee(s) asked for opinion(s) Date announced in plenary	DEVE ENVI JURI 14.12.2004 14.12.2004 27.1.2005
Not delivering opinion(s) Date of decision	
Rapporteur(s) Date appointed	Johan Van Hecke 15.11.2004
Previous rapporteur(s)	
Simplified procedure Date of decision	
Legal basis disputed Date of JURI opinion	
Financial endowment amended Date of BUDG opinion	
European Economic and Social Committee consulted Date of decision in plenary	
Committee of the Regions consulted Date of decision in plenary	
Discussed in committee	14.3.2005 13.6.2005
Date adopted	12.7.2004
Result of final vote	for: 28 against: 0 abstentions: 2
Members present for the final vote	Jean-Pierre Audy, Enrique Barón Crespo, Jean-Louis Bourlanges, Daniel Caspary, Françoise Castex, Giulietto Chiesa, Christofer Fjellner, Béla Glattfelder, Jacky Henin, Alain Lipietz, Caroline Lucas, Helmuth Markov, David Martin, Javier Moreno Sánchez, Cristiana Muscardini, Georgios Papastamkos, Godelieve Quisthoudt-Rowohl, Bogusław Rogalski, Peter Šťastný, Robert Sturdy, Johan Van Hecke, Zbigniew Zaleski
Substitutes present for the final vote	Margrietus van den Berg, Philip Bradbourn, Jorgo Chatzimarkakis , Saïd El Khadraoui, Jörg Leichtfried, Maria Martens
Substitutes under Rule 178(2) present for the final vote	Raimon Obiols i Germà, Antonio Masip Hidalgo
Date tabled – A6	19.7.2005 A6-0242/2005
Comments	...