

CONSULTATION ON THE PROPOSED REGULATION ON COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS

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SUMMARY

1. This consultation relates to the details of implementation of a proposal for an EU Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Comments upon the form and the impact of the proposed implementation are requested from interested parties. Your attention is drawn in particular to the issues detailed below:

- i) The Scope of the proposal
- ii) Authorisation from the Rights Holder
- iii) Adequate Remuneration to the Rights Holder
- iv) Anti-Diversion Measures
- v) Safety and Efficacy of the Generic Products

2. This proposed Regulation arises from the negotiations at the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPs) Council on taking forward the Doha Ministerial Declaration on TRIPs and Public Health in 2001. It allows for compulsory licences to be granted in the EU for the export of medicines to countries with no or insufficient manufacturing capacity.

History of the Proposal

3. The Doha Ministerial Declaration in 2001 on the TRIPS Agreement and Public Health stressed that it is important to implement and interpret the WTO (World Trade Organisation) Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines.

4. The TRIPs Agreement sets the minimum standards for Intellectual Property (IP) Rights. It places restrictions on the issuing of compulsory licences of patents. In particular, it requires that products manufactured under a compulsory licence must be predominantly for the domestic market. However, many developing countries lack the manufacturing capability in pharmaceutical products which means that use of compulsory licences as a method for obtaining generic versions of patented products is hindered, as they will need another country to manufacture the pharmaceutical product and export it to them.

5. The WTO Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement, seeks to overcome this difficulty by allowing 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. This is achieved by waiving the restriction on compulsory licences for export in appropriate countries.

6. The proposed Regulation aims to implement the WTO Decision at Community level allowing EU manufacturers to export under compulsory licences in these circumstances.

7. The proposal also includes safeguards against trade diversion and rules to ensure transparency, and provides for future replacement of the WTO Decision by an amendment to the TRIPs Agreement.

Purpose of the consultation

8. This consultation is intended to consult all interested parties, including patent applicants/ proprietors and generic manufacturers, and to seek their views on the benefits and disadvantages, of the compulsory licensing proposal. The consultation exercise will enable decisions to be taken on whether to proceed with these or other proposals in full knowledge of users' views.

Who is being consulted

9. Responses are welcome from anyone in the UK or abroad who is interested in the operation of the intellectual property system in the UK or in Europe or those with an interest in translations, but especially from those who have been, are, or expect to be users of the system. Copies of this consultation document have been sent to the organisations listed in Annex F and to a small number of individuals. Further copies, including large print, may be requested from the Patent Office by contacting Fraser Daviss, tel. 01633 814322, e-mail Fraser.Daviss@patent.gov.uk

10. This consultation document has been prepared in accordance with the Government Code of Practice on Written Consultations. The Code criteria are set out in Annex E.

How and when to respond

11. There is a consultation response form at the end of this summary which you may wish to use to reply if it is helpful to you. Alongside this consultation, a forum on the Patent Office website and a meeting involving Patent Office focus groups is to be carried out. Responses may be sent by post, e-mail or fax. Please send your responses by Monday 23rd May to the following address, or if you have any questions about the consultation please contact:

Andrew Jenner
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Concept House
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Newport
NP10 8QQ

Fax: +44 (0)1633 814922
Tel: +44 (0)1633 813736
E-mail: medicinesexport@patent.gov.uk

12. Please could you also indicate in what capacity your response is submitted. If you are responding on behalf of a representative group, please also give a summary of the people and organisations that you represent. You may also wish to comment on the Regulatory Impact Assessment [Annex A.]

13. If you have any comments or complaints about how this consultation process is being handled, please contact the Patent Office's Consultation Co-ordinator, whose details are included in Annex E.

Openness

14. This is part of a public consultation exercise. As such, your responses may also be made public.

Confidentiality

15. If you do not want all or part of your response or name made public, please state this clearly in the response and please give your reasons for claiming confidentiality.

16. We will handle any data you provide appropriately in accordance with the Data Protection Act 1998 and the Freedom of Information Act 2000.

Background and Proposals

17. The full text of the Agreement is included at Annex B and the WTO Decision of August 2003 (hereinafter referred to as the Decision) is included at Annex C. A partial Regulatory Impact Assessment is included at Annex A, which details some of the implications. Comments on this document are also welcome.

18. As matters currently stand, the proposal will be discussed in the European Council and be submitted to the European Parliament, following the Co-decision Procedure. Responses to the consultation must be submitted before **23 May 2005**, after which the consultation will close. However, due to the possibility of rapid agreement, it would be helpful if respondents return their responses by the **18 March 2005**.

The Scope of the proposal

19. The Scope of the Decision refers to “eligible importing Members” (Article 2(a)) which implies that any country importing under this Decision must be a member of the WTO. The WTO Decision states: ‘The obligations of an exporting Member under Article 31(f) of the TRIPs Agreement shall be waived with respect to the grant of a compulsory licence to the extent necessary for the purposes of production of pharmaceutical products and its export to eligible importing Members’. The obligations of the exporter country under 31(f) may not be waived under the Decision if the importing country is not a WTO member. This means that if the exporting member did export to a non WTO member, they could potentially be held in contravention of the TRIPs Agreement.

20. The proposal is consistent with the Decision by stating that eligibility is based on WTO members affected by health problems (Article 1). Article 4 defines the eligible importing WTO members as: any least-developed country member of the WTO; or any other member of the 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 a whole or limited way.

21. However, it may be the case that inclusion of WTO members only is deemed as being too restrictive in scope. There may be countries who are not WTO members who could benefit from access to generic products. There may also be low income countries that are not least developed countries and not WTO members, who could benefit from the proposal. Canada and Norway have implemented the Decision in their national legislation and have included non-WTO members.

22. The definition of "pharmaceutical product" in Article 2(1) of the proposal is consistent with the Decision. However, this definition goes beyond the definition of "medicinal products" in the medicinal products Directives (Article 1 of 2004/27/EC and 2004/28/EC), by including active ingredients and diagnostic kits.

Authorisation from the Rights Holder

23. Under the TRIPs Agreement, before a compulsory licence may be issued, the applicant must attempt to negotiate a voluntary licence with the rights holder "on reasonable commercial terms and conditions" (Article 31(b)). If those efforts do not succeed "within a reasonable period of time", then a compulsory licence is issued by the competent authority.

24. The proposal states that an applicant shall provide evidence to show that they have made efforts to obtain authorisation from the rights holder on reasonable commercial terms (Article 7). If such efforts are not successful in a 'reasonable period of time' (same wording as the Decision), a compulsory licence is issued.

25. This reasonable period of time is set by the competent authority, which in the UK is the Patent Office. A flexible system may be desirable as a 'reasonable period of time' in the event of a national emergency may be very short. However, applicants and rights holders may feel that a set time limit gives them the necessary clarity during which negotiations can occur.

Adequate Remuneration to the Rights Holder

26. Similar to paragraph 23 above the TRIPs Agreement states that "adequate remuneration" must be paid to the rights holder (Article 31(h)). The proposal states that adequate remuneration for the rights holder is determined by the competent authority (Article 8(9)). The UK has legal precedent in this area and therefore it may be fitting for national authorities to decide remuneration levels. There are also economic variations between EU member states and therefore national authorities may be best positioned to decide respective remuneration levels.

27. However, it may be that the proposal is too vague on adequate remuneration. There may other methods of calculating the remuneration, such as the formula proposed by Canada which takes into account the UN's Human Development Index and the value of the supply agreement.

Anti-Diversion Measures

28. The proposal includes safeguards against trade diversion and rules to ensure transparency, both of which are required by the Decision. Article 8 of the proposal states that that the products made under licence shall be clearly identified through specific labelling or marking, and distinguished from products made by the rights holder by special packaging. Special colouring or shaping of the products themselves shall also be required unless the applicant can prove that such distinction is not feasible or has a significant impact on price.

29. Article 11 makes clear that any product manufactured under compulsory licence under the Regulation cannot be imported into the EU. It may be advisable to extend this to any product manufactured under these compulsory licence arrangements wherever manufactured, not just those manufactured in the Community.

30. The role of customs authorities is detailed in Article 12.

Safety and Efficacy of the Generic Products

31. It is important to ensure that any generic products made under the proposal are of sufficient quality. The applicant may prove safety and efficacy by demonstrating that the product concerned is a generic of a reference medicinal product which is or has been authorised (Article 16(1)). If the applicant is not the marketing authorisation holder they may also avail themselves of the scientific opinion procedure (Article 16(2)).

32. These methods of proving safety will provide the importing countries with the reassurances they need that the generic products are of the same quality as a product with marketing authorisation in the EU. It is also important to ensure that the exclusive rights of the rights holder are not undermined by the proposal.

**REGULATION ON COMPULSORY
LICENSING OF PATENTS**

CONSULTATION RESPONSE FORM

The closing date for this consultation is 23/05/2005

The Patent Office may be required by the Freedom of Information Act 2000 to make available, on public request, individual consultation responses. This will extend to your response. If however your response contains information which you regard as confidential, please let us know and give your reasons for treating the information as confidential.

Even if you request confidentiality of your comments, we would still like your name and organisation to be supplied. This will help us to more accurately assess the views of your market sector.

Name: _____

Organisation (if applicable): _____

Address: _____

If you are responding on behalf of a representative group, please give a summary of the people and organisations that you represent.

Please return completed forms by 23 May 2005 to the following address, or if you have any questions about the consultation please contact:

Andrew Jenner
Intellectual Property & Innovation Directorate
Room 3B36
The Patent Office
Concept House
Cardiff Road
Newport
NP10 8QQ

Fax: +44 (0)1633 813736
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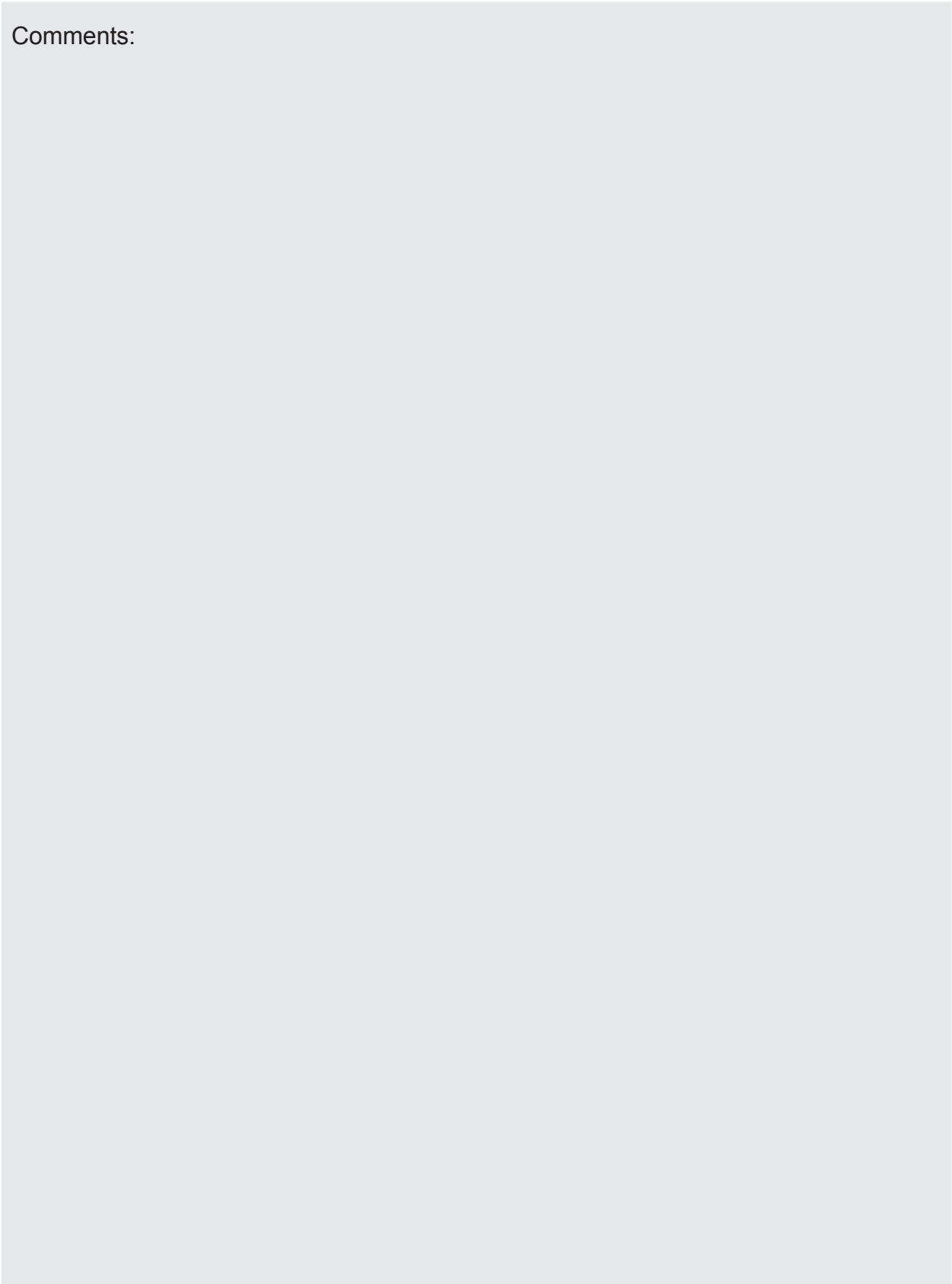
Please tick one box from the list of options that best describes you as a respondent. This enables views to be presented by group type.

| | |
|--|------------------------------------|
| | Rights Holder |
| | Generic Manufacturer |
| | Representative Organisation |
| | Non-Governmental Organisation |
| | Interest Group |
| | Small to Medium - sized Enterprise |
| | Local Government |
| | Central Government |
| | Other (please describe): |

Question 1

Please give your views on whether the proposed Regulation is a fair representation of the WTO Decision of August 2003.

Comments:



Question 2

Please give your views on the scope of the proposal (Article 1) and the definition of eligible importing countries (Article 4). Should the scope of the proposal be extended to include:

- i) non-WTO member least developed countries?
- ii) non-WTO member developing countries?

Comments:

Question 3

Please give your views on the proposed Article 7 which states that an applicant shall provide evidence to show that they have made efforts to obtain authorisation from the rights holder on reasonable commercial terms. If such efforts are not successful in a reasonable period of time, a compulsory licence is issued. The reasonable period of time is determined by the competent authority:

- i) Should a set time limit be introduced to replace the reasonable period of time to increase clarity for the applicant and rights holder?
- ii) If so, what might the set time limit be?

Comments:

Question 4

Please give your views on Article 8(9) which states that the competent authority determines the payment of adequate remuneration for the rights holder.

Should the payment of adequate remuneration be determined by other means?

Comments:

Question 5

Please give your views on whether the anti-diversion measures within the proposal are sufficient.

Comments:

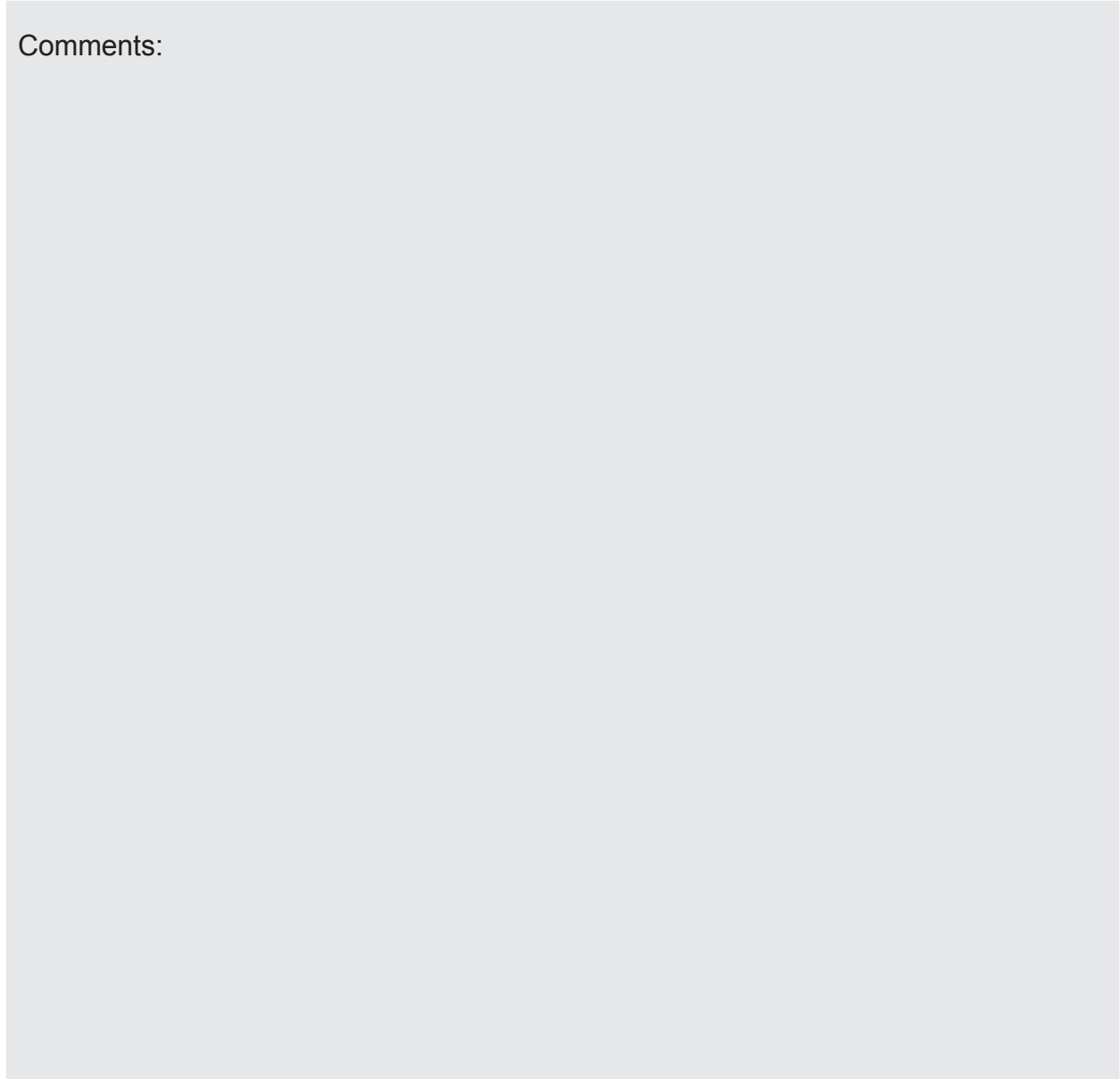
Question 6

Please give your views on Article 16 which seeks to ensure that the exported generic products have the same quality as the products with marketing authorisation in the EU.

Comments:

Do you have any comments that might aid the consultation process as a whole?

Comments:



Thank you for taking the time to let us have your views.

The Patent Office consults interested parties on a range of topics related to intellectual property. As your views are valuable to us, would you be willing to be included in our list of people or organisations we regularly consult?

Yes

No

PARTIAL RIA

1. Title of proposal

1.1 A 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 (04) 737)

2. Purpose and intended effect of measure

(i) The objective

2.1 This Regulation arises from the negotiations at the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPs) Council on taking forward the Doha Ministerial Declaration on TRIPs and Public Health in 2001. It allows for compulsory licences to be granted in the EU for the export of medicines to countries with no or insufficient manufacturing capacity.

2.2 The TRIPs Agreement sets the minimum standards for Intellectual Property (IP) Rights. It places restrictions on the issuing of compulsory licences of patents. In particular, it requires that products manufactured under a compulsory licence must be predominantly for the domestic market. However, many developing countries lack the manufacturing capability in pharmaceutical products which means that use of compulsory licences as a method for obtaining patented pharmaceutical products is hindered, as they will need another country to manufacture the pharmaceutical product and export it to them.

2.3 Actual use of this system within the EU will be minimal due to the higher generic manufacturing costs involved, but it sends a clear signal to developing countries that the EU takes developing country issues seriously. If the system was used then appropriate developing countries would be able to import generic medicines from the EU in order to address public health problems. The generic based industry may receive some benefit by acting as the exporter of pharmaceutical products under compulsory licence, and the research based pharmaceutical industry may lose market exclusivity within the importing developing countries.

(ii) The background

2.4 The Doha Ministerial Declaration in 2001 on the TRIPs Agreement and Public Health stressed that it is important to implement and interpret the WTO TRIPs Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines.

2.5 The WTO Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement, seeks to overcome this difficulty by allowing 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. This is achieved by waiving the restriction on compulsory licences for export in appropriate countries. The proposal seeks to implement this Decision on an EU wide basis.

2.6 The proposal is a voluntary one both for the countries in need who seek to obtain affordable medicines and the companies who intend to supply them. Once the legislation comes into force, compulsory licences will be granted by national authorities on the basis of applications from companies and notifications by developing countries that they require particular pharmaceutical products.

(iii) Risk assessment

2.7 Currently, national EU member state legislation precludes the issuing of compulsory licences for export of generic medicines to appropriate developing countries. This results in developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector, having insufficient quantities of medicines to address public health problems.

3. Options

3.1 Option 1: Do nothing

3.2 The current status quo would continue. EU member states can amend their laws to allow compulsory licences to be issued but this likely to result in distortion of competition, and may not sufficiently guard against re-exportation back into the EU of patented generic medicines manufactured under compulsory licence. Patent holders¹ may continue to sell certain pharmaceutical products to developing countries at 'cost price'² but this may still be too expensive for some developing countries. This will also be insufficient to address the breadth and scale of the health care needs of developing countries.

3.3 Option 2: Support the Commission's proposal - compulsory licences for export

3.4 There will be concerns from patent holders that they will lose their exclusive rights to supply certain countries. There will also be concerns from patent holders that the proposal undermines their patent protection, if products are illegally diverted from markets for which they are intended. This may increase their enforcement costs.

3.5 The WTO August 2003 Decision includes measures to prevent diversion or re-exportation of the generic products which have been produced under the system. These measures include: producing the amount of product necessary to meet the needs of the eligible importing Member(s) and that reasonable measures should be taken by both the exporter and the importer to prevent diversion or re-exportation of the generic products. The proposal reflects the anti-diversion measures inherent in the August 2003 Decision.

3.6 Option 3: Governments act as procurer

3.7 This would enable developing countries with public health problems to be given the quantity of medicines they required. However, due to the wide range of patented medicines required and the number of developing countries with public health problems the cost would be considerable.

¹ The term "patent holder" covers both the situation where the patent holder and the manufacture are one and the same and when a company manufactures under license. This doesn't change the analysis - we are most interested in who makes decisions about sales and R&D, namely the patent holder.

² In March 2001 Merck announced "we would [will] sell our current HIV/AIDS medicines in the poorest developing countries and those hardest hit by the HIV epidemic, at prices where Merck will not profit from the sales of these medicines.

3.8 Option 4: Intermediaries act as procurers

3.9 Similar to option 3 but intermediaries e.g. UN, EU, NGOs act as procurers instead of Governments. Again similar to option 3, developing countries would receive the medicines they require but the cost would be considerable.

3.10 Option 5: Regulation forcing sales at cost price

3.11 This would have similar implications to options 3 and 4 but instead the patent holders would have to bear the considerable costs involved. Due to the extra costs involved with the manufacture of medicines within the research based industry (which includes research and developments costs) it is likely that the end products will be considerably more expensive than corresponding generic products. It is also likely that developing countries would not be able to afford the required 'cost price' medicines. Also there is no guarantee that patent holders would seek to supply developing country markets under these conditions but if they did costs may be passed to developed country markets through higher drug prices.

4. Benefits

4.1 Option 1: Patent holders (normally the research based pharmaceutical industry) will not lose their exclusive rights to supply certain countries. The patent protection of patent holders will not be undermined by possible diversion of generic medicines.

4.2 Option 2: This would show that the EU is sympathetic to the needs of developing countries. It would ensure that the conditions for the granting of compulsory licences for export are the same in all EU Member States. It also avoids distortion of competition for operators in the EU single market and applies uniform rules to prevent re-exportation into the territory of the European Union of generic pharmaceutical products manufactured under compulsory licences. The generic based industry may receive some benefit by acting as the exporter of pharmaceutical products under compulsory licence

4.3 Option 3: The developing world would receive the necessary medicines they require and the research based pharmaceutical industry would potentially increase sales. Governments may have more significant bargaining and purchasing power than one or more developing countries and hence may be able to negotiate a lower price.

4.4 Option 4: Same as for option 3 in paragraph 4.3.

4.4 Option 5: The developing world would potentially receive the necessary medicines they require which would be financed by the private sector.

Business sectors affected

4.5 The main sectors affected are the research based pharmaceutical industry and to a lesser degree, the generic based industry.

Issues of equity and fairness

4.6 The effect on the patent holders will be limited.

5. Costs

(i) Compliance costs

5.1 Option 1: None

5.2 Option 2: Minimal costs apply to the UK research based pharmaceutical industry (normally the patent holders) as they will not be manufacturing the medicines for export. Adequate remuneration is payable to the right holder by the licensee which takes into account the economic value of the use that has been authorised under the licence. The adequate remuneration is determined by the competent authority which in the case of the UK is the Patent Office.

5.3 Option 3: None

5.4 Option 4: The research based pharmaceutical industry would have to ensure that sufficient quantity of medicine was produced in order to supply both the developed and developing worlds in order to recuperate research and development costs.

(ii) Other costs

5.5 The proposal is a voluntary one both for the countries in need who seek to obtain affordable medicines and the companies who intend to supply them. Once the legislation comes into force, compulsory licences will be granted by national authorities on the basis of applications from companies and notifications by developing countries that they require particular pharmaceutical products. No financial assistance by the UK is required.

(iii) Costs for a typical business

Negligible.

6. Consultation with small business: the Small Firms' Impact Test

6.1 Due to the nature of the proposal, it will have a limited impact on SMEs. There may be some SME generic manufacture who may wish to take advantage of the proposal for commercial gain but there is no requirement to for generic manufacturers to use the proposal.

7. Competition Assessment

7.1 The competition filter test shows that there are no substantive competition issues (see annex).

8. Enforcement and sanctions

8.1 On the whole there will be no enforcement costs as patent rights are private law. However, in order to prevent diversion of generic medicines from their intended market there is a requirement in the proposal for the generic products to be distinguished from those made by the right holder through special packaging.

9. Monitoring and review

9.1 Three years after the entry into force of this Regulation, the Commission shall present a report to the European Parliament, the Council and the Economic and Social Committee on the operation of this Regulation and the contribution it has made to the implementation of the system established by the Decision. The Patent Office will monitor the effect of the proposal according to its usual monitoring and review processes to ensure that the objectives are met.

10. Consultation

(i) Within government

10.1 DTI Legal, Better Regulation Team, DTI, DFID, DOH, MHRA, FCO, HMT, HMCE and UKREP

(ii) Public consultation

10.2 The Patent Office has already issued a web notice in order to solicit initial views from interested parties. This will be followed up with a formal consultation according to established procedures.

11. Summary and recommendation

11.1 It is recommended that option 2 be pursued. This would demonstrate that the EU considers increasing access to medicines as a critical part of the global effort to improve health in the developed world and to tackle key diseases such as HIV/AIDS, tuberculosis and malaria. It would ensure that the conditions for the granting of compulsory licences for export are the same in all EU Member States.

12. Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed:

(This remains blank until the legislation is to be sent to Parliament. It then becomes a final RIA)

Date:

Lord Sainsbury of Turville
Parliamentary Under-Secretary of State for Science and Innovation
Department of Trade and Industry

Contact point:

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THE COMPETITION FILTER TEST

| Question | | Answer Yes or No |
|----------|---|---------------------|
| Q1. | In the market(s) affected by the new regulation, does any firm have more than 10% market share? | Yes |
| Q2. | In the market(s) affected by the new regulation, does any firm have more than 20% market share? | Yes |
| Q3. | In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share? | Yes |
| Q4. | Would the costs of the regulation affect some firms substantially more than others? | No |
| Q5. | Is the regulation likely to affect the market structure, changing the number or size of firms? | No |
| Q6. | Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet? | No |
| Q7. | Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet? | No |
| Q8. | Is the sector characterised by rapid technological change? | No |
| Q9. | Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products? | No |

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2004) 737

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

EN

EXPLANATORY MEMORANDUM

1. Background

This proposal 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 (WT/L/540 of 2 September 2003).

By waiving WTO Members' obligations under Article 31(f) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (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. It includes substantial safeguards against trade diversion and rules to ensure transparency, and provides for future replacement of the Decision by an amendment to the TRIPs Agreement.

2. Need for a Community intervention

Given the active role played by the European Communities and their Member States in the adoption of the Decision, their commitment made at the WTO to fully contribute to the implementation of the Decision and their appeal to all WTO Members to ensure that the right conditions are put in place to allow the system set up by the Decision to operate efficiently, it is important for the Community to contribute to the system set up by the Decision through implementation in the Community legal order.

Within the Community uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all 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.

In view also of the very specific nature of the provisions of the Decision, the fact that national arrangements for compulsory licensing already exist, and the need for urgent action to allow for the export of medicines to countries with public health problems, the Commission proposes implementation by way of a Regulation based on Articles 95 and 133 of the Treaty.

3. Proposed provisions

Article 1

The Regulation sets out a procedure and conditions for the grant of compulsory licences in line with the Decision. While supplementary protection certificates are not mentioned in the Decision, within the EU they entail the same effects as patents and so are included.

Article 2

The definition of the term "pharmaceutical product" is taken from the Decision, with text to reflect the definition of medicinal product in Directive 2001/83/EC.

Article 3

The competent authorities for granting compulsory licences pursuant to the Regulation will be those notified by the Member States.

Article 4

Eligibility is based on notifications and declarations to the WTO.

Article 5

This includes key elements of information required under the Decision and the TRIPs Agreement. The requirement to provide evidence of a specific request to the applicant by the importing country or from its authorised representatives should help ensure effective control of the amount of product supplied under compulsory licences.

Article 6

Competent authorities should verify whether basic conditions to trigger the system set out in the Decision have been met.

Article 7

Paragraph 1 reflects Article 31(b) of the TRIPs Agreement. While the TRIPs Agreement allows this requirement to be waived in the case of a national emergency or other circumstances of extreme urgency, here it is retained (paragraph 2) in view of the speed of modern communications and the desirability of voluntary agreements.

Article 8

This provision takes over the conditions set out in paragraph 2(b) of the Decision. In addition it reflects conditions usually found in licensing agreements.

Article 9

This specifies under which conditions a competent authority can refuse an application.

Article 10

Paragraph 2(c) of the Decision requires the exporting Member to notify the WTO Council for TRIPS about the grant of any licence. As the Commission is the usual interlocutor before the WTO for matters falling under the Common Commercial Policy, such notifications should be made via the Commission.

Articles 11 – 13

These are based on equivalent provisions in Council Regulation (EC) No 953/2003 on trade diversion.

Article 14

Termination of the licence is provided for if (a) the licence conditions are not respected, or (b) the circumstances which led to grant of the licence cease to exist (Article 31(g) of the TRIPs Agreement).

Article 15

Article 31(i) and 31(j) of the TRIPs Agreement require provision to be made for review of decisions.

Article 16

As the licensee will not necessarily hold a medicinal products marketing authorisation within the EU for the product manufactured under a compulsory licence for export, the Regulation provides for licensees to ask for a scientific opinion from the European or national regulatory authorities if they should need this for export to the country concerned. Derogations from data protection and caducity rules are provided.

Article 17

This provides for review three years after entry into force of the Regulation.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

Whereas:

- (1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.
- (2) On 30 August 2003 the General Council of the WTO adopted the Decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter “the Decision”. Subject to conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement, to address the needs of WTO Members with insufficient manufacturing capacity.
- (3) Given the Community’s active role in the adoption of the Decision, its commitment made at the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

¹ OJ C, p.

² OJ C, p.

³ OJ C, p.

- (4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all Member States and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to this Regulation.
- (5) This Regulation is intended to be part of the wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines.
- (6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. It should not be used with the primary purpose of addressing other objectives, and in particular objectives of a purely commercial nature.
- (7) Products manufactured pursuant to this Regulation should reach those who need them and should not be diverted from those for whom they were intended. Compulsory licences issued under this Regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which these products will be exported.
- (8) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence and which a person attempts to re-import into the territory of the Community.
- (9) To avoid facilitating overproduction and possible diversion of products, competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant.
- (10) Since the objectives of the action to be taken, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

Article 1

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

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

Article 2

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

- (1) “pharmaceutical product” means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council⁴, active ingredients and diagnostic kits;
- (2) “right holder” means the holder of any patent or SPC in relation to which a compulsory licence has been applied for under this Regulation; in cases where more than one right holder is involved, for the purposes of this Regulation the singular term should be read as plural;
- (3) “importing WTO member” means the name of the WTO member to which the pharmaceutical product is to be exported;

Article 3

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

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

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

Article 4

The following are eligible importing WTO members:

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

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

⁴ OJ L 311, 28.11.2001, p. 67

Article 5

1. Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.
2. If the person applying for a compulsory licence is submitting applications to competent authorities in more than one Member State for the same product, he shall indicate that in each application, together with details of the quantities and importing WTO members concerned.
3. The application pursuant to paragraph 1 shall set out the following:
 - (a) the name and contact details of the applicant and of any agent or representative the applicant has appointed to act for him before the competent authority;
 - (b) the name of the pharmaceutical product or products the applicant intends to manufacture and sell for export under the compulsory licence, including any additional information needed to ensure the precise identification of the product or products in question;
 - (c) identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought;
 - (d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;
 - (e) the importing WTO member or members;
 - (f) evidence of prior negotiation with the right holder pursuant to Article 7;
 - (g) evidence of a specific request to the applicant from authorised representatives of the importing WTO member and indicating quantity of product required.
4. The competent authority may prescribe additional formal or administrative requirements for efficient processing of the application.

Article 6

1. The competent authority shall verify that each importing WTO member cited in the application has made a notification to the WTO pursuant to the Decision of 30 August 2003 of the General Council of the WTO on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter “the Decision” in respect of each of the products covered by the application that:
 - (a) specifies the names and expected quantities of the product(s) needed;

- (b) unless the importing WTO member is a least-developed country, confirms that the importing WTO member has established that it either has no manufacturing capacities in the pharmaceutical sector or has examined its manufacturing capacity in that sector and found that, excluding any capacity owned or controlled by the right holder, it is currently insufficient for meeting its needs;
 - (c) confirms that where a pharmaceutical product is patented in the territory of the importing WTO member, that WTO member has granted or intends to grant a compulsory licence for import of the product concerned in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.
2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to the WTO by the importing WTO member(s), and that, taking into account other compulsory licences ordered in the Community, the total amount of product authorised to be produced for any importing WTO member does not significantly exceed the amount notified to the WTO by that member.

Article 7

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

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

Article 8

1. The licence granted shall be non-exclusive and non-assignable. It shall contain the specific conditions set out in paragraphs 2 to 8 to be fulfilled by the licensee.
2. The amount of patented product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing WTO member or members cited in the application.
3. The licence shall be strictly limited to the acts of manufacturing the product in question and selling for export to the WTO member or members cited in the application. No product made under the compulsory licence shall be offered for sale or put on the market in any country other than the WTO member(s) cited in the application.
4. Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the right holder through special packaging. The packaging and any associated literature shall bear an indication that the product is

subject of a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and sale in the importing WTO member or members concerned.

Unless the applicant proves that such distinction is not feasible or has a significant impact on price, special colouring or shaping of the products themselves shall also be required.

5. Before shipment to the importing WTO member or members cited in the application, the licensee shall post on a website the following information:
 - (a) the quantities being supplied under the licence and the WTO members to which they are supplied
 - (b) the distinguishing features of the product or products concerned.

The website address shall be communicated to the competent authority.

6. If the product(s) covered by the compulsory licence are patented in the importing WTO members cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import and sale of the products.
7. The licensee shall keep complete and accurate books and records of all quantities of product manufactured and of all dealings therein. The licensee shall make these books and records available on request to an independent person agreed by the parties, or otherwise appointed by the competent authority, for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met.
8. The licensee shall be required to provide proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation or putting on the market certified by an authority of the importing WTO member, and shall retain such records for at least three years. Upon request these proofs must be supplied to the competent authority.
9. The licensee shall be responsible for the payment of adequate remuneration to the right holder as determined by the competent authority taking into account the economic value of the use that has been authorised under the licence to the importing WTO member(s) concerned.

Article 9

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

Article 10

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

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

- (a) the name and address of the licensee;
 - (b) the product or products concerned;
 - (c) the quantity to be supplied;
 - (d) the country or countries to which the product or products are to be exported;
 - (e) the duration of the licence;
 - (f) the address of the website referred to in Article 8 (5).
2. The Commission shall forward the information referred to in paragraph 1 to the Council for TRIPS.

Article 11

1. It is prohibited to import into the Community products subject of a compulsory licence under this Regulation for the purposes of release for free circulation, reexport, placing under suspensive procedures or placing in a free zone or free warehouse.
2. Paragraph 1 shall not apply in the case of re-export to the importing WTO member cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing WTO member.

Article 12

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

2. The relevant national authority and the manufacturer or exporter of the products concerned shall be informed without delay of the suspended release or detention of the products and shall receive all information available with respect to the products concerned. Due account shall be taken of national provisions on the protection of personal data, commercial and industrial secrecy and professional and administrative confidentiality. The importer, and where appropriate, the exporter, shall be given ample opportunity to supply the relevant national authority with the information which it deems appropriate regarding the products.
3. The procedure of suspension or detention of the goods is carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.
4. If the relevant national authority finds that products suspended for release or detained by customs authorities were intended for import into the Community contrary to the prohibition in Article 11 (1), that authority shall ensure that these products are seized and disposed of in accordance with national legislation. These procedures are carried out at the expense of the importer. If it is not possible to recover these expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.
5. Where products suspended for release or detained by customs authorities subsequent to further control by the relevant national authority are found not to violate the prohibition in Article 11(1), the customs authority shall release the products to the consignee, provided that all customs formalities have been complied with.
6. The relevant national authority shall inform the Commission of any decisions on seizure or destruction which are adopted pursuant to this Regulation.

Article 13

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

Article 14

1. Subject to adequate protection of the legitimate interests of the licensee, a compulsory licence granted pursuant to this Regulation may be terminated by a decision of the competent authority or by one of the bodies referred to under Article 16 in either of the following cases:
 - (a) if the conditions of the licence are not respected by the licensee;
 - (b) if and when the circumstances which led to the grant of the licence cease to exist and are unlikely to recur.

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

2. Termination of a licence granted under this Regulation shall be notified to the Commission who shall inform the WTO.
3. Within a reasonable time following termination of the licence the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need or otherwise as prescribed by the competent authority in consultation with the right holder.

Article 15

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

Article 16

1. Where the application for a compulsory licence concerns a medicinal product authorised in accordance with Article 6 of Directive 2001/83/EC, the provisions of Article 24(4) and (5) and of Article 14(4) and (5) of Regulation (EC) No 726/2004 of the European Parliament and the Council⁵ shall not apply.

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

2. Where the application for a compulsory licence concerns a medicinal product and the applicant for the compulsory licence is not the holder of a marketing authorisation valid within the Community for the product concerned, he may avail himself of the scientific opinion procedure provided for under Article 58 of Regulation (EC) No 726/2004 or any similar procedure provided under national law.
3. For the purposes of obtaining a scientific opinion under paragraph (2) and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or Article 3 of Regulation (EC) No 726/2004.

⁵ OJ L 136, 30.4.2004, p. 1.

Article 17

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

Article 18

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

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

Done at Brussels, [...]

For the European Parliament
The President

For the Council
The President

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

Decision of the General Council of 30 August 2003 *

The General Council,

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

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

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

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

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

Decides as follows:

1. For the purposes of this Decision:

¹Notes:

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

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

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

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

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

6. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement. [back to text](#)

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

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

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

- (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)
- (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
- (c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

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

- (a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed (5);
 - (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
 - (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);
- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
 - (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

- (iii) before shipment begins, the licensee shall post on a website (7) the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

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

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

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

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

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or

least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

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

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

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

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

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

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

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Assessment of Manufacturing Capacities in the Pharmaceutical Sector

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

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

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

OR

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

ORGANISATIONS TO WHICH THE CONSULTATION HAS BEEN SENT

Organisation

ABPI
 ACID
 Agricultural Engineers Association
 Allvoice
 Arnander Irvine & Zietman
 Ashurst Morris Crisp
 Association Of British Insurers
 Astra Zenica
 AURIL
 Babcock International Ltd
 Baker & Mckenzie
 Berwin Leighton
 Bharat Electronics Ltd
 Bioindustry Association
 Biotechnology And BSRC
 British Generics Manufacturers Association
 Ltd
 British Library
 British Pharmaceutical Group Ltd.
 British Poultry & Meat Federation
 British Retail Consortium
 Cable & Wireless
 Chemical Industries Association
 CIMMYT
 Cardiff Law School
 Chartered Institute of Patent Agents
 Consumers Association
 Cranfield University
 Crop Protection Association
 Davenport Lyons
 Deloitte & Touche
 Department for Constitutional Affairs
 Department of Trade and Industry
 Translations Service
 EC Laws Committee - LES Britain &
 Ireland
 Eli Lilly
 Enforcement Focus Group members
 Eureka Manufacturing Co. Ltd
 Europe Analytica
 Federation of Small Businesses
 Federation Of The Electronics Industry
 Frank B Dehn
 Freshfields
 Gallafent & Co

Organisation

Glaxo Smith Kline
 Greenpeace
 Harbottle & Lewis
 Intellectual Property Advisory Committee
 members
 Patent Office Patents Directorate
 Patent Office Focus Groups
 Inventorslink Inc
 Institute of Linguists
 Institute of Translation & Interpreting
 Linklaters & Paines
 Lancaster University
 Lovells
 Magister Ltd
 Marketforce Communications
 Merck Ltd
 Microsoft Limited
 Mischon de Reya
 Mewburn Ellis
 Norton Rose
 Olswang
 Pfizer Limited
 PJB Publications
 Preventative Medicines Tech Inc.
 RWS Group
 SIBLE University Of Sheffield
 Simmons & Simmons
 State Patent Bureau Of The Republic Of
 Lithuania
 The Bar Council
 The British Agrochemicals Association Ltd
 The British Brands Group
 The Centre of Research for Intellectual
 Property and Technology (SCRIPT)
 The Law Society
 Trade Marks, Patents and Designs
 Federation
 University Of Alicante
 University Of Cambridge
 University Of Oxford
 University of Strathclyde
 University Of Queen Mary & Westfield
 College
 Vereenigde
 Visteon Global Technologies
 Wedlake Bell

THE CONSULTATION CODE OF PRACTICE CRITERIA

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation coordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.
7. The complete code is available on the Cabinet Office's web site, address <http://www.cabinetoffice.gov.uk/regulation/docs/consultation/pdf/code.pdf>

Comments about the consultation process

8. If you have any comments or complaints about how this consultation process is being handled, please tell the Patent Office's Consultation Co-ordinator, who is:

Kath Gibbs
Consultation Co-ordinator
The Patent Office
Concept House
Cardiff Road
Newport
NP10 8QQ

Tel: +44 (0)1633 813775
Fax: +44 (0)1633 814509
E-mail: kath.gibbs@patent.gov.uk