



Consultation on the Proposed Regulation on the compulsory licensing of patented pharmaceutical products for export to countries with public health problems

Introduction

The formal consultation document was launched on 1 March 2005 with responses requested by 23 May 2005. The consultation document was sent to a number of individuals and to the organisations listed in Annex D. The consultation document was also available on this website, and via the directgov website . During the consultation period the website received **653** unique visitors. A number of email and telephone enquiries were also made during the course of the consultation.

Overview

The consultation related to the implementation of an EU Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. 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 appropriate countries with no or insufficient manufacturing capacity.

This consultation sought comments from all interested parties, including patent applicants/proprietors or generic manufacturers on the proposed compulsory licensing Regulation . Specific comments were requested on the following areas:

- i. Whether the Regulation is a fair reflection of the WTO Decision.
- ii. The Scope of the Regulation in relation to eligible countries who may use the proposed Regulation
- iii. Determination of the period for negotiation with the rights holder
- iv. Determination of adequate remuneration levels to the rights holder
- v. Anti-diversion measures within the proposed Regulation
- vi. Safety and efficacy of the generic products produced under the proposed Regulation

Responses

Written Responses

Written responses were received from Oxfam, Medecins Sans Frontieres (MSF), the European Federation of Pharmaceutical Industries (EFPIA), the Association of the British Pharmaceutical Industry (ABPI), GSK, AstraZeneca, Competition Law

Association (CLA), the Chartered Institute of Patent Agents (CIPA) and various academic institutions.

These responses may be viewed on request.

Contact details:

Andrew Jenner
Senior Policy Advisor
Intellectual Property & Innovation Directorate
UK Patent Office
Concept House
Cardiff Road
Newport NP10 8QQ
Tel: +44 (0) 1633 813736
Fax: +44 (0) 1633 814922

Further consultation

A meeting with interests took place on the 14 March 2005 with representatives from Oxfam, Action Aid, ABPI, GSK, AstraZeneca in attendance. The minutes of this meeting can be viewed on this website.

Conclusion

A fair reflection of the WTO Decision

- Most respondents felt that the draft Regulation was a fair representation of the August 30 2003 Decision, although some elements could be improved or clarified (see below).

Scope of the draft Regulation

- Some respondents want the scope extended to include non-WTO least developed countries (LDCs) and non-WTO developing countries. Other respondents noted that there were questions surrounding the legality in WTO law of extending the Regulation to non-WTO countries but that, should a suitable legal solution prove possible, then extension to non-WTO LDCs would not pose problems. However, it was also stated that an extension beyond non-WTO LDCs would present difficulties. Some respondents stated that any extension would need recipient countries to assume the anti-diversion commitments provided within the Regulation and the WTO TRIPs Agreement.

Determination of the period for negotiation with the rights holder

- Some respondents wanted a limit of thirty days with flexibility to reduce this in the case of emergency. Other respondents considered that it was not possible to conclude negotiations in 30 days and believed that 60 days was the minimum period required. Others felt that the competent authority was in the best position to judge the appropriate time limit.

Determination of adequate remuneration for the rights holder

- Some respondents felt that remuneration should be determined by a formula (such as the Canadian formula). Some wanted to leave the issue of remuneration to the competent authority, believing that the UK Patent Office has historic knowledge in assessing adequate remuneration which would enable it to tailor remuneration to each case

Anti-diversion measures

- Most respondents considered that the anti-diversion measures were not controversial but wanted to see the involvement of the right-holder, not just the generic company

Quality of exported generic products

- Some respondents considered that Article 16 of the draft Regulation required clarification and it was unclear from a legal perspective. It was fine for the drugs in question to be quality approved via the normal EU mechanisms but this should not lead to a marketing authorisation in the EU.

Recommendations

The UK will seek to extend the scope of the Regulation to appropriate non-WTO countries. The UK will ensure that the anti-diversion measures within the Regulation and WTO Decision are maintained and apply to all potential users of the system. The UK will push for a fixed period of negotiation with the rights holder, rather than a flexible time limit and will investigate the feasibility of an EU wide formula for determining levels of adequate remuneration.