European Economic and Social Committee

INT/260
Compulsory licensing of patents/pharmaceutical products

Brussels, 8 June 2005

OPINION

of the European Economic and Social Committee
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) 737 final – 2004/0258 (COD)

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On 15 December 2004, the Council decided to consult the European Economic and Social Committee, under Article 251 of the Treaty establishing the European Community, 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) 737 final – 2004/0258 (COD).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 23 May 2005. The rapporteur was **Mr Braghin**.

At its 418th plenary session, held on 8 and 9 June 2005 (meeting of 8 June), the European Economic and Social Committee adopted the following opinion by 64 votes to one with one abstention.

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1. Gist of the opinion

1.1 The EESC endorses the European Commission's proposal, which aims to implement the Decision that was adopted by the WTO General Council on 30 August 2003. It also appreciates the Commission's active role - with international bodies and other stakeholders - in seeking appropriate solutions to the serious health problems affecting developing countries with no pharmaceuticals production capacity and inadequate health structures.

1.2 The EESC supports both the procedure governing the compulsory licensing of pharmaceutical products covered by a patent or a supplementary protection certificate and the chosen control arrangements.

1.3 Furthermore, the EESC recommends strengthening the operational provisions in order to ensure:

- full compliance with current legislation, particularly in relation to production quality control,
- that the conditions for compulsory licensing are reinforced (Article 8), particularly in relation to the arrangements used to differentiate between a licensed pharmaceutical product and its original, in order that illegal re-export within the EU or to third countries is avoided,
- a coordinated effort with the authorities of the importing countries in order to avoid fraud, counterfeiting and uses other than those originally provided for,
- that the implementation of Member States' customs rules and sanction arrangements are closely monitored to deter illicit operations,

- wider disclosure of compulsory licensing to better safeguard intellectual property rights.

1.4 The EESC hopes that the scope is extended to include veterinary medicinal products in view of possible health emergencies arising from outbreaks of contagious animal diseases or contamination of food products of animal origin.

1.5 Lastly, the EESC hopes that the European Commission continues its worldwide efforts to ensure that emergency medicines and adequate health structures are also made available to non-WTO developing countries.

2. Introduction

2.1 The health situation in many parts of the world is highly critical and is marked by a constant risk of epidemics, inadequate structures and treatment and very high morbidity and mortality rates. The challenge is a global one, requiring better health and social services not just in the developing countries, but even in those relatively developed ones that do not allocate sufficient resources to solving their health and social problems.

2.2 Health care aid provided by the more developed countries is insufficient to resolve the problems, and therefore new instruments must be sought. It is not enough to provide medicines for emergencies, as is usually the case with developing countries; the aim should be to improve the overall performance of the system. This means targeting scarce resources on real priorities, ensuring resource management and control capabilities benefit those who actually need them, finding solutions to shortcomings in pharmaceuticals production and services and ensuring the latter are managed efficiently.

2.3 The Commission has been particularly active in this field, acting on several health-related fronts and seeking suitable forms of cooperation and aid. One example is the action programme to tackle the three diseases that impact most on the high mortality rate in the less developed and developing countries (HIV/Aids, tuberculosis and malaria)[1]. The programme also aims to strengthen local health systems, increase opportunities to secure the necessary medication at reasonable prices and promote research into medicines and vaccines to combat these diseases.

2.4 The Commission has also adopted an active, positive approach in terms of awareness-raising and the search for common solutions with international bodies and other stakeholders. The aim is to improve the availability of basic medicines and to ensure equal access for the poorest populations whilst defending the intellectual property rights enshrined in international trade agreements, and eliminating the risk of speculative re-importation or sale to third countries.

1 OJ C 133 of 6.6.2003

2.5 The Commission's work has been decisive in advancing discussions of these objectives at the World Trade Organisation (WTO) in relation to the TRIPS Agreement[2]. WTO Member States adopted a declaration on the TRIPS Agreement and public health[3] at the Conference of Ministers which was held in Doha in 2001. The Declaration cleared up the issue of the degree of flexibility allowed in implementing the agreement in the context of national health policies. The Conference also established the basic principles for ensuring that less developed countries with limited or no pharmaceuticals production capacity can have recourse to compulsory licensing, a matter which is predominantly regulated by the national authorities.

2.6 The above-mentioned Doha declaration on public health asserted the principle that TRIPS agreements were to be interpreted and implemented in such a way as to support the right of public health protection and to promote access to medicines for all, and, in particular, the right of every WTO Member State to establish what constitutes a "national emergency" or "circumstances of extreme urgency" with a view to justifying granting compulsory licensing. Furthermore, after taking note of the problems facing countries with limited or no pharmaceuticals production capacity, the declaration authorised the General Council to find a speedy solution to the problem.

2.7 The WTO General Council reached a solution with its Decision of 30 August 2003[4]. The Decision clearly defines the principles and commitments of the various players, in order to ensure that the products imported under the system are genuinely used to meet public health needs without trade diversion. Furthermore, it acknowledges the case for cooperation among the WTO Member States with a view to encouraging technology transfers and creating productive capacity in the pharmaceutical sector, in accordance with Article 66(2) of the TRIPS Agreement.

2.8 The official statement which the chairman of the General Council[5] made when the Decision was adopted, is of some significance. It highlights the obstacles encountered in this wide-scale national and international action to resolve the problem, and sheds light on the logic and fairness of the adopted measures, thus enhancing the content of the Decision. The statement also notes that some WTO members, including the Member States of the European Union, have resolved not to use this particular compulsory licensing mechanism for imports of proprietary medicines.

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2 TRIPS stands for *Agreement on Trade-Related Aspects of Intellectual Property Rights*: the agreement regulates the possibility of making compulsory changes to intellectual property rights, binding them to certain conditions.

3 *Declaration on the TRIPS Agreement and public health*, adopted on 14 November 2001, http://www.wto.org

4 Decision of the General Council on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreements and public health, http://www.wto.org

5 The General Council chairperson's statement, 30 August 2003, http://www.wto.org

2.9 The General Council's Decision stipulated that it would cease to apply when the TRIPS Agreement was amended to comply with the provisions of the Decision. Despite the tight deadlines, the initiative of the General Council has not yet led to such a resolution. Consequently, some initiatives to bring the Decision into effect have been adopted autonomously by some WTO Member States and the Commission is moving in the same direction with its proposed regulation.

3. Gist of the proposal for a regulation

3.1 The 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. By waiving WTO members' obligations under Article 31(f) of the WTO Agreement on trade-related aspects of intellectual property rights, this decision enables them to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to requesting third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

3.2 The 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, with a view to improving access to affordable medicines in WTO Member States facing national emergencies or circumstances of extreme urgency.

3.3 The Decision 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.

3.4 The Commission believes that it is important for the Community to contribute to the system set up by the Decision through implementation in the Community legal order, because of 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 its implementation 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.

3.5 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 any distortions 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.

3.6 In view 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.

4. **Comments**

4.1 The EESC fully agrees that action is needed to ensure that countries with limited economic and productive resources - and consequently lacking the necessary instruments to combat endemic diseases and tackle health crises - are provided with basic pharmaceutical products. The proposed Regulation, in compliance with the patents system, enables the supply of patented pharmaceuticals under very specific conditions. However, it does not address the problem of the lack of unpatented medicines in developing countries, as this is not covered by the content of the WTO decision.

4.2 The EESC therefore welcomes the Commission's initiative, which aims to promote the full and uniform implementation of the procedure for granting compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products to countries that have requested them in order to address a significant health problem, and believes that the chosen arrangements are basically suitable. Nonetheless, it believes that the wording relating to some specific points could be improved, as the following comments show.

4.3 The definition of "pharmaceutical product" explicitly refers to Directive 2001/83/EC of the Parliament and of the Council[6] on medicinal products for human use. The WTO General Council Decision does not mention veterinary medicinal products: nevertheless, in order to be able to cope with health emergencies which could occur as a result of animal diseases transferring to humans or contamination of food products of animal origin, the EESC hopes that the scope of the Directive is extended to include veterinary medicinal products, through the adoption of a specific WTO General Council Decision, if necessary.

4.4 The regulation is applicable to WTO members (Article 4), which is logical, being an instrument used to implement an internal decision of this international organisation. The EESC calls upon the Commission and the Member States to continue international discussions and to seek globally applicable solutions that comply with intellectual property rights and current international agreements.

4.5 Article 5 lays down that "Any person may submit an application for a compulsory licence". The EESC believes that the blanket term "person" used to describe the applicant stems from the desire to offer the greatest possible number of production opportunities. Nonetheless, it believes that it is advisable to specify that the applicant must meet all the requirements of European legislation relating to pharmaceutical products so that current production regulations governing citizens' health in the EU can be enforced even if in the case in question the product is intended solely for export.

6 OJ L 311 of 28.11.2001

4.6 The EESC believes that all the relevant authorities need to monitor compliance with production quality standards, which must be the same for the internal market and for exports to countries that do not have adequate health control structures. When implementing the Regulation, adequate checks must be devised for importer country control arrangements, and coordinated action will be particularly necessary in order to avoid (i) fraud or counterfeiting, thus ensuring patients are protected in their home territory (ii) pharmaceutical products subject to compulsory licensing being diverted to another destination, or (ii) illegal re-importation.

4.7 On the sensitive issue of authorised production volumes, the EESC notes a discrepancy between Article 6(2) which lays down that "the total amount of product authorised to be produced [must] not significantly exceed the amount notified to the WTO" and Article 8(2) which asserts that "the amount of ... product(s) manufactured under the licence shall not exceed what is necessary to meet needs". To resolve the discrepancy, the EESC suggests modifying the text of Article 6(2) with a view to clarifying that production should not exceed the necessary requirements.

4.8 Since the system implies limited ownership rights, the regulation rightly provides that it should be used in good faith (6th recital) and that the products manufactured pursuant to it should reach those who need them and should not be diverted from those for whom they were intended (7th recital). However, it would be preferable to have these assertions – to which the EESC fully subscribes – written into those Articles setting out the detailed implementation arrangements (e.g. Articles 5 and 6), or in the ones that provide for suspension procedures and the termination of compulsory licences (Articles 12 and 14).

4.9 The EESC endorses the measures envisaged to avoid the unfair use of the compulsory licence. Moreover, it would like to see a specific reference to the fact that the holder of a patent or supplementary protection certificate can report or object to any matters that have not been complied with, particularly with respect to proof of prior negotiation and conformity of production checks as laid down in Article 8 (paragraphs 4, 5 and 8 in particular).

4.10 Article 8(1) appears to contain an error as it refers only to subsequent points 1 through 8, whereas it should also include point 9, which also deals with the licensee.

4.11 Article 8(4) lays down the labelling, marking and packaging rules that govern products manufactured under the present regulation in order to ensure that the product is exclusively exported to and sold in the requesting importing country. The EESC suggests that it should be specified that trademarks, graphic logos and packaging colour too should be distinctive with a view to hindering illegal re-exportation to the EU or third countries.

4.12 Article 10, which lays down that the Commission shall be notified of the compulsory licence granted by EU Member States, does not appear to provide for adequate disclosure with regard to the right holder and the players in the sector. The EESC hopes that, provided that

confidential information is protected, suitable arrangements can be made so that these details may be made available to the interested parties.

4.13 The wording of Article 11(2) does not appear to be sufficient to avoid unfair practices, particularly in the case of medicines that are not manufactured in the EU but pass through EU territory, and it consequently lacks teeth. The EESC calls on the Commission to monitor the control arrangements and the implementation of the sanctions approved by the Member States to ensure that, in compliance with the customs Regulation[7], they are genuinely effective, proportionate and dissuasive, thereby avoiding fraud and counterfeiting.

4.14 Lastly, the EESC urges that the European Commission consider how best to implement arrangements, such as bilateral agreements, in order that similar arrangements can also be implemented in non-WTO developing countries.

Brussels, 8 June 2005.

The President of the European Economic and Social Committee	The Secretary-General of the European Economic and Social Committee
Anne-Marie Sigmund	**Patrick Venturini**

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7 Chapter V, Article 18 of Regulation 1383 (2003).