



## **EGA Position Paper**

Outcome of the WTO Ministerial Conference, Doha, November 2001

Declaration on the TRIPS agreement and Public Health

**February 2002**

The EGA represents over 400 companies in Europe  
dedicated to the production and supply of affordable generic medicines.

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## Doha Reinforces the Balance in TRIPs

The Doha Declaration on the TRIPs agreement and Public Health<sup>1</sup> is welcomed since it reinforces the “balance” of rights and interests that exist in TRIPs.

Importantly it recognises the right of countries to grant compulsory licenses as well as ‘*the freedom to determine the grounds upon which such licenses are granted*’ (Paragraph 5, point b).

It also acknowledges that countries have the right to determine **what constitutes national emergency** and decide on their own rules the implementation of **parallel imports**.

In addition, least developed countries (LDCs) have been given a 10-year extra period to provide pharmaceuticals patents, this means that the deadline for compliance is now 2016 for LDCs, at the earliest.

## But what about Export to countries without a manufacturing base?

However, the Doha meeting did not resolve the issue of production for export to countries with insufficient or no manufacturing capacity for pharmaceuticals.

It is vital that companies from a country other than the country issuing the compulsory license should be allowed to supply the products covered by the compulsory license. This is particularly important if the country that issues the license has no manufacturing capacity since it will not be able to meet its healthcare requirements. The ability to respond to such compulsory licenses should be irrespective of the patent situation in the third country.

It should be noted that in Paragraph 6, the Council of TRIPs is required to find a solution to this “problem” by the end of 2002.

Therefore what needs to be agreed by the EU before the end of 2002 is:

- that under TRIPs the manufacture and supply of pharmaceutical goods in response to a compulsory license can be done from any country and not only from countries where the compulsory license has been issued;
- that national patent laws of the EU Member States, the proposed Community Patent Regulation<sup>2</sup> and the proposed Review to the Pharmaceutical Legislation<sup>3</sup> should make it clear that “*the manufacture of medicines by companies other than the patent holder for the purposes of export in response to compulsory license in an other country will not be regarded as a breach of the patent*”.

Moreover, as an answer to the paragraph 6 of the Doha Declaration on TRIPs and Public Health, the EGA proposes the following interpretation of **Article 30 of TRIPs** on *Exceptions to Rights Conferred by a patent*:

***Under Article 30 of the TRIPs agreement, Members may provide an exception to the exclusive rights conferred by a relevant patent to permit acts associated with the production for export to a third country of the patented invention; where the export addresses health needs in the third country; and the product and/or process is either (a) not patented; or (b) a compulsory license has been granted or government use made of the relevant patent in the third country.***

A major opportunity rises for the EU to take a lead on this issue both in seeking a positive interpretation of TRIPs by end of 2002 and to make changes in relevant EU and national laws.

<sup>1</sup> [http://www-chil.wto-ministerial.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](http://www-chil.wto-ministerial.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf)

<sup>2</sup> *Proposal for a Council Regulation on the Community Patent COM (2000) 412 final, Brussels 1-8-2000).*

<sup>3</sup> *Proposal for a Directive amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use*