



EGA Position Paper

Outcome of the WTO Ministerial Conference, Doha, November 2001

Declaration on the TRIPS agreement and Public Health

20 December 2001

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

P.O. Box 193, B-1040 Brussels 4
Phone + 32-2 736 84 11
Fax + 32 2 736 74 38
E-mail: info@egagenerics.com
Website: www.egagenerics.com



Doha Reinforces the Balance in TRIPs

The Doha Declaration on the TRIPs agreement and Public Health¹ 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:

1. 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;
2. that national patent laws of the EU Member States, the proposed Community Patent Regulation² and the proposed Review to the Pharmaceutical Legislation³ 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”***.

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.

¹ http://www-chil.wto-ministerial.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf

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

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