

Screening process
Explanatory meeting with Croatia and Turkey
Brussels, 7 February, 2006

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

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General framework

Doha Declaration on TRIPs Agreement and Public Health – November 2001

WTO General Council Decision - August 2003



Need for a Community Intervention



Regulation: represents an instrument that will allow the compulsory licensing procedure of the WTO decision to fit within the context of MS' national patent law

Main provisions of the Regulation (1)

- **Establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates (SPC) concerning the manufacture and sale of pharmaceutical products (Art.1)**
- **No specific restrictions on the pharmaceutical products covered**
- **Definitions (Art. 2)**
- **Requires notification (Art. 3)**

Main provisions of the Regulation (2)

- **Eligible importing countries (Art. 4 & Art. 4a):**
 - **WTO members**
 - **non WTO members**
- **Prohibits re-importation**
- **Safety and efficacy of medicines for export (Art. 16)**

Timetable

- **Adoption of the proposal of the Regulation – 29 October 2004**
- **Vote in the EP – 1 December 2005**
- **Adoption as point a of the Council – February/March 2006 ?**
- **Entry into force – on the 20th day after publication in the OJ**

Regulation on Compulsory licensing

For further information:

DG Internal Market & Services - D/2 (Industrial Property)

http://europa.eu.int/comm/internal_market/en/indprop/index.htm

DG Trade

http://europa.eu.int/comm/trade/issues/sectoral/intell_property/index_en.htm