Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 29/10/2004 - Legislative proposal

PURPOSE : to allow manufacturers of generic pharmaceuticals to produce patented medicines for export to "countries in need" without sufficient capacity to produce them.

PROPOSED ACT : Regulation of the European Parliament and of the Council.

CONTENT : this proposal aims to implement, at Community level, the WTO General Council Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health. The WTO Decision allows WTO Members to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

The proposed Regulation would set up a system for companies who wish to manufacture medicines for export to apply to national authorities for the grant of a "compulsory licence" from a patent holder who has exclusive rights over the manufacture and sale of the products concerned. Most national laws at present do not allow compulsory licences for export because until recently the WTO TRIPS Agreement provided for compulsory licences only "predominantly for the supply of the domestic market". The Doha declaration on trade and health adopted in November 2001 agreed to address the difficulties raised by this restriction for developing countries with no manufacturing capacity. After long negotiations, on 30 August 2003 WTO members agreed on a waiver giving these countries access to much needed generics. Provided countries in need notify to the WTO the medicines they need, it would be up to generic companies to decide to apply for licences to manufacture them. Once export takes place, all parties have an interest in seeing that medicines are not diverted from those who need them. The Commission's proposal would prohibit re-importation into the EU and provide for customs authorities to take action against goods being re-imported. The patent holder could use existing national procedures to enforce its rights against re-imported goods if they do enter the EU, and the licence could be terminated.

While the EU does not require a medicinal marketing authorisation for exported products, importing countries may want to ensure that medicines are safe and effective. In the proposal provision is made for use of the EU's scientific opinion procedure for evaluating medicines under Regulation 726/2004/EC.

The rules also ensure that marketing authorisations do not lapse for reason of non-use in the EU, and set out exemptions from data protection rules which usually require manufacturers of generic medicines to wait for eight years before they can obtain authorisations using data from previous clinical trials conducted by others.

FINANCIAL IMPLICATIONS : the proposed mechanism is a voluntary one both for the countries in need who seek to obtain affordable medicines and the companies who intend to supply them. Once the legislation comes into force, compulsory licences will be granted by national authorities on the basis of applications from companies and notifications by developing countries that they require particular

pharmaceutical products. No financial assistance is involved. Human and administrative resource requirements will be covered from within the budget at EUR 108.000 per year. The duration of the action shall be from 2005-2010 with a total cost of action set at EUR 648.000.