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

2004/0258(COD) - 01/12/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Johan VAN HECKE (ALDE, BE) by 543 votes in favour, 21 against and 35 abstentions, making several amendments to the Commission's proposal. These compromise amendments were agreed in informal negotiations with the Council.

It is made clear that requests for licensing can come from Non-Governmental Organisations authorised by importing countries or from UN bodies or other international health organisations. In addition:

-Parliament stated in the recitals that the compulsory licensing system should not be used by countries to pursue industrial or commercial policy objectives. This Regulation is designed to create a secure legal framework and to discourage litigation.

-Where pharmaceutical products produced under a compulsory licence have been seized under this Regulation, the competent authority may, in accordance with national legislation and with a view to ensuring that the intended use is made of the seized pharmaceutical products, decide to send these products to the relevant importing country according to the granted compulsory licence.

-In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as, rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic format.

-The simple formula for setting remuneration is intended to accelerate the process of granting a compulsory licence in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement. The figure of 4% could be used as a reference point for deliberations on adequate remuneration in circumstances other than those listed above.

-the scope of the Regulation should not be limited to WTO members but should also include developing countries and least-developed countries. This includes any country that is not a member of WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a GNP per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way. In consequence, a new Article is inserted making provision for notification to the Commission, and for the competent authority to terminate a license if the importing country has failed to honour its obligations with regard to public health only criteria.

-Parliament made some amendments to the clauses dealing with the procedure for application of compulsory licences. It inserted separate headings for "Verification" and "Prior negotiation", and "Compulsory licence conditions", and made some changes to the provisions on these matters.

-A new clause states that the duration of the licence shall be indicated.

- The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority shall give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

-A further new clause states that the procedure of suspension or detention or seizure of the goods is carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

-When the importing country notifies that the amount of pharmaceutical product has become insufficient for meeting its needs, the competent authority may, following an application by the licensee, modify the conditions of the licence permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the licensee's application shall be processed in accordance with a simplified and accelerated procedure. In situations where Article 7(1) applies but the derogation set out in Article 7(2) does not apply, no further evidence of negotiation with the rights-holder will be required, provided that the additional amount requested does not exceed 25% of the amount granted in the original licence.

-Parliament called for the Commission to report to Parliament and the Council every three years on the application of the Regulation, presenting proposals for amendments where necessary.