



**COUNCIL OF
THE EUROPEAN UNION**



C/06/120

Brussels, 28 April 2006

8745/06 (Presse 120)

Adoption of a Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

The Council adopted¹ today in first reading a Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. (*PE-CONS 3674/05*)

This Regulation aims at facilitating and regulating at Community level the granting of compulsory licences for the supply of patented pharmaceutical products to countries in need. After its entry into force, it will allow to handle cases of public health emergencies, such as the avian flu, in poor developing countries lacking the capacity to manufacture such medicines locally.

Intensive cooperation between the Council and the European Parliament has allowed the rapid adoption of this Regulation which is directly applicable in all Member States since the date of its entry into force i.e. on the twentieth day following its publication in the Official Journal of the EU.

The two co legislators agreed to modify the Commission's proposal in particular by widening the list of countries eligible to benefit from the import of products licensed under the Regulation to include not only members of the WTO but also other least-developed and developing countries.

¹ The German delegation abstained.

P R E S S

The text of the Regulation makes clear that the compulsory licensing system set up by this Regulation is intended to address public health problems and therefore it should not be used by countries to pursue industrial or commercial policy objectives. Moreover it specifies that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended.

The issuing of compulsory licences under this Regulation imposes clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which the products will be exported.
