WRITTEN QUESTION E-2482/08
by Jean-Pierre Audy (PPE-DE)
to the Commission

Subject: Effectiveness of compulsory licences and need to review that system

As a result of the Doha Declaration on trade and health of November 2001, supplemented by the 2003 Agreement, it was decided that the issuing of compulsory licences for patents should be possible when the applicant country was beset by serious public health problems. That provision of the Doha Declaration was transposed in Regulation (EC) No 816/2006[1] of the European Parliament and of the Council.

The aim is to enable – where a need exists for pharmaceutical products still covered by a patent in an importing country which qualifies for this system and which is experiencing public health problems but lacks manufacturing capacities – any authorised person to apply for a compulsory licence in order to manufacture those products and export them to the country concerned. However, the conditions that must be fulfilled before a compulsory licence can be granted still appear to be very restrictive in practice, and it may therefore be that those agreements are failing to fully resolve the issue of access to medicines in developing countries.

At a time when numerous problems concerning the counterfeiting of medicines are emerging, can the Commission take stock of the effectiveness of that system and of the guarantees provided for mitigating the risk of re-importation into developed countries and, more generally, of respect for intellectual property rights in this sector?

Would it not be appropriate to contemplate the introduction by the European Union of other mechanisms, more consistent with respect for intellectual property rights, for remedying the public health problems of developing countries?

[1] OJ L 157, 9.6.2006, p. 1.