WRITTEN QUESTION P-3425/05
by Jana Hybášková (PPE-DE)
to the Commission

Subject: Implementation of Directive 89/105/EEC in the Czech Republic

The current system in the Czech Republic concerning the setting of prices and reimbursement levels for pharmaceutical products seems to be in conflict with European legislation.

The Transparency Directive (89/105/EEC[1]) requires that all Member States' decisions concerning the specific and individual amount of reimbursements must be taken in accordance with a transparent procedure and on the basis of objective and verifiable criteria. In addition, they must be supported by a statement of reasons and be subject to judicial review.

Pharmaceutical companies active in the Czech Republic have complained that both Czech legislation and the procedures applied by the Ministry of Health in practice conflict sharply with these key principles of Directive 89/105/EEC. The Czech Pharmaceutical Association MAFS (Mezinarodni asociace farmaceutickych spolecnosti) has apparently provided the Commission with extensive information on the Czech system of pricing and reimbursement and has explained how this system infringes the Directive and the relevant parts of the acquis communautaire.

1. Is the Commission satisfied that the current system in the Czech Republic complies with Directive 89/105/EEC?

2. If the Commission is not satisfied, what steps is it considering, and can it inform Parliament once it has taken each of those steps?

3. Has the Commission already raised the matter with the Czech authorities, or is it planning to do so?

[1] OJ L 40, 11.2.1989, p. 8.