WRITTEN QUESTION P-1533/03
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to the Commission

Subject: Innovative medicinal products in the enlarged European Union

The enlargement of the European Union became a reality in Athens on Wednesday, 16 April 2003 when the Accession Treaty was signed by ten new Member States. This historic event has already had a tangible impact in that the new Member States are already beginning to participate in Community affairs. In this respect, enlargement gives rise to a number of questions concerning the protection of pharmaceutical innovation in some accession countries.

The European Commission and the European Parliament have on several occasions voiced the need to safeguard pharmaceutical innovation, not least by means of the registration data protection granted at the time marketing authorisation is issued for new products.

It now seems necessary to ensure the full and inclusive application of registration data protection, which is an integral part of the Community acquis, in the new Member States as soon as they join the European Union.

There are still certain doubts and fears as regards the situation vis-à-vis registration data protection for products that are covered within the European Union by a Community marketing authorisation granted via the centralised route.

Could the Commission indicate, in these specific but very frequent cases:

- whether the registration data protection granted under the centralised Community procedure for placing on the market will apply in full in the new Member States as soon as they join the European Union;

- and whether the marketing authorisations granted by local authorities in the candidate countries to generic copies of such products prior to accession will become null and void as soon as those countries join the European Union, with the de facto result that these copies are withdrawn from the market?