WRITTEN QUESTION E-2840/01
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to the Commission

Subject: The use of bibliographical data in pharmacological research

Progress in medical science means that expensive research projects must also be carried out on active pharmacological substances which are already on the market, in order to

- record the latest findings on their effectiveness and safety for the existing indication
- develop fields of application in addition to the existing indication or
- demonstrate their effectiveness in certain groups of patients (for example children or high-risk groups).

In particular, this involves clinical trials which can often incur costs of several million euros each.

As the European Court of Justice established some time ago, however, data on out-of-patent active substances can also be used at any time by third-party firms for the approval of their own products, without these firms having to contribute to the sometimes high financial cost of producing the data.

1. Which existing rules does the Commission believe promote the objective laid down in Directive 1999/83/EC[1], fourth recital?

2. What measures does the Commission consider necessary to protect firms engaged in research with regard to the use of bibliographical data by third parties in approval procedures?

3. Is the Commission considering an amendment to the existing approval directive, e.g. introducing terms of copyright for the use of existing data or ensuring that third parties bear a share of the cost?

4. What further steps will the Commission take, for example in the context of the 2001 review, to prevent any disadvantage to pharmaceutical companies which are willing to carry out innovative scientific investigations - which are thus covered by the rules - as part of research into products they already have on the market, as a result of the current competitive situation in the European Union?

[1] OJ L 243, 15.9.1999, p. 9.