The European Federation of the Pharmaceutical Industry Associations published in 1988 a "Memorandum on the Necessity to restore the effective duration of patents for pharmaceutical products"; moreover, additional industry contributions documenting the problem of pharmaceutical product patent erosion were sent to the Member States in 1989.

In 1980, the Commission took the view that it was necessary to protect innovating firms. Directive 87/21/EEC therefore introduced, without prejudice to patent protection, a mechanism which, in particular for "high-technology" medicinal products, prevents a second applicant for marketing authorization from presenting a smaller-scale application for a period of 10 years from the first authorization for marketing of the product in the Community.

The Commission takes the view that it is time to protect further new medicinal products, but that it would be premature to make this proposal a measure of general application without having assessed the need for such a generalised measure or the urgency therefor.

Nevertheless, although it is confined for the time being to medicinal products, the Commission does not exclude the possibility of a medium-term adjustment which, while extending the effects of the proposal to other categories of products, might provide either for a similar or a different legal mechanism, in light of the circumstances and the experience gained in the pharmaceutical sector.

4. Far from being a discriminatory measure in favour of a particular sector, the present proposal for a Regulation aims at guaranteeing laboratories working to develop new medicinal products a level of protection equal to that enjoyed by research in other sectors.

The manifold consequences of maintaining the status quo are reasons enough to have convinced the Commission of the need to try to find a solution at the Community level adapted to the particular problem and taking balanced account of all the legitimate interests involved.