Pharmaceutical industry: products single market

1998/2225(COS) - 25/11/1998 - Non-legislative basic document

PURPOSE : The purpose of this Commission Communication is to launch a debate on the operation of the pharmaceutical market in the European Union. CONTENT : The Communication describes the progress made to date in the pharmaceutical sector : the Community procedures for the authorisation and supervision of medicinal products, the ability to patent innovations in the field of biotechnology, and various breakthroughs in facilitating access to third country markets with the conclusion of the first phase of ICH (the International Conference on Harmonisation) and the signature of mutual recognition agreements with Canada and the United States. The completion of the single market is the most important step needed to make Europe a more attractive R&D investment location, but it is not the only one. Action will have to be taken in parallel to address various other factors shaping the overall climate in which research and innovation take place, such as : access to venture capital, public funding of research, programmes to exploit synergies between the academia and industry or between basic and applied research, public understanding and acceptance of new technologies, including biotechnology and gene therapy. The purpose of the completion of the single market in pharmaceuticals is not just to provide an environment which is favourable for pharmaceutical innovation and industrial development, it is also to improve consumer choices in pharmaceuticals of the required quality, safety and efficacy, at affordable cost. It must be clear that these policy orientations have to lead up to improvements in the provision of healthcare for all citizens. Looking towards the future, the first key question has to be whether the parties to this discussion can agree a set of common objectives founded on agreed basic assumptions. The Communication confirms the basic principle that pharmaceuticals should not be exempted from the Single Market because they are used in healthcare systems; furthermore, it notes that the existence of price control systems are not themselves contrary to the free movement of goods. Parallel trade acts as an important driving force for market integration where there are important differences in prices between Member States. According to the Communication, the practical next steps with respect to the pharmaceuticals sector might be the following : - Discussions between the Commission and the Member States to develop ideas for greater reliance on market mechanisms to meet regulatory objectives and to develop increased competition in the context of individual national health systems; - An assessment, in the light of the above discussions, of the eventual need to modify the Transparency Directive. Key parts of that assessment would concern the reasons for delays in launching products on to the market and consideration of whether the Directive needed updating to take account of evolutions in healthcare systems since the original Directive was agreed; - Address and promote co-operation on the evaluation of the therapeutic value of pharmaceuticals, in particular in comparison to alternatives, as well as the systematic collection and analysis of data on the utilisation of data and brands, especially prescription and consumption patterns.