Basic information

1998/2225(COS) COS - Procedure on a strategy paper (historic)	Procedure completed
Pharmaceutical industry: products single market **Subject** 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ECON Economic and Monetary Affairs, Industrial Policy	READ Imelda Mary (PSE)	08/02/1999

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Consumer Protection	COLLINS Kenneth D. (PSE)	17/03/1999

Council of the European Union

Key events

Date	Event	Reference	Summary
25/11/1998	Non-legislative basic document published	COM(1998)0588	Summary
08/03/1999	Committee referral announced in Parliament		
21/04/1999	Vote in committee		
21/04/1999	Committee report tabled for plenary	A4-0205/1999	
04/05/1999	End of procedure in Parliament		
01/10/1999	Final act published in Official Journal		

Technical information

Procedure reference	1998/2225(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 148 Rules of Procedure EP 050

Stage reached in procedure	Procedure completed
Committee dossier	ECON/4/10592

Documentation gateway				
European Parliament				
Document type	**Committee**	**Reference**	**Date**	**Summary**
Committee report tabled for plenary, single reading		A4-0205/1999 OJ C 279 01.10.1999, p. 0005	21/04/1999	
Text adopted by Parliament, single reading		T4-0368/1999 OJ C 279 01.10.1999, p. 0023-0079	04/05/1999	Summary
European Commission				
Document type		**Reference**	**Date**	**Summary**
Non-legislative basic document		COM(1998)0588	25/11/1998	Summary

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.

Pharmaceutical industry: products single market

1998/2225(COS) - 04/05/1999 - Text adopted by Parliament, single reading

Without debate, the European Parliament adopted the resolution by Imelda Read (PSE,UK) on the communication from the Commission on the single market in pharmaceuticals. The report warmly welcomes the Commission communication and calls on the Commission to bring forward a proposal to complete the internal market in pharmaceuticals, based on the following principles: - encouraging innovation through a competitive market and an appropriate regulatory framework; - protecting new medicinal products by intellectual property rights both in the EU and in third countries; -

guaranteeing the availability of medicinal products providing optimum health protection for European citizens; - guaranteeing the availability of medicinal products providing optimum health protection for European citizens; - creating the right economic conditions so that important medicinal products are actually available throughout the Union; - developing EU-wide measures to promote research on innovative therapies which are particularly important from the point of view of public health and encouraging research into diseases which cannot yet be treated satisfactorily and into rare diseases. The Commission is called upon to establish a framework for a dialogue between all stakeholders (governments, patients' organisations, the pharmaceutical industry, trade unions etc.) on how to manage jointly the fast pace of change in the health area. The Parliament notes, once again, that the pharmaceutical industry has a different economic structure in comparison to other industries. It urges the Commission to remember that the further development of a European-based pharmaceutical industry forms a positive contribution to pharmaceutical competition, including both SMEs and research-based firms. It demands that the Commission continue to monitor closely mergers and competitive structures in the pharmaceutical sector in compliance with Community competition policy, especially given the ability of SMEs in the sector to innovate in direct competition with larger enterprises. The Parliament believes that it is essential to complete the internal market in pharmaceuticals, but stresses that this market must first and foremost consider the needs of the public for safe, effective and high quality pharmaceutical products, while ensuring that European citizens have timely access to innovatove and affordable medicines. It strongly urges the Commission, when formulating its proposal to complete the single market in pharmaceuticals, to distinguish between the three sub-sectors of the industry: medicines that are available for sale directly to patients without prior medical endorsement ("over-the-counter" medicines), medicines which are patent-expired ("generic" medicines) and medicines which are still in-patent. Any legislation needs to provide for there to be appropriately trained staff available to advise customers who are purchasing over-the-counter products. The Parliament would welcome a proposal for a comprehensive evaluation of the pharmocovigilance system, including the European Medicines Evaluation Agency (EMEA). It recalls its belief in the importance of transparent procedures which define the method by which prescription medicines can be transferred to non-prescription status. Finally, the report calls for a review of the directive on the transparency of measures regulating the prices for medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC) to ensure that the delays observed by the Commission for pharmaceutical products to reach the market are minimised.