Procedure file

Basic information

COS - Procedure on a strategy paper (historic)	1994/2032(COS)	Procedure completed
Pharmaceutical industry: outlines of an instrustrial policy for the pharmaceutical sector Subject 4.20.04 Pharmaceutical products and industry		

Key players

European Parliament			
Council of the European Union	Council configuration	Meeting	Date
	Consumers	1917	23/04/1996

Key events

01/03/1994	Non-legislative basic document published	COM(1993)0718	Summary
02/05/1994	Committee referral announced in Parliament		
19/03/1996	Vote in committee		Summary
18/03/1996	Committee report tabled for plenary	A4-0104/1996	
16/04/1996	Debate in Parliament		
16/04/1996	Decision by Parliament	T4-0170/1996	Summary
16/04/1996	End of procedure in Parliament		
23/04/1996	Resolution/conclusions adopted by Council		Summary
13/05/1996	Final act published in Official Journal		

Technical information

Procedure reference	1994/2032(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142
Stage reached in procedure	Procedure completed
Committee dossier	ECON/3/05324

Documentation gateway					
Non-legislative basic document		COM(1993)0718	02/03/1994	EC	Summary
Committee report tabled for plenary, single reading		A4-0104/1996 OJ C 141 13.05.1996, p. 0006	19/03/1996	EP	
Text adopted by Parliament, single reading		T4-0170/1996 OJ C 141 13.05.1996, p. 0020-0063	16/04/1996	EP	Summary

Pharmaceutical industry: outlines of an instrustrial policy for the pharmaceutical sector

This communication aimed to outline the industrial policy guidelines to be applied to the pharmaceutical sector in the Community. On the basis of the idea that this industry required a market that was better integrated and where competition was freer, the Commission intended to give priority to the following aspects: - consolidating and progressively updating existing pharmaceutical legislation in a manner that was codified, transparent and easily accessible to health enterprises and professions, and ensuring that Community legislation was fully and correctly transposed by the Member States; - implementing as soon as possible the future system for the authorisation of medicines for human and animal use, particularly by contributing to the establishment of the European Medicines Evaluation Agency, in close cooperation with the competent national authorities and firms concerned; - ensuring and improving the protection of intellectual property for genuinely innovative therapeutic inventions, so as to ensure protection similar to that available in the main rival markets; - creating a more favourable environment for biotechnology through the adaptation of the regulatory framework to the needs of research and current international developments; - promoting the integration and coordination of research and development work in the pharmaceutical sector within the context of the fourth framework programme for R&D; - monitoring the effects on the operation of the internal market of national measures to control prices and reimburse medicines where they were of a discriminatory nature and with the aim of ensuring transparency and exploring the need to adapt Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, in the light of experience; - increasing competition in the pharmaceutical market, by making it more transparent and by making it possible to encourage competition through prices; - providing health professionals and consumers with sufficient information to promote the rational use of medicines, particularly through the harmonisation of labels and indications for use, and the updating of a computerised database on medicines that would subsequently be available to the public (ECPHIN); - continuing and stepping up harmonisation efforts at global level in order to reduce the costs of research and development in the pharmaceutical sector and facilitate the opening up of external markets to medicines produced in the Community. ?

Pharmaceutical industry: outlines of an instrustrial policy for the pharmaceutical sector

The report by Mrs Irene SOLTWEDEL-SCHÄFER (V, D) on the outlines of an industrial policy for the pharmaceutical sector was adopted by the Committee on Economic and Monetary Affairs with a very small majority (26 in favour, 24 against). Given the very close vote and the extremely broad differences of opinion on most of the amendments, the chairman asked the rapporteur to try to reach a compromise before the vote in the House. Many amendments were tabled (66 in all); some of the main points adopted were as follows: - ensuring that governments cut back the cost of using medicines. A critical eye would need to be kept on this process of restructuring to ensure that monopoly situations did not arise; - monitoring mergers in this sector and increasing the cost-effectiveness of research rather than implementing a policy based on deregulation and subsidies; - putting an end to the industry's frenetic use of advertising; - encouraging real innovation; - protecting new medicinal products through intellectual property rights; - enabling pharmaceutical companies to begin, in advance of patent or protection certificate expiry, such laboratory experiments and regulatory preparations as may be required for the registration of generic products so that they may be available on the market after the expiry of the patent; - concentrating research on innovative therapies, diseases which could not yet be treated satisfactorily and rare diseases; - establishing dialogue between politicians, employers, unions and patients; - improving access for SMEs to research and technological development, particularly in the field of biotechnology; - developing the European Medicine Evaluation Agency (EMEA) as a Europe-wide licensing authority; - reducing the number of animal experiments; - improving the marketing of herbal and homeopathic medicines by adjusting the authorisation procedure and setting up a Traditional Medicines Evaluation Agency; - promoting responsible self-medication; - implementing a responsible export policy. ?

Pharmaceutical industry: outlines of an instrustrial policy for the pharmaceutical sector

In adopting the report by Mrs Irene SOLTWEDEL-SCHÄFER (V) by 233 votes to 162 and 5 abstentions, Parliament called for: - governments to cut back the cost of using medicines. A critical eye should be kept on the resultant restructuring, to ensure that monopoly situations do not arise; - the close monitoring of mergers in this sector, an increase in the cost effectiveness of research rather than the pursuit of an industrial policy based on deregulation and subsidies; - an end to the industry's frenetic use of advertising; - the encouragement of genuine innovation; - the maintenance of protection for new medicinal products by intellectual property rights; - the introduction of measures, in advance of patent or supplementary protection certificate expiry, enabling the beginning of such laboratory experiments and regulatory preparations as may be required for the registration of generic pharmaceuticals, so that they may be available on the market after the expiry of the patent; - the focusing of research on innovative therapies, diseases which cannot yet be treated satisfactorily, and rare diseases; - the establishment of a dialogue between the politicians, employers, unions and patients; - better access to research and development for SMEs, particularly in the biotechnology field; - the development of the European Medicines Evaluation Agency into a Community-wide licensing authority; - the reduction of animal experiments; - improvement in the marketing of herbal and homeopathic medicines through the adjustment of the authorization procedure and the setting-up of a Traditional Medicines Evaluation Agency; - the encouragement of responsible self-medication; - the introduction of a responsible policy on exports; - the Commission to consider what instruments were best suited to disseminating information, independent of the industry, on the effects and the risks of medicinal products (Green amendments). It should be noted that

Parliament accepts that, whilst some fears have been expressed about the risks of genetic engineering, it is justified and desirable that all types of research should continue, with scrupulous respect for human and animal life, particularly in the development of new therapies for diseases which are not as yet susceptible to any form of treatment. ?

Pharmaceutical industry: outlines of an instrustrial policy for the pharmaceutical sector

The Council formally adopted a resolution on an industrial policy for the pharmaceuticals sector, the text of which was contained in the press release issued at the Industry Council meeting of 28 March 1996 (doc. 6059/96, Presse 75).