Procedure file

Basic information

INI - Own-initiative procedure	2001/2270(INI)	Procedure completed
Health implications of the Directive 93/42/EEC of 14 June 1993 on medical devices Subject 4.20.02 Medical research 4.20.04 Pharmaceutical products and industry 4.60.02 Consumer information, advertising, labelling 4.60.08 Safety of products and services, product liability		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy	PSE MALLIORI Minerva Melpomeni	22/01/2002

Key events

17/01/2002	Committee referral announced in Parliament		
23/04/2003	Vote in committee		Summary
23/04/2003	Committee report tabled for plenary	A5-0125/2003	
03/06/2003	Decision by Parliament	T5-0232/2003	Summary
03/06/2003	End of procedure in Parliament		
18/03/2004	Final act published in Official Journal		

Technical information

Procedure reference	2001/2270(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Implementation
Legal basis	Rules of Procedure EP 54; Rules of Procedure EP 142-p2
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/15650

Documentation gateway

Committee report tabled for plenary, single reading		A5-0125/2003	23/04/2003	EP	
Text adopted by Parliament, single reading		T5-0232/2003 OJ C 068 18.03.2004, p. 0023-0085 E	03/06/2003	EP	Summary

Health implications of the Directive 93/42/EEC of 14 June 1993 on medical devices

The committee adopted the own-initiative report by Minerva Melpomeni MALLIORI (PES, GR) on the health implications of Directive 93/42/EEC on medical devices. It said that some medical devices needed to be reclassified and that the directive provided a suitable legal framework for this purpose. The committee stressed, however, that a distinction should be made between medical devices having a pharmacological effect (which were subject to another directive drawn up in 2001) and those which did not. Clinical data needed to be available and relevant for the medical device in question, in particular for Class IIA, IIB and III devices. The Commission was asked to explain in writing whether soft PVC medical devices complied with the essential requirements laid down in the 1993 directive. The report underlined that post-market surveillance (PMS) must be improved so as to reflect the risks involved with the device and recommended that a system be put into place for tracking high risk devices. Amongst its other recommendations, the committee stressed the need for correct informative labelling and leaflets containing instructions for use, which also describe any possible side-effects of the devices. The Member States were urged to ensure that single-use devices were not re-used, given the risk which such re-use posed for patients and hospital staff. Steps should be taken to promote research and studies in this area. Lastly, the report wanted to see the implementation and follow-up of the findings and conclusions of the working group on Notified Bodies (NBOG) set up in July 2000. ?

Health implications of the Directive 93/42/EEC of 14 June 1993 on medical devices

The European Parliament adopted a resolution based on its own-initiative report drafted by Minerva Melpomeni MALLIORI (PES, Greece) on the health implications of certain medical devices. (Please see the summary dated 23/04/03).?