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

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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.