Procedure file

Basic information

COS - Procedure on a strategy paper (historic)	2002/2171(COS)	Procedure completed
Health protection: breast implants, Community and national measures Subject 4.20.01 Medicine, diseases		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy	PSE STIHLER Catherine	10/07/2002
	Committee for opinion	Rapporteur for opinion	Appointed
	FEMM Women's Rights and Equal Opportunities (Associated committee)	PPE-DE OOMEN-RUIJTEN Ria	22/01/2002
	PETI Petitions	PPE-DE FOURTOU Janelly	22/11/2001
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events

15/11/2001	Non-legislative basic document published	COM(2001)0666	Summary
02/09/2002	Committee referral announced in Parliament		
22/01/2003	Vote in committee		Summary
22/01/2003	Committee report tabled for plenary	A5-0008/2003	
13/02/2003	Debate in Parliament		
13/02/2003	Decision by Parliament	T5-0063/2003	Summary
13/02/2003	End of procedure in Parliament		
19/02/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/2171(COS)

Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142; Rules of Procedure EP 57
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16488

Documentation gateway

Non-legislative basic document		COM(2001)0666	15/11/2001	EC	Summary
Committee report tabled for plenary, single reading		A5-0008/2003	22/01/2003	EP	
Text adopted by Parliament, single reading		T5-0063/2003 OJ C 043 19.02.2004, p. 0281-0363 E	13/02/2003	EP	Summary
Follow-up document		SEC(2003)0175	14/02/2003	EC	Summary

Health protection: breast implants, Community and national measures

PURPOSE : to propose measures aiming to improve the quality and safety of breast implants. CONTENT : the present Communication gives a follow-up to this consensus and sets out the various measures both at Community and at national level that should be taken to address the issues raised. These relate to the requirements in relation to breast implants themselves and accompanying measures, not directly related to Community legislation on breast implants, but necessary to provide an appropriate health protection. In 1998, petitions were introduced to the European Parliament, by a group of women having received silicone gel breast implants. In the light of these petitions, the European Parliament ordered a study on "Health risks posed by silicone implants in general with special attention to breast implants". The report presented confirmed the absence of scientific evidence on a link between disease and silicone gel breast implants. It noted, however, that problems do occur, mainly because of the design and characteristics of the product. In subsequent debates between the Commission, European Parliament and national authorities, a widely accepted consensus was generated in favour of a Community wide policy under which the present legal framework would be maintained, but critical specific measures would be introduced to increase and improve information for patients, tracking and surveillance, quality control and assurance, and key research. The present Communication gives a follow-up to this consensus and sets out the various measures both at Community and at national level that should be taken to address the issues raised. These relate to the requirements in relation to breast implants themselves and accompanying measures, not directly related to Community legislation on breast implants, but necessary to provide an appropriate health protection. The proposed measures can be summarised as follows: - information to patients : the Commission considers of utmost importance that, before the intervention, women receive all appropriate information in relation to potential benefits and risks of surgical intervention and breast implants.It invites the Member States, in consultation with all interested parties, including patient organisations and support groups, to adopt measures implementing, at national level, a system of adequate and comprehensive patient information followed by documenting in writing the Patient's Consent. The consultation procedure may include the provision of a 'cool off period' and also recommendations on minimum age for the procedure. It also invites the Member States to ensure, as part of a policy on information to women interested in undergoing a breast implant operation, that in the light of inherent risks related to breast implants, advertising for these products provides balanced information, and that the advertising also suggests that women seek appropriate independent advice, e.g. consult their physician; - research and development, innovation : the Commission proposes an efficient policy in this field should be based on a number of elements, such as before breast implants are placed on the market, manufacturers must collect clinical data on the characteristics and performance of the product; Once breast implants have been placed on the market, or have been implanted, manufacturers must keep up to date a systematic procedure toreview experience gained from devices in the post-production phase including prospective clinical evaluations and implement appropriate means to apply any necessary corrective action. The Commission invites manufacturers, notified bodies and national authorities to take due account of the relevant Directive's provisions; manufacturers must notify the competent authorities of incidents; - medical follow-up : good Medical Practice requires that women, having received a breast implant, are medically followed over a long period of time, to record the effect on health, and to monitor long-term secondary effects. The Commission invites Member States to verify with the medical profession mechanisms under which such monitoring can best take place. The Commission invites Member States to examine the need and possibility to set up, with due respect for confidentiality and the protection of privacy, national registers for breast implantation that should constitute the basis for traceability and long term research on breast implants. Lastly, the Commission invites Member States to transmit to the Commission the national measures adopted in relation to this Communication. It will regularly examine, with national authorities, the impact of the measures promoted by this Communication.?

Health protection: breast implants, Community and national measures

The committee unanimously adopted the report by Catherine STIHLER (PES, UK) welcoming the Commission communication. Among its recommendations, the committee wanted the Member States to ban direct advertising to the public for breast implants or breast implant operations, as France had done. Since breast implants always entailed risks, MEPs demanded that objective, non-commercial information be provided through national public health services instead. The committee said there was a need to regulate advertising in some Member States, which was fuelling the demand for implants without providing balanced information. Advertising for "cosmetic surgery" should carry clear bold health warnings, and 'Before and after' pictures should not be used in such advertisements. Moreover, the focus should be on promoting and securing acceptance of women as they actually are "rather than allowing unregulated advertising practices to impose an ideal conception of

beauty as the norm". MEPs also called for better information for patients, tracking and surveillance, quality control and research. It was necessary to raise general public awareness of the potential risk of breast implants, including adverse effects in the event of pregnancy or for nursing mothers. Implants in women under 18 should be authorised only on medical grounds. The committee called for a compulsory annual follow-up examination and also urged that details of breast implant operations be recorded by a compulsory National Breast Implant Registration system in each Member State, to enable both producers and patients to be traced. Finally, it said that the cost of implants should include a pre-meeting with the surgeon, clear informed discussion of the implications of having implants as well as the alternatives, with a properly trained and accredited independent counsellor, a cooling-off period of no less than four to six weeks, a detailed pre-implant case history, post-implant counselling and periodic review.?

Health protection: breast implants, Community and national measures

The European Parliament adopted a resolution based on the report by Catherine STIHLER (PES, UK) on the Commission Communication. (Please refer to the summary of 22/01/03.) Parliament welcomed the fact that the Commission has adopted virtually all of Parliament's suggestions, particularly with regard to advertising, the information required to be given to patients, the greatest possible guarantees of the quality of implants and the keeping of national registers. It called for the adoption of specific measures to improve information provided to patients, tracking and surveillance, quality controls and quality guarantees, key research on silicone breast implants and their components, and on their clinical evaluation after they are placed on the market, in particular in relation to: - the life span of implants; - methods of improving the protection of the recipient's health; - a full assessment of the health implications and risks; Parliament supported the proposed reclassification of implants as a Class III product under Directive 93/42/EEC, as this will have the welcome effect of reinforcing assessment procedures. It considered silicone breast implants a health priority and requested that funds be made available in the EU research programmes, focusing specifically on the shortcomings of some of the research to date. The labelling of silicone-gel implants should include a warning of the potential health risks. The European Parliament went on to state that there must be comprehensive international lists of specialist medical practitioners in plastic surgery and that this specialist area must, moreover, extend to breast implant surgery and include expertise in the removal of old and defective implants. Member States are asked to ensure that frequent inspections are carried out, particularly in the case of private clinics that perform breast implant operations, using national/regional public health inspectors. The Commission is asked to undertake a review of national measures adopted in relation to this Communication within three years.?

Health protection: breast implants, Community and national measures

PURPOSE : to present a working paper on national measures adopted by Member States in Relation to Breast Implants . CONTENT : the report follows the November 2001 Commission Communication on breast implants which proposed a range of measures to improve the quality of breast implants and patient protection. This communication noted that breast implantation remains an intervention that has, like any other medical intervention, inherent risks. In particular where implantation takes place for cosmetic reasons, women should be able to carefully balance benefits against risks, having all relevant information available. Special rules on minimum age or cool-off period may be necessary to protect the young and impressionable. As advertising can influence decisions, special scrutiny or even prohibition may be necessary. Long term follow-up mechanisms, such as national registers, can be useful although this raises issues of privacy and accuracy of data. In this context, this Commission working paper outlines the measures that Member States have taken since the Commission - in its November 2001 Communication - launched a series of recommendations in this field. Although the Commission has no formal powers in this area, Member States have taken up the challenge of updating or reconsidering existing measures. The Communication, report, and follow-up work, offer a valuable tool to interest groups and national health authorities to promote "best practice" across Europe in health protection. Whilst the report deals with national policies regarding breast implantation, the Commission has focused on rules to increase quality and safety of breast implants themselves. It therefore proposed in February 2003 a Directive which reinforces the verification of quality and safety, making all implants subject to a specific certificate of compliance with these rules. Finally, the Commission has formally invited the European Committee for Standardisation to reconsider the current European standard for breast implants, which will help manufacturers to meet the directive's essential requirements as detailed in the Communication. ?