Basic information

2002/2171(COS) COS - Procedure on a strategy paper (historic)	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	STIHLER Catherine (PSE)	10/07/2002

Committee for opinion	Rapporteur for opinion	Appointed
FEMM Women's Rights and Equal Opportunities (Associated committee)	OOMEN-RUIJTEN Ria (PPE-DE)	22/01/2002
PETI Petitions	FOURTOU Janelly (PPE-DE)	22/11/2001

Council of the European Union

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
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	Decision by Parliament	T5-0063/2003	Summary
13/02/2003	Debate in Parliament		
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 148 Rules of Procedure EP 57_o
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16488

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, single reading		A5-0008/2003	22/01/2003	
Text adopted by Parliament, single reading		T5-0063/2003 OJ C 043 19.02.2004, p. 0281-0363 E	13/02/2003	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2001)0666	15/11/2001	Summary
Follow-up document	SEC(2003)0175	14/02/2003	Summary

Health protection: breast implants, Community and national measures

2002/2171(COS) - 15/11/2001 - Non-legislative basic document

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

2002/2171(COS) - 13/02/2003 - Text adopted by Parliament, single reading

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

2002/2171(COS) - 14/02/2003 - Follow-up document

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.