EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0008/2003

23 January 2003

REPORT

on the communication from the Commission on community and national measures in relation to breast implants
(COM(2001) 666 – C5-0327/2002 – 2002/2171(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Catherine Stihler

Draftsman (*) : Ria Oomen-Ruijten, Committee on Women's Rights and Equal Opportunities

(*) Hughes Procedure

CONTENTS

Page

(*) Hughes Procedure

PROCEDURAL PAGE

By letter of 15 November 2001, the Commission forwarded to Parliament a communication from the Commission on community and national measures in relation to breast implants (COM(2001) 666 – 2002/2171(COS)).

At the sitting of 2 September 2002 the President of Parliament announced that he had referred the communication to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Women's Rights and Equal Opportunities and the Committee on Petitions for their opinions (C5-0327/2002).

At the sitting of 5 September 2002 the President of Parliament announced that the Committee on Women's Rights and Equal Opportunities, which had been asked for its opinion, would be involved in drawing up the report, under the Hughes Procedure.

The Committee on the Environment, Public Health and Consumer Policy had appointed Catherine Stihler rapporteur at its meeting of 10 July 2002.

The committee considered the Commission communication and the draft report at its meetings of 9 December 2002 and 22 January 2003.

At the last meeting it adopted the motion for a resolution by 42 votes to 0 , with 0 abstention.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo and Anneli Hulthén, vice-chairmen; Catherine Stihler, rapporteur; Hans Blokland, John Bowis, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Chris Davies, Anne Ferreira, Karl-Heinz Florenz, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Jutta D. Haug (for Torben Lund), Heidi Anneli Hautala (for Patricia McKenna), Marie Anne Isler Béguin, Karin Jöns (for Riitta Myller), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Paul A.A.J.G. Lannoye, Peter Liese, Giorgio Lisi (for Avril Doyle), Jules Maaten, Minerva Melpomeni Malliori, Jorge Moreira da Silva, Emilia Franziska Müller, Ria G.H.C. Oomen-Ruijten, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini (for Giuseppe Nisticò), Karin Scheele, Ursula Schleicher (for Marialiese Flemming), Horst Schnellhardt, Inger Schörling, Astrid Thors, Antonios Trakatellis, Elena Valenciano Martínez-Orozco, Kathleen Van Brempt, Phillip Whitehead.

The opinions of the Committee on Women's Rights and Equal Opportunities and the Committee on Petitions are attached.

The report was tabled on 23 January 2003.

MOTION FOR A RESOLUTION

European Parliament resolution on the communication from the Commission on community and national measures in relation to breast implants (COM(2001) 666 – C5-0327/2002 – 2002/2171(COS))

The European Parliament,

– having regard to the Commission communication (COM(2001) 666 – C5-0327/2002[1]),

– having regard to Article 152 of the Treaty,

– having regard to Directive 93/42/EEC of the Council of 14 June 1993 concerning medical devices [2],

– having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[3] ,

– having regard to Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma[4],

– having regard to its resolution of 13 June 2001 on the petitions declared admissible, concerning silicone implants (Petitions 0470/1998 and 0771/1998) [5],

– having regard to Rule 47(1) of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Women's Rights and Equal Opportunities and the Committee on Petitions (A5-0008/2003),

A. whereas there is a lack of information on the potential risks with breast implants,

B. whereas thousands of women have petitioned the European Parliament to take a stand on the dangers inherent in the use of silicone breast implants,

C. whereas, in its resolution of 13 June 2001, the European Parliament focused in particular on the safety and quality of products and pre- and post-operative support, recommending a number of specific measures at Community and national level,

D. whereas patients need to know that, for some patients, implants are not for life and may need to be replaced or removed; whereas patients also need to be informed about implant quality and the suitability of implants for the patient concerned,

---

[1] OJ not yet published.
[2] OJ L 169, 12.7.1993, p. 1
[3] OJ L 331, 7.12.1998, p. 1
[4] OJ L 313, 13.12.2000, p. 22
[5] OJ C 53, 28.2.2002, p. 21.

E. whereas rupture occurs significantly, from 5-51% according to studies. Some studies point to a rupture rate of 50% after 7-10 years and up to 95% after 20 years,

F. whereas many women have implants for cosmetic purposes and self-help groups argue that if fuller information on risks and implications was given before surgery fewer women would opt for implants,

G. whereas lack of registration of implants in Europe means that the overall numbers of women with implants are unknown,

H. whereas there are shortcomings of the existing research, e.g., lack of long-term data, no figures for numbers of implants, mixing of different implant types in studies, and insufficient information about the durability of implants,

1. Calls for no complete ban, but the adoption and implementation of critical specific measures to improve information for patients, tracking and surveillance, quality control and assurance and key research on silicone breast implants and their components, and on their clinical evaluation after they are placed on the market, in particular into:
   - the life span of implants;
   - better protection of the health of implant recipients; and
   - full assessment of the health implications and risks;

2. Recommends that implants in women under 18 years of age should be authorised only on medical grounds;

3. Seeks guaranteed marketing control over breast implants to avoid incorrect and misleading information;

4. Underlines the need to facilitate consensus, promotion and support of effective surveillance systems to report adverse effects and long-term effects;

5. Welcomes the fact that the Commission, with a view to addressing the many problems posed, has declared itself in favour of a Community-wide policy, and has set out in its communication to Parliament the Community and national provisions already applying in this area;

6. Welcomes 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;

7. Supports the proposed reclassification of implants as a Class III product under the Medical Devices Directive 93/42/EEC as this will have the welcome effect of reinforcing assessment procedures;

8. Considers silicone breast implants a health priority and requests that funds be made available in the EU research programmes, specifically focusing on the shortcomings of some of the research to date;

9. Considers that labelling of silicone-gel implants should carry warning of potential health risks;

10. Welcomes the Commission proposals to facilitate consensus on a breast implant consent form, including information relating to alternatives, benefits and risks;

11. Believes that all potential patients should have access to free, comprehensive information drawn up by independent experts and points out that doctors and nurses have a particular responsibility to provide reliable, objective, complete and scientifically up-to-date information on all the details of their implants (identification number, volume and type) in writing and in language the patient can understand, and need to be involved after the operation, to facilitate future care; calls on the Member-State authorities to lay down standards for the provision of information;

12. Takes the view that it is necessary to raise general public awareness of the potential risks of silicone-gel breast implants; in particular, women should be aware that in some patients breast implants have to be replaced after a time period that will be different from one person to the other; women, including young women, should be comprehensively and appropriately informed that adverse effects or genotoxic risks in the event of pregnancy or for nursing mothers cannot be completely excluded;

13. Calls for a compulsory annual follow-up examination, the results of which should be made available for research and further development purposes in the interests of patient safety and implant-toleration;

14. Recognises that patients who have already received breast implants may need retrospective information, advice and medical supervision, to screen for cancer and intra- and extra-capsular rupture; points out that for this purpose the use of medical imaging techniques such as scanning, magnetic resonance and echography help surveillance and the accuracy of diagnosis;

15. Recommends the fostering of tolerance and self-esteem and other conceptual alternatives to breast implants, in collaboration with active groups in this field;

16. Urges Member States to concentrate on promoting and securing acceptance of the image of women as they actually are by running positive information campaigns, rather than allowing unregulated advertising practices to impose an ideal conception of beauty as the norm;

17. Calls for alternative methods of operating to maintain breast structure using the body's own tissues to be made better known and more widely promoted;

18. Points out that where Member States apply minimum age limit for the implantation procedure that reconstructive surgery on medical grounds is sometimes necessary at an early age;

19. Urges Member States to prohibit (following the example set by France) advertising direct to the general public for breast implants or breast implant operations (surgical treatment); and instead to disseminate objective, non-commercial information through

their national public health services, in particular - but not exclusively - on the Internet; in any case, in order to avoid incorrect and misleading information there is a need to regulate the advertising in some Member States, which is fuelling the demand for implants without providing any balanced information, and proposes that advertising of 'cosmetic surgery' breast implants should contain a statement that relevant information is available and carry clear bold health warnings;

20. Urges that 'Before and after' pictures should not be used in such advertisements;

21. Recommends urgently that details of breast implant operations should be recorded in the EU by compulsory National Breast Implant Registration in each Member State; calls on Member States to subscribe to the International Breast Implant Register (IBIR) and to assume the costs incurred for national subscription to the international register;

22. Considers that national breast-implant registers are essential as a means of enabling both producers and patients to be traced (in the event of implants being identified as defective it will, in particular, be essential for them to be traceable to the patients concerned after the operation); points out that every effort will have to be made in that connection to ensure compliance with existing provisions on protecting personal privacy in the processing of personal data, and that access to the registers will have to be restricted and their contents treated as confidential;

23. Proposes that manufacturers should supply only to surgeons who observe the European register; an independent monitoring body should monitor this and the results of the monitoring should be published;

24. Also calls for a sound certification procedure for practitioners, to reduce the damage to health from incorrect operations;

25. Considers that, together with the liability on the part of manufacturers of implants, guarantees for patients in respect of surgeons and clinics should be laid down;

26. Suggests that the cost of breast implants should include the following - pre-meeting with the surgeon involved; clear informed discussion of the implications of having implants, as well as the alternatives, with a properly trained and accredited independent counsellor with no financial interest in the patient's eventual decision; a cooling-off period of no less than four to six weeks; detailed pre-implant case history; post-implant counselling and periodic review;

27. Believes 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;

28. Urges the Member States to carry out thorough and frequent inspections particularly in the case of private clinics that perform breast implant operations, using the national/regional public health inspectors;

29. Calls on the Commission to undertake a review of national measures adopted in relation to this Communication within three years;

30. Instructs its President to forward this resolution to the Council, Commission and the parliaments of the Member States.

EXPLANATORY STATEMENT

There is a good deal to welcome in this Commission Communication on Community and National Measures in Relation to Breast Implants but it is regrettable that the document itself has only advisory status for member states. The implantation of silicone-gel breast implants is an important topic, all the more so as the number of implants carried out in member states is apparently increasing. The need to underline its importance is highlighted by the fact that at the time of writing this report only seven of the member states (Belgium, France, Germany, Denmark, Netherlands, Spain and the United Kingdom) have responded to a Commission Report on National Measures Adopted by Member States Related to Breast Implants.

The origins of this Communication lie in lobbying by self-help groups of women who claimed to be suffering adverse effects from silicone-gel breast implants. In 1998, petitions were introduced to the European Parliament calling for a ban on the use of silicone-gel breast implants. In the light of these petitions, the European Parliament ordered a STOA research study on "Health risks posed by silicone implants in general with special attention to breast implants".[1]

Silicone implants were used for years before there was regulation or surveillance of their use. Health concerns about the use of silicone–gel breast implants surfaced in the US and Canada in the 1980s, spreading to Europe in the 1990s. Since 1992 in the US silicone breast implants are only available for women with special medical needs who need breast reconstruction and are willing to become part of a clinical trial approved by the US Food and Drugs Administration (FDA). In Canada a moratorium on the marketing and use of silicone-gel filled breast implants was passed in 1992. Saline-filled breast implants are available.

All EU member states – except France – have no restrictions on the use of silicone-gel breast implants. In France since 1992 silicone breast implants have been restricted. In 1995, all breast implants except saline-filled implants were banned. Surgeons must apply for exemptions in the case of specific medical needs (reconstruction after mastectomy) for silicone implants.

The focus on silicone-gel implants since the 1990s have led to many different epidemiological studies that have consistently showed no evidence of serious risk for major diseases. However, as the studies have started so recently, most cannot look at long-term effects, have mainly focused on links with certain systemic diseases, especially cancer and connective tissue diseases, and have not always controlled for the different types of implants. Hundreds of different types have been marketed and used since they were introduced in 1962. Alongside the medical studies a significant body of women claimed to be experiencing symptoms which they think are linked with their implants. However, the STOA report presented to the European Parliament 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

[1] Health risks posed by silicone implants in general, with special attention to breast implants. PE 168.396/Fin.St/rew; http://www.europarl.eu.int/stoa/publi/pdf/99-20-02_en.pdf.

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:-

Classification of Breast Implants

Breast implants are covered by Directive 93/42/EEC on medical devices[1] as modified by Directives 98/79/EC[2] and 2000/70/EC[3], hereafter the Directive. The Directive contains the essential requirements, in terms of quality and safety, which medical devices like breast implants have to meet, in order to ensure a high level of health protection. These essential requirements are supported by harmonised standards, presenting technical options to meet those essential requirements. The Directive also contains obligations imposed on the manufacturer regarding labelling and information provided to the patient and the physician.

The Directive defines four classes of medical devices (I, IIA, IIB and III), that determine the various conformity assessment procedures to be followed for medical devices. Breast implants are class IIB. The Commission will now present, on the basis of Article 7 of Directive 93/42/EEC, a decision under which breast implants, by way of derogation to the general classification rules, will be Class III products, in order to ensure that, in the framework of a full quality assurance system, the technical file is explicitly the subject of an approval by the Notified Body. This will have the welcome effect of reinforcing assessment procedures. Annex 1 also lists applicable essential requirements, including provisions on information and labelling, and the applicable provisions on clinical evaluation in relation to breast implants.

Informed Patient Consent

Throughout the debate with the European Parliament and national authorities, and through discussions with women, it has become clear that measures applicable exclusively to the technical requirements in relation to breast implants are insufficient to provide the best guarantees for health protection. Implants, like any other surgical interventions, can present side effects. Patients can react differently to interventions or to the implants. Women should be aware that breast implants have to be replaced after a time period that will be different from one person to the other. Because the benefits of breast implantation tend to be of a subjective nature, it is particularly important for women to be adequately informed about the associated risks, so that they can balance these against their personal assessment of the benefits.

[1] OJ L 169, 12.7.1993.
[2] OJ L 331, 7.12.1998.
[3] OJ L 313, 13.12.2000.

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

The Commission proposes that an efficient policy on innovation should be based on a number of elements. 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 to review 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 further 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.

Monitoring National Measures

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.

The Rapporteur broadly welcomes these Commission proposals as a valuable step forwards. She maintains the position adopted in the Environment Committee Opinion on Silicone-Gel Breast Implants. That Opinion supported proposals in line with Option 3 identified by the STOA Report, that is, 'no complete ban, but the adoption and implementation of critical specific measures to improve information for patients, tracking and surveillance, quality control and assurance and key research'.[1]

[1] Health risks posed by silicone implants in general, with special attention to breast implants, p.9. PE

However, further amendments are suggested under each of the headings, which feature in the Commission Communication. These amendments aim to tighten manufacture, usage and monitoring and to further the debate on providing prospective patients and the general public with information on silicone-gel breast implants.

168.396/Fin.St/rew; http://www.europarl.eu.int/stoa/publi/pdf/99-20-02_en.pdf.

18 December 2002

OPINION OF THE COMMITTEE ON WOMEN'S RIGHTS AND EQUAL OPPORTUNITIES

for the Committee on the Environment, Public Health and Consumer Policy

on the communication from the Commission on community and national measures in relation to breast implants

(COM(2001) 666 – C5-0327/2002 – 2002/2171(COS))

Draftsperson*: Ria G.H.C. Oomen-Ruijten

* Hughes procedure

PROCEDURE

The Committee on Women's Rights and Equal Opportunities appointed Ria G.H.C. Oomen-Ruijten draftsperson at its meeting of 22 January 2002.

The committee considered the draft opinion at its meetings of 5 November 2002 and 3 December 2002.

At the last meeting it adopted the following conclusions unanimously.

The following were present for the vote: Anna Karamanou, chairperson; Marianne Eriksson and Olga Zrihen Zaari vice-chairpersons; Ria G.H.C. Oomen-Ruijten, draftsperson; María Antonia Avilés Perea, Regina Bastos, Lone Dybkjær, Ilda Figueiredo, Marie-Hélène Gillig, Lissy Gröner, Karin Jöns, Christa Klaß, Rodi Kratsa-Tsagaropoulou, Astrid Lulling, Maria Martens, Christa Prets, Amalia Sartori, Miet Smet, Patsy Sörensen, Feleknas Uca and Sabine Zissener.

CONCLUSIONS

The Committee on Women's Rights and Equal Opportunities calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its motion for a resolution:

– whereas breast implants are needed for both aesthetic breast correction and breast reconstruction but many women can suffer seriously as a result of such surgery because of inadequate information, incorrect insertion of implants or the use of an inappropriate product,

– whereas the lack of information often relates to the information given to patients, and the quality and life-span of implants or their suitability for the patients concerned,

– welcoming the communication on Community and national measures in relation to breast implants and noting the incorporation of many of the recommendations made by the European Parliament in its resolution on silicone implants, but underlining the fact that matters relating to public health and health care are mainly competences of the Member States,

1. Emphasises that high priority should be given to research into breast implants and their components, and into their clinical evaluation after they are placed on the market, in particular into

– the life-span of implants,
– better protection of the health of implant recipients, and
– full assessment of the health implications and risks;

2. Points out that doctors and nurses have a particular responsibility to provide reliable**,** objective, complete and scientifically up-to-date information on all the details of their implants (identification number, volume and type) in writing and in language the patient can understand and need to be involved after the operation, to facilitate future care; calls on the Member States authorities to lay down standards for the provision of information;

3. Stresses the need to provide women, including very young women, with full and appropriate information on the consequences and genotoxic risks in the case of pregnancy and breast-feeding;

4. Recommends that the Member States introduce a sound certification and traceability procedure for implants and the products used in order to increase the reliability of implants and hopes that information on this will be made available;

5. Also calls for a sound certification procedure for practitioners, to reduce the damage to health from incorrect operations;

6. Calls for alternative surgical techniques, preserving the breast by using the patient’s own tissue, to be made more widely known and encouraged;

7. Calls on the Member States’ authorities to establish a national register of breast implant patients, providing a clear record of their medical aftercare, experience and best practice;

to this end considers that patients should give their consent in writing, after a period of consideration, on its use for the purposes of scientific research; points out that due account must be taken of existing law on the protection of privacy when processing personal data, that access to the registers must be restricted and that their content must be treated as confidential;

8. Considers that there is a need to regulate the advertising in some Member States**,** which is fuelling the demand for implants without providing any balanced information;

9. Underlines the importance of medical supervision after breast implant surgery, to screen for cancer and intra- and extra-capsular rupture; points out that for this purpose the use of medical imaging techniques such as scanning, magnetic resonance and echography help surveillance and the accuracy of diagnosis;

10. Calls for the introduction of a passport for implant recipients, and for compulsory aftercare examinations at an interval of no more than 12 months, the results of which must in the interest of safety and compatibility be made available for research and further development;

11. Urges the Member States to carry out thorough and frequent inspections particularly in the case of private clinics that perform breast implant operations, using the national/regional public health inspectors.

16 December 2002

OPINION OF THE COMMITTEE ON PETITIONS

for the Committee on the Environment, Public Health and Consumer Policy

on the communication from the Commission on Community and national measures in relation to breast implants
(COM(2001) 666 – C5-0327/2002 – 2002/2171 (COS))

Draftsman: Janelly Fourtou

PROCEDURE

The Committee on Petitions appointed Janelly Fourtou draftsman at its meeting of 22 November 2001.

It considered the draft opinion at its meetings of 3 and 9 December 2002.

At the latter meeting it adopted the following conclusions unanimously.

The following were present for the vote: Roy Perry, vice-chairman and acting chairman; Janelly Fourtou, draftsman; Nuala Ahern (for Jean Lambert pursuant to Rule 153(2)), Proinsias De Rossa, Marie-Hélène Descamps, Glyn Ford, Margot Kessler, Ioannis Koukiadis and Eurig Wyn.

SHORT JUSTIFICATION

I. Background to the Commission proposal

It should be pointed out that it is thanks to two petitions addressed to Parliament by citizens concerned about the safety of silicone breast implants that this communication has been published. The report presented by Parliament relating to those petitions - based on a STOA study and adopted unanimously – essentially called for rules to protect patients' health and to improve the marketing, quality and testing of implants, without, however, recommending a total ban on implants.

We consequently welcome the Commission communication, the purpose of which is to lay down the measures to be adopted at the Community and national level in order to address issues relating to requirements in respect of breast implants themselves and the accompanying measures necessary to ensure a suitable level of health protection.

II. Assessment of the proposal

We are pleased to note that the Commission communication is along the right lines.

Virtually all of the suggestions put forward by the European Parliament in its resolution of 13 June 2001 have been adopted, including those relating to advertising, the information required to be given to patients, greater guarantees of the quality of implants and the call to the Member States to keep national registers and to provide for a consent form.

However, we consider that the proposal should be improved in relation to the following points:

- The communication states that '*The consultation procedure may include the provision of a 'cool off period' and also recommendations on minimum age for the procedure.*' We consider that patients under 18 years of age should not receive breast implants for cosmetic surgery purposes, in accordance with the position adopted by the European Parliament in its resolution of 6 June 2001.
- Under the proposal, manufacturers bear almost all of the liability, and there is no reference to authorisation of surgeons or clinics. It is essential, with a view to protecting patients' health, that surgeons or clinics provide guarantees.
- Finally, the communication does not adopt the idea of the 'passport', which we believe would provide an effective basis for the European database that is to be set up. Furthermore, such a 'passport' would enable patients to be fully informed about the operation which they have undergone and the implant itself.

III. Conclusions

We therefore welcome the Commission communication on breast implants. For us, this is a way of demonstrating to petitioners that we fulfil our commitments.

CONCLUSIONS

The Committee on Petitions calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. whereas thousands of women have petitioned the European Parliament to take a stand on the dangers inherent in the use of silicone breast implants,

2. whereas the May 2000 STOA (Scientific and Technological Options Assessment) report on 'Health risks posed by silicone implants in general with special attention to breast implants' did not rule out these dangers,

3. whereas the Committee on Petitions submitted a report to the European Parliament on petitions declared admissible concerning silicone implants, and whereas the relevant resolution was adopted unanimously by Parliament on 13 June 2001 (A5-0186/2001)[1],

4. whereas, in that resolution, the European Parliament focused in particular on the safety and quality of products and pre- and post-operative support, recommending a number of specific measures at Community and national level,

5. Welcomes the fact that the Commission, with a view to addressing the many problems posed, has declared itself in favour of a Community-wide policy, and has set out in its communication to Parliament the Community and national provisions already applying in this area;

6. Welcomes 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;

7. Calls for patients under 18 years of age not to receive breast implants for cosmetic surgery purposes;

8. Considers that, together with the liability on the part of manufacturers of implants, guarantees for patients in respect of surgeons and clinics should be laid down;

9. Calls for the idea to be adopted of issuing persons who have received an implant with a 'passport' containing various information on the implant itself and on the surgical operation undergone.

[1] OJ C 053E/2002