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COMMUNICATION FROM THE COMMISSION

**ON COMMUNITY AND NATIONAL MEASURES IN RELATION
TO BREAST IMPLANTS**

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(Text with EEA relevance)

Table of contents

1.	Background	3	
2.	Directive 93/42/EEC and its application to breast implants	3	
3.	Content of Informed Patient Consent	4	
4.	Research and Development; Innovation	5	
5	Monitoring of policy measures.....	6	
Annex 1 - ESSENTIAL SAFETY REQUIREMENTS AND CONFORMITY ASSESSMENT SCHEMES OF DIRECTIVE 93/42/EEC ON MEDICAL DEVICES IN RELATION TO BREAST IMPLANTS.....			7
I.	Introduction	7	
II.	General Requirements.....	7	
III.	Pre-market assessment.....	8	
IV.	Post-market surveillance by the manufacturer	11	
V.	Information – Labelling	11	
Annex 2 - INFORMATION TO BE PROVIDED TO WOMEN WHO ARE CONSIDERING RECEIVING BREAST IMPLANTS			13
I.	Information on implants.....	13	
II.	Information on surgery	14	
III.	Effects	14	
IV.	Contraindications.....	15	
V.	Monitoring/who to contact.....	15	
VI.	General information.....	15	

1. BACKGROUND

Although overall figures are not available, it is estimated that in Europe an increasing number of women receive breast implants. Breast implants can be used either for reconstructive surgery, or for cosmetic reasons in plastic surgery. Breast implants are placed in the breast as part of a surgical operation.

There are various types of breast implants, based on the filling material: silicone gel breast implants, saline filled breast implants, hydrogel or soybean oil filled breast implants. They present different characteristics, such as consistency-viscosity and “feeling”, expected life-time, or molecular migration.

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”, carried out by a team of scientific advisers led by Prof. Moreno. The report presented¹ 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. These relate mainly to bleeding (diffusion of small molecules of the liquid component of silicone through the intact shell), capsular contracture (shrinkage of the fibrous capsule, notable as an apparent hardening of the breast) and rupture of the shell (phenomenon that can be due to handling and trauma).

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.

This Communication deals only with breast implants. Throughout this communication reference is made to women, although men may undergo similar surgery.

2. DIRECTIVE 93/42/EEC AND ITS APPLICATION TO BREAST IMPLANTS

Breast implants are covered by Directive 93/42/EEC on medical devices² as modified by Directives 98/79/EC³ and 2000/70/EC⁴, hereafter the Directive. The Directive contains the essential requirements, in terms of quality and safety, which medical devices like

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.

² OJ L 169, 12.7.1993.

³ OJ L 331, 7.12.1998.

⁴ OJ L 313, 13.12.2000.

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.

In order to ensure a consistent implementation of the Directive's provisions, the Commission.

- Considers that the applicable essential requirements, including provisions on information and labelling, and the applicable provisions on clinical evaluation in relation to breast implants, are to be applied by taking into consideration the elements contained in Annex I to this Communication.
- Will submit, in conformity with the provisions of Directive 98/34/EC⁵, a mandate to CEN, inviting CEN to reconsider the European standard EN 13350 on breast implants in the light of this Communication.
- Will 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.

3. CONTENT OF 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.

The Commission considers therefore 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.

Therefore, bearing in mind the provisions of article 152 of the Treaty, the Commission

- Invites 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

⁵ OJ L 204, 21.7.1998.

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 draws the attention to the elements contained in Annex II, that might constitute a basis for action at national level.

- Invites 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.

4. RESEARCH AND DEVELOPMENT; INNOVATION

The Commission acknowledges the importance to be attached to a continuous search for improvement in the clinical performance of breast implants, to improve the knowledge of the quality of breast implants, to increase the knowledge of short and long-term effects on health of breast implants and to the knowledge of side effects.

An efficient policy in this field should be based on a number of elements, part of which are already contained in Directive 93/42/EC⁶:

- Before breast implants are placed on the market, manufacturers must collect clinical data on the characteristics and performance of the product. Annex I indicates the way the Commission expects manufacturers, notified bodies and national authorities to implement the Directive's provisions in relation to pre-clinical data and clinical evaluation.
- 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.
- In accordance with the Directive, manufacturers must notify the competent authorities of incidents⁷ as indicated in the Directive. Member States must take steps to ensure that such information is recorded and evaluated centrally. Data thus obtained will be part of the European database, currently being set up under the Directive.
- 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.

⁶ OJ L 169, 12.7.1993.

⁷ Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to above to systematic recall of devices of the same type by the manufacturer.

- 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.
- The Commission is aware that Member States and third countries have launched vast research programs and reviews, such as the UK 1998 Report on Silicone breast implants by Independent Review Group. The Commission will regularly discuss the outcome of studies in the expert meetings it has with national authorities and manufacturers.

5 MONITORING OF POLICY MEASURES

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.

Annex 1

ESSENTIAL SAFETY REQUIREMENTS AND CONFORMITY ASSESSMENT SCHEMES OF DIRECTIVE 93/42/EEC ON MEDICAL DEVICES IN RELATION TO BREAST IMPLANTS

I. INTRODUCTION

This annex refers to the essential requirements laid down in Annex I of Directive 93/42/EEC and the applicable provisions on conformity assessment of the said Directive, with a view to specify relevant Community provisions applying to breast implants.

Regarding Annex I of the Directive, this communication refers, in particular, to the general requirements under section I, the requirements on chemical, physical and biological properties under point 7, section II, as well as requirements on information supplied by the manufacturer under point 13, section II.

Regarding conformity assessment schemes, particular attention is given to the clinical evaluation as defined under section 1 of Annex X of Directive 93/42/EEC.

In order to ensure a consistent and correct application of the provisions referred to above in relation to these medical devices, the legislated requirements are to be understood along the following lines.

II. GENERAL REQUIREMENTS

Breast implants must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition, the safety or the health of patients. Any residual risks or undesirable side-effects that may be associated with their use must constitute acceptable risks when weighed against the benefits to the patient taking into account their benefit is primarily deemed to be aesthetic and psychological in nature, whether the application is for reconstructive and/or cosmetic purposes.

When designing breast implants the manufacturer must perform a risk analysis to ensure that all known and anticipated hazards are clearly identified and take all appropriate and well documented measures to eliminate or reduce risks as far as practicable.

Risk analysis and conformity evaluation shall be performed on the filler material, the shell and the breast implant.

The main questions regarding the use of breast implants are:

- the rate of rupture;
- the rate of capsular contracture;
- potential for migration of the filler;

- bleed of the filler.

Specific attention must be paid to ensure that the clinical condition and safety of the patient is not compromised during the expected lifetime of the device under conditions of normal use.

III. PRE-MARKET ASSESSMENT

The manufacturer shall address in his assessment the items enumerated below. He shall evaluate the data and submit his design specifications to the Notified Body concerned for evaluation in accordance with the applicable assessment procedures. The data obtained shall be taken into account in the risk analysis.

1. Design attributes

The following factors shall be taken into account:

- materials and their biocompatibility, including wear and degradation products from materials used;
- physical, mechanical and chemical properties of materials taking into account effect of manufacturing processes;
- extent and effects of leakage and/or diffusion of filler substances through an intact shell (bleed);
- ability to detect rupture;
- compatibility between the implant and body tissues;
- ability to implant, to remove and to replace the implant.

2. Pre-clinical data

Materials used for implants and coatings for the manufacture of breast implants shall be selected with regard to properties required for the intended purpose of the implant, taking into account the effects of manufacturing processes on materials and the possible reactions of the device after implantation. The effect of ageing on the chemical, biological and mechanical properties of the materials shall be investigated.

A comprehensive pre-clinical technical dossier shall be established and evaluated covering the points specified hereafter.

In particular, *in vivo* studies may be necessary to investigate the way the body handles the filler materials and to characterise potential toxic hazards (including immunotoxicity and reproductive toxicity) arising from chronic exposure.

A. Materials and components

A.1. Chemical analysis

a) Shell material, silicone elastomer or coated materials

An analysis of the extractable or releasable chemicals (especially low molecular weight materials characterisation and quantification) is necessary for the assessment of the safety of the device.

b) Filler materials

A detailed chemical characterisation of the filler material shall be established.

Long term stability data, established under physiological conditions, and accelerated ageing studies shall be provided to demonstrate the effects of time and temperature on the physical and chemical characteristics of the device.

A.2. Toxicology

The local and systemic toxicity of any substance introduced into the body by the breast implant shall be assessed.

The toxicological evaluation shall be based on the chemical characterisation and toxicokinetics of the materials, available scientific data addressing toxicological hazards or risks and, where necessary, specific testing.

The evaluation shall address the potential for short-term and long-term effects, including cytotoxicity, haemo-compatibility, genotoxicity, immunotoxicity and other forms of systemic toxicity, reproductive toxicity and carcinogenicity. This evaluation shall be taken into account in the risk analysis (see Section II, general requirements).

Knowledge of the toxicokinetics of potentially toxic or reactive ingredients or degradation products is necessary when these could be released into the body in substantial quantities following implantation. Information on distribution, transformation and elimination applicable to the route of exposure is thus necessary.

A.3. Mechanical properties

All testing shall be performed on finished sterilised devices or components.

a) Cohesivity of silicone gel

Cohesivity testing shall be performed to measure both the rheological properties and the integrity of the gel in order to allow optimising between clinical performance and safety.

b) Rupture of shell

In order to ensure a sufficient low rupture risk, test data with

respect to ultimate elongation, tensile strength and tear resistance of the shell material shall be considered, following appropriate test methods. The adequacy of the pass/fail criteria adopted shall be verified prior to testing.

B. The shell

The bleed rate of the filler through the lastomer shell shall be determined.

Compatibility between the filler material and the shell shall be demonstrated by providing long terms data on shell performance and integrity.

Effects of shell surface texture on surrounding tissues shall be evaluated.

Each type of patch/shell joint and valve/shell joint shall ensure an appropriate resistance to failure.

C. The implant

Static rupture testing, fatigue rupture testing and impact testing shall be performed on the device following appropriate test methods and test data analysed so as to ensure a low rupture rate of the device during normal conditions of use. The adequacy of the pass/fail criteria adopted shall be verified prior to testing.

Possible reactions of implants with radiation and electromagnetic fields shall be evaluated.

Surface abrasion/wear of the shell shall be tested by a method stimulating in vivo conditions.

3. **Clinical evaluation**

The purpose of the clinical evaluation is to estimate the frequency and rate at which local complications, in particular capsular contracture and ruptures/deflation of implants, occur after a correct implementation of a breast implant.

The secondary surgical procedures required for correction of complications shall be assessed. Other complications could be detected such as post-operation infection, folding, etc. which however are related to surgical conditions rather than to the actual breast implant.

The clinical data shall be based upon an appropriate duration of patient follow-up and a sufficient number of representative patients, to allow for an accurate analysis of the results.

The clinical data provided by the manufacturer shall originate:

- either from prospective clinical investigations performed with the concerned breast implants in compliance with an appropriate programme or,

- from the literature, from previously performed clinical investigations or data based on experience from the use of implants having the same design parameters and performance characteristics as the breast implants to be evaluated.

When using data from the literature, or obtained using other products, a number of criteria must be fulfilled, namely:

- Equivalence between the subject device and those that are the subject of the reports must be demonstrated in terms of critical design parameters and performance characteristics.
- All data used must be generated from well-controlled clinical trials or properly designed and conducted cohort or case/control studies or well-documented case histories. Clinical data should be generated, reported and critically assessed by appropriately experienced and knowledgeable experts. Ideally, data should be published in peer review journals. Evidence put together from isolated case reports, random experience, reports lacking sufficient detail to permit scientific evaluation or unsubstantiated opinions is inadequate for this purpose.

The criteria for acceptance (i.e. safety and effectiveness) of clinical evaluation shall be clearly identified in order to allow a risk/benefit assessment and to provide evidence of the safety and the performance of the implant.

4. Arrangements for post-market surveillance

As part of the pre-market requirements, the manufacturer must also institute arrangements for prospective clinical evaluation of long term performance and complication rates. These arrangements must foresee for the analysis of capsular contracture rate, rupture rate and systemic effects after pre-established periods of time.

IV. POST-MARKET SURVEILLANCE BY THE MANUFACTURER

When the pre-market evaluation of a specific breast implant has been successfully completed, the manufacturer must implement the post-market clinical evaluation programme for the implant concerned in line with the arrangements established during the pre-market assessment.

V. INFORMATION – LABELLING

The manufacturer shall supply the following information on the label or as data in the instructions for use:

- for the user, in particular:
 - a device description and indications for use;
 - contra-indications for implantation, if any, precautions for surgery;

- instructions for implantation /explantation, training requirements;
- training opportunities available;
- effects of the implants on diagnostic techniques (e.g. mammography)
- how and how often to evaluate the implant integrity;
- for the patient, an information package, in written form, containing in particular the following information:
 - potential complications and their possible resolution;
 - anticipated benefits and risks;
 - activities which could damage the implant;
 - possible need for device removal/replacement.
 - expected longevity of the breast implant, preferably expressed as percentage survivorship at ten years (or earlier if ten-year information is not yet available), in accordance with the Kaplan Meier method.
- on the label, the following information:
 - traceability information batch code/serial numbers and expiry date;
 - the word “STERILE”
 - the words “SINGLE USE”.

Annex 2

INFORMATION TO BE PROVIDED TO WOMEN WHO ARE CONSIDERING RECEIVING BREAST IMPLANTS

Women who are considering receiving breast implants should receive all relevant and up to date information allowing them to make a well-informed and considered decision, in full knowledge of the potential risks and benefits of the intervention and the breast implants. Women should be aware that breast implants are a long-term commitment.

As a basis for the information to be prepared at national level, meant to be provided to women, the elements indicated hereafter might be used. They have been identified through a comparative analysis of systems of informed patient consent, as promoted in various countries⁸, and by the European Committee on Quality Assurance and Medical Devices in Plastic Surgery (EQUAM),

Information should be provided exclusively in the interest of the women receiving the breast implant, in a way that is easily understandable and in the national language(s). This information may be presented as an information pack containing information on implants, surgery, potential effects, contra-indications, monitoring information, contact details and information of a general nature.

Given the relation between the physical and health position of women and expected benefits or risks, the person best placed to provide this information is the physician experienced in the field. It is their task to provide information on an objective basis, in line with medical ethics and professional codes of practice.

This does not exclude that part of the information to be discussed between the women and the physician has to be provided by the manufacturer, in written form, as part of their obligations in putting the product on the market. The information provided by the manufacturer is described in annex I section 13 of Directive 93/42/EEC and additional clarification is provided in annex I of this communication.

This annex does not deal with issues relating to the consequences for insurance coverage or cost.

I. INFORMATION ON IMPLANTS

Women should receive all relevant information on breast implants, including guidance criteria for the selection of given types of breast implants.

This includes:

- Types of implants (e.g. silicone, saline.....), characteristics, differences
- Status/legal position of types of breast implants
- Information by the manufacturer on the product

⁸ In particular United Kingdom, France, Canada and the United States.

- Benefits and risks, particularly rupture, bleeding, capsular contracture; symptoms related to these risks.
- Expected life-span; implant removal and implant replacement
- Criteria for selection

II. INFORMATION ON SURGERY

Women should receive all relevant information on the surgery itself. They should be informed on the various surgery procedures and techniques, and on the limitations of surgery. They should be aware that further surgery might be necessary, and that the outcome may be determined by personal factors. They should be informed on follow-up to be given to the surgery. They should have realistic expectations of outcome, also concerning the aesthetic aspects over time.

Information should relate in particular to the following elements:

- Reconstruction and augmentation procedures; what can be achieved; alternatives to implants (tissue expansion....)
- Selection of surgery techniques; position of implants; anesthesia
- Timing of surgery
- Additional surgery
- Post operative care
- Symptoms to be reported
- Special conditions, e.g. for women with breast cancer
- Health checklist to assess the risks for women.

III. EFFECTS

Women should know about the potential effects of breast implants. This should concern short term and long term effects. A distinction should be made about effects on health and, as dissatisfaction with the result is an element that is found in all current forms on Informed Patient Consent, aesthetic considerations. Women should know that effects can be irreversible.

Special attention should be given to the following:

- Short term health effects, such as bruising, pain, swelling, bleeding, infection, nipple sensitivity, likely recovery time;
- Long term health effects, such as wrinkles, folds, capsule formation, rupture linked to the implant, calcification, symptoms to be noted;

- Aesthetic effects, such as position of pockets, symmetry, appearance of scar, displacement of the implant, dissatisfaction with result
- Effect on breastfeeding
- Effect on cancer detection, screening, mammography
- Hypothesized risks, such as connective tissue diseases and related disorders; symptoms, cancer, effect on children in particular through breast-feeding
- Precautions to be taken (sport, driving, alcohol, smoking).

IV. CONTRAINDICATIONS

The physicians should pay particular attention to women who are not indicated for breast implants and to the absence of safety and effectiveness for patients with conditions such as auto-immune diseases, conditions that interfere with wound healing and blood clotting, a weakened immune system, reduced blood supply to breast tissue.

V. MONITORING/WHO TO CONTACT

Women should be aware of the need to be closely monitored after surgery, both at the short and at the long term. They should know the effect of breast implants on living conditions. The physician may have to be involved.

Elements to be taken into account are:

- Post operation monitoring
- Long term monitoring
- Breast self-examination
- Participation in surveillance programs
- Screening for rupture
- Symptoms to be noted; actions to be taken
- Information to the general practitioner on suggested follow up and possible long-term health effects.

VI. GENERAL INFORMATION

Finally, information of a general nature should be made available. This can concern:

- Scientific evidence made available by public authorities on effects of breast implants, on fillers.

- R&D carried out in co-operation with or under the aegis of public authorities
- Information made available to the public by manufacturers
- Health organizations
- Patients' organizations
- Public authorities.