European Parliamentary Petitions Committee

Women & Children Exposed to PIP Implants Denied COMPASSION, TRUTH, TRANSPARENCY, Access to HEALTHCARE & JUSTICE

The Institutional Victimisation & Abuse of Women Exposed to PIP Implants

"Given the sensitivity of the issue … the Ombudswoman urges the Commission to closely follow possible new scientific data in this particular area, in order to ensure that its position is as accurate and up-to-date as possible."

"The objective of the Petitions Committee is to provide a response to all petitions and, when possible, to provide a non-judicial remedy to legitimate concerns on issues related to the EU fields of activity which petitioners raise with us."

https://youtu.be/DiL3ASZQp1o

The Problem

More than 100,000 EU women and well over half a million women worldwide are believed to have been exposed to CE Marked PIP implants. In 2012, the SCENIHR scientific committee was asked by Parliament to report on the emerging public health crisis. The SCENIHR report was finally published in October 2014, almost 4 years after the warning was sounded and the PIP factory was closed by French police. The conclusions were completely at odds with the experiences of the women, many hospitals, clinics, surgeons and doctors.

The most striking of all was the SCENIHR conclusion that no action was necessary.

No urgent need to remove PIP. No need for monitoring. No need for patient information or advice. No treatment algorithm, no concerns for developing embryos, breast-fed infants or pregnant women, recovering cancer patients or for previously healthy women of reproductive age who had undergone elective surgery.

There were no risk assessments or health impact reports. Other agencies such as the European Chemicals Agency had not been consulted and REACH regulations had been ignored.

The SCENIHR report concluded there was simply no good evidence to justify doing anything at all. Which completely vindicated the British who had already resolved to do nothing.

The Complaint

Acting on behalf of women with PIP implants, PIP Action Campaign submitted a complaint to the EU Ombudswoman in 2015.

- Case: 174/2015/FOR
- Opened on 27 Feb 2015 - Decision on 27 Oct 2015
- Institution(s) concerned: European Commission
- Field(s) of law: Environment, consumers and health protection
- Types of maladministration alleged – (i) breach of, or (ii) breach of duties relating to: Impartiality, independence and objectivity [Articles 8 and 9 ECGAB]
- Subject matter(s): Institutional and policy matters

The Ombudswoman made a concluding remark:

The Commission should continue to evaluate new scientific data relating to the safety of PIP implants.

The European Commission, PIP Implants & Breast Implant Cancer

Shortly after the publication of the Ombudswoman's decision, responsibility for Class III Medical Devices was moved from DG Sanco (consumers) to DG Enterprise & Industry (business). After some delay and a re-writing of the Rules of Procedure for the scientific committees and disbanding of SCENIHR, the Commission announced a *Call for Information* as an intermediate step necessary to determine whether new evidence on PIP was available. The SCHEER Committee made the Call for Information on PIP and a separate Call for information on ***breast implant cancer***.

Both calls were of concern to women with PIP. The SCHEER committee on PIP comprised three men and did not include a medical doctor: both breaches of the Rules of Procedure for a review.

While women were waiting for the SCHEER committee to report on the *Call for Information*, DG Santé (Health) appeared to take responsibility for the findings of the SCHEER committee and advised PIP Action Campaign, in a tweet, there had been a delay in the report of the findings of the committee as "***more work was needed"***.

PIP Action Campaign had taken part in the PIP *Call for Information* and had submitted over 75 relevant, peer-reviewed papers, in the format required by the committee along with a document titled REAL WORLD EVIDENCE - the information collected in a health survey completed by women with PIP.

In October 2017 PIP Action Campaign received an email from the SCHEER Secretariat stating that while there is new evidence relating to PIP there is insufficient new evidence to justify a review. Therefore the conclusions of the 2012-14 SCENIHR stand, unchanged.

The Concerns

Women exposed to PIP are actively obstructed from receiving help, information, diagnostics, histologies and the treatment they need as a direct consequence of the SCENIHR report and SCHEER *Call for Information* which have had the effect of undermining the seriousness of the risk to women's health, safety and well-being.

VIOLATIONS of Rights & Entitlements

Women and children have rights to the highest attainable standard of health (UNITED NATIONS article 12 of the International Covenant on Economic, Social and Cultural Rights) and an entitlement to a system of health protection which provides the highest attainable level of health. Discriminatory Practices and violation of obligations to ***respect***, ***protect*** and ***fulfil*** have all adversely impacted women and children exposed to PIP implants.

Contraventions

1) Failure to recognise women's rights to access appropriate high standard of healthcare: including appropriate diagnostics, histology, treatment, monitoring, early-warnings and research.

   Treaty on the Functioning of the European Union - PART THREE: UNION POLICIES AND INTERNAL ACTIONS - TITLE XIV: PUBLIC HEALTH - Article 168 (ex Article 152 TEC)

2) Failure to ensure all those exposed to PIP implants receive timely access to affordable, preventative and curative health care of good quality health care including surgery to safely remove PIP implants

   Pillar of Social Rights 16. Health care

   EU Charter of Fundamental Rights Article 35 A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

3) The Commission has acted to limit liability to women exposed to PIP implants. Both its self-referenced reports are inherently flawed, the importance of peer review cannot be over-emphasized. Peer review is the means by which experts can evaluate and validate the quality of a scientific report. The Commission's reports have taken years to produce and have resulted in documents that deny a causal link between defect and damage and assert there is no evidence of toxicity, carcinogenicity, harm or injury. Council Directive 85/374/EEC **liability for defective products** Article 4 : The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

4) Failure to protect the physical well-being of the consumer

Council Directive 85/374/EEC **liability for defective products** : the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect.

5) Failure to act on Adopted Texts and Resolutions of the European Parliament Strasbourg 2001 (Annex I) and Strasbourg 2003, (Annex II) resulting in prolonged and unnecessary suffering, particularly for vulnerable women, recovering cancer patients, pregnant women and mothers exposed to PIP.

6) Failure to acknowledge scientific uncertainty associated with PIP implants and failure to adequately assess, appraise, manage and communicate risks.

   Failure to utilise RAPEX (Rapid Alert System for dangerous products) resources specifically designed to keep consumers safe https://europa.eu/!wv67qv

   Communication from the Commission on Precautionary Principle http://europa.eu/rapid/press-release_IP-00-96_en.htm

7) The Commission has determined an unacceptable level of risk for women and their babies exposed to PIP and has failed to take any responsibility for the standard of inquiry into PIP implants by so called “experts” in the preparation of the SCENIHR Report and the SCHEER *Call for Information*. The Commission has failed to provide a reasoned and structured framework for action in the face of scientific uncertainty. Communication from the Commission on Precautionary Principle http://europa.eu/rapid/press-release_IP-00-96_en.htm

8) Failure to insist on the Precautionary Principle with particular regard to exposure to chemicals found in PIP or still unidentified. Not limited to but including:

   1,1,2,2-tetrachloroethane

   D4 Octamethylcyclotetrasiloxane

   D5 Decamethylcyclopentasiloxane

   Vinyl Chloride: International Agency for Research on Cancer (IARC) has recognised vinyl chloride as a 'human carcinogen' since 1979.

   Phthalates

Ethylene Oxide (EO) C/EDC: Ethylene Oxide is an important industrial chemical used mainly in the manufacture of other chemicals and chemical products such as antifreeze, polyester, solvents, detergents, and polyurethane foam. It is also used as a fumigant (foods and spices), as a steriliser (medical and dental), and for pest control (textiles, books, furniture, product packaging). It is found in breast implants (as a result of the sterilizing process)

CONSOLIDATED VERSION OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION, PART THREE, UNION POLICIES AND INTERNAL ACTIONS, TITLE XX, ENVIRONMENT Article 191 1. Union policy on the environment shall contribute to pursuit of the following objectives: protecting human health,

9) Failure to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, and has failed to follow-up and update scientific and technical knowledge concerning the safety of PIP implants in particular and breast implants in general.

Directive 2001/95/EC General Product Safety Article 9 a,b and c.

10) Failure to ensure a high level of **consumer** protection for women exposed to PIP implants. Failure to contribute to protecting the health, safety and economic interests of consumers exposed to PIP implants. Failure to respect and promote women's rights to information and education. Women affected have been excluded from all review meetings and their representatives from acting to safeguard women's interests by participating in consultations.

Lisbon Treaty Article 169

Directive 2001/95/EC General Product Safety

11) Failure to acknowledge and respect women's victims rights.

Directive 2012/29/EU Victims Rights

12) Failure to insist on basic safety protections for medical devices patients, in particular women with PIP implants for medical reasons including BRCA and Breast Cancer

Lisbon Treaty Article 168, Article 4: European Parliament and the Council, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(c) setting high standards of quality and safety for medicinal products and devices for medical use.

13) Failure to handle the PIP implant Public Health Crisis fairly and within a reasonable time.

EU Charter of Fundamental Rights Article 41 - Right to good administration

14) Lack of transparency and discharge of regulatory duties, including adverse event reporting, by private companies acting as regulatory authorities. Preventing access to information on measures taken in response to concerns raised by Health Professionals and National Competent Authorities, and failing to protect the health and safety of consumers.

93/42/EEC Article 20 Confidentiality
General Product Safety Directive 2001/95/EC CHAPTER VII Final provisions Article 16

15) Failure to ensure exposed women, pregnant women and mothers access to up-to-date and accurate information
General Product Safety Directive 2001/95/EC Article 9 1. a,b,c

16) Failure to insist upon a high level of independent inquiry and study into the dangers of PIP implants to all those exposed, including children.

General Product Safety Directive 2001/95/EC Article 9 1. (b)

17) Provide easy access to redress, compensation and restorative justice for women exposed to PIP, Rofil in EU and worldwide. (EU : Collective Redress, Victims Rights and key protections. Directive 2012/29/EU establishing minimum standards on the rights, support and protection of victims of crime

18) Failure to conduct an adequate Risk Assessment examining the available evidence to assess the extent of the immediate and long-term damage to health of exposed women, embryos, infants and children to leaking and/or ruptured PIP implants. (EU:Precautionary Principle) Treaty establishing the European, Community Part Three: Community policies Title XIII: Public health Article 152

Commission failure to conduct adequate Risk Assessment involving

(a) *Hazard Identification*: a determination of potential adverse consequences of the product or action, and the strength of the evidence;
(b) *Exposure-Response Analysis*: a determination of the relationship between the exposure to the hazard and the probability of resultant harm; and
(c) *Exposure Assessment*: a determination of the exposure of individuals, populations or the environment to the hazard and hence the degree of harm that they might suffer.

19) Failure to conduct an adequate Risk Assessment examining the available evidence to assess the extent of the immediate and long-term damage to health of exposed embryos, infants and breast-fed children to leaking and/or ruptured PIP implants.

EU Charter of Fundamental Rights Article 24 - The rights of the child (2). In all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration.

20) Failure to provide support, including immediate assistance, longer-term physical and psychological assistance and practical assistance:

Directive 2012/29/EU minimum standards on the rights, support and protection of victims of crime

21) No urgency to remove leaking and ruptured PIP implants: failure to obviate PIP implants as a source of danger to physical and mental health

Lisbon Treaty Article 168

22) Failure to ensure a high level of consumer protection for women with PIP implants. Failure to contribute to protecting the health, safety and economic

interests of women with PIP implants. No consideration for time off work and impact on mental health or family life for the women affected, including very vulnerable women. Lisbon Treaty Article 169

23) No Civil liability provision. Notified Body has not activated CIVIL Liability Insurance as set out in Medical Devices Directive 93/42/EEC Annex XI Article 6.

24) Failure to insist on compassion, respectful treatment and recognition as victims for women exposed to PIP.

Directive 2012/29/EU minimum standards on the rights, support and protection of victims of crime

25) Failure to provide victims with protection from intimidation, retaliation and further harm by notified body in court proceedings.

Directive 2012/29/EU minimum standards on the rights, support and protection of victims of crime

26) Failure to ensure that victims are aware of their rights and understand them, and are able to participate in proceedings.

Directive 2012/29/EU minimum standards on the rights, support and protection of victims of crime

EU Charter of Fundamental Rights Article 47 Right to an effective remedy, a fair trial and access to legal aid and representation.

The Worrying Developments Overlooked by the Commission & scientific committees

- **Breast Implant Cancer (BIA-ALCL, BI-ALCL)**
- Causal link established between breast implants with texturized implants such as PIP *confirmed* by IARC and WHO.
- Women with ruptured and leaking PIP implants have *died* from Breast Implant Cancer (BIA-ALCL)
- **Toxicity**
- D4 (now partially banned in EU) is a cyclic siloxane and endocrine disruptor chemical found at high levels in PIP implants. *Octamethylcyclotetrasiloxane or* D4 CAS 556-67-2 has been classified as REPRO-TOXIC for many years. D4 and the other toxins in the D-series of toxic contaminants, are of a low molecular weight and can migrate throughout the body, cross the placenta and can be found in breast milk. All of most particular concern to PIP implant mums and dads with poorly babies.
- Evidence of the spread of silicone is demonstrated in a published autopsy report.
- **Persistent Organic Pollutants**
- European Council recommended D4 to the **Stockholm Convention** as a Persistent Organic Pollutant of serious concern.
- **Banned Phthalates & other carcinogens in PIP**
- Commercial secrets and confidentiality clauses in the Medical Devices Directive prevent patients, doctors, researchers and regulators from understanding the true risks to health of PIP implants in particular, and breast implants in general.
- **Carcinogens, Xenoestrogens & Endocrine Disruptor Chemicals found in PIP**
- Confidentiality clauses in the MDD mean women and surgeons are prevented from knowing what is in implants, or what evidence of safety has been provided to CE License implants. It prevents patients from taking properly informed decisions about the true risks & costs of breast implant surgery.
- **Infants exposed to developmental toxins in PIP during pregnancy & while breastfeeding**
- Experiments of no scientific merit have been relied on as evidence to evade a duty of care to women, particularly vulnerable and pregnant women.

- **Monitoring and incidence of other types of cancer including breast, brain, lung and liver cancer, autoimmune illness and deaths in women and children exposed to PIP implants.**
- There is still no functioning Compulsory Registry, in most member states.
- **Imposed financial pressures on all women exposed to PIP including young single mothers, low-paid families, women with mental and physical health problems, recovering breast cancer patients and low-paid and unemployed women, particularly in times of economic austerity.**
- Private clinics have been unable to activate Civil Liability Insurance to help patients with urgent revision surgeries, some are not qualified to help. Plastic Surgeons undergo general medical training, then as many as 7yrs more years developing the skills, knowledge, judgment, safety and ethics in the specialism. A Cosmetic surgeon is not a recognised term by any professional medical body in the world. In fact, anyone can call her or himself a "cosmetic' surgeon and some vets, GPs, opticians, beauticians do. People have suffered unimaginable harm from unqualified surgeons in the EU and abroad. Patients desperate to remove PIP implants are vulnerable and easy to exploit with offers of cheap surgeries by unqualified people.

- **Patients, Drs, Surgeons, front-line emergency staff, radiologists, oncologists, hematologists and breast cancer clinics should all have access to the peer reviewed reports and encouraged to submit patient reports. Self referenced reports, of questionable scientific value to support a policy of inaction in a Public Health crisis is a scandal.**

- Plastic surgeons treating women with PIP need support and information to deal with leaking and ruptured PIP, lymph node involvement, Breast Implant Cancer testing and capsule removal surgeries, which are often complex and lengthy surgeries for women to undertake.

The Implications for women exposed to PIP implants are serious, so why are they ignored in favour of a policy of denial & inaction?

- Without financial resources women have been prevented from accessing help to remove PIP implants.
- Patient & doctor reported observations missing
- No information or treatment algorithms for surgeons, radiographers, for front line medics such as GPs or Emergency Department doctors
- Recognition of Symptoms: missing
- Removals and future on-going biomonitoring: missing
- Incomplete treatments
- Incorrect diagnostics
- Failure to monitor
- No psychological support
- No Long Term Studies
- No Recognition or monitoring in PIP exposed infants & children
- No Recommendation to preventatively remove all banned PIP implants.
- No collective redress or compensation
- No health impact reports
- No operational registers
- No patient information or follow-up
- No involvement from medical doctors or women affected or their representative organisations.

The impact of the Commission's self-referenced reports into PIP implants has been, and continues to be, unimaginable pain and wholly avoidable harm.

We have attached the parliamentary resolutions of 2001 and 2003, that unequivocally demonstrate the level of care and safety women with silicone implants were assured by the European Parliament, almost two decades ago. (*Annexes I and II*)

Our Petition

Women exposed to PIP implants ask the European Parliamentary Petitions Committee to bring about meaningful change for all affected: to insist on truth, transparency and accountability in Medical Devices Regulation and insist on respect and dignity and access to a high standard of healthcare for all the victims of the international PIP health crisis.

Parliament should immediately remove all the obstructions to access to information healthcare, diagnostics, future long term monitoring for victims and any PIP exposed children.

We ask the European Parliament to act urgently and insist the Commission respects women's basic rights and legal protections. Regulators should urgently implement CIVIL LIABILITY indemnity and assist with access to healthcare, treatment guidelines, ongoing future monitoring and collective redress.

Parliament should immediately recognise the need for funding to support ongoing treatment protocols, information portals for patients and doctors, access to appropriate diagnostics, monitoring, healthcare and therapies and independent scientific inquiry.

Parliament should not accept self-referenced, politically motivated documents of little or no scientific merit to address a global health crisis recognised by the World Health Organisation.

Parliament should never accept misogyny, victimisation and negative stereotyping of women as fair, proportionate or appropriate response to an international public health crisis.

Parliament should publicly distance itself and women from the damaging SCENIHR report and SCHEER *Calls for information* and the fake science generated by manufacturers and Commission's scientific committees.

Parliament should publicly apologise to the doctors and victims of the PIP scandal for the role of the Commission in prolonging trauma, pain and suffering.

Parliament should lend political support for justice for all women exposed to the dangers of PIP and other non-compliant breast implants.

Charter of Fundamental Rights

The right guaranteed in this Article is the right guaranteed by Articles 20 and 227 of the Treaty on the Functioning of the European Union. In accordance with Article 52(2) of the Charter, it applies under the conditions defined in these two Articles.

Article 44 - Right to petition

Any citizen of the Union and any natural or legal person residing or having its registered office in a Member State has the right to petition the European Parliament.

Annex I

Parliamentary Resolution 2001

European Parliament resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/1998 and 771/1998) (2001/2068(INI))

1. Welcomes the fact that the Commission will be issuing a communication in 2001 setting out measures to ensure that implants meet the highest possible standard of safety and quality;

2. Points out that, as far as silicone implants are concerned, attention must focus primarily on the safety and quality of the products and one pre- and post-operative support;

3. Recommends in particular that the measures to be proposed should cover the following points:

(a) all patients should have access to complete information free of charge from independent experts,
(b) any advertising for breast implants for use in cosmetic surgery should carry health warnings and warnings of the risks, residual risks and sequelae inherent in every surgical operation,
(c) every person in whom an implant has been inserted should be issued with a passport listing the specifications of the implant and the post-operative precautions to take; the passport should constitute the consent form and be signed by the surgeon and the patient,
(d) detailed information about breast implantations, necessary follow-up operations and other follow-up measures should be recorded in the EU, and, to that end, each Member State should keep a compulsory national breast implant register,
(e) the above mentioned patient register should serve as a database for long-term research into silicone implants and must be compiled in such a way as to respect the principle of confidentiality and patients' privacy,
(f) in the case of an implantation, pre- and post-operative support should comprise: a preliminary meeting with the surgeon who will be performing the operation, clear information about the residual risks and possible side-effects of an implantation and the alternative solutions, a sufficient cooling-off period, an

exhaustive inquiry into the patient's medical history, to be completed beforehand, and post-operative care, including an annual check-up

(g) breast implants for cosmetic surgery should not be inserted into patients under 18 years of age;

4. Stresses the need to draw up research programmes in order to bring about European legislation seeking to expand and perfect the measures affording better protection of the health of persons in whom implants have been inserted and to improve certification, marketing and testing of implants and the technical standards governing implants;

5. Recommends that further scientific and clinical research be carried out, specifically focusing on some of the shortcomings of research to date:

- long-term outcomes - illness and health, systemic health effects at sites distant from the implant (not just autoimmune disorders and cancer), and possible effects on the health of children of women with implants;

- reliable techniques for measuring silicone concentrations in body fluids and tissues, and tissue responses to the presence of silicone;

- local complications, including local effects at the site of the implant;

6. Recommends treatment and aftercare for victims of silicone implant damage in accordance with the latest research findings;

7. Considers that the Commission must do everything possible to be consistent with the philosophy underlying the criteria of the European precautionary principles;

8. Instructs its President to forward this resolution to the Commission, the Council, and the petitioners.

Annex II

Parliamentary Resolution 2003

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))

1. Calls for the adoption and implementation of essential specific measures designed 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;

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

3. Seeks a guaranteed control over the marketing of breast implants, so as to avoid incorrect and misleading information;

4. Underlines the need to facilitate consensus on, and to promote and support, effective surveillance systems to report adverse 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 applicable 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 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, focusing specifically on the shortcomings of some of the research to date;

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

10. Insists that before a date for a silicone-gel implant operation is agreed with a patient, she must be handed a copy of the patient information and advice sheet drawn up by the relevant national authority (e.g. the formula proposed by EQUAM) containing a warning of potential health risks; this should, moreover, contain a recommendation urging that an operation should only be agreed to after all outstanding questions have been unambiguously settled;

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

12. Calls for the introduction of an implant recipient's passport in which the special characteristics of the implant and post-operative follow-up care measures are specified; the passport must be signed by the surgeon and the patient, and be valid as a consent form for the operation;

13. 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 implants (identification number, volume and type) in writing and in language the patient can understand; considers that they also 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 ;

14. 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 cases, breast implants have to be replaced after a period of time that varies from person to person; 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;

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

16. Recognises that patients who have already received breast implants may need retrospective information, advice and medical supervision, screening for cancer and for 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;

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

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

19. Calls for the alternative operative methods of maintaining breast structure by using the body's own tissues to be made better known and more widely promoted;

20. Points out that where Member States apply minimum age limits for the implantation procedure, reconstructive surgery on medical grounds is sometimes necessary at an earlier age;

21. Urges Member States to ban, following the example set by France, the direct advertising to the general public of breast implants or breast implant operations (surgical treatment) and, instead, to disseminate objective, non-commercial information through 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 advertising in some Member States, which is fuelling demand for implants, without providing any balanced information; proposes that advertising of "cosmetic surgery" breast implants should contain a statement stipulating that relevant information is available and should also carry clear, bold health warnings;

22. Urges that "Before and after" pictures should not be used in such advertisements;

23. Urgently recommends that details of breast implant operations should be recorded in the EU in the form of a 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;

24. Considers that national breast-implant registers are an essential means of enabling both producers and patients to be traced (in the event of defective implants being identified they will, in particular, be essential in tracing 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;

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

26. Also calls for a sound certification procedure for practitioners, so as to reduce the damage to health as a result of incorrect operations;

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

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

29. 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;

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

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

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