PIP Action Campaign

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For the Urgent Attention of the EU Ombudswoman, Emily O'Reilly

London, 3 November 2017

Dear Ms Emily O'Reilly,

Further to our complaint 174/2015/FOR and the last of your remarks: " ***The Commission should continue to evaluate new scientific data relating to the safety of PIP implants",*** we are writing to inform you that the Commission separated our concerns and made Calls for information on PIP Implants and on breast implant cancer. A step, they said, was necessary to assess whether new evidence was available for a review.

PIP Action Campaign submitted over 70 relevant, full text, peer reviewed papers which had not been included or published at the time of the SCENIHR report, in response to the PIP implant call for information, and submitted them in zip files to the Scheer secretariat by the deadline date.

This was by no means an easy task. Full text, published research papers are usually only available through subscriptions to medical journals intended for health professionals and usually involve substantial subscription costs. Nevertheless, with the help of concerned health professionals, chemists, pathologists, toxicologists, regulatory experts, medical researchers, surgeons and doctors, we were able to submit a large number of relevant, peer reviewed papers, in the format required by the committee and in accordance with the Rules of Procedure governing the Scheer committee.

We also compiled our own data, based on information shared by our members and produced a document which referenced our member health survey and other documents such as individual doctors or surgeons case notes, reports by the Dutch Public Health Authority RIVM and publications from ANSM, the French Competent Authority responsible for the collection of the most comprehensive evidence available based on 30,000 PIP removal surgeries in France. We called this document PIP Action Campaign's Real World Evidence. Our document was fully cited and referenced and we sent copies to you and to Mrs Evans at DG Grow who forwarded our document to the SCHEER committee.

Just over a year later, we were informed by email received on the 27th October 2017 that our submissions had been dismissed by the Scheer committee:

"Regarding the submitted information PIP Action Campaign does a summing up of many possibilities and many

questions on the safety of PIP implants. SCHEER shares these concerns. However, SCHEER, as a scientific committee, does have in place its own strict methodological procedures, according to which an Opinion of SCHEER needs to be scientifically based and verifiable.

So, an Opinion or Advice needs to be supported by scientific information available in the literature. For PIP the only scientific information available at the moment, in relation to toxicity/health risk is the rupture rate which is high when compared to other brands of SBI as it is addressed in the Advice on PIP toxicity."

In February of 2017 as we waited for the publication of the Scheer report, we were informed by EU Health in a tweet, there had been a delay in the publication of the report because "***more work was needed"***. We were encouraged at first that the matter was to be addressed by Health rather than Business at the Commission and then appalled when, after a very long delay on the 27th October 2017, we were informed in the case of PIP ***the SCHEER committee found there is new evidence BUT that it is insufficient evidence to justify a review.***

We were also shocked to learn that the breast implant cancer call for information had also been shrugged off by Scheer. PIP Implants are implicated in BIA-ALCL deaths with one of the most highly implicated brand Silimed closely resembling PIP 2 gels.[1]

It seems the European Commission has failed to grasp the seriousness of non-compliant Class III, medical devices and the health consequences for women.

These horrifying, ***self-referenced*** conclusions, from Scheer & SCENIHR, ***have the direct effect of imposing unnecessary and prolonged suffering on sick and vulnerable women by undermining and obstructing access to care, diagnostics, treatment, research and future monitoring.***

In the UK and Ireland women have not been advised to remove banned PIP implants and many women still have them. It is well-known that contaminants found in PIP are Endocrine disrupting chemicals, recognised as reprotoxic xenoestrogens by REACH. ECHA has conducted two Public Consultations into D4 and D5 , the first resulted in a proposed BAN on these chemicals in shampoo and other wash-off products, a move Germany along with a number of NGOs including Breast Cancer UK argued, in an open letter, simply did not go far enough.

[1] The presence of the cyclosiloxanes in order number A072238 was verified by gas chromatography hyphened to a mass spectrometer (GC- MS). From this analysis, D4, D5 and D6 appeared to be present, as well as the larger cyclosiloxanes D7, D8 and D9 (Figure 3.5).

Quantitation of the signals in order number A072238 showed that it contains 8 ppm D4, 156 ppm D5 and 918 ppm D6 (based on extrapolation of the signal of the D5 reference standard). These values are comparable to those found in PIP2 SBI [20] RIVM 2016 page 26 http://www.rivm.nl/bibliotheek/rapporten/2015-0100.pdf

PIP Action Campaign prepared and submitted a substantial dossier on D4 and D5 to the first consultation. Sadly and predictably the second consultation did not include health effects of these regulated **pbt and vPvB substances.**

Indeed Sweden also identified the Commission's inertia on the matter of chemical exposures to EDCs and took the matter to the European Court of Justice, which ruled against the Commission and its delaying tactics and took action to protect citizens from harm.

Still, with the chemical council spending as much as €12million euros annually on lobbying perhaps the reasons for the failure to recognise toxicity of PIP contaminants is the same reason two public consultations were necessary. The industry is opposed to their regulation.

Chemical exposures are issues of particular importance to women exposed to PIP implants. The majority of whom are of reproductive age, many are mothers, some have been pregnant and breast fed with leaking and ruptured PIP implants.

***There is no safe level of EDC exposure** for a developing embryo or a breast fed infant.*

Endocrine Disruptors[2]: "Chemicals are an essential component of our daily lives. But some chemicals, known as endocrine disruptors, can have harmful effects on the body's endocrine (hormone) system. Hormones act in very small amounts and at precise moments in time to regulate the body's development, growth, reproduction, metabolism, immunity and behaviour. Endocrine disruptors interfere with natural hormone systems, and the health effects can be felt long after the exposure has stopped. **Exposure to endocrine disruptors in the womb can have life-long effects and can even have consequences for the next generation."** Read more here: EU Environment on Endocrine Disruptor Chemicals

The xenoestrogenic effect of the contaminants are also of concern to recovering breast cancer patients with oestrogen-positive, malignant tumours.

With so much evidence of harm being overlooked we have begun to recognise regulatory capture in medical devices regulation at the European Commission. ***Regulatory Capture*** is a pernicious and extremely dangerous form of healthcare corruption, where regulating authorities put the interests of the manufacturers before the safety of patients.

As time goes by, the evidence of regulatory capture is growing.

In 2016, RIVM, the Dutch public health authority carried out a surveillance review of implant manufacturers' Technical Dossiers and made several extremely worrying findings: first, that ***of the 10 manufacturers with CE Marked Class III breast implants available in the Netherlands, all ten had incomplete and/or inaccurate Technical Dossiers. This means all ten manufacturers are***

[2] EU Environment on exposure to EDCs http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm

non-compliant with current medical devices regulations and the notified bodies, competent authorities and the European Commission are all aware of it.

Meanwhile the SCENIHR report has become a key reference & tool for undermining new evidence on PIP and other brands of implant. The 2016 RIVM surveillance report dismisses dangerous D4 and D5 levels and concerns over non-compliance with one sentence:

"*According to the recent SCENIHR opinion SBIs [10], this is well below levels of toxicological concern, so although it is a shortcoming, it does not raise a concern for patient safety. " page 26*

Regulatory non-compliance puts patients' safety at risk. ***Technical Dossiers are required to be complete and accurate in order for products to be awarded the CE mark. Article 8, 93/42/EEC Medical Devices Directive refers to the Safeguarding actions relating to the Essential Requirements, which must be met under the directives. Patient safety is a priority of the regulations, and non-compliance is the first sign patients are at risk.***

Also in 2016, the ANSM, the French medical devices regulator, asked a committee of experts to review the evidence of biocompatibility or safety of textured breast implants available in France. ***The expert committee concluded there is no safety data for textured implants including PIP.***

Biocompatibility or safety evidence is another of the ***Essential Requirements of Annex I ,*** 93/42/EEC of the Medical Devices Directive and absolutely critical to patient safety.

ANSM gave manufacturers 12 months to produce safety data for textured implants.

Incomplete and/or inaccurate Technical Files and no biocompatibility data for textured implants should be of serious concern to the Ombudswoman. This is clear, irrefutable and easily verifiable evidence that non-compliant textured breast implants like PIP, are knowingly on the market bearing a CE Mark. In fact, this is evidence PIP was not a fraud at all, but business as usual for the Commission, the notified bodies and for the implant manufacturers.

Regulatory capture is putting the lives and safety of women with toxic PIP and other carcinogenic breast implants at risk, to protect the profits of the breast implant industry and the matter must now be addressed at the very highest level and as a matter of urgency.

In 2001, the European Parliament produced a resolution on Silicone implants A5-0186/2001 following two petitions:

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

In 2003, twenty thousand women signed a petition addressed to the European Parliament **ANNEX II** with clear intent to make breast implants safer. As far as we can see ***none of Parliament's***

recommendations were acted on or implemented even though breast implants were reclassified, at the request of the French and British authorities, from Class IIb to high risk, Class III devices.

By 2011 women with PIP were dying from Breast Implant Cancer.

In 2016, the European Court of Justice in the case of Schmitt Vs TÜV Rheinland, ruled that Notified Bodies, required by the regulations to insure for public liability, maybe liable in the event of negligence. The evidence from PIP not only points to flaws in Medical Devices regulation, but endemic failures at every level in the European system of regulation of medical devices. Every citizen needs to be able to rely on the safety & efficacy of medical devices and in the assurance provided by the CE Mark. It's all too easy to ignore the evidence, name a public health crisis a fraud and produce reports to undermine the seriousness to the health and wellbeing of patients. Denial, albeit cheap, is an inappropriate and unacceptable response to a public health crisis. In 2016 and again in 2017 PIP Action Campaign wrote to the Commission to insist on Safeguarding action to protect patients from non-compliant implants and recommend removal to women with PIP.

The pattern of inaction is dangerous. PIP was not a fraud but the inevitable consequence of the Commission's failure to act on repeated resolutions of the European Parliament and the concerns of injured women, raising petitions via the Parliamentary petitions committee.

More than one hundred thousand women and their families in the EU have been harmed by banned, non-compliant PIP implants and many more exposed to non-compliant textured implants.

Initially, we considered requesting our complaint be urgently referred to the Committee on Petitions to initiate infringement proceedings against the Commission on behalf of all women exposed to and injured by PIP and by other textured breast implants. However, we see this is a route that has been tried before with no effect.

We are deeply grateful to you for your concern for women to date, many of whom are mothers and of course women who have battled breast cancer and who have undergone major reconstructive surgery. We ask you now, in the name of all the women in the EU and worldwide, suffering as a consequence of non-compliant implants bearing the CE mark, and on behalf of all the women who have suffered from ruptured or leaking PIP implants, such as Susan Grieve, a young mother of two, from the UK, who died from BIA-ALCL Breast Implant Cancer and ruptured PIP implants in 2012, to assist us in initiating a legal claim against the Commission and the CE Mark in the European General Court or the Court of Justice.

We wish to assert our rights to access to information, diagnostics, healthcare, treatment, research and future monitoring for ourselves and our children, and on behalf of all other patients, doctors, clinics and hospitals relying on the safety and efficacy of a CE marked Class III medical device. We wish to defend our basic rights as citizens, as women and as victims of the crimes against us and demand our

protections under Article 152 of the treaty establishing the European Community, EU Charter of Fundamental Rights Article 35, as well as Articles 168 and Article 169 of the Lisbon Treaty.

Women with PIP are vulnerable, they are victims and they have been treated without dignity. Women are suffering from the pain, symptoms and trauma of PIP implants. They are frightened, not only because of media attention on breast implant cancer but from their own first hand experience and worrying symptoms.

Women with PIP are still not being taken seriously by health professionals because of the Scenihr and Scheer reports. They are not offered the most appropriate diagnostics, they are not receiving the best treatment or testing or biopsies and in many cases, are simply left to fend for themselves as they are forced back into the unregulated private sector to pay for cosmetic treatment rather than having access to the medical treatment they need. This utterly appalling situation has persisted for years now. Women must remove leaking and ruptured banned PIP implants and they need access to the appropriate health care and monitoring for themselves and for their PIP exposed children.

The European Commission's behaviour towards women with PIP implants is not only a disgraceful abdication of duty but an unforgivable attempt to deny women with breast implants their basic rights in favour of an industry, grown rich on the exploitation of women.

Women in Europe have been waiting a long time for the announcement from the European Commission that obviating the dangers of PIP to human health, promoting research into PIP and BIA-ALCL, as well as health information and education will be forthcoming. In the past week the Scheer committee, the head of the European Commission's medical devices department, Mr Salvatore D'Acunto and Commissioner Mr Vytenis Andriukaitis have all clearly indicated no help will be made available to PIP injured women.

Therefore, we are left with no alternative but to insist that our concerns are heard in the highest court of the EU where we wish to defend our rights and hold the European Commission and the CE Mark to account.

We look forward to your very earliest reply.

Yours truly,

Jan Spivey & Marie Robinson
On behalf of the Members of PIP Action Campaign

References

1. Decision in case 174/2015/FOR on the Commission's alleged failure to investigate conflicts of interests relating to the adoption of a report on the safety of removing PIP breast implants

https://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html.bookmark

2. CALL FOR INFORMATION – SAFETY OF PIP SILICONE BREAST IMPLANTS
https://ec.europa.eu/health/scientific_committees/consultations/calls/scheer_call_info_02_en

3. CALL FOR INFORMATION - POSSIBLE ASSOCIATION BETWEEN BREAST IMPLANTS AND ANAPLASTIC LARGE CELL LYMPHOMA
https://ec.europa.eu/health/scientific_committees/consultations/calls/scheer_call_info_03_en

4.RULES OF PROCEDURE The Scientific Committees on Consumer Safety (SCCS) and Health, Environmental and Emerging Risks (SCHEER) APRIL 2016
http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

5. PIP Action Campaign Responding to European Commission's SCHEER Committee Call for Information on PIP BREAST IMPLANTS with REAL WORLD EVIDENCE
http://pipactioncampaign.org/PIPActionCampaignECSubmission.pdf

6. Silicone breast implants in the Netherlands A market surveillance study RIVM Letter report 2015-0100 P. Keizers et al. http://www.rivm.nl/bibliotheek/rapporten/2015-0100.pdf

7. ECHA Committee for Socio-economic Analysis concludes on restricting D4 and D5
https://echa.europa.eu/view-article/-/journal_content/title/committee-for-socio-economic-analysis-concludes-on-restricting-d4-and-d5

8. Open Letter from European Environmental Bureau On behalf of European and international NGOs
http://env-health.org/IMG/pdf/reach_committee_letter_d4d5_phthalates_nano_final.pdf

9. ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION D4 and D5
https://echa.europa.eu/documents/10162/9a53a4d9-a641-4b7b-ad58-8fec6cf26229

10. Evidence Submission PIP Action Campaign ECHA review of Octamethylcyclotetrasiloxane (D4) & Decamethylcyclopentasiloxane (D5) http://pipactioncampaign.org/PIPActionCampaignECHAsubmission.pdf

11. EU court hearing puts spotlight on Commission delay over hormone disrupting chemicals
http://www.env-health.org/resources/press-releases/article/eu-court-hearing-puts-spotlight-on

12. Lobby Planet: Our guide to the murky world of corporate EU lobbying
https://corporateeurope.org/lobbyplanet

13. Do Endocrine Disrupting Chemicals (EDCs) have a safe limit?
http://www.chemtrust.org/do-endocrine-disrupting-chemicals-edcs-have-a-safe-limit/

14. European Commission Environment Chemicals EDCs website
http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm

15.Study on Corruption in the Healthcare Sector HOME/2011/ISEC/PR/047-A2 October 2013 European Commission – Directorate-General Home Affairs
https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf

16. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31993L0042

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG%3A1993L0042%3A20071011%3Aen%3APDF

17. ANSM TEMPORARY SPECIALIST SCIENTIFIC COMMITTEE "Breast implant biocompatibility evaluation strategy"
http://ansm.sante.fr/var/ansm_site/storage/original/application/29c2a7ac5134600ba2724aa07129d559.pdf

18. ANSM Guideline for demonstrating textured breast implant biocompatibility
http://ansm.sante.fr/var/ansm_site/storage/original/application/aa533f4eacc8b36bd6504894235f7f29.pdf

19. European Parliament resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/1998 and 771/1998) (2001/2068(INI)) **ANNEX I**
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52001IP0186%2801%29&qid=1509418066713&from=EN

20. 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)) **ANNEX II**
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52003IP0063&qid=1509418066713&from=EN

21. OPINION OF ADVOCATE GENERAL SHARPSTON delivered on 15 September 2016 Case C‑219/15 Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH (Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany)
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509418066713&uri=CELEX%3A62015CC0219

22. Treaty establishing the European Community (Amsterdam consolidated version) - Part Three: Community policies - Title XIII: Public health - Article 152 - Article 129 - EC Treaty (Maastricht consolidated version) - Article 129 - EEC Treaty http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:11997E152

23. EU Charter of Fundamental Rights Article 35 Health care
http://fra.europa.eu/en/charterpedia/article/35-health-care

24. Article 168 Lisbon Treaty Title XIV - Public Health
http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-the-functioning-of-the-european-union-and-comments/part-3-union-policies-and-internal-actions/title-xiv-public-health/456-article-168.html

25. Article 169 Lisbon Treaty Title XV - Consumer protection
http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-the-functioning-of-the-european-union-and-comments/part-3-union-policies-and-internal-actions/title-xv-consumer-protection/457-article-169.html

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Annex I

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

12. Silicone implants

A5-0186/2001

28.2.2002 Official Journal of the European Communities C 53 E/231

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52001IP0186%2801%29&qid=1509418066713&from=EN

A. having regard to the serious problems raised by the petitioners,
B. whereas the Commission is drawing up a communication on silicone implants (programme number 2001/261 on the measures to be taken in 2001),
C. whereas at the request of the Committee on Petitions, the Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities have delivered their opinions,
D. whereas those opinions favour option 3 in the STOA report, which stops short of a total ban on silicone implants but calls for specific measures to be adopted and implemented as regards patient information and closer monitoring as well as product quality and basic research,
E. whereas foreign implants are being practised on ever younger people and the number of cosmetic operations is steadily increasing,
F. whereas to date there has been insufficient systematic analysis of implants,

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 abovementioned 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 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

P5_TA(2003)0063

Breast implants

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, more- over, 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.