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COMMISSION STAFF WORKING PAPER

on National Measures adopted by Member States in Relation to Breast Implants

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1. INTRODUCTION

Following the publication by the European Parliament of the report on "*Health risks posed by silicone implants with special attention to breast implants"*[1], the Commission, the European Parliament and national authorities arrived at the consensus to maintain the present legal framework on breast implants. However, they also agreed on the need to introduce specific measures in order to deal with specific problems that had been identified in the report, including the need to increase and improve the information given to patients intending to receive a breast implant.

The Commission, in its *"Communication on Community and National Measures in relation to Breast Implants"*[2], gave a follow-up of this consensus and described the measures both at Community and national level that should be taken in order to respond to these specific concerns.

The present report deals with national policy measures covered by Annex II of the Communication, falling within the ambit of article 152 of the Treaty, relating mainly to informed patient consent, national registers and advertising for breast implantation. It is based on information received from national authorities on the basis of a questionnaire from the Commission. National authorities have been given the possibility to comment on this report before its publication.

2. NATIONAL POLICY MEASURES

The following sections contain a summary of the information received by the Commission from national authoritieson the following issues:

(1) Adequate patient information

(2) Informed patient consent, including "cool-off period" and minimum age

(3) Rules on advertising for breast implants

(4) Need for and practicability of national registers and long-term medical follow-up of women with breast implants.

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1 *"Health risks posed by silicone implants with special attention to breast implants*" (PE168.396/fin.St/rew); May 2000; http://www.europarl.eu.int/stoa/publi/pdf/99-20-02_en.pdf

2 *COM (2001) 666 final*

2.1 Adoption of a patient information system

One of the main concerns expressed by womens' organisations that contacted the European Parliament and the Commission was the lack of information in relation to advantages and disadvantages of breast implants. It was the strong view of womens' interest groups that women considering breast implants should receive all relevant 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 surgical intervention.

The Commission Communication therefore suggested a number of items on which information should be given. These were based on a comparative analysis of systems of informed patient consent promoted in various countries[3] *and by the European Committee on Quality Assurance and Medical Devices in Plastic Surgery (EQUAM).*

Belgian authorities are at the moment in a consultation phase with different bodies, including the Commission of Consumer protection and the Commission for evaluation of Medical devices, as well as with diverse professional organisations, on a draft document providing information based on Annex II of the Commission Communication. A document is intended to be published by the end of February 2003.

In Denmark, the National Board of Health, on 6 January 2000, sent out guidelinesto medical practitioners concerning information to be provided prior to cosmetic operations. Practitioners are required to inform patients about the results previously achieved, complications, later effects and so on, as well as providing details of their experience in the operation concerned. The guidelines concern information to be provided both orally and in written form. Oral information is intended to complement written information taking into account the individual patient's needs. The patient must have an opportunity to read the written information before receiving the oral information and must be given an opportunity to ask questions and receive answers.

Under German law, doctors are required to inform patients in such a way that they are in a position to assess the type, scope and significance of the operation and related health risks. The Federal Institute for Medicines and Medical products (BfArM) envisages for the near future a revision of its departmental risk assessment of silicone breast implants in order to prepare updated documentation available via its Internet homepage. BfArM also gave information about its intention to publish on their homepage, with the agreement of EQUAM, the patient and health information drawn up on behalf of the European Commission and published as Annex II of MEDDEV 2.5/6 Rev 1[4]. In the medium term, BfArM intends to draw up a patient info-brochure on breast implants based on publications already available on this issue, in collaboration with professional associations, the medical sector, patients' initiatives and self-help groups. However, German authorities in no way intend to replace with this publication the individual doctor-patient discussions required in each case.

In Spain, doctors are obliged to provide all necessary information to their patients according to the General Health Act[5] No 14/1986, modified by the Basic Law[6] Nº 41/2002 on rights and

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3 In particular Canada, United States, United Kingdom and France

4 http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/baseguidelines.htm

5 "*Ley 14/1986, de 25 de abril, General de Sanidad (B.O.E. nº 102, de 29 de abril de 1986) ».*

6 "*Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y*

duties of patients regarding clinical information and documentation. In addition, more particularly as regards breast implants, information has to be provided in conformity with a Resolution of the Directorate General for Pharmacy and Medical Devices concerning the conditions for the placing on the market and use of breast implants, adopted in 1992[7], to which a Protocol on Breast Implants Surgery[8] is attached. This resolution has not been published in the Spanish Official Bulletin but it has been distributed among doctors, industries and the competent authorities in charge of compliance. The Protocol is applicable to every breast implantation carried out in Spain. Spanish authorities informed the Commission that the Protocol is being revised in accordance with the recommendations of the Commission Communication.

In France, besides the general existing rules obliging doctors to provide all necessary information to their patients, they must inform the patients in particular of the relevant residual risks of breast implants, the uncertainties about the durability taking into account the nature of prostheses and filling materials, as well as the other alternatives.

Recommendations have been elaborated in collaboration with experts from the competent French authority *"l'Agence française de sécurité sanitaire des produits de santé"* (AFSSAPS). They are addressed in particular to patients intending to have breast implantation with silicone gel fillings. The information includes the durability, the risks linked to the silicone gel fillings, some complementary data related to the medical follow up and other surgical alternatives. This will be soon accessible to the public on the AFSSAPS web site.

The Irish Department of Health and Children has informed all hospitals of the Communication and requested that they bring its contents to the notice of all clinical staff and ensure that hospitals have a policy in place for the provision of information for patients undergoing breast implantation. The Department of Health and Children has also informed all surgeons of the provisions of Annex II of the Commission Communication.

In addition, the Department of Health and Children is planning the development of adequate and comprehensive information for women considering breast implants, having regard to the elements contained in Annex II of the Commission Communication.

In Italy the Ministry of Health has asked the Superior Council of Health for an opinion on the content and modalities of the information to be given to the patients regarding the intervention as well as the type prostheses to be implanted. An ad-hoc group in the Council has been created to examine this issue.

Luxembourg has forwarded the Commission Communication to the Luxembourg association representing patients, to the association of practitioners and to the relevant services in hospitals.

In the Netherlands, the Ministry of Health, Welfare and Sport is preparing a brochure about breast implants addressed to women considering breast implantation.

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documentación clínica (B.O.E. nº 274, de 15 de noviembre de 2002) ».

7 *"Resolución de la Dirección General de Farmacia y Productos Sanitarios por la que se dictan Condiciones para la Comercialización y Utilización de Prótesis Mamarias en España"*

8 "*Protocolo de Implantación de Prótesis Mamarias*". This resolution has not been published on the Official Bulletin.

In Austria, common principles of Civil Law[9] require adequate information for patients on medical interventions and possible risks. This information has to be even more comprehensive before elective surgical interventions, as is the case with breast implants. Austrian authorities plan to elaborate a patient leaflet together with all interested parties on the basis of Annex II of the Commission Communication.

In Portugal, a brochure is under preparation for women who are considering receiving breast implants, to be published either by INFARMED, the competent authority in the field of Medical Devices, or by establishments forming part of the National Health Service. This information, accessible and comprehensible for all interested parties, will contain data on implants such as surgery, potential risks, contra-indications, monitoring after implantation, the monitoring system, biographical references and contacts for further information.

In Finland, the patient information requirement is covered by the Act on the status and rights of patients. Under the terms of this Act, the patient must be given adequate information on operations and their possible risks.

In Sweden, existing national regulations[10] instruct doctors responsible to provide information of the type described in Annex II of the Commission Communication. The Swedish professional associations concerned have, via their representatives in EQUAM, participated in drawing up existing recommendations for patient information aimed at obtaining the patient's informed consent.

In the United Kingdom, the information provided to breast implants patients is regulated by national minimum standards[11]. The Department of Health issued an information booklet for women considering breast implants[12]. It summarises the issues in breast implant surgery and includes questions to ask in order to enable patients to make an informed choice. The booklet includes in particular information on the types of breast implants, the operation, consequences and potential risks, including short term effects, scarring, appearance, breast size, creasing and folds, nipple sensation, infection, bleeding and fluid collection.

2.2 Patient consent, including cool-off period and minimum age required

Appropriate information is the basis on which women should give their consent to a breast implant. A sufficient period of time should be given to the patient to consider the matter before coming to a decision. During this time, women should have all the elements to evaluate the issue and weigh the advantages and disadvantages of the intervention. It was therefore necessary to verify whether mechanisms exist for explicit consent, and whether specific rules intended to protect women exist, such as a cool-off period and minimum age requirements.

In Denmark, according to the national Act on patient's information rights[13] no treatment may start without the patient's informed consent.

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9 Allgemeines Bürgerliches Gesetzbuch

10 Health and Medical Care Act (1982:763)

11 Standard C2, pages 6 & 7; Acute National Minimum Standard A1 (page 50) ensures that patients receive clear written information about their treatment.

12 http://www.doh.gov.uk/bimplants.

13 Act N° 482, §6, 01.07.98

The information must be provided in good time, so that the patient has sufficient opportunity to consider the information and discuss the matter with relatives or others before agreeing to the operation.

Rules on informed consent are also found in the Order on information and consent and the communication of information relating to health[14].

As concerns minimum age, no specific minimum age is required in Denmark for breast implant intervention. However, under article 8 of the above-mentioned Act on patient's rights, there is an age limit of 15 for consent to a treatment. In the case of young people aged between 15 and 18, the parent or guardian must be informed.

In Greece, the National Organisation for Medicines intends to adopt a decision obliging doctors to inform patients of the potential risks of breast implantation and obliging both patients and doctors to sign a consent document before surgery. Finally, breast implants will have to be accompanied by a form for patient consent.

In Spain, the patient consent matter is covered by the Protocol on Breast Implants Surgery, notably by its chapter 4, which also includes a model consent declaration. The patient receives all relevant information on the benefits and potential complications which may arise from surgery. In full knowledge of this, the person freely gives her consent and signs the informed consent declaration.

In Ireland, all surgery is subject to patient consent. The development of rules in relation to issues such as cool-off period and minimum age is presently under consultation with stakeholders.

In Italy, the content of the informed consent form to be submitted to the patient before the intervention is being examined by the Superior Council of Health as requested by the Ministry of Health.

As mentioned before, Luxembourg has forwarded the Commission Communication to the Luxembourg association representing patients, to the association of practitioners and to the relevant services in hospitals.

In the Netherlands, the patient information requirement is covered by the Medical Treatment Contracts Act, which entered into force on 1st April 1995. This Act specifies the reciprocal rights and obligations of patients and care providers, which arise from the contract to provide medical treatment. The intention of the Act is to strengthen the legal position of the patient by clarifying her rights in relation to the health care provider. The Act lays down the principal rights of patients and covers issues such as patient consent, the right to be informed, free access to medical records, confidentiality, and the legal position of minors and adults not competent to give consent.

In the Netherlands there is no cool–off period for breast implants.

In Austria, patients must receive all information on surgical interventions in good time, so that depending on the urgency of the intervention, the patient is guaranteed a considerable period of time to decide whether or not to give her consent to the operation. The information leaflet planned will also recommend explicitly that patients take into consideration the cooling-off

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[14] Order N° 665, 14.09.98

period and also respect a minimum age for surgery. The existing legislation[15] stipulates the consent of the parent or guardian for significant surgical interventions, as is the case with breast implants, when a patient is below 18 years of age.

Portuguese authorities are considering the matter in order to adopt a measure at national level.

In Finland, professional healthcare supervision, responsibility for which lies with the National Board of Medico-Legal Affairs, is targeted particularly at the monitoring of operations on persons who are under age[16].

In Sweden, according to national regulations[17] the patient must be informed prior to giving her consent to the operation. The age limit of 18 applies for cosmetic surgery where the guardian has not given his/her consent. The profession has a very restrictive attitude to carrying out surgery before the age of 18 years old and a long reflection period applies.

The Department of Health in the United Kingdom has issued guidance on consent, entitled "Reference Guide to Consent for Examination or Treatment"[18]. This document provides guidance on what information the patient should receive about the surgical procedure prior to undergoing treatment and, if required, the anaesthesia used. It also outlines how consent should be given and obtained in order for it to be valid.

In the United Kingdom, a consent form must be signed by an adult before undergoing breast implant surgery.

There is no legal minimum age for having breast implant surgery in the United Kingdom. An operation on a person under 18 can legally be carried out with her consent alone, if she is able fully to understand the issues involved. If the person is not competent to give consent, a person with parental responsibility then needs to give consent on her behalf for the operation to go ahead. It is good practice in the United Kingdom to encourage young persons to involve their parents in decision-making.

In April 2002 the National Care Standards Commission (NCSC) was established in order to regulate independent health care providers. One of the standards that providers have to meet[19] refers to the cool-off period between initial consultation and the surgery. This standard states that no patient should be admitted for cosmetic surgery on the same day as having the initial consultation.

2.3 Rules on advertising for breast implantation

Rules on advertising for breast implants can influence decisions by women in relation to breast implants. Advertising should be distinguished from providing information to the extent that advertising is directed towards convincing women to have breast implants, and towards influencing their decisions. Different regimes were reported by womens' organisations regarding national rules on advertising. Some womens' organisations complained about publicity campaigns considered as particularly aggressive and misleading.

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15 § 146 c of *Allgemeines Bürgerliches Gesetzbuch*, ABGB (General Civil-Code)

16 information on the minimum age should be provided

17 Health and Medical Care Act (1982:763)

18 http://www.gov.uk/consent/.htm

19 National Minimum Standard A26.3 (page 73). Prior to consultation of the standards, this stated that no patient is admitted for the procedure to be carried out sooner than two weeks after initial consultation unless there is good clinical reason. This has since been revised to the current minimum standard.

According to the information received from the Belgian authorities, this subject is under evaluation by the Health authority[20] and the Commission for evaluation of medical devices.

In Denmark, advertising for breast implants related to the product is covered by the Order on advertising for medical devices[21]. Article 1 of the Order establishes that advertising of Medical Devices intended for human use must be adequate and objective and must not be capable of jeopardising the safety or health of patients, users or a third party. Article 5(2) also prohibits publicity to target groups other than doctors, dentists and professional purchasers of medical devices regarding medical devices that are exclusively intended to be used by doctors and dentists in connection with the treatment of patients.

Advertising for breast implants related to the treatment is covered by the Act on the advertising of health services[22]. Article 3 states that advertising for health related activities has to be factual, objective and comprehensive. The National Board of Health monitors advertising to ensure that it complies with the law and lays down more detailed rules for breast implants advertising.

In France, publicity for breast implants intended for the general public is forbidden. Instructions for use as well as advertising documents intended for medical uses should mention the specific residual risks and indications on the durability of the prostheses. These instructions should be in relation to the nature of prostheses, the filling materials and the alternatives proposed. The advertising documents have to be lodged with the AFSSAPS on the day of their first publication.

The Irish authorities declared that this matter is at the moment under consultation with stakeholders.

In the Netherlands there are no specific rules applied on advertising for medical devices such as breast implants.

Under Austrian law[23], there is a general ban on advertisements for breast implants (and other implants) addressed to lay people.

In Finland, the National Agency for Medicines monitors the appropriateness of advertising relating to healthcare equipment and supplies, including breast implants.

The Swedish authorities informed us that they have no knowledge of product advertising directed at the general public in Sweden. The current Marketing Act[24] encompasses advertising for breast implants.

In the United Kingdom, private health care providers have to comply with the requirements of the Advertising Standards Agency[25]. In addition, the standards that the National Care Standards Commission (NCSC) will adopt vis-à-vis private health care providers will ensure that their advertisements do not mislead patients about the hospital or treatments provided.

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20 *« Administration des Soins de Santé »*

21 Order N° 695, 28.09.1998

22 Act N° 463 of 10.06.97. §3

23 article 104 of the *medizinproduktegesetz* published under the Federal Government Gazette n°657/1996

24 *Marknadsföringslagen ;* (1995:450)

25 National Minimum Standard A2 (page 50) ensures that any advertisements comply with the Advertising Standards Authority, and are not misleading.

There is no requirement for advertising to state that women should seek independent advice or that there should be a "health warning".

2.4 Need and practicability of national registers and mechanisms for long-term medical follow-up of women with breast implants

Regarding a mechanism for long-term medical follow-up, it is important to highlight that there are substantial differences between the post market surveillance imposed by directive 93/42/EEC and the follow-up of patients having undergone a surgical breast implant under national policy, as covered by article 152 of the Treaty. The first refers to the responsibility imposed on manufacturers to keep up-to-date a systematic procedure to review the products once they have been placed on the market and have been implanted. The mechanism that falls under the scope of article 152 of the Treaty concerns national health policy, and the relationship between the women and the medical profession, as opposed to the manufacturer.

However, this type of measure raises issues such as the principle of confidentiality applied by medical doctors vis-à-vis their patients as well as other ethical rules applied to the exercise of the medical profession.

Belgian authorities indicate that the implementation of a national register for breast implants can be taken into consideration only after dealing with some preliminary questions, such as whether practitioners are prepared to supply data on their patients, which organisations will be able to collect the data and how to find a balance between maintaining a national register and medical confidentiality. This matter is currently under discussion with the "Technical Council for Implants" of INAMI, the Belgian public sickness insurance scheme, and the "Evaluation Commission of Medical Devices".

As regards the medical follow-up, Belgian authorities took the option on the occasion of the implementation of directive 93/42/EEC to extend the obligation of the notification of accidents not only to the manufacturers but also to practitioners responsible for the supply and distribution of the product. Following a perceived absence of declarations of incidents by practitioners, the government envisages adopting a circular to prompt different groups to notify all the accidents encountered and making it easy to identify problems with implants.

In Denmark, a national register for breast implants will be under the responsibility of the Danish Plastic Surgery Register[26], which will meet Denmark's need for a national breast implants register and for follow-up of women with breast implants.

In Germany, as regards long-term mechanisms for follow-up, reference should be made to the regulation on the recording, assessment and reduction of risks from medicinal products, Medicinal Products Safety Plan Regulation (NPSV),. This provides for a detailed decentralised register containing information on implanted products, and details of patients, doctor or institution. This allows the authorities to trace the patients concerned if any risk emerges. This regulation is applied to all devices, including breast implants.

In Greece, the measures that the National Organisation for Medicines intends to adopt include the obligation to register every surgical intervention, the obligation to follow-up patients and the notification to the National Organisation for Medicines of any undesirable effects after the implantation.

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[26] *Dansk Plastikkirurgisk Mammaregister* (http://www.dadlnet.dk/ufl/ufl0112/v_p/35701.htm)

In Spain, this matter is covered by the Protocol on Breast Implants Surgery. The patient monitoring includes (a) post operation review rates, (b) obligation of the doctor to inform the health authorities of any adverse effect or rejection to be attributed to the implant, (c) implant cards recording the details of the patient, doctor health care institution (one copy of the card remains in the clinical record, another is given to the patient, two others are kept by the enterprise that supplied the implant). Spanish authorities intend to set up a national register on the basis of the information contained on the cards in order to improve patient monitoring.

France experiences some difficulties in relation to a register for long-term medical data. The French authorities informed the Commission that for the moment, no national register has been considered necessary. However, the AFSSAPS informed the Commission about its intention to ask the manufacturers of silicone gel products for a prospective data collection of patients who have undergone an implantation. The objective of this monitoring is to establish the durability of the implants by type of model as well as to define the rate of prostheses complications. All of this information and recommendations for patients is planned to be made available on the Internet site of AFSSAPS.

In Ireland, the Department of Health and Children is developing a National Health Information Strategy, intending to address the issue of developing a national register for medical follow-up purposes. This would be expected to identify early prosthesis failure and provide easy identification of patients if an accident occurs.

In Italy, the feasibility and the modalities of the implementation of a national register of its adoption are under examination by the ad hoc group created at the Superior Council of Health.

In the Netherlands, the practicability of a national register for breast implants is still under evaluation and consultation with stakeholders.

Austria has been running a voluntary breast implants register since 1996, set up by EQUAM Austria in collaboration with the Austrian Society for Plastic, Aesthetic and Reconstructive surgery. The Federal Ministry of Social Security and Generations is currently examining the merits of this register with the help of the above Society. The duty to advise patients of the need for long-term medical monitoring of breast implants recipients is already written into the contract for medical treatment, rendering further legal steps unnecessary. However, the need for long-term medical check-ups will be explicitly indicated in the information leaflet planned to be given to patients prior to the operation.

In Portugal, the government envisages the creation of a centralised system for national registration of breast implants. The question is at the moment being discussed by experts from INFARMED and by medical experts specialised in the field of cosmetic and reconstructive surgery in Portugal.

In Finland, the national Agency for Medicine does not see at present any particular need for a nation-wide breast implant register, as this does not prove any particular usefulness in monitoring the safety and performance of implants due to the excessive number of variables.

The Act on healthcare equipment and supplies obliges operational health care units to keep a record of all human implants that are intended to be permanent. However, the disclosure of the data contained in medical records to third parties is subject to the patient’s written consent.

In Sweden, the National Board of Health and Welfare has investigated the possibility of a national breast implant register and the need for compiling data. For the moment, it has been decided that such a register can and should be established in accordance with the principles governing the existing “quality register for implants”. Maintaining a breast implant quality register allows for long-term follow-up of the women concerned.

In the United Kingdom, the National Breast Implant Registry (NBIR) was set up in July 1993 in response to a recommendation by the UK Department of Health's Independent Expert Advisory Group. Data are collected from both private and public sector hospitals and, to date, around 145,000 breast implants in over 60,000 women have been registered.

The aim of the registry is to hold a comprehensive and confidential record of breast implant procedures performed in the United Kingdom, to report trends in breast implants usage, and to maintain a patient cohort for research studies into breast implantation and associated effects. A pilot study using NBIR data to investigate the evaluation of outcome measures commenced in 2001.

The Medical Devices Agency funds the National Breast Implant Registry, but has no direct access to confidential information such as patient names. The NBIR produces annual reports of its activities and, in addition, provides reports to reporting centres on their registration activities. Besides the statutory provisions of the Medical Devices Directive establishing a Vigilance System, the United Kingdom runs in parallel the MDA’s established voluntary user reporting system.

3. SUMMARY CONCLUSIONS

Member States have national policies in place or are implementing national policies in relation to breast implantation. Several Member States use the Commission’s Communication to update or to reconsider policy measures.

Different mechanisms are being used. In some countries, this matter is covered by legislation of a general nature, in other countries measures have been adopted specifically relating to breast implants. Similarly, instruments of a different nature are being used, most of them being mandatory, others being forms of self-regulation, voluntary standards or ethical codes.

Positions as regards the possibility of introducing registers are quite diverse. Similarly, there are significant differences as regards advertising.

The matters covered by this working document are of national competence, and possibilities to adopt measures at Community level are extremely limited. However, the Communication and the elaboration of this working document have already produced a significant effect and will continue to provide useful elements for interest groups and authorities at national level. They will promote "best practice" and may inspire further actions. Furthermore, where the need for co-ordination of national registers would arise, or where Member States are interested in European networking or coordination of national databases and the availability of collated data at a European level, the Commission, through the Joint Research Centre, can certainly provide scientific and technological assistance.