Health protection: breast implants, Community and national measures

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PURPOSE : to propose measures aiming to improve the quality and safety of breast implants. CONTENT : the present Communication gives a follow-up to this consensus and sets out the various measures both at Community and at national level that should be taken to address the issues raised. These relate to the requirements in relation to breast implants themselves and accompanying measures, not directly related to Community legislation on breast implants, but necessary to provide an appropriate health protection. In 1998, petitions were introduced to the European Parliament, by a group of women having received silicone gel breast implants. In the light of these petitions, the European Parliament ordered a study on "Health risks posed by silicone implants in general with special attention to breast implants". The report presented confirmed the absence of scientific evidence on a link between disease and silicone gel breast implants. It noted, however, that problems do occur, mainly because of the design and characteristics of the product. In subsequent debates between the Commission, European Parliament and national authorities, a widely accepted consensus was generated in favour of a Community wide policy under which the present legal framework would be maintained, but critical specific measures would be introduced to increase and improve information for patients, tracking and surveillance, quality control and assurance, and key research. The present Communication gives a follow-up to this consensus and sets out the various measures both at Community and at national level that should be taken to address the issues raised. These relate to the requirements in relation to breast implants themselves and accompanying measures, not directly related to Community legislation on breast implants, but necessary to provide an appropriate health protection. The proposed measures can be summarised as follows: - information to patients : the Commission considers of utmost importance that, before the intervention, women receive all appropriate information in relation to potential benefits and risks of surgical intervention and breast implants.It invites the Member States, in consultation with all interested parties, including patient organisations and support groups, to adopt measures implementing, at national level, a system of adequate and comprehensive patient information followed by documenting in writing the Patient's Consent. The consultation procedure may include the provision of a 'cool off period' and also recommendations on minimum age for the procedure. It also invites the Member States to ensure, as part of a policy on information to women interested in undergoing a breast implant operation, that in the light of inherent risks related to breast implants, advertising for these products provides balanced information, and that the advertising also suggests that women seek appropriate independent advice, e.g. consult their physician; - research and development, innovation : the Commission proposes an efficient policy in this field should be based on a number of elements, such as before breast implants are placed on the market, manufacturers must collect clinical data on the characteristics and performance of the product; Once breast implants have been placed on the market, or have been implanted, manufacturers must keep up to date a systematic procedure toreview experience gained from devices in the post-production phase including prospective clinical evaluations and implement appropriate means to apply any necessary corrective action. The Commission invites manufacturers, notified bodies and national authorities to take due account of the relevant Directive's provisions; manufacturers must notify the competent authorities of incidents; - medical follow-up : good Medical Practice requires that women, having received a breast implant, are medically followed over a long period of time, to record the effect on health, and to monitor long-term secondary effects. The Commission invites Member States to verify with the medical profession mechanisms under which such monitoring can best take place. The Commission invites Member States to examine the need and possibility to set up, with due respect for confidentiality and the protection of privacy, national registers for breast implantation that should constitute the basis for traceability and long term research on breast implants. Lastly, the Commission invites Member States to transmit to the Commission the national measures adopted in relation to this Communication. It will regularly examine, with national authorities, the impact of the measures promoted by this Communication.