Health protection: breast implants, Community and national measures

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PURPOSE : to present a working paper on national measures adopted by Member States in Relation to Breast Implants . CONTENT : the report follows the November 2001 Commission Communication on breast implants which proposed a range of measures to improve the quality of breast implants and patient protection. This communication noted that breast implantation remains an intervention that has, like any other medical intervention, inherent risks. In particular where implantation takes place for cosmetic reasons, women should be able to carefully balance benefits against risks, having all relevant information available. Special rules on minimum age or cool-off period may be necessary to protect the young and impressionable. As advertising can influence decisions, special scrutiny or even prohibition may be necessary. Long term follow-up mechanisms, such as national registers, can be useful although this raises issues of privacy and accuracy of data. In this context, this Commission working paper outlines the measures that Member States have taken since the Commission - in its November 2001 Communication - launched a series of recommendations in this field. Although the Commission has no formal powers in this area, Member States have taken up the challenge of updating or reconsidering existing measures. The Communication, report, and follow-up work, offer a valuable tool to interest groups and national health authorities to promote "best practice" across Europe in health protection. Whilst the report deals with national policies regarding breast implantation, the Commission has focused on rules to increase quality and safety of breast implants themselves. It therefore proposed in February 2003 a Directive which reinforces the verification of quality and safety, making all implants subject to a specific certificate of compliance with these rules. Finally, the Commission has formally invited the European Committee for Standardisation to reconsider the current European standard for breast implants, which will help manufacturers to meet the directive's essential requirements as detailed in the Communication.