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Dear ...

Reintroduction of polyurethane-coated breast implants in the UK

I am writing to you about the decision by Polytech Silimed Europe GmbH, to supply their Micro-Polyurethane Surfaced (MPS) mammary implants for use in the UK, as from April 2005. Polyurethane-coated implants have not been available in the UK since 1991. The purpose of this letter is to bring to the notice of plastic surgeons the risks and claimed benefits associated with these implants, so that surgeons can reach an informed judgement on the suitability of the implants and be able to give appropriate advice to women considering their implantation.

Background

Silicone gel filled breast implants covered with polyurethane foam coating were introduced to clinical use in the 1970s with the aim of reducing the rate of capsular contracture. They were withdrawn worldwide in 1991 following concern that the polyurethane coating might release a carcinogenic breakdown product. One such breast implant (the MPS implant) was subsequently reintroduced in Europe and the Medical Devices Agency (MDA, now MHRA) issued two Advisory Notices¹ to draw attention to the carcinogenic risk and to advise surgeons that these implants should not be used in the UK.

Evidence of Risk

The carcinogenic risk arising from polyurethane-coated breast implants was assessed by the Committee on Carcinogenicity² (COC) in 1991 and 1994. The COC concluded that the implants give rise to a small, unquantifiable carcinogenic risk because the breakdown of the polyurethane coating over a number of years leads to the release of small amounts of the probable genotoxic carcinogen, 2,4-toluenediamine (2,4-TDA). No evidence has emerged since 1994 that would alter the COC's conclusions.

In 2001, MDA prepared a report on the safety of polyurethane-coated breast implants. This report presented the opinion of the COC and discussed factors relevant to the carcinogenic risk assessment. It noted that there were reports of a reduction in capsular contracture with polyurethane-coated breast

¹ MDA Safety Action Bulletin SAB(94)39 and MDA Safety Notice SN 9620, published in 1994 and 1996 respectively. These notices have now been withdrawn.

² The Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment provides expert advice to the Chief Medical Officer and UK Government Departments.



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implants but insufficient evidence was available at that time to demonstrate the long-term benefits of these devices over other products.

Further Developments

In 2003, in response to the MDA report, Polytech Silimed provided MHRA with a review of evidence for a lower, quantifiable rate of capsular contracture with polyurethane-coated breast implants. The manufacturer claimed that the clinical benefits of these implants therefore outweighed the potential risks.

In November 2003, the above reports were reviewed by the Committee on the Safety of Devices³ (CSD). The CSD concluded that, on the basis of the evidence available at that time, the benefits were not substantial and did not outweigh the remote but unquantifiable carcinogenic risk. They therefore could not recommend the re-introduction of polyurethane-coated breast implants into clinical use in the UK. In 2004 the manufacturer provided additional evidence which they claimed further supported the clinical benefit of these implants.

In January 2005, the manufacturer informed MHRA of their intention to supply MPS mammary implants in the UK. As the implants are CE marked medical devices, the MHRA accepts that they can legitimately be placed on the UK market, provided users and potential recipients are appropriately informed about their risks and benefits.

MHRA has placed details of the CSD discussion and a copy of its 2001 report on the safety of these implant on its website for the information of plastic surgeons⁴. Information on the benefits claimed for these implants can be obtained from the manufacturer⁵. Plastic surgeons may also find the attached information sheet useful when discussing the suitability of these implants with their patients.

Yours sincerely,

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³ The Committee on Safety of Devices advises Ministers and complement the work of the Medicines and Healthcare products Regulatory Agency (Devices sector).

⁴ MHRA's 2003 submission to the CSD, the 2001 MDA report and an extract of the minutes of the November 2003 CSD meeting, are available on the MHRA website at

⁵ MicroPolyurethane-foam-Surfaced silicone gel-filled breast implants – A survey of literature. POLYTECH SILIMED Europe GmbH, 1st February 2005



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