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16th March 2016

Re: BCG medac, Powder and solvent for suspension for intravesical use,
PA 0623/004/001

Dear XXX

Please find enclosed details of an adjustment to the SmPC for BCG medac, Powder and solvent for suspension for intravesical use, PA 0623/004/001, manufactured by medac GmbH.

Should you require any further information please do not hesitate to contact me or your local representative.

Yours Sincerely



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**Important information for healthcare
professionals
Update of safety information
BCG bacteria
BCG-medac, Powder and solvent for suspension for intravesical use
MA no.: PA 0623/004/001**

Dear Healthcare Professional,

medac GmbH would like to inform you of the following adjustment in the SmPC:

*The safety information for BCG-medac has been updated based on continuous pharmacovigilance monitoring. As a consequence the SmPC has been adjusted in the following section:
4.6 (Fertility, pregnancy and lactation)*

Fertility

Intravesical BCG therapy was found to adversely affect spermatogenesis and might cause oligospermia or azoospermia. Animal studies suggest that these effects might be transient and reversible. However, men should seek advice about the possibility of sperm preservation before starting therapy.

The package information leaflet has been revised accordingly.

Please ensure that all relevant staff are made aware of the content of this letter.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Adverse events should also be reported to drugsafety@medac.deIf you have any questions, please contact contact@medac.de

Yours sincerely,

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Medical Director
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