

Cabinet Secretary for Health, Wellbeing and Sport
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In 2014 Scotland Welcomes the World



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Our ref: A9864035
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Dear Mr Stewart,

I refer to your letter to my colleague Alex Neil, former Cabinet Secretary for Health and Wellbeing, seeking clarification on a number of issues in respect of polypropylene mesh medical devices.

I welcome your support for the Independent Review of transvaginal mesh procedures, announced on 17 June. I firmly believe that no one should have to experience the distress that some of these women have therefore support the important work of the Independent Review. The Chair of the Review Group, Dr Lesley Wilkie, has indicated that it will make its recommendations in March 2015.

The Acting Chief Medical Officer wrote on 20 June requesting that all health boards consider suspending transvaginal mesh procedures until the Independent Review has concluded. The letter also outlined that where women, having discussed the risks and benefits with their clinician, decided that they preferred to continue with surgery then this should go ahead. The new patient information and consent leaflet, <http://www.scotland.gov.uk/Publications/2014/06/2806>, for treatment of stress urinary incontinence should form the minimum content for women considering surgery. This leaflet fully outlines the risks associated with this procedure and the alternatives available before women make a decision on whether they wish to proceed.

The letter also outlines that where women are being considered for entry into clinical trials then use of mesh can be approved for women following this option, again on the provision that these women have consented, fully aware of the risks and benefits. The SIMS trial is a publically funded clinical trial, independently assessed and approved. Part of the approvals process includes review by a research ethics committee, which includes independent lay and expert members to assess if the information for patients deciding whether to take part is complete and easy to understand.

The Committee will recall that MHRA is responsible for the regulation of medical devices and has the authority to withdraw these products; however existing evidence suggests that a majority of women appear to benefit from this type of surgery without complications. Recently the CMO in England asked MHRA to review the evidence from the regulatory system on the benefits and risks of vaginal mesh implants. This report was published on 28 October (<http://www.mhra.gov.uk/NewsCentre/Whatsnew/CON472714>) and outlines MHRA's position that for the majority of women, the use of vaginal mesh implants is safe and effective. The Independent Review will take account of this report and other evidence before making its recommendations.

The Scottish Government is working with MHRA, NHSScotland's Incident Reporting and Investigation Centre (IRIC) and the professional bodies to strengthen reporting of adverse events. Actions include the consideration by IRIC of systems using transvaginal mesh procedures as a reference point. In addition, the Deputy Chief Medical Officer has written to the Chair of the National Caldicott Scrutiny Panel requesting that Caldicott Guardians assist local clinicians in accessing the database to record outcomes data for stress incontinence surgery. This national clinical audit is important, informing future improvement in patient care.

I hope this letter clarifies the position in respect of the issues raised in your letter and reassures you that the Scottish Government is taking every action possible to address these issues.

SHONA ROBISON