

PE1517/HH

Medicines and Healthcare Products Regulatory Agency Email of 9 September 2016

After appearing at the Scottish Parliament Public Petitions Committee on 24th Feb 2015 for petition PE1517 Polypropylene Mesh Medical Devices, I committed to pass information back to the committee on ongoing projects MHRA are aware of associated with researching the long-term safety and effectiveness of vaginal mesh implants.

Projects that have reported to date include the following :-

- 1) 'Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women : Interim report' published Oct. 2015 :
<http://www.gov.scot/Publications/2015/10/8485/0>
- 2) NHS England Mesh Working Group : Interim Report, published Dec. 2015 :
<https://www.england.nhs.uk/ourwork/qual-clin-lead/mesh/>
- 3) EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) scientific opinion on the safety of surgical meshes used in urogynaecological surgery. Published December 2015. The Opinion looks at the risks associated with the use of surgical meshes for various conditions, how to identify high risk patient groups and further assessment needs.

The full text of the final Opinion is available at :

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en.htm plus an easy-to-read fact-sheet on surgical meshes is available at:
http://ec.europa.eu/health/scientific_committees/docs/citizens_surgicalmeshes_en.pdf

- 4) MHRA paper : 'In vivo response to polypropylene following implantation in animal models: a review of biocompatibility'
<https://www.gov.uk/government/news/interrogating-research-to-protect-public-health> peer reviewed and published May 2016 in the 'International Urogynecology Journal' : <http://link.springer.com/article/10.1007%2Fs00192-016-3029-1> (this is the paper that you referred to in your recent enquiry to MHRA)

Ongoing projects we are aware of that are yet to report :

- 5) SIMS Trial – Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension-Free Mid-Urethral Slings in the Surgical Management of Female Stress Urinary Incontinence; A Pragmatic Multicentre Non-Inferiority Randomised Controlled Trial -
https://w3.abdn.ac.uk/hsru/sims/?_ga=1.164172095.1091477097.1467628155

- 6) PROSPECT Trial - PROlapse Surgery : Pragmatic Evaluation and randomised Controlled Trials – a Department of Health funded project
<https://w3.abdn.ac.uk/hsru/Prospect/>
- 7) NICE announced in March 2016 - intention to update their CG171 Clinical Guideline on Urinary incontinence in women : management'
<https://www.nice.org.uk/guidance/cg171>

I hope this is helpful . If you have any further queries, please direct them to DH Parliamentary Branch Ben Sneddon (ben.sneddon@dh.gsi.gov.uk) and Phillip Morrison (phillip.morrison@dh.gsi.gov.uk) in the first instance.

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