Medicines & Healthcare products Regulatory Agency

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Kath Sansom
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Our Ref: **FOI2026/01426**

13 November 2026

Dear **Kath Sansom,**

Thank you for your Freedom of Information (FoI) request received on 18 October. You wrote:

> *Please could you tell me:*
>
> *1. When calculating the MHRA estimate that the risk of complications from pelvic mesh is 1-3%, did the MHRA include dyspareunia as a complication within that risk estimate?*
>
> *2. If dyspareunia was not included, please provide the rationale, methodology, criteria, or decision-making process explaining why it was excluded from the risk estimate.*
>
> *3. Please provide any internal correspondence, briefing papers, emails, reports, meeting minutes or other documents discussing whether dyspareunia should be included in the risk estimate.*
>
> *4. Please identify the specific complications that were included in the calculation of the 1-3% risk estimate.*

MHRA Response

We can confirm that the Agency holds this information. However, some of the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

We have interpreted your request as referring to the MHRA's report. A summary of the evidence on the benefits and risks of vaginal mesh implants, published on 28 October 2014, which is available at the following link:

MHRA – A summary of the evidence on the benefits and risks of vaginal mesh implants

The report summarises the available evidence concerning vaginal mesh implants used in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP), including findings from an independent review of published clinical literature commissioned by the MHRA and undertaken by the York Health Economics Consortium (YHEC) in 2012.

We have addressed your questions below on the basis of this interpretation.

1. Was dyspareunia included in the MHRA's 1–3% complication risk estimate?

The 1–3% figure originates from the findings of the independent literature review undertaken by YHEC. It is important to clarify that this figure was not an overall complication rate calculated by the MHRA for all pelvic mesh procedures.

Rather, the figure represents a general range of adverse-event rates reported across different surgical techniques using vaginal tapes for SUI.

The evidence also considered deterioration in sexual function, which was reported separately from the general 1–3% range. A rate of approximately 9% was reported for deterioration in sexual function associated with one SUI surgical technique. For POP procedures, deterioration in sexual function was reported at approximately 14–15%.

Dyspareunia, defined as painful sexual intercourse, is a recognised complication of vaginal mesh procedures and is explicitly acknowledged within the MHRA report under the category of sexual difficulties.

However, the published summary does not establish whether dyspareunia was separately captured within the individual adverse-event categories contributing to the 1–3% range.

2. If dyspareunia was not included, what was the rationale for its exclusion?

As outlined above, the 1–3% figure was not calculated as a composite risk estimate encompassing all recognised complications of vaginal mesh procedures.
Instead, it reflects a general range of adverse-event rates identified from published clinical literature, with certain outcomes, including deterioration in sexual function, reported separately.

The MHRA's 2014 report does not identify a specific decision to exclude dyspareunia from the 1–3% range, nor does it provide an explicit rationale for such an exclusion.

The methodology and outcome definitions used in the original YHEC review are relevant to understanding how individual complications were categorised and reported.

3. Internal correspondence, briefing papers, emails, reports, meeting minutes or other documents discussing whether dyspareunia should be included in the estimate.

Following searches of the relevant records, the MHRA has not identified any internal correspondences or briefing papers specifically discussing a decision to include or exclude dyspareunia from the reported 1–3% range of adverse-event rates.

However, the MHRA has published information relevant to this matter in its 2014 report, A summary of the evidence on the benefits and risks of vaginal mesh implants.

The report draws on an independent review of published clinical literature undertaken by the York Health Economics Consortium (YHEC) in 2012. It acknowledges dyspareunia as a recognised complication of vaginal mesh procedures and reports deterioration in sexual function separately from the general 1–3% range.

The original YHEC review has also previously been made publicly available through MHRA Freedom of Information response FOI 22/909.

These publications provide information on the evidence considered but do not establish that a specific decision was made to exclude dyspareunia from the reported range.

4. Which specific complications were included in the calculation of the 1–3% risk estimate?

As explained above, the 1–3% figure was not derived from a single calculation combining a defined list of complications. Rather, it summarised the rates of different adverse outcomes reported in the published literature for surgical techniques using vaginal tapes for SUI. Section 4.4 of the MHRA's 2014 report discusses the findings of the YHEC review, including adverse outcomes such as:

- Post-operative pain or discomfort
- Mesh erosion
- Deterioration in sexual function
- Need for re-operation
- Organ perforation

These outcomes were assessed individually in the underlying literature, and their reported frequencies varied according to the surgical technique and outcome being evaluated.
It should therefore not be assumed that all the complications listed above were included within the 1–3% range. In particular, deterioration in sexual function was reported separately at a higher rate for certain procedures.

Further details of the individual outcomes and reported complication rates can be found in Section 4.4 of the MHRA report and the underlying YHEC review.

We hope this information clarifies the origin and interpretation of the reported figures.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

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If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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