Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00004**

30 January 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 3 January. You wrote:

FOI REQUEST: Cobalt / Chrome / Dual-Taper Modular Hip Stems

A. Adverse Event & Safety Reporting

1. Please provide the number of Yellow Card reports received by the MHRA relating to:

- *cobalt or chromium ion release*
- *corrosion, fretting, or taper junction failure*
- *modular neck or dual-taper hip stems*

broken down by year from 2010 to present.

2. Of these reports, how many:

- *involved revision surgery*
- *involved systemic cobalt or chromium toxicity*
- *involved local tissue reactions (ALTR / pseudotumours)*

3. Please provide any trend analysis or internal summaries held by MHRA regarding increasing or decreasing reports related to modular hip stem designs.

B. Device Types & Design Risk

4. Does the MHRA classify dual-taper or modular neck hip stems as:

- *higher risk than monoblock stems?*
- *equivalent risk?*

Please provide any internal guidance, assessments, or policy documents addressing this.

5. Has the MHRA issued any warnings, alerts, or internal safety concerns specifically regarding:

- *cobalt-chrome modular necks*
- *mixed-metal taper junctions (e.g. Ti stem + CoCr neck)*

6. Please provide copies of any MHRA safety notices, field safety notices, or internal advisories relating to modular hip stems that were not publicly issued.

C. Manufacturer & Regulatory Oversight

7. Please list all manufacturers for whom the MHRA has:

- *received adverse event data*
- *conducted post-market surveillance*

relating to modular hip stems since 2010.

8. Has the MHRA ever:

- *requested design changes*
- *imposed restrictions*
- *required enhanced surveillance*

on any modular hip stem system due to cobalt/chromium concerns?

If yes, please provide:

- *dates*
- *manufacturers involved*
- *nature of the action taken*

D. Post-Market Surveillance & Evidence Base

9. What post-market surveillance data does the MHRA rely on to assess the long-term safety of modular hip stems?

10. Has the MHRA identified any evidence gaps relating to:

- *long-term ion release*
- *taper corrosion*
- *outcomes beyond 5–10 years*

11. Please provide any risk–benefit analyses, internal reviews, or expert panel discussions held by the MHRA concerning modular hip stem designs.

E. Monitoring & Patient Safety Guidance

12. Has the MHRA issued or considered issuing guidance on:

- *routine cobalt/chromium blood testing*
- *imaging surveillance (MRI / MARS MRI)*

for patients with modular hip stems?

13. If such guidance exists but is not public, please provide it.

14. If no such guidance exists, please confirm whether the MHRA considers:

- *systemic metal exposure*
- *delayed corrosion failure*

to be a recognised patient safety risk.

F. Comparative Risk & International Context

15. Has the MHRA reviewed or considered:

- *international regulatory actions*
- *recalls or restrictions in other jurisdictions*

relating to modular hip stems?

16. Please provide correspondence or reports where the MHRA:

- *compared UK outcomes to international data*
- *discussed divergence from other regulators' positions.*

G. Internal Communications (High-Value Question)

17. Please provide copies of internal MHRA emails, memoranda, or briefing papers since 2010 that discuss:

- *cobalt/chromium risk*

- *modular neck or dual-taper hip stems*
- *corrosion or taper failure concerns*

(If redaction is required, please redact personal data only.)

MHRA Response

We can confirm we hold information requested, but it is exempt from disclosure under section 12(1) of the Freedom of Information Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(1) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being that the number of documents and emails identified that will require screening is large and would take over 24hours of staff hours in order to review and identify whether they include the requested information. An initial search for documents across the MHRA servers and email accounts containing emails potentially relevant to this FOI request identified 389 email accounts (containing one or more emails) and 998 documents that may or may not contain the information you request. It would take a member of staff 69.35 hours to review the files to determine whether we hold the information you require. This costing applies to the following parts of your request:

A3. Please provide any trend analysis or internal summaries held by MHRA regarding increasing or decreasing reports related to modular hip stem designs.

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In addition, to answer your request, a further search of our adverse incident data would be required to identify the yellow card reports that may or may not contain the information requested in section A1 & A2.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit. The following points may help you when considering how to propose your new request.

- Provide more specific details of the information you require, potentially narrowing the scope of the request to focus on a specific area.
- Given the breadth of manual review of files required to fulfil this request we would advise that you narrow down the dates of your request.

We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit.

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

Your right to complain under the Freedom of Information Act

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 Contact Information or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/