



Ref: FOIA Reference 2018/19-465

Royal Stoke University Hospital
Quality, Safety and Compliance Department
Newcastle Road
Stoke-on-Trent
Staffordshire
ST4 6QG

Date: 10th December 2018

Tel: 01782 676474
Email FOI@uhn.nhs.uk

Dear

I am writing in response to your email dated 3rd November 2018 (received into our office 5th November) requesting information under the Freedom of Information Act (2000) regarding Essure.

As of 1st November 2014 University Hospitals of North Midlands NHS Trust (UHNM) manages two hospital sites – Royal Stoke University Hospital, and County Hospital (Stafford). Therefore the response below is for the two sites combined from that date where appropriate.

Q1 On the 16 July 2017 a letter was forwarded to you from Bayer, headed

Field Corrective Action Request for voluntary, temporary suspension of clinical use for Essure® product including Information for Essure® Patients (page 2)

The guidance was removed last year, and the supplier requested below. (Taken from letter from Bayer) this was dated 16 August 2017, and headed Field Corrective Action.

A voluntary suspension of further fitting is recommended. If you currently hold stock, Bayer recommends suspending the implantation of all Essure® medical devices until discussions regarding the CE certification are concluded. Please take the following actions: Temporarily suspend any implantation of Essure®: Review your current inventory and, if you have unused Essure® units, temporarily quarantine remaining inventory until further notice.

Also a letter was sent to you for Essure patients, can you confirm if this letter went out to ladies who had already been implanted with Essure to give them a voice.

Questions

1 Did the letter go out directly to ladies who had Essure placed previously, if Not, why not.

A1 There was no notification received from Bayer to the Trust regarding letters to patients.

Q2 How many Essure devices have been placed in your hospital Trust in total?
i before the guidance removal
ii after the guidance removal

A2 (i) Before any guidance was received the Trust removed 89 devices and removed ten failures.
(ii) The Trust has not received any guidance

Q3 Were the Essure units placed in quarantine?

A3 Yes

Q4 Why do you actively still promote Essure with posters on the hospital wards?

A4 The Trust does not promote Essure with posters on the hospital wards.

*Please note that any individuals identified do not give consent for their personal data to be processed for the purposes of direct marketing.

UHNM NHS Trust is a public sector body and governed by EU law. FOI requestors should note that any new Trust requirements over the EU threshold will be subject to these regulations and will be advertised for open competition accordingly.

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An anonymised copy of this request can be found on the Trust's disclosure log, please note that all requests can be found at the following link: <http://www.uhnm.nhs.uk/aboutus/Statutory-Policies-and-Procedures/Pages/Freedom-of-Information-Disclosure-Log.aspx>

This letter confirms the completion of this request. A log of this request and a copy of this letter will be held by the Trust.

If you have any queries related to the response provided please in the first instance contact my office.

Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and request an assessment of the manner in which the Trust has managed your request.

The Information Commissioner may be contacted at:

Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF or via www.ico.org.uk.

If following review of the responses I can be of any further assistance please contact my secretary on 01782 676474.



University Hospitals
of North Midlands
NHS Trust

Yours,

L Carlisle

Leah Carlisle
Deputy Head of Quality, Safety & Compliance

