



Ref: FOIA Reference 2019/20-070

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

Date: 16th May 2019

Email foi@uhn.nhs.uk

Dear

I am writing in response to your email dated 5th May 2019 (received into our office 7th May) requesting information under the Freedom of Information Act (2000) regarding unlicensed SCAT.

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 I would like to request information about the availability of unlicensed systemic anticancer therapy (SCAT) being offered at your hospital, outside a clinical trial, for the treatment of acute myeloid leukaemia or acute lymphoblastic leukaemia (referred as "indications" below) between April 2017 and April 2019.

Question 1

Does your hospital offered any unlicensed SCATs for these indications that was provided by drug company via a free-of-charge scheme, managed access scheme or patient access scheme that was not commissioned or reimbursed by NHS England.

A1 Yes.

Q2 Which drugs were involved in these schemes? If not able to provide name, please state total number.

A2 Quizartinib for acute myeloid leukaemia (AML)

Q3 How many patient received treatment under these schemes?

A3 We are unable to provide the information you require in the requested format as to release this data could lead to the identification of the person(s) involved due to the low numbers involved, and would breach the Trusts obligations under Data Protection Act 2018. Accordingly, this aspect of your request is exempt from disclosure under the terms of Section 40(2) of the FOI Act: *Personal information*. However as the Trust is committed to openness and transparency we can band the numbers of being less than five.

Q4 Please provide your local procedure/policy for access to unlicensed SCAT that is not commissioned or reimbursed by NHS England. Who is responsible for approval of these requests in your organisation?

A4 The Clinical Director of Oncology and Haematology, and the Clinical Director of Pharmacy and Medicines Optimisation or deputy is responsible for approval of these requests in our organisation. Please refer to the attached document for the local procedure/policy.

Q5 Please provide your local pharmacy procedure/policy for quality control or quality reassurance of these unlicensed medications when they are delivered to hospital.

A5 Please refer to the attached documents.

*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.

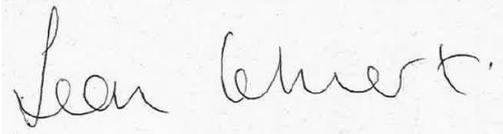
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and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

Yours,

A handwritten signature in black ink on a light grey background. The signature reads "Jean Lehnert" in a cursive script.

Jean Lehnert
Information Governance Manager