



Ref: FOIA Reference 2018/19-411

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

Date: 6th November 2018

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

Dear

I am writing in response to your email dated 12th October 2018 requesting information under the Freedom of Information Act (2000) regarding use of unlicensed medicines.

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 Does your Trust have a policy on the use of unlicensed medicines? Please Answer Yes or No. If yes, please provide a copy of the policy and all other relevant documentation

A1 Please see attached UHNM Policy No. MM04, Trust Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines. Please note that this policy is currently being reviewed.

Q2 Does your Trust have a policy or protocol on obtaining informed consent from patients when an unlicensed medicine is used? Please answer Yes or No. If yes, please provide copies of all relevant documentation including copies of template informed consent materials used to consent patients where an unlicensed medicine is to be administered.

A2 As answer 1 however please note that in the Trust Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines, page 9, section 5.4 states that the prescriber of an unlicensed medicine is responsible for ensuring that the Trust policy relating to obtaining patient consent is complied with. UHNM Policy C43, consent for treatment is the Trust policy for obtaining patient consent. This is the general Trust consent policy and the Trust does not have a specific policy or protocol on obtaining informed consent when an unlicensed medicine is used. Please see attached policy.

Q3 Please state which Board level job role(s) is (are) responsible for patient safety and consenting.

A3 The Medical Director is the Executive Lead for the Trust Consent for Treatment Policy and the Trust Unlicensed Medicines Policy.

- Q4 Does your Trust have, or intend to introduce, a policy that makes compounded bevacizumab routinely available to treat wet age-related macular degeneration? If yes please supply a copy of your policy**
- A4 No. The Trust does not have a policy in place that makes compounded bevacizumab routinely available to treat wet age-related macular degeneration and there is no plan in place to introduce one at the current time.
- Q5 Does your Trust currently have a wholly NHS owned pharmacy with an aseptic unit for compounding/aliquotting medicines? Please answer Yes or NO. If yes, is this NHS pharmacy the same legal entity as that of your hospital Trust?**
- A5 Yes. The Trust has a MHRA licensed aseptic unit which is wholly owned by the Trust and is therefore part of the same legal entity. The unit is based at the Royal Stoke Hospital
- Q6 Does your Trust currently host on its premises a privately owned pharmacy with an aseptic unit for compounding/aliquotting medicines? Please answer Yes or NO. If yes, please provide details of the third party provider of your pharmacy services.**
- A6 No
- Q7 Over the past two years has your Trust, on more than one occasion, used compounded Avastin (bevacizumab) for ophthalmic use? Please answer Yes or No.**
- A7 Yes
- Q8 If you answered yes to Q5 or Q6:**
- 8) Is the pharmacy referred to above in Q5 or Q 6 currently providing, or potentially able to provide, compounded Avastin (bevacizumab) for ophthalmic use? Please answer Yes or No**
- A8 The Pharmacy aseptic unit referred to in question 5 is not currently providing compounded Avastin (bevacizumab), but is potentially able to provide compounded Avastin (bevacizumab) for ophthalmic use if stability data and additional staffing made available
- Q9 Does the pharmacy referred to above in Q5 or Q6 currently hold an MHRA license for the manufacture of specials? Please answer Yes or No**
- A9 Yes
- Q10 If you answered yes to Q5 or Q6 but no to Q9:**
- When was the pharmacy referred to above in answer to Q5 or Q6 last inspected by the CQC?**
- A10 Not applicable
- Q11 If you answered no to questions Q5 or Q6 above, but yes to question Q7:**

Please provide information regarding from whom your Trust has or obtained/purchased compounded Avastin (bevacizumab). If you cannot provide the name of any commercial supplier, please provide as much information as possible.

A11 Not applicable

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

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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,





**University Hospitals
of North Midlands**
NHS Trust

Leah Carlisle
Deputy Head of Quality, Safety & Compliance

