County Durham and Darlington NHS
NHS Foundation Trust

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Request for Information Reference: 12.18.07

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Email only

4th January 2019

Freedom of Information Act 2000 – Request for Information

Thank you for your correspondence received on 4 December 2018 in relation to the County Durham and Darlington NHS Foundation Trust (Trust). This contained requests for further information with respect to an earlier request handled under the Freedom of Information Act (reference – 10.18.07). We are dealing with your correspondence as a new request under the provisions of the Freedom of Information Act 2000.

You requested information regarding the implementation of a specific Policy for the use of Compounded Bevacizumab (CB) in treating new patients for Age-related Macular Degeneration (AMD) The further information which you specifically requested information was follows:

4. Please confirm whether the Trust plans to implement the Policy and, if so, how (providing as much detail as possible regarding the sourcing of the CB specially the supplier/type of supplier, anticipated volumes of supply and estimate batch sizes) and in what timeframe?

5. We note with concern that, in the interim, eleven of the Defendant CCGs have issued press releases announcing that following the Judgment "your local NHS can now offer you a drug called Avastin for the treatment of wet AMD". The fact and content of the press releases are concerning for any number of reasons, but it is particularly concerning that the press releases should mischaracterise the Policy under challenge as providing for untrammelled patient choice. It does not: the Policy states in terms that 'Avastin' contemporaneous emails disclosed by the CCGs in the Administrative Court proceedings, this exercise in persuasion is to be carried out without apparent regard for express and informed patient consent.

8. Respond to paragraph 7 of our letter – that paragraph sought confirmation that the Trust planned to implement the Policy and, if so, how (providing as

much detail as possible regarding the sourcing of the CB, specifically the supplier/type of supplier, anticipated volumes of supply and estimated batch sizes) and in what timeframe."

9. Please clarify the area in which compounding of CB will take place?

10. Please confirm whether your facilities are subject to inspections under EL (97)52? If so, please state who carries out such inspections, against what safety standards, and by what method? As regards the applicable standards, please confirm whether one such standard is that medicines are prepared in response to prior patient-specific prescriptions (we refer in that regard to point 15 of Annex A to EL997)52). Please also indicate how, in relation to the manufacture of CB, you propose to carry out the required quality assessments envisaged by EL (97)52 or if such a quality assessment has been carried out, please provide us with a copy of the report.

County Durham and Darlington NHS Foundation Trust replies:

1. (Response to your paragraph 4 above) The Trust is planning to implement the Policy for new patients.

a. Supplies will be purchased from either a commercial supplier or NHS unit.

b. New patient referrals typically number approximately 30 per month

c. Volumes of supply will depend on patient uptake

d. Batch sizes will be determined by the supplier

e. The Policy will be implemented once a consistent supply of high quality medication can be supplied and in-house information materials agreed

2. (Response to your paragraph 5 above) Patients will be offered a choice of treatment with bevacizumab, aflibercept or ranibizumab. At this point, in-house patient information has not been finalised. No patient will receive bevacizumab without their informed consent.

3. (Response to your paragraph 8 above). We have now supplied a full response as per 1 above.

4. (Response to your paragraph 9 above) Aseptically manufactured items made in house under Section 10 exemption of the Medicines Act are made in a Grade A environment (isolator) located within a Grade D clean room. However this is not relevant as the Trust's intention is to purchase compounded bevacizumab externally rather than to manufacture it in-house.

5. (Response to your paragraph10 above) CDDFT is subject to inspections under EL (97)52. These inspections are carried out by regionally appointed appropriately qualified Quality Assurance pharmacists against the standards as set out in the "Quality Assurance of Aseptic Preparation Services: Standards 5th Edition". A copy of the report is provided. These arrangements and the attached report are not relevant however to the provision of intravitreal compounded bevacizumab however, as the intention is not to manufacture it in-house.

In line with the Information Commissioner's directive on the disclosure of information under the Freedom of Information Act 2000 your request will form part of our disclosure log. Therefore, a version of our response which will protect your anonymity will be posted on the County Durham and Darlington NHS Foundation Trust website.

If you have any queries or wish to discuss the information supplied, please do not hesitate to contact me on the above telephone number or at the above address.

If you are unhappy with the way your request for information has been handled, you can request a review by writing to:

The Chief Executive
County Durham & Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
DL3 6HX

If, you remain dissatisfied with the handling of your request or complaint, you have a right to appeal to the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Telephone: 0303 123 1113
Website: www.ico.gov.uk.

There is no charge for making an appeal.

Yours sincerely

Joanna Tyrrell

County Durham and Darlington NHS
NHS Foundation Trust

Freedom of Information Officer

with you all the way