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Request for Information Reference: 10.18.07

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Email only

5 November 2018

### **Freedom of Information Act 2000 – Request for Information**

Thank you for your request for information received on 5 October 2018 in relation to the County Durham and Darlington NHS Foundation Trust (Trust). We are dealing with your request under the provisions of the Freedom of Information Act 2000.

You requested information regarding the producing of CB. Specifically you asked for:

#### ***Request for information under the Freedom of Information Act 2000.***

***(1) Does the Trust currently possess facilities that produce, or are capable of producing, CB in-house at the scale necessary to implement the Policy for the Trust's patients?***

Answer: Yes

***(2) If the Trust does consider that it possesses such facilities, please provide a full description of:***

***a. What those facilities comprise.***

Answer: Grade A isolators in a Grade D background clean room

***b. Whether such facilities are registered as a pharmacy with the GPC.***

Answer: No

***c. The qualifications of staff involved, in particular the role of any registered or unregistered pharmacists.***

Answer: Pharmacists possess BPharm or MPharm in Pharmacy with registration with the General Pharmaceutical Council. Pharmacy Technicians possess an NVQ3 in

Pharmacy Services and registration with the General Pharmaceutical Council. Pharmacy Assistants have a NV2 in Pharmacy Services with additional modules in NVQ3.

***d. The volumes of CB that, at full capacity, are or could be produced***

Answer: Capacity would vary according to clinical demand (including patient preference) for CB. It will also depend on other aseptically produced compounds and available staffing. The facilities available could meet the demand with appropriate staffing.

***e. Whether CB has been compounded in the past; and if so, how regularly and in what amounts.***

Answer: CB has not been compounded

***f. The equipment that would be/has been used for such manufacture.***

Answer: Envair negative pressure isolator

***g. The arrangements made/to be made for maintaining sterility during the compounding process.***

Answer: All compounding would be undertaken in a Grade A clean area using sterile components

***h. The shelf life of any CB that has been produced or would be produced.***

Answer: 7 days

***i. The inspection regime applicable to such facilities (whether CQC or GPC).***

Answer: Not applicable

***Please provide copies of recent inspection reports.***

Answer: Not applicable as above.

***j. The arrangements (if any) in place to secure that any CB compounded is compounded in response to and in respect of a specific patient's prescription.***

Answer: The unit works under a Section 10 exemption of the Medicines Act – this is not a requirement.

***k. The pharmacy guidance and other relevant manufacturing standards and controls that would be followed in preparing CB for ophthalmic use.***

Answer: Quality Assurance of Aseptic Preparation Services: Standards – Part A (5th Ed)

***(3) If you cannot answer some or any of the above questions or do not have any documents that address these points, please confirm this in writing.***

Answer: Not applicable

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](http://www.ico.gov.uk).

There is no charge for making an appeal.

Yours sincerely

**Joanna Tyrrell**  
**Freedom of Information Officer**