University Hospitals of North Midlands NHS Trust

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

Tel: 01782 676474
Email foi@uhnm.nhs.uk

Ref: FOIA Reference 2018/19-046

Date: 21st May 2018

Dear

I am writing in response to your email dated 20th April 2018 requesting information under the Freedom of Information Act (2000) regarding rituximab.

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 am writing to request information under the Freedom of Information Act regarding the use of rituximab at University Hospitals of North Midlands NHS Trust.

1.Do you have local clinical pathways or standard operating procedures (SOPs) for the use of MabThera? If so are you able to share these? For instance, is one cycle of MabThera intravenous (IV) always used before initiating the patients on MabThera subcutaneous (SC) in oncology indications?

A1 In haematology standard practice at UHNM is to give intravenous rituximab when in combination with chemotherapy. Subcutaneous rituximab is only used maintenance treatment where patients have already received intravenous rituximab. This is prescribed according to standard regimens and is not available as a SOP.

Q2 Number of patients treated* using MabThera subcutaneous versus MabThera intravenous in oncology indications between 2016-2018, if only partial data is available please indicate the timeframe the data refers to:

Oncology		
Financial Year	Number of patients treated using **MabThera Intravenous** *(if possible, please provide number of patients excluding those who were switched to MabThera subcutaneous)*	Number of patients treated using **MabThera Subcutaneous**

FY 2016-17		
FY 2017-18		

*__if number of patients treated is not available please provide information in units that you have available (e.g. vials, preparations…)__

A2 Please see below:

Oncology		
Financial Year	Number of patients treated using MabThera Intravenous *(if possible, please provide number of patients excluding those who were switched to MabThera subcutaneous)*	Number of patients treated using MabThera Subcutaneous
FY 2016-17	159	82
FY 2017-18	97	97

Q3 Total number of patients treated* with MabThera (intravenous and subcutaneous) vs Rixathon vs Truxima in oncology and rheumatology indications between 2016-2018, if only partial data is available please indicate the timeframe the data refers to:

Financial Year	Drug	Number of patients treated in Oncology	Number of patients treated in Rheumatology
FY 2016-17	**MabThera**		
	Truxima		
	Rixathon		
FY 2017-18	**MabThera**		
	Truxima		
	Rixathon		

if number of patients treated is not available please provide information in units that you have available (e.g. vials, preparations…)

A3 Please see below:

Financial Year	Drug	Number of patients treated in Oncology	Number of patients treated in Rheumatology
FY 2016-17	MabThera	263	Information not held by the Trust, however Staffordshire and Stoke on Trent Partnership Trust (SSOPT) may hold the information; you can find them at the following email: foi@ssotp.nhs.uk
	Truxima	0	As above
	Rixathon	0	As above
FY 2017-18	MabThera	194	As above
	Truxima	82	As above
	Rixathon	0	As above

Q4 **Do you have local clinical pathways or standard operating procedures (SOPs) for the initiation of new patient treatment regimens? If so are you able to share these?**

A4 There are no standard operating procedures for treatment initiation at UHNM. The haematology department follows BSH guidelines; there are no separate local clinical pathways.

Q5 **Specifically, are new patients directly prescribed biosimilar rituximab (i.e. Truxima or Rixathon) instead of MabThera?**

A5 In haematology new patients are prescribed biosimilar intravenous rituximab - Truxima

Q6 **Are existing patients being switched from MabThera intravenous to biosimilar rituximab (i.e. Truxima or Rixathon)? If so is there a set point in their treatment pathway when patients are switched and how is this managed?**

A6 At UHNM only new patients have been transferred to intravenous biosimilar, existing patients have remained on MabThera until their course of chemotherapy is complete.

Q7 Are any existing patients being switched from MabThera subcutaneous to biosimilar rituximab (i.e. Truxima or Rixathon)? If so is there a set point in their treatment pathway when patients are switched and how is this managed?

A7 At UHNM only new patients have been transferred to intravenous biosimilar, existing patients have remained on MabThera until their course of chemotherapy is complete.

Q8 Number of patients treated* using rituximab biosimilars (Truxima and Rixathon) instead of MabThera (intravenous and subcutaneous) between 2016-2018, if only partial data is available please indicate the timeframe the data refers to:

Financial Year	Drug	Oncology		Rheumatology	
		New patients treated directly with the biosimilar instead of MabThera	Existing patients switched from MabThera to the biosimlar	New patients treated directly with the biosimilar instead of MabThera	Existing patients switched from MabThera to the biosimlar
FY 2016-17	Truxima				
	Rixathon				
FY 2017-18	Truxima				
	Rixathon				

***if number of patients treated is not available please provide information in units that you have available (e.g. vials, preparations…)**

A8 Please see below:

Financial Year	Drug	Oncology		Rheumatology	
		New patients treated directly with the biosimilar instead of MabThera	Existing patients switched from MabThera to the biosimlar	New patients treated directly with the biosimilar instead of MabThera	Existing patients switched from MabThera to the biosimlar
FY 2016-17	Truxima	0	0	Information not held by the Trust, however Staffordshire and Stoke on Trent Partnership Trust (SSOPT)	

				may hold the information; you can find them at the following email: foi@ssotp.nhs.uk
	Rixathon	0	0	As above
FY 2017-18	Truxima	82	0	As above
	Rixathon	0	0	As above

Q9 As an organisation, are you aware of any financial savings made by using biosimilar rituximab (i.e. Truxima or Rixathon) vs MabThera between 2017-2018, if only partial data is available please indicate the timeframe the data refers to and the methods used to calculate the financial savings.

Year	**Scheme** *(e.g. discounting, gainshare…)*	**Approximate saving (£)**

A9 Not applicable as there is no financial saving to the Trust as drug cost get passed through to NHS England

Q10 Please provide information on the current contracts for Truxima, Rixathon, MabThera intravenous (IV) or subcutaneous (SC):

Drug	**Contract value (£)***	**Volume of contract (number of vials)**	**Is price tiered by volume?**	**Length of contract**		**Renewal frequency**	**Services included**	
				Date of contract	**Date of contract**		**Yes/No**	**Which services**

			(Yes/No)	initiation	expiry			*(e.g. biosimilar education, patient support program…)*
Rixathon								
Truxima								
MabThera IV								
MabThera SC								

*__if the total contract value is not available, please provide the price range for each drug__

A10 The Trust considers your request to be exempt from disclosure in accordance with section 43(2) of the Freedom of Information Act as to release this information would, or would be likely to, prejudice the commercial interests of the Trust. The Trust has applied the public interest test to this request and feels that the public interest in maintaining the exemption outweighs the public interest in disclosure.

However information may be available by contacting the Commercial Medicines Unit (CMU) at the following link:
https://www.gov.uk/government/collections/commercial-medicines-unit-cmu

Q11 Related to question 10, if contracts are tiered by volume, could you please provide the thresholds for each tier and what is the price percentage difference between tiers?

A11 As answer 10.

*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.

University Hospitals of North Midlands NHS Trust

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.

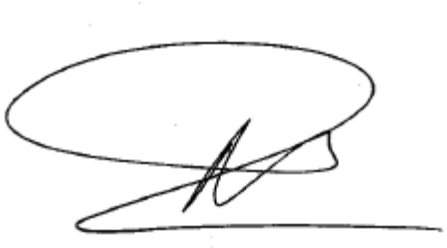
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and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



Mojgan Casillas
Interim Information Governance Manager