St Helens and Knowsley Teaching Hospitals NHS Trust

Ref no:	180300719
From:	Commercial
Date:	30/07/19
Subject:	Unlicensed medicines

REQUEST & RESPONSE

1. 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.

Yes – please see attached extract of medicines policy (Appendix 1).

2. 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.

Please see attached extract of medicines policy and copy of patient leaflet (Appendix 1)

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

Medical Director

   a. If no Board level job role(s) is (are) responsible for patient safety and consenting, please state which job role in the organisation is responsible for this

4. 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.

No.

5. Over the past two years has your Trust, on more than one occasion, used compounded Avastin (bevacizumab) for the treatment of wet age-related macular degeneration? Please answer Yes or No

Yes.

If yes to 5:

6. Was the compounded Avastin (bevacizumab) for the treatment of age-related macular degeneration produced within an aseptic department owned/run by the Trust? Please answer Yes or No

No.

If yes to 6:

7. Does the Trust's aseptic department, referred to above, currently hold an MHRA license for the manufacture of specials? Please answer Yes or No

Not applicable.

8. When was the Trust's aseptic department, referred to above, in answer to Q5 last inspected by the CQC?

Not applicable

If you answered no to question 5, but yes to question 4:

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

Considered commercially confidential information. 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.

Appendix 1.

Extract from the Trust Medicines Policy in relation to unlicensed medicines

16a UNLICENSED MEDICINES
There are two main categories:

1. Drugs which have no MHRA product licence in the UK. This includes drugs licensed in other countries, drugs manufactured by a specials manufacturer, individually-prepared medicines made by a pharmacy
2. Off-label use of licensed drugs – ie. prescribed for an indication not listed in the licensed indications which are detailed in the drug's summary of product characteristics.

Considerations when prescribing unlicensed medicines for the Trust's patients:

- Medicines should be prescribed within their licensed indications whenever possible. Off-label use is only appropriate when there is no suitable product which is licensed and available for the required indication. Sometimes national and expert guidance recommends the use of medicines for off-label indications. Examples include amitriptyline in neuropathic pain and many drugs used in paediatrics & palliative care.
- Medicines which have a product licence for use in the UK by the MHRA will be prescribed and supplied unless there is adequate justification eg. allergy to excipients, formulation unavailable
- Prescribers take on extra responsibilities when prescribing for off-label indications or for unlicensed medicines. There must be adequate clinical justification and medicolegal consequences should be considered.
- Pharmacists should make the prescriber aware that a prescribed medicine is unlicensed in the UK.
- Patients should agree to treatment with an unlicensed or off-label drug before it is prescribed. The process of informed agreement may be performed in the same way that agreement for treatment with other medicines is gained from patients without requirement for additional specific documentation.
- A patient information leaflet explaining unlicensed medicines should be provided to patients. This is available from Pharmacy.
- Patient-specific decisions about unlicensed medicines should be documented in the patient's medical records.
- Pharmacy, through the Drug and Therapeutics Group, will regularly review unlicensed drugs usage and to encourage the use of licensed alternatives where possible.
- Pharmaceutical Quality Control NW (QCNW) guidance on the supply of unlicensed medicines will be followed within the Trust.
- Supplies of unlicensed medicines may be quarantined whilst quality control assessment is conducted if the supplier is not a QCNW-approved supplier. This may lead to delay in supply. Exception to release a quarantined medicine prior to QC test results may only be made in very urgent situations when the clinical need of a patient provides justification. The permission of the consultant, purchasing pharmacist and the patient should be provided.
- Detailed advice is available from Pharmacy Medicines Information on ext 1565