St Helens and Knowsley Teaching Hospitals NHS Trust

Ref no:	079171018
From:	Commercial
Date:	17/10/18
Subject:	Pharmacy policies and protocol

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

Trust Medicines Policy (June 2018)

Section 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*

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.

   Yes – general Trust Policy for Consent used. Clinical Consent Policy July 2018 provided. No current specific documentation to consent for unlicensed medicines.

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

   Director of Nursing – Patient Safety

   Medical Director – Clinical Consent Policy

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*

   *The Trust is monitoring the ongoing situation along with other hospitals trusts and local commissioners. Trust Policy may be reviewed in light of developments.

5) 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?

   Yes

   The aseptic unit is within the Trust's Pharmacy Department and is part of the Trust's legal entity

6) 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.

   No

7) 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.

   No

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

   Yes

9) 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

   Yes

If you answered yes to Q5 or Q6 but no to Q9:

10) When was the pharmacy referred to above in answer to Q5 or Q6 last inspected by the CQC?

    N/A

If you answered no to questions Q5 or Q6 above, but yes to question Q7:

11) 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.

    N/A