

Reference:	FOI.1057.19
Subject:	Unlicensed medicines
Date of Request:	26 June 2019

Requested

1. Does your Health Board 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
2. Does your Health Board 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.
3. Please state which Board level job role(s) is (are) responsible for patient safety and consenting
 - 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
3. Does your Health Board 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
5. Over the past two years has your Health Board, on more than one occasion, used compounded Avastin (bevacizumab) for the treatment of wet age-related macular degeneration? Please answer Yes or No

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 Health Board? Please answer Yes or No

If yes to 6:

7. Does the Health Board's aseptic department, referred to above, currently hold an MHRA license for the manufacture of specials? Please answer Yes or No
8. When was the Health Board's aseptic department, referred to above, in answer to Q5 last inspected by the CQC?

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

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

Response:

1. Yes, Hywel Dda University Health Board (UHB) does have a policy on the use of unlicensed medicines. A copy has been provided as Attachment 1.
2. Yes, the UHB does a policy on obtaining informed consent from patients prior to using an unlicensed medicine. Further information can be provided within policy provided (Attachment 1),

the UHB has also provide a copy of its 'Non-Formulary or Unlicensed/'Off label' Medicines Request Form' (Attachment 2).

3. Patient safety and monitoring standards of practice relating to such matters as consenting sits within the portfolio of Mandy Rayani, Director of Nursing, Quality and Patient Experience.
4. The UHB does not currently have a policy to make compounded Bevacizumab routinely available to treat wet age-related macular degeneration. The UHB will continue to adhere to guidance provided by The National Institute for Health and Care Excellence (NICE), professional bodies and NHS Wales.
5. No, the UHB has not used compounded Bevacizumab for the treatment of wet age-related macular degeneration within the last two years.
6. Please see response to question 5.
7. Not applicable.
8. Not applicable.
9. Not applicable.