Policy for the use of Unlicensed Medicines and Medicines used outside their Market Authorisation
Contents:

1 Executive Summary ........................................................................................................ 2
  1.1 Scope of policy ........................................................................................................ 2
  1.2 Definition ................................................................................................................ 2

2 Aims .................................................................................................................................. 3

3 Policy Statement .............................................................................................................. 3

4 Responsibilities .............................................................................................................. 4
  4.1 Use of product without UK Market Authorisation (Unlicensed Medicine) ................. 4
  4.2 Purchase of “specials” or supply of extemporaneously prepared products. ............... 5
  4.3 Use of a licensed medicine outside its Market Authorisation .................................... 6
  4.4 Continuing supplies of Unlicensed Medicines in Primary Care ............................... 6
  4.5 Ward Stocks .............................................................................................................. 8

5 Training ............................................................................................................................ 8

6 Audit .................................................................................................................................. 8

7 References ....................................................................................................................... 9

8 Appendices ...................................................................................................................... 10
  8.1 Appendix 1: Specialist Prescribing Advisory Group – List of Unlicensed Medicines . ... 10
  8.2 Appendix 2: Form - Request to use an unlicensed medicine ................................. 12
  8.3 Appendix 3: Form – Request to use a Licensed Medicines for an unlicensed Use or “Off-Label Use” ......................................................................................... 13
  8.4 Appendix 4: Guidance from the General Medical Council (GMC) .......................... 14
  8.5 Appendix 5: Prescribing of medicines recommended by hospital specialists .......... 16
1 Executive Summary

The Specialist Prescribing Advisory Group (SPAG) is responsible for monitoring adherence to the Health Board’s Unlicensed Medicine Policy. This includes reviewing requests for:

- The introduction of new medicine entities.
- Non-formulary medicines.
- Different presentations of formulary medicines.
- Unlicensed medicines or licensed medicines used for unlicensed indications.

The majority of medicines used within the Health Board have a Market Authorisation issued by the Medicines and Healthcare Product Regulatory Service (MHRA) and are used within the terms of their Market Authorisation. Wherever possible, licensed products should be used to treat patients.

There are issues related to the liability associated with the use of unlicensed medicines or the use of licensed medicines outside their Market Authorisation. The Health Board, the clinician and the pharmacist may be exposed to increased legal liability through such use.

1.1 Scope of policy

The policy applies to all prescribers employed by, or working for, Aneurin Bevan Health Board and to all pharmacists responsible for the purchasing, quality assurance and supply of these medicines.

The policy covers the use of licensed medicines outside their Market Authorisation and the use of medicines without a Market Authorisation. The policy does not apply to products used in clinical trials, extemporaneous preparations or extemporaneously prepared syringes used in palliative care, or medicines administered via enteral feeding tubes.

The Gwent Joint Formulary process applies to medicines that fall within this policy.

1.2 Definition

There are three principal categories of medicines covered under this policy:
Aneurin Bevan Health Board

Policy for the use of Unlicensed Medicines and Medicines used outside their Market Authorisation

Clinical Director, Pharmacy

Policy for the use of Unlicensed Medicines and Medicines used outside their Market Authorisation

Clinical Director, Pharmacy

Status: Issue 2
Issue date: 29 September 2010
Approved by: Clinical Standards & Policy Group
Review date: 29 September 2012
Expiry date: 29 September 2013

Page 3 of 16

• **Medicines which do not have a UK Market Authorisation (an unlicensed medicine).** These may include medicines manufactured by a licensed manufacturer which are awaiting a UK Market Authorisation, are manufactured for export, have been withdrawn from the UK market, or where the manufacturer does not intend to apply for a UK licence. These products are usually obtained on a "named patient" or "named clinician" basis.

• **Unlicensed medicines prepared by a manufacturer with a Special Manufacturing Licence.** These are widely referred to as “specials”. Pharmacy supplies a small number of patient specific products that are made in a manufacturing unit that holds a Manufacturing License (Specials) issued by the MHRA.

• **The use of licensed medicines outside their Market Authorisation.** The indication may be unlicensed, the dose or the age of the patient may be outside the licence, the route or the method of administration may be outside the licence. In some circumstances, the product may require unlicensed reformulation before administration.

2 Aims

There are valid situations where the above use is clinically appropriate or essential. The Health Board is asked to acknowledge this situation and accept liability on behalf of its employees in such circumstances, provided the agreed policy is followed.

The Health Board acknowledges the use of unlicensed medicines as ward base stock does not comply with the MHRA Guidance Note No. 14 since it is not possible to provide an audit trail of patients receiving unlicensed medicines. This policy identifies how this risk should be managed.

The Welsh Risk Pool acts as Insurer for the Health Board against financial loss.

The Healthcare Inspectorate Wales, under Standard 19 requires Health Boards to ensure that quality, safety and security issues of medicines are managed.

3 Policy Statement

Liability for problems arising from the use of unlicensed medicines, or the use of licensed medicines outside their Market Authorisation, will be accepted by the Health Board if the agreed policy is followed.
4 Responsibilities

The BNF and BNF for Children state “Prescribing unlicensed medicines or medicines outside the recommendations of their Marketing Authorisation, alters and probably increases the prescribers’ professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines”.

It is a pharmacist’s professional duty to assist prescribers in ensuring that a pharmaceutical special is only used where there is no possible licensed alternative and in many cases it is preferable to give a licensed product via an unlicensed route (e.g. an injection given orally), than to prepare a special formulation. It is also the professional responsibility of the pharmacist to ensure that cost effective medicines are used.

Guidance from the GMC on prescribing unlicensed medicines and for prescribing medicines for use outside the terms of their license are in Appendix 4.

This policy aims to support the prescriber in the use of these medicines within a framework where the Health Board will accept liability on behalf of its employee.

4.1 Use of product without UK Market Authorisation (Unlicensed Medicine)

The pharmacy will purchase such products, usually on a “named patient” basis, on receipt of a written request (prescription) from a consultant or a member of his/her team on behalf of the consultant. In an emergency, this may be supplied retrospectively after discussion between the pharmacist and the prescribing consultant. The pharmacy will hold the name of the patient and let the supplier be aware of the name of the consultant. (Supply of a patient’s name to suppliers may have implications for confidentiality and may transgress data protection legislation). Details of the patient will be recorded within the pharmacy department.

Acceptance of liability for the use of a product without a UK Market Authorisation by the Health Board will depend on the concept of “peer group support”. This will be based on the use of published evidence, standard text and specialised text.

Pharmacy will forward a form, (see Appendix 2) for completion by the consultant for a new request for an unlicensed medicine. It is the responsibility of the consultant to ensure that the form (Appendix 2) is completed and returned to pharmacy to support the purchase of an unlicensed medicine.
A number of unlicensed medicines are included in the BNF and the BNF for Children, which is indicated after the entry. It is accepted that the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines. **Use supported by the BNF and the BNF for Children will be accepted as peer group approved and form Appendix 2 will not be required.**

A directorate or an individual consultant who routinely uses an unlicensed medicine (not supported by the BNF or the BNF for Children) could pre-complete the appendix 2 form which would be kept on file to cover all such prescribing for patients under their care for a particular unlicensed medicine. This information will be reviewed by SPAG and via the Health Board’s clinical governance processes.

Pharmacy will ask suppliers for written English translation of product information and SPC for imported products wherever available.

Pharmacy will report to the Specialist Prescribing Advisory Group (SPAG) on the issue of unlicensed medicines as stipulated in Section 6 – Audit.

An unlicensed medicine should not form part of a Patient Group Direction (PGD) or Patient Specific Direction (PSD) except in exceptional circumstances.

The Chartered Institute of Physiotherapy recognises the mixing of medicines in physiotherapy is customary.

Mixing two licensed medicines such as a local anaesthetic and corticosteroids constitutes, under the terms of the Medicines Act, the manufacture of a new unlicensed product. Physiotherapists can administer mixed medicines under a PSD for a named patient in accordance with a doctor’s direction. In these situations such administration is the doctor’s direct responsibility.

Such administration is not permitted under a PGD.

### 4.2 Purchase of “specials” or supply of extemporaneously prepared products.

It is the responsibility of pharmacy to take all reasonable steps to establish the quality of the product in line with their procedures. A Certificate of Analysis will be obtained whenever possible. Where the quality of the product is judged to be unsuitable or cannot be established, the prescriber will be informed.

Although it is the professional responsibility of the pharmacist to ensure that cost effective medicines are used it should be noted that costs in Primary Care can be highly variable.
4.3 Use of a licensed medicine outside its Market Authorisation

The Health Board will accept liability for problems associated with such use if the use has peer group support (see 4.1). Prescribers have a duty to ensure that they are aware of their use of medicines. When pharmacists are aware of the use of a medicine outside the terms of its licence they must ensure that the prescriber is aware of the risks and benefits of use. (Prescribers will be required to provide written acknowledgement that they have been informed that they are using a medicine outside its licence). (See Appendix 2).

Where the BNF or BNF for Children suggests a use (or route) that is outside the licensed indication of a product (“off label use”) this will be accepted as peer group approved and form Appendix 2 will not be required.

A directorate or an individual consultant who routinely uses an “off label” medicine (not supported by the BNF or the BNF for Children) could pre-complete the Appendix 2 form which would be kept on file to cover all such prescribing for patients under their care for a particular unlicensed medicine. This information will be reviewed by SPAG and via the Health Board’s clinical governance processes.

Supplementary prescribers and Independent Prescribers may prescribe licensed medicines for use outside of their licensed indications provided they form part of a Clinical Management Plan.

Where medicines are prescribed outside of their licence it is good practice for the prescriber to obtain the patient’s consent.

Non medical Independent and Supplementary prescribers may now prescribe unlicensed medicines under the terms of this policy.

The information provided on the Appendix 2 form will be reviewed by SPAG, Gwent Partnership Medicine and Therapeutics Committee (GPMTC) as appropriate.

4.4 Continuing supplies of Unlicensed Medicines in Primary Care

Medicines initiated and dispensed within secondary care remain the responsibility of the initiating consultant until timely, accurate and adequate communication on treatment and diagnosis is received by primary care. GPs still have the discretion to choose whether to prescribe an off label or unlicensed product. In order to enable the GP to make an informed decision whether to agree to prescribe the drug or not, the following information should be provided:

- Patient details
• Medicine
• Dose
• Indication
• Evidence for the use of the medicine including if it is listed in the BNF or BNF for children
• Anticipated duration of therapy
• Relevant comments on diagnosis
• Monitoring required

If a medicine is unlicensed or if a medicine is used outside the terms of its license (Off Label) then full justification for the use of the medicine should be given by the consultant to the GP when requesting such treatment is prescribed. Note: Such uses are often necessary in paediatric practice – see Appendix 4.

A GP can prescribe unlicensed medicine but in doing so he/she must:
  i) Be satisfied that an alternative licensed medicine would not meet the patient’s needs. (For determining the best option for the patient, information can be sought from ABHB Medicines Information or the ABHB Locality prescribing teams).
  ii) Be satisfied that there is sufficient evidence base and/or experience of using this medicine to demonstrate is safety and efficacy. The BNF and cBNF would be considered as acceptable evidence.
  iii) Take responsibility for prescribing the unlicensed medicine and for overseeing the patient’s care, including monitoring and any follow up treatment
  iv) Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

GPs remain professionally accountable for their judgements in prescribing of unlicensed medicines or off label use of licensed medicines and where GPs have concerns they may choose to use the GPMTC-endorsed form to decline a request from a hospital specialist to continue prescribing unlicensed medicines. See Appendix 5.

Emergency prescribing of critical unlicensed medicines by clinicians within the Out of Hours Service will assume prior consent, via the terms of this Policy has been confirmed by the originating prescriber.

Commonly used off label medicines not in the BNF or cBNF will be identified by primary care clinicians and may be referred to GPMTC so that appropriate advice can be developed.
4.5 Ward Stocks

A number of unlicensed medicines, medicines used outside of their Market Authorisation and specials are held as ward stocks within the Health Board. Clinical Directors will be supplied with an up-to-date list of these products and will be asked to authorise the use of these products by clinicians within their Directorate. (See Appendix 1). The appropriate Clinical Director will be asked to approve any requests for additional unlicensed medicines to be held as ward stocks.

The Health Board cannot supply unlicensed medicines to community pharmacies. Community pharmacists should be referred directly to the manufacturer of the unlicensed medicine. In an emergency, the Community Pharmacist should be referred to the Procurement Pharmacist or nominated deputy.

5 Training

Clinical Directors will ensure that clinicians within the Directorate are aware of this policy and the list of unlicensed medicines kept as ward stocks.

Pharmacy managers will ensure that pharmacists are aware of the policy and their responsibilities.

The Procurement Pharmacist will ensure that members of the pharmacy procurement team are aware of the policy and their responsibilities.

6 Audit

Suppliers of unlicensed medicines ordered at the request of a consultant will be recorded by pharmacy. Supplies made to individual patients will be recorded on the pharmacy computer system. The issue of “specials” will be recorded on the pharmacy computer system. Pharmacy will report on the issue of unlicensed drugs annually to the Specialist Prescribing Advisory Group including those used in the community.
7 References


Dear

Re: Unlicensed Medicines held as Ward Stock

The Medicines Health and Regulatory Agency (MHRA) on behalf of the UK Licensing Authority (LA) regulates medicinal products for human use in accordance with the Medicines or Human Use regulations 1994 and Medicines Act 1968.

The MHRA has issued Guidance Note No: 14 “The supply of unlicensed relevant medicinal products for individual patients” and compliance is a statutory requirement. This guidance note requires an audit trail of named patients receiving an unlicensed medicine. For unlicensed medicines held as ward stock this audit trail is not feasible. The Health Board, through the use of Unlicensed Medicines Policy, has been asked to acknowledge this situation and accept liability on behalf of its employees, provided the following authorisation has been received from each Clinical Director.

I have therefore, attached a list of unlicensed medicines kept as ward stocks in the wards to which your patients are admitted. Please would you sign and return the attached form to approve the use of these medicines within your Directorate. Should you wish to remove any items from the list, please indicate this on the list and return to the Procurement Pharmacist at the Royal Gwent Hospital. A new list will then be sent to you for authorisation.

Thank you for your help in this matter.

Yours sincerely

Stuart Linton
Chairman
Specialist Prescribing Advisory Group
LIST OF UNLICENSED MEDICINES ON WARD

I hereby sign that I have approved the use of the attached list of unlicensed medicines used on wards indicated: .................................................................

and that all medical personnel within the Directorate are aware of the legal status of these medicines.

Name of Clinical Director: .................................................................

Signature of Clinical Director: ..........................................................

Date: ..........................................................................................

Form to be returned to:
Procurement Pharmacist
Pharmacy Department
Royal Gwent Hospital/Nevill Hall Hospital
(delete as appropriate)
### 8.2 Appendix 2: Form - Request to use an unlicensed medicine

<table>
<thead>
<tr>
<th>Patient Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Name:</strong></td>
</tr>
<tr>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Sex:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug and preparation requested (including strength and formulation) and dosage (including strength and frequency):</strong></td>
</tr>
</tbody>
</table>

**Clinical Indication for use:**

What alternative treatments are available for this condition and have been tried?

What is the reason for preferred use of the named product and proposed benefits to the patient?

What are the serious and common side effects of the medicine?

Summary of evidence available for indication (attach any information which supports the use of this treatment):

<table>
<thead>
<tr>
<th>Procurement (pharmacist to complete)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Which supplier can the product be obtained from and what is the country of origin?</strong></td>
</tr>
<tr>
<td>Are there any anticipated problems with continuation of supply? Y/N</td>
</tr>
<tr>
<td>If Yes – details:</td>
</tr>
<tr>
<td>Is there an English version of the Patient Information Leaflet available with the product? Y/N</td>
</tr>
</tbody>
</table>

The manufacturer is only likely to be found liable if harm results from a defect in the product. In situations where the product is not licensed or where the product is used outside its licensed indications the manufacturer carries no legal liability should an untoward event arise, putting a greater responsibility on individual prescribers and the Health Board. The ultimate responsibility for prescribing any drug lies with the doctor who signs the prescription and is professionally accountable for his/her judgement. Doctors have a duty in common law to take reasonable care and to act in a way consistent with practice of a responsible body of their peers of similar professional standing. If use of this product is deemed to have significant risks, the request will be referred to the Medical Director.

The purpose of this policy is to provide an internal means of assessing the use of these products, thereby safeguarding patients against the risk of injury as well as minimising the likelihood of claims against the Health Board.

**Declaration by Consultant**

1. I have read the above and understand that the named product is an unlicensed medicine.
2. I accept responsibility for fully informing the patient of the fact that the product is unlicensed and has no UK Market Authorisation. I will initiate each prescription for the patient and obtain their consent.
3. Providing the above has been undertaken, I understand that this prescription and its consequence will be covered for vicarious liability under terms of my contract with the Health Board.

<table>
<thead>
<tr>
<th>Consultant Name:</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>Directorate:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Team Leader Pharmacist:</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

Send the completed form to the Procurement Pharmacist, Royal Gwent Hospital.
### 8.3 Appendix 3: Form – Request to use a Licensed Medicines for an unlicensed Use or “Off-Label Use”

#### Patient Details

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Surname:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth:</th>
<th>Site/Location:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex:</th>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Medicine Details

<table>
<thead>
<tr>
<th>Drug and preparation requested (including strength and formulation) and dosage (including strength and frequency):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Indication for use:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What alternative treatments are available for this condition and have been tried?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What is the reason for preferred use of the named product and proposed benefits to the patient?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are the serious and common side effects of the medicine?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

The manufacturer is only likely to be found liable if harm results from a defect in the product. In situations where the product is not licensed or where the product is used outside its licensed indications the manufacturer carries no legal liability should an untoward event arise, putting a greater responsibility on individual prescribers and the Health Board. The ultimate responsibility for prescribing any drug lies with the doctor who signs the prescription and is professionally accountable for his/her judgement. Doctors have a duty in common law to take reasonable care and to act in a way consistent with practice of a responsible body of their peers of similar professional standing. If use of this product is deemed to have significant risks, the request will be referred to the Medical Director.

The purpose of this policy is to provide an internal means of assessing the use of these products, thereby safeguarding patients against the risk of injury as well as minimising the likelihood of claims against the Health Board.

#### Declaration by Consultant

1. I have read the above and understand that the named product is to be used for an unlicensed indication.
2. I accept responsibility for fully informing the patient of the fact the prescribed use is currently unlicensed. I will initiate each prescription for the patient and obtain their consent.
3. Providing the above has been undertaken, I understand that this prescription and its consequence will be covered for vicarious liability under terms of my contract with the Health Board.

<table>
<thead>
<tr>
<th>Consultant Name: …………………………………………</th>
<th>Signature: ……………………………………………………</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date: ………………………………………………………...</th>
<th>Directorate: ……………………………………………………</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Send the completed form to the Procurement Pharmacist, Royal Gwent Hospital.
8.4 Appendix 4: Guidance from the General Medical Council (GMC)

Taken from Good Practice In Prescribing Medicines – Guidance for Doctors

Prescribing unlicensed medicines:
You can prescribe unlicensed medicines but, if you decide to do so, you must:
• Be satisfied that an alternative, licensed medicine would not meet the patient's needs
• Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
• Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment (see also paragraphs 25-27 on prescribing for hospital outpatients)
• Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

Prescribing medicines for use outside the terms of their license (off-label):

You may prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children. Currently pharmaceutical companies do not usually test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.

When prescribing a medicine for use outside the terms of its license you must:
   a. Be satisfied that it would better serve the patient's needs than an appropriately licensed alternative
   b. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources
   c. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so (see also paragraphs 25-27 on prescribing for hospital outpatients)
   d. Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine.
Information for patients about the license for their medicines:

You must give patients, or those authorising treatment on their behalf, sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions. This is to enable them to make an informed decision.

Some medicines are routinely used outside the scope of their license, for example in treating children. Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the license when seeking consent. However, it is good practice to give as much information as patients, or those authorising treatment on their behalf, require or which they may see as significant. Where patients, or their carers express concern you should also explain, in broad terms, the reasons why medicines are not licensed for their proposed use. Such explanations may be supported by written information, including the leaflets on the use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice produced by the Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines.

However, you must explain the reasons for prescribing a medicine that is unlicensed or being used outside the scope of its license where there is little research or other evidence of current practice to support its use, or the use of the medicine is innovative.

For specific information on prescribing medicines for children see the websites of the Royal College of Paediatrics and Child Health and the British National Formulary for Children.
8.5 Appendix 5: Prescribing of medicines recommended by hospital specialists

**PRESCRIBING OF MEDICINES RECOMMENDED BY HOSPITAL SPECIALISTS**

**PREScriber**

Complete this form if you are unwilling to take responsibility for prescribing medicines recommended by a hospital specialist

<table>
<thead>
<tr>
<th>Patient’s NHS Number: (10 digit)</th>
<th>Please blank out or omit in copy going to Interface Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of consultant or other requesting specialist:</td>
<td>Speciality:</td>
</tr>
<tr>
<td>Hospital/Trust:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of drug</th>
<th>Dose &amp; Frequency</th>
<th>Indication</th>
<th>Duration of Treatment</th>
</tr>
</thead>
</table>

I have been asked to accept the responsibility for prescribing this drug for the named patient, however I feel I am not in a position to do this for the following reason(s):  

1. **PRESCRIBING RESPONSIBILITY SHOULD STAY WITH THE SPECIALIST**
   - Drug is designated ‘RED’ in the Gwent Traffic Light Classification and is for specialist prescribing only.
   - Hospital CLINICAL TRIAL drug.
   - UNLICENSED drug/dose/indication *(delete as applicable)* where use is not endorsed by the BNF or BNFc and/or where an approved Shared Care Protocol does not exist and the GP is unwilling to take clinical responsibility.

2. **MONITORING BY SPECIALIST REQUIRED**
   - Drug requires regular specialist monitoring AND/OR the majority of care and monitoring is to be applied by the hospital.
   - Patient not stabilised on the drug.

3. **LACK OF INFORMATION / EXPERIENCE**
   - Drug is not designated ‘RED’ *(specialist prescribing only)* but GP feels unable to accept clinical responsibility. *(please state reason below in General Comments box)*
   - Drug NON FORMULARY in Gwent. Hospital prescribers are asked not to ask GPs to initiate or continue treatment with non-formulary medicines. Includes use of medicines for other than their formulary listed indication.

4. **GENERAL COMMENTS** *(continue overleaf if necessary)*

---

Print Name: ……………………………………
Signature: ………………………………………
Date: ……………………………………………

*Note: Responsibility for prescribing should not be refused on the grounds of drug cost. If this is an issue please contact your ABHB Locality Medicines Management Team for guidance.*

A COPY OF THIS FORM (IN WORD FORMAT) CAN BE FOUND ON THE GPMTC WEBSITE AT: http://www.gpmtc.wales.nhs.uk