Unlicensed Medicines Policy
### Executive Summary:
This policy describes the prescribing, supply and use of unlicensed medicines in East Cheshire NHS Trust and includes the form for requesting new unlicensed medicines. This Policy must be used alongside the Trust Safe & Secure handling of Medicines Policy.

It **excludes** the unlicensed use of licensed medicines i.e. off-label use.

### Supersedes:
Version 6.0

### Description of Amendment(s):
Referral to GP to collect further supplies removed

### This policy will impact on:
All healthcare professionals involved in the prescribing, supply, authorisation and use of unlicensed medicines.

### Financial Implications:
Reduce the risk associated with use of unlicensed medicines.

### Approval Record

<table>
<thead>
<tr>
<th>Committees / Group</th>
<th>Date</th>
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<tbody>
<tr>
<td>Consultation:</td>
<td>February 2017</td>
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<tr>
<td>Medicines Management Group</td>
<td></td>
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<tr>
<td>Chief Pharmacist</td>
<td>April 2017</td>
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<td>Approved by:</td>
<td>April 2017</td>
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<tr>
<td>Chief Pharmacist &amp; Chair of Medicines Management Group</td>
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<td>Received for information:</td>
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<td>Healthcare at Home Service Providers, for East Cheshire Trust</td>
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1 Scope and Definitions

Unlicensed medicines are those which have been specially prepared by the holder of a Manufacturers Specials Licence or imported in response to or in anticipation of the order of a doctor or dentist to meet the special needs of individual patients.

Unlicensed medicinal products must only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it. In exceptional circumstances use outside of these criteria may be approved by the Medicines Management Group.

All unlicensed medicines used by East Cheshire NHS Trust, other than those procured and supplied by homecare service providers are supplied by the Pharmacy Department and in accordance with this policy.

Exclusions

This policy does not cover products used outside their licensed indications (“off-label” use), investigational medicinal products (clinical trials materials), products dispensed within the Trust in response to a prescription, products prepared under exemptions (sections 9, 10 or 11) of the Medicines Act 1968, non-medicines, medical devices, intermediate products, repackaged licensed products, or reconstituted IV additives and CIVAS (central intravenous additive service) products.

“Off-label” use includes administering a medicine in a way not described in its summary of product characteristics (SPC) e.g. crushing tablets to administer to a patient with difficulty in swallowing. In such cases advice should be sought from the Pharmacy Medicines Information Dept (ext 1268)

It is the responsibility of the pharmacy operational manager to ensure that all products are of an appropriate quality and suitable for their intended use.

2 Consent of Patients, Carers and Parents

Health professionals must respect the right of patients, carers and parents to participate in discussions regarding the health care of the patient and to seek to ensure that these decisions are properly informed.

No additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents/carers for the use of unlicensed medicines.

3 Informing the Out Patient/Discharged Patient

The patient should receive a generic Patient Information Leaflet, (as shown in Appendix 1). The Patient Information Leaflet should explain why it is necessary to prescribe unlicensed medicines and should be widely available in hospitals and pharmacies which may help to allay any concerns that patients and carers may have about unlicensed medicines.
4 Roles and Responsibilities

This policy details the responsibilities of all staff involved in the prescribing, authorisation and supply of unlicensed medicines.

4.1 Prescribers

Prescribers of unlicensed products carry their own responsibility and are professionally accountable for their judgement in so doing. Some unlicensed medicines may be restricted to only consultant prescribing on the decision of the Medicines Management Group. Prescribers are responsible for the patient’s welfare and in the case of adverse events they may be called upon to justify their actions.

4.2 Pharmacists

Pharmacists are responsible for ensuring that prescribers are always aware that a medicine they have requested is only available as an unlicensed product.

Pharmacists share responsibility as the purchaser of the product and are responsible for ensuring that the manufacturer holds the appropriate licence to manufacture and that the product complies with the product specification

Pharmacists or other pharmacy staff who dispense or supply unlicensed medicines in response to prescriptions are professionally accountable for any harm caused by a defect in the medicine which is attributable to their own actions or omissions.

The Deputy Chief Pharmacist is designated as having overall responsibility for controlling the procurement and supply of unlicensed medicines and is referred to as the “Designated Pharmacist”. However, it is not unusual for several pharmacists to be involved in the decision making process from the Ward / Clinical Pharmacist who receives the request through to the person who signs the order or authorises the invoice. In the absence of the Designated Pharmacist, the roles and responsibilities as outlined above would lie with the Chief Pharmacist.

When an unlicensed medicine is to be ordered for the first time there needs to be critical, evidence based evaluation for its use and the designated pharmacist has an important and responsible role in assessing the evidence and challenging use. The pharmacist must also ensure that all the controls specified within this policy are applied including the maintenance of appropriate records of use.

4.3 Medicines Management Group

The Medicines Management Group is responsible for the approval for use of new unlicensed medicines in the Trust. However, in the case of urgent clinical need, the Chief Pharmacist and/or Designated Pharmacist may authorise use subject to formal ratification at the next MMG meeting. The Group risk assesses unlicensed medicines and ensures that their use is justified by published evidence or sound therapeutic argument. The Group also ensures appropriate audit systems are in place to monitor compliance with this policy.
4.4 Directorates

The Associate Director for each directorate of East Cheshire NHS Trust will receive a copy of the Unlicensed Medicine Application Form. As part of the authorisation process, they will be responsible for signing the form indicating that they acknowledge and approve the application for the use of an unlicensed medicine and the subsequent cost pressure to their directorate associated with that supply.

4.5 Homecare Service Providers

It is the responsibility of the homecare service providers for East Cheshire NHS Trust to operate and conform to the East Cheshire NHS Trust Policy for Unlicensed Medicines for the prescribing, authorisation, supply and use of all unlicensed medicines for patients of East Cheshire NHS Trust.
5 Specific Roles

5.1 Prescriber Responsible for the Care of the Patient

Initiation of treatment using unlicensed medicines must be undertaken by the Consultant or the Specialist Registrar of the Consultant responsible for the care of the patient.

1. Ensures that the use of the unlicensed medicine is justified by the clinical condition of the patient and no licensed alternative preparation is available.
2. Ensures that the Unlicensed Medicine request form completed is for treatment of patients under their direct care, and is not transferrable to patients requiring the same medicine under the care of another Consultant/ Specialist Registrar.
3. Ensures that junior doctors within their team caring for the patients receiving the unlicensed medicine are familiar with the status of the medicine and know the protocols that control its use.
4. Ensures that Trust policy relating to informed patient consent is complied with.
5. Ensures that records detailing the reason for request/ use are made in the Patient’s clinical notes.
6. Ensures that incidents of patient reactions are recorded and reported to the MHRA via the yellow card scheme and to the Trust’s critical incident reporting scheme.
7. Ensures that where responsibility for ongoing care is to be transferred to the patient’s general practitioner, that the general practitioner is informed of the unlicensed status of the medicine and that he or she is willing to accept clinical and legal responsibility for prescribing.
8. The hospital doctor is responsible for continuing treatment if the GP will not accept responsibility for continuing care.
9. Subject to risk assessment, communicate with patients the implications of using the unlicensed medicine. An example of a suitable Patient Information Leaflet for this purpose is given in Appendix 1.

5.2 Pharmacy Staff

5.2.1. Designated Pharmacist

1. Ensures that written procedures to cover all aspects of the procurement and issue of unlicensed medicines are produced, authorised, and reviewed.
2. Ensures that arrangements are in place to ensure that Prescribers are aware of the unlicensed status and accept the responsibility for the use of each new unlicensed medicine.
3. Ensures that arrangements are in place to make sure that unlicensed medicines are used only when an equivalent licensed product is unavailable.
4. Monitors and audits the handling of unlicensed medicines in the Pharmacy Department.
5. Monitors the range and quantities of unlicensed medicines purchased, keeping a list of unlicensed medicines currently approved by the Trust.
6. Communicates with the MHRA and the prescriber to process any reports of adverse reaction.
7. Prepares specifications for new unlicensed medicines (previously unavailable i.e. commissions a new unlicensed medicine from a supplier) in conjunction with Quality Control North West.
8. Ensures that applications for unlicensed medicines that have not previously been used in the Trust are submitted to the Associate Directors of each Directorate and MMG for approval.
9. Authorises new unlicensed medicines for use that are for urgent clinical need, before they can be formally assessed and approved by MMG.
10. Authorises new unlicensed medicines for use that are to be used as a temporary substitute for an unavailable licensed preparation, before they can be formally assessed and approved by the Directorates and MMG.
11. Informs Associate Director and MMG of the potential cost implication of the temporary use of unlicensed medicines as alternatives to licensed preparations, if they are unavailable.
12. Quarantines all unlicensed medicines from non-NHS suppliers on receipt within the Trust until the following assessment is carried out.
13. On receipt of unlicensed medicines from non-NHS suppliers, ensures that their packaging and labelling are inspected, Certificates of Analysis are assessed and copies are sent to Quality Control North West. If necessary arranges testing of samples with Quality Control North West.
14. Ensures all batches of unlicensed medicines are released as suitable for use within the Trust.

5.2.2. Procurement Function

Pharmacy staff involved in the procurement of unlicensed medicines: -

1. Ensure that the person making the request is authorised to do so.
2. Ensure that purchases of unlicensed medicines are in accordance with written procedures, and that the Designated Pharmacist is aware of the purchase.
3. Ensures the Designated Pharmacist is aware of the potential cost implications of using a temporary unlicensed medicine as an alternative to a licensed preparation, so that this information can be cascaded to both the Associate Directors of each Directorate and MMG
4. Obtain advice from Quality Control as required.
5. Liaise with the supplier as appropriate.
6. Ensure any special requirements of suppliers are met.
7. Process deliveries in accordance with procedure.
8. Ensure correct storage arrangements.
9. Keeps appropriate records

As specified in Pharmacy Department's Standard Operating Procedures “Unlicensed Medicines” (SOP: SD 016)

5.2.3. Clinical Function

The clinical pharmacist:-

1. Ensures that the use of an unlicensed medicine is justified by the clinical circumstances.
2. In conjunction with the Designated Pharmacist and with the Medicines Information Department, ensures that the use of an unlicensed medicine is justified by published evidence or sound therapeutic argument.
3. Ensures that no licensed alternative product is available.
4. Ensures that the prescriber is made fully aware of the clinical and legal implications of using the selected medicine.
5. Ensures that the Designated Pharmacist is fully briefed on the pharmaceutical requirements of the product.
6. In conjunction with the Prescriber, ensures that the patient has been informed that they are being treated with an unlicensed medicine, and that the patient is informed as to the reasons why it is necessary to use an unlicensed medicine as part of their treatment.
7. In conjunction with the Prescriber, is responsible for documenting that the patient has been informed (Point 6) in the clinical notes.

5.2.4. Dispensing/Supply Function

Pharmacy staff involved in the dispensing of unlicensed medicines:

1. Ensure that requests for unlicensed medicines are processed in accordance with Trust procedures.
2. Where appropriate, communicate with patients the implications of using the unlicensed medicine.
3. If appropriate, make arrangements for patients to have continuing supplies of treatment.
4. Make appropriate records of supply.
5. Ensures an English translation (or equivalent) patient information leaflet is issued with all unlicensed medicines where available.
6. Communicates clearly and in a timely manner with Patient, Clinical Pharmacist and Prescriber on the procurement, availability and supply of the unlicensed medicine.

6 Prescriber Request and Risk Assessment Form

In conjunction with the Clinical Pharmacist, the prescriber completes the form (Appendix 2) fully, including evidence to support the request, and submits it to the Designated Pharmacist for processing. Once the documentation is complete and all authorisation signatures have been obtained, the request will be passed onto MMG for approval.

In exceptional circumstances (urgent clinical need), the Chief Pharmacist and/or Trust Designated Pharmacist may authorise use and supply subject to formal ratification at the next MMG meeting.

The MMG will ensure that the completed documentation is retained appropriately.

7 Evaluation of Unlicensed Medicines

7.1 Risk Assessment

The attached decision tree (Appendix 3) forms part of the risk assessment process.

The exact product details must be clearly identified, including approved medicine name, strength(s) of preparation(s) and formulation.
Consideration is given to the clinical reasons for using an unlicensed product in preference to a similar UK licensed one. The risk assessment identifies clear clinical evidence in support of the product use. Reference sources are quoted.

Contraindications, side effects, precautions and the potential for harm are identified and accurately assessed in relation to the clinical condition.

7.2 Procurement Risk Assessment

The country of origin is determined. For countries outside the EU or for those without a mutual recognition agreement, Quality Control North West is contacted for advice.

The language used on the packaging is determined along with details of who will supply the translation of the patient information leaflet and label.

An assessment of the supply chain is carried out, and the ease at which further supplies can be obtained. The cost of the drug and any special funding needs are determined. Responsibility for continued supply is identified.

The assessment process should take into account any issues raised by Quality Control North West.

7.3 Approval Process

The Medicines Management Group approves the use of all unlicensed medicines new to the Trust. This can be a retrospective process in the case of urgent clinical need.

When considering a request to approve an unlicensed medicine, the Group must be certain that there is no suitable licensed alternative product available. It reviews the supporting clinical data and takes a view on the likelihood of supply chain difficulties, the possibility of interruptions to patient treatment, and any consequences.

8 Clinical Evidence Database

For newly commissioned products a copy of the Product Request and Risk Assessment form will be made available on the Quality Control North West web site, and the full documentation can be requested directly from the originating Trust. Responsibility for accuracy of data on the forms rests with the originating Trust.

9 Adverse Drug Reactions and Defective Products

Adverse drug reactions and defective products are handled and reported in the same way as licensed medicines. All healthcare professionals as well as members of the public can and should report serious adverse drug reactions to the Medicines and Healthcare Regulatory Agency using the Yellow Card System http://yellowcard.mhra.gov.uk/ and to the MMG via the Trust Incident reporting scheme.

Suspected defects in unlicensed medicines are reported to the Pharmacy Department or the on-call pharmacist (out-of-hours) who will report them to Quality Control North West following the Regional Drug Defect Reporting procedure.
## Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Certificate of Analysis</strong></td>
<td>This is a certificate issued by the supplier of an unlicensed medicine to its recipient giving details of analytical testing which has been carried out on the unlicensed medicine and the results of this testing.</td>
</tr>
<tr>
<td><strong>Designated Pharmacist</strong></td>
<td>This is a pharmacist employed by the Trust who has been designated as having responsibility for the procurement and supply of unlicensed medicines within the Trust.</td>
</tr>
<tr>
<td><strong>Extemporaneously Dispensed</strong></td>
<td>This is a medicine which has been prepared by or under the supervision of a pharmacist in response to or in anticipation of a prescription.</td>
</tr>
<tr>
<td><strong>Manufacturers Specials Licence</strong></td>
<td>This is a licence issued by the Medicines Healthcare Products Regulatory Agency (MHRA) to organisations wishing to place unlicensed medicines on the market in the UK. Further details of the controls applying to Manufacturers Specials Licenses are given in MHRA Guidance Note 14 <a href="http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm">http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm</a></td>
</tr>
<tr>
<td><strong>Off-label use</strong></td>
<td>Medicines are considered to be being used off label when they are used for clinical indications which are not included in the list of approved indications for that product in its product licence details.</td>
</tr>
<tr>
<td><strong>Sections 9, 10 and 11</strong></td>
<td>These are sections of the Medicines Act 1968 describing the exemption from the need to hold a manufacturers licence by doctors (Section 9), pharmacists (section 10) and nurses (section 11) when preparing medicinal products</td>
</tr>
<tr>
<td><strong>Specials</strong></td>
<td>These are unlicensed medicines which have been specially prepared by the holder of a Manufacturers Specials Licence or imported in response to or in anticipation of the order of a doctor or dentist to meet the special needs of individual patients.</td>
</tr>
<tr>
<td><strong>Unlicensed medicine</strong></td>
<td>These are medicines which do not have a UK product licence or European Market authorisation for use in the UK.</td>
</tr>
<tr>
<td><strong>Wholesale dealer's licence</strong></td>
<td>This is a licence issued by the MHRA to organisations carrying out wholesale dealing of licensed and/or unlicensed medicines.</td>
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</tbody>
</table>
11 References

MHRA Guidance Note 14, The supply of unlicensed relevant medicinal products for individual patients. MHRA, London, 2000 (under review 2012)


Quality Control North West: Approved Suppliers of Unlicensed Medicines - February 2012


Pharmacy Services East Cheshire NHS Trust – Unlicensed Medicines Standard Operating procedure 1.29 (2011)

Currently, this product does not have a full U.K. pharmaceutical product license. Medicines are often used in this way. This can be for many reasons, for example:

- It is awaiting the granting of a U.K. license from the Government
- It is undergoing a clinical trial
- Usage of the medicine is low and therefore it is not economic for the makers to send the product for approval or it would be difficult to get enough patients to do a clinical trial
- It has been withdrawn from the U.K. market

However, please be reassured that your doctor and pharmacist have thought very carefully about what is the best medicine for you. If you have any concerns regarding this medicine please contact the pharmacy department.

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- It is awaiting the granting of a U.K. license from the Government
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- It has been withdrawn from the U.K. market

However, please be reassured that your doctor and pharmacist have thought very carefully about what is the best medicine for you. If you have any concerns regarding this medicine please contact the pharmacy department.
APPENDIX 2 – Request/ Application Form

Request Form for Unlicensed Medicines

The prescriber should complete this form in conjunction with the clinical pharmacist and the Trust Designated Pharmacist (the Operational Pharmacy Services Manager). When complete it should be submitted to The Medicines Management Group (via the Chief Pharmacist) for approval.

Before completing this form, you must have read the Trust Policy on the Prescribing, Use and Supply of Unlicensed Medicines and must be aware of your responsibilities under this policy.

This form should be used in conjunction with the Procurement and QC Division Tree given in Appendix 3 of the Trust Policy.

Part 1: Unlicensed Medicine Details – to be completed by the prescriber

Product Name (Approved medicine name and Brand where appropriate):
(include formulation and strength)

Manufacturer (if known):

Indication/ For the treatment of:

Dose, frequency and route:

Duration of Treatment:

Approx. no. of patients per year:

Indicate below why an Unlicensed Medicine is required (delete where appropriate)?

*Pharmaceutically Equivalent Licensed product temporarily unobtainable YES / NO
(If YES then go to Part 3 “Procurement Details”)

*Equivalent UK licensed product unavailable/unsuitable because:

*Other, give details:
Part 2: Clinical Evidence - to be completed by the Prescriber and/or Clinical Pharmacist

Is there any evidence to support its use for the proposed indication? Yes / No

If not, is there any evidence to support its use for other indications? Yes / No

Is there evidence to support its proposed administration schedule (including dose, duration of treatment, concentration for parenteral products and route)? Yes / No

Is the active drug currently in a licensed product for use via the same route? Yes / No

Is the product licensed for the specified indication in an EU member state? Yes / No / Unknown

Is the product licensed for the specified indication in a non-EU member state? Yes / No / Not known

Are other NHS Trusts using this medicine? Yes / No
If so, name:

What are the risks to the patient of not using this drug?

Is there patient information appropriate for the intended use? Yes / No
If so, attach:

Will there be any primary care implications (e.g. need for a shared care agreement)? If so, describe: Yes / No

Is any monitoring required? If so, describe: Yes / No

Summarise below the supporting evidence for your application. List references and attach copies where possible. Please include details of contraindications, precautions in use, side effects, known reported adverse events and any other risks to the patient.

(use a supplementary sheet if needed)
Part 3: Procurement Details - to be completed by the Senior Technician Stores & Procurement and/or Trust designated pharmacist

1. Is the medicine to be obtained from:
   An NHS specials unit
   A commercial specials manufacturer
   A licensed importer
   A company which already has licensed products of the same active ingredient
   A licensed pharmaceutical wholesaler

   If yes, specify………………………………and go to 6.

2. Is a specification available?
   Yes / No

   If yes, attach a copy.
   If no, then a full product specification will need to be drawn up in conjunction with Quality Control North West. (Only required if commissioning a new product to be manufactured).

3. Is the product available “off the shelf”?
   Yes / No

4. Is the manufacturer on the Manufacturer List given in the Quality Control North West Guidance Document GD 109g?
   Yes / No

5. Is the manufacturer in the UK?
   Yes / No

   If no, complete questions 1 to 13 below:

   1. Which country?
   2. Is this country within the EU?
   3. If no, does this country have a mutual recognition agreement with the UK for the manufacture of medicinal products? (If no seek QCNW Advice)
   4. Importer:
   5. Does the importer have a Wholesale Dealer Import Licence?
   6. What is the quoted importation time?
   7. What quantity is to be imported?
   8. What language is used on the label?
   9. If not in English, is a translation available?

10. Who will provide the translation?

11. Is an English Translation of the Patient Information Leaflet available?

12. Who will provide the translation?

13. Are the English Translations Certified?
    If yes, by whom:

   Yes / No
6. Are there any problems associated with continuity of supply? Yes / No

If so, describe:

7. What are the costs involved in obtaining this drug?

8. Any issues raised by Quality Control North West?

Part 4: Details of Persons Completing the Form

Clinical Pharmacist(s) Name(s):

Signature:

Position:

Date:

Prescriber's Name:

Speciality:

I have read the Trust Policy on the prescribing, use and supply of this unlicensed medicine and accept full responsibility for its use.

Signature:

Date:

Part 5: Authorised Signatures

5.1 Directorate

Name of Directorate:

Name of Associate Director:

I have read the Trust Policy on Unlicensed Medicines and confirm I have reviewed this application and have assessed and accepted any potential cost pressures to this Directorate as a result of its use.

Signature:

Date:
5.2 Pharmacy

Name of Designated Pharmacist:
I have read the Trust Policy on Unlicensed Medicines and confirm I have reviewed this application and have assessed the evidence presented and risks of supplying/ not supplying this medicine to the patient.

Signature:
Date:

Name of Senior Technician Stores & Procurement:
I confirm that the medication requested in this application has been procured in line with the Trust Policy on Unlicensed Medicines

Signature:
Date:

Part 6: Medicines Management Group Assessment & Authorisation

Medicines Management Group Approval for use? Yes / No
If no, give reasons:

Is the medicine to be added to the formulary? Yes / No

Are there any restrictions on prescribing and use? Yes/No
If yes, please state:

Review Date:
(Max 5 years)

Signature:

Name:
(Chair of MMG)

Date:
Appendix 3.1 UNLICENSED MEDICINES IN HOSPITALS PROCUREMENT AND QC DECISION TREE - PROCUREMENT

**PHARMACEUTICAL PRODUCT**

1. Does the product have a PL or EMEA Marketing Authorisation?
   - Yes
     - Place order for licensed product
   - No
     - Ensure prescriber knows license status
     - Is there a definite clinical need for this product? Risk Assessment/clinical evaluation
       - Yes
         - Is there an equivalent licensed product available?
           - Yes
             - Prepare specification in consultation with QCNW
           - No
             - Agree specification
       - No
         - Is there an equivalent licensed product available?
           - Yes
             - Prepare specification in consultation with QCNW
           - No
             - Agree specification
     - Is the supply deemed acceptable?
       - Yes
         - Place order requesting C of A
       - No
         - Place order requesting C of A

2. Is the product available from EU or country with EU mutual recognition?
   - Yes
     - Agree
     - Place order, requesting C of A and labelling/PIL if available.*
   - No
     - Refer to QC for assessment
     - Is the supply deemed acceptable?
       - Yes
         - Place order requesting C of A
       - No
         - Place order requesting C of A

3. Is the manufacturer in the UK?
   - Yes
     - Is the manufacturer on the QCNW approved list?
       - Yes
         - Prepare specification in consultation with QCNW
       - No
         - Refer to QC for assessment
     - Is the NHS hospital unit?
       - Yes
         - Agree specification
       - No
         - Agree specification
   - No
     - Is the product available "off the shelf"?
       - Yes
         - Prepare specification in consultation with QCNW
       - No
         - Prepare specification in consultation with QCNW

4. Is the manufacturer an NHS hospital unit?
   - Yes
     - Identify approved supplier with appropriate ML
   - No
     - Apply local QC if appropriate

5. Is the product to be prepared in-house?
   - Yes
     - Prepare under ML or section 10
   - No
     - Place order

*If manufacturer is outside the UK, order via approved importer and specify labelling/PIL in English.
Appendix 3.2 Decision Tree  QC and Release
(From QCNW Guidance Document 109g)

**UNLICENSED PHARMACEUTICAL PRODUCT RECEIVED**

- Has it been produced by an NHS Manufacturing Unit approved by QCNW?
  - Yes
  - No

  **Quarantine and refer to designated Trust pharmacist**

- Is the Labelling/PIL in English?
  - Yes
  - No

  **Can the supplier provide a translation?**

  - Yes
    - Obtain translation and relabel
    - Is the Manufacturer/product on the Manufacturer list (Appendix 1)
      - Yes
      - Refer sample and C of A to QCNW who will carry out QC testing to confirm product meets specification
      - No
      - Assess C. of A.
      - Supplement C. of A. with testing by QCNW if required
    - No
      - Assess C. of A.
      - Supplement C. of A. with testing by QCNW if required
      - Release/Reject

  - No
    - Obtain translation from the importer and relabel, prepare ‘English language’ leaflet as necessary
    - Is the Manufacturer/product on the Manufacturer list
      - Yes
        - Check for appearance and labelling
        - Assess C. of A.
        - Supplement C. of A. with testing by QCNW if required
        - Release/Reject
      - No
        - Assess C. of A.
        - Supplement C. of A. with testing by QCNW if required
        - Release/Reject

**Release**