University Hospitals of Derby and Burton NHS Foundation Trust

**TRUST POLICY FOR THE USE OF UNLICENSED MEDICINES**

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# TRUST POLICY FOR POLICY FOR THE USE OF UNLICENSED MEDICINES

## 1. Introduction

In order to ensure that medicines are safe, effective and of appropriate quality, manufacture, sale or supply is controlled by national and EU legislation. Accordingly, no medicinal product may be "placed on the market" unless a Product Licence (PL) has been granted. However, in order to preserve prescribers' clinical freedom, the legislation gives some exemptions from full control. Thus, medicinal products that are not licensed may be prescribed in order to fulfil special needs in individual patients on the direct personal responsibility of the prescribing clinician.

Therefore for good clinical reasons the use of unlicensed medicines and the use of licensed medicines for an unlicensed indication are widespread in hospitals (and in primary care). Were this practice to be curtailed, the treatment of many patients would be impeded. It is therefore important that University Hospitals of Derby & Burton NHS Foundation Trust and its prescribers and pharmacists should be aware of the associated medico-legal implications. These include but are not limited to, the Consumer Protection Act and product liability legislation.

Whilst licensed medicinal products are subject to stringent control by the Medicines and Healthcare Products Regulatory Agency (MHRA), neither prescriber nor pharmacist can make the same assumptions of quality, safety and efficacy about unlicensed products.

This Policy does not cover the following situations:

- **UK licensed** products used outside their licensed indications ("off-label" use).
- Investigational medicinal products (clinical trials materials).
- Products prepared under exemptions (sections nine, ten or 11) of the Medicines Act 1968. Repackaged licensed products or reconstituted IV additives and CIVAS (central intravenous additive service) products.
- Non-medicines or medical devices.
- Products covered by the Early Access to Medicines Scheme (EAMS).

"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 Department (01332 785379 or ext: 85379) or your local ward pharmacist (contact information available via switchboard).

## 2. Purpose and Outcomes

- To clarify the Trust's position on the use of unlicensed medicines.
- To offer guidance to those health care professionals involved in the prescribing, procurement, supply and administration of unlicensed medicines.
- To ensure safe systems are in place for the appropriate use of unlicensed medicines within the Trust.

## 3. Definitions Used

### Licensed Medicine

A UK- licensed medicine is one that has been granted a PL, also known as a marketing authorisation (MA) by the MHRA. They can be marketed in the UK for the treatment of medical conditions as defined in its PL ie: its licensed indication. The Summary of Product Characteristics (SPC) contains

information, produced and approved as part of the licencing process that provides healthcare professionals with information relating to use of the product within its licence. Note: some devices do not require a licence as a medicine even if they contain what could be considered a medicine, eg: Posiflush (sodium chloride 0.9% in a syringe for flushing cannulas), provided they are used in the way specified by the manufacturer. Device 'licensing' is indicted by the use of the CE mark.

**Unlicensed Medicine**

Unlicensed means the product has no UK product licence but may be available for use because it is:

- Manufactured as a 'special' to the specification of an authorised purchaser, usually a pharmacist because it is not available as a licensed product anywhere in the world usually because demand does not justify commercial production and licensing.
- Imported from outside the UK where it is available / licensed.
- available as part of a clinical trial, on a 'named patient' or 'compassionate supply' basis because it
    - is waiting for a licence to be granted
    - is undergoing clinical trials
    - has had its licence withdrawn
    - is only manufactured for export

Licensed products can be rendered unlicensed by:

- Using the licensed product as an ingredient in preparing a medicine for a specified patient in accordance with a prescriber's instructions, known as extemporaneous dispensing, for example, combining 2 licensed ointments together with a diluent in specified proportions. Provided principles of Good Manufacturing Practice are adhered to in the preparation, premises and personnel involved the risk in converting a licensed medicine to an unlicensed medicine in this way is small but justified if the clinical need cannot be met any other way.
- Repackaging of a licensed product, for example, preparing 5 packs of 20 tablets for use as patient discharge packs for Emergency Department from a manufacturers pack of 100 tablets would 'de-license' the product. Provided the process, packaging, labelling and records are appropriate the risk involved is minimal and justified if the operational need cannot be met in another way. MHRA guidelines exist to limit such activity to a small scale. Alteration of the product from its intended mode of administration, for example, crushing tablets or opening capsules to put down a feeding tube, also is use outside of the product licence. Provided advice is sought from the Pharmacy, so the suitability of that particular drug can be determined using peer reviewed data, this is considered to be low risk and is acceptable where there is a clinical need and no suitable alternative.

**Off label**

Sometimes medicines are used for a clinical indication or in a way that is not covered by the licence (e.g. crushing tablets to administer to a patient with difficulty in swallowing). This would constitute unlicensed use of a licensed medicine. In neonatal or paediatric medicine, drugs are often used "off label" (outside their licence limits) because the cost and ethical considerations for clinical trials in children discourage manufacturers from applying for a licence for use in children.

## 4. Key Responsibilities/Duties

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

**Drugs & Therapeutics Group (D&T)**

The Group will approve or deny requests for unlicensed medicines for use in the Trust based on a consideration of a clinical assessment of the medication and a risk assessment of the product. This can be a retrospective process in the case of urgent clinical need. D&T will monitor the range and quantities of unlicensed medicines purchased, keeping a list of unlicensed medicines currently approved by the Trust. D&T is responsible for ensuring that arrangements are in place to make sure that unlicensed medicines are used only when an equivalent licensed product is unavailable. D &T is responsible for producing an annual review of unlicensed medicines prescribing within the trust to be reported to the Medicines Safety Group.

**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 they use unlicensed medicines approved by D&T. If there is an urgent clinical need for an unapproved product, the requesting Clinician will ensue a fully completed concession form is sent to pharmacy for approval.
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 (GP) 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.

**Pharmacy Staff**

**Governance Lead 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. This authority is delegated to the Lead Pharmacist and Clinical Pharmacist.

**Clinical Pharmacist**

1. Ensures that the use of an unlicensed medicine is justified by the clinical circumstances.
2. In conjunction with the Lead 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 Divisional Lead 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.
8. Communicates with the MHRA to process any reports of adverse reactions.

**Pharmacy Procurement team**

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, a risk assessment has been completed and that the Lead Pharmacist is aware of the purchase.
3. Ensures the Lead Pharmacist is aware of the potential cost implications of using a temporary unlicensed medicine in the event of a supply chain failure of a licensed preparation, so that this information can be cascaded to both the Division and D&T.
4. Obtains advice from Quality Control as required.
5. Liaises with the supplier as appropriate.
6. Ensures any special requirements of suppliers are met.
7. Processes deliveries in accordance with procedure. Monitors and audits the handling of unlicensed medicines in the Pharmacy Department.
8. Ensures correct storage arrangements & ensure unlicensed medications are not released for use until formal product releasing procedures have been completed.
9. Keeps appropriate records.

**Pharmacy dispensary staff**

Pharmacy staff involved in the dispensing of unlicensed medicines: -

1. Ensures that requests for unlicensed medicines are processed in accordance with Trust procedures, including checking the products have been assess by pharmacy logistics staff and appropriately released for use.
2. Where appropriate, communicate with patients the implications of using the unlicensed medicine.
3. If appropriate, makes arrangements for patients to have continuing supplies of treatment.
4. Makes appropriate records of supply including recording of batch numbers
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**.**

**Head of Pharmacy Manufacturing Unit**

1. The Head of the Pharmacy Manufacturing Unit is able to provide advice and guidance to the

pharmacy department on the risk assessment and releasing of unlicensed products.

## 5. Prescriber Request and Risk Assessment Form

In conjunction with the Clinical Pharmacist, the Prescriber should complete the D&T new product request form, available on the intranet, fully and submit it to the Lead Pharmacist for processing. Once the documentation is complete and all authorisation signatures have been obtained, the request will be passed onto D&T for evaluation.

In exceptional circumstances (urgent clinical need), the Chief Pharmacist and/or Divisional Lead Pharmacist may authorise use and supply subject to formal ratification at the next D&T meeting. In this circumstance a D&T concessional form, available on the intranet, should be completed.
D&T will ensure that the completed documentation is retained appropriately.
The risk of using an unlicensed product is assessed by considering:

| Risk rating | Clinical effectiveness of the medicine | Quality Assurance of Manufacturing process |
|---|---|---|
| **Low** | Drug known to be safe and effective | Manufactured in UK licensed unit |
| **Minimal** | Drug known to be safe and effective but not in this indication | Manufactured with PL in EU or (or equivalent) licensed unit |
| **Moderate** | Some evidence of efficacy or safety but not when used as described | Manufactured without PL in EU (or equivalent) licensed unit |
| **High** | Very little evidence of safety or efficacy of the drug | Manufactured in non EU or US licensed unit |
| **Extreme** | Very little evidence of safety or efficacy of the drug<br>Evidence of adverse effects – withdrawn from use. | Manufactured by unlicensed non EU, unit |

When assessing a product the risk of not using it should also be considered. Pharmacy staff will provide information and advice on completing the concession form or new product request form. If the product is not new, for example if an unlicensed product is the only alternative during a temporary shortage of an essential licensed product, the Chief Pharmacist or, in their absence, a Divisional Lead Pharmacist can approve the use of the unlicensed medication.

## 6. Quality assurance

Prior to procurement the quality assurance arrangements of the manufacturer and/or supplier are considered as part of the risk assessment process. On receipt of unlicensed products a formal release procedure is undertaken and recorded in line with pharmacy standard operating procedures (SOP). The release procedure includes consideration of the suitability of:

- The product received against what was ordered
- The labelling
- The packaging including the patient information leaflet
- The license status and scope of the manufacturer
- The licensed status of the product in the country of origin
- The QA arrangements of the manufacturer
- The Certificate or Conformity / Certificate of Analysis.

## 7. Patient information and consent

Wherever possible, patients will be made aware that they have been prescribed an unlicensed medicine. Individual patients (and/or their carers/parents) should be given adequate information about any unlicensed medicines they are prescribed. D&T have provided a blanket approval to all current unlicensed medication supplied by the hospital pharmacy as of January 2019. Information on which products are available can be found on the hospital formulary. All new unlicensed products have to be reviewed by D&T in accordance with this Policy.

The Department of Health recommends that if treatment is being offered of an experimental nature, but not as part of a clinical trial, this must be clearly explained to the patient before their consent is sought. Written patient consent should be obtained to use unlicensed medicines which have not yet been authorised by the D&T, or those which have been classified high or extreme risk (see risk rating in section five).

This practice may not be practicable in paediatric or neonatal care, because so large a proportion of medicines would require this information at the time of prescribing, that the patient or carer would be overwhelmed. A 'blanket' notice regarding the likely use of unlicensed and 'off label' medicines in children will be available on the Trust internet website for all patients to see.

It is accepted that there are circumstances where involving patients in decisions on unlicensed drug use is inappropriate and impractical (e.g. clinical emergencies, unconscious patients, patients without the ability to comprehend). In those cases, it is considered that presenting for care constitutes consent to the use of unlicensed medicines if that constitutes 'best practice'.

A generic patient information leaflet explaining what an unlicensed medicine is will be available (see appendix one).

## 8. Procurement of unlicensed medicines

Appendix two shows the decision tree for procurement of unlicensed medicines. It will be used when a new unlicensed product is requested to ensure the appropriate procurement process is adhered to.

The order paperwork will indicate that the item is an 'unlicensed medicine' and include a request for a Certificate of Analysis or Conformity and an English Patient Information Leaflet where appropriate.

On receipt, unlicensed products will be kept in quarantine until formal release. The location and means to quarantine stock to ensure it will not be issued before release will be provided. The requirement to quarantine unlicensed stock before release will be part of the induction / training for all pharmacy staff.

Senior pharmacists or an approved pharmacy technician must release the first consignment of any unlicensed product and complete and sign an Unlicensed Product Summary Sheet see appendix three.

Any authorised person can release unlicensed products if the product conforms exactly to the signed Unlicensed Product Summary Sheet.

All receipts are recorded in the Unlicensed Product register. This register or a summary from it will form a part of the annual report on unlicensed medicines use for D&T.

## 11. Record Keeping

On receipt / release of unlicensed medicines the following information is recorded in the Unlicensed Product log as per local SOP.

Records of issue of unlicensed medicines to patients or to ward / clinical areas are made in the pharmacy computer system.

All records should be kept for five years to comply with Statutory Instrument SI1994/3144.

## 12. Adverse events & defective products

Should an unexpected adverse drug reaction occur in a patient when an unlicensed medicine has been prescribed and administered then the 'yellow card' reporting scheme should be used.

Any other defects found when the medicine is used which relate to the quality of the product rather than its clinical action should be reported to Pharmacy and an incident form completed. Suspected defects in unlicensed medicines should be reported to D&T, the manufacturer, as well as considering informing the MHRA. The advice of the Quality Assurance Manager of PMU should be sought.

## 13. Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template:

| | |
|---|---|
| Monitoring Requirement : | Prescribing compliance with formulary |
| Monitoring Method: | Monitoring concession process (and via unlicensed medicines prescribing in ePMA) |

| | |
|---|---|
| Report Prepared by: | Concessions are collated by the Lead Commissioning pharmacist.<br>Information Department |
| Monitoring Report presented to: | Drugs & Therapeutics Group |
| Frequency of Report | Monthly |

## 14. References


1. MHRA Guidance Note 14: The supply of unlicensed relevant medicinal products for individual patients. Medicines and Healthcare products Regulatory Agency, May 2005.
2. The purchase and use of unlicensed medicines in hospitals. Policy Statement No. 006, Guild of Healthcare Pharmacists, January 1997.
3. Medicines for Children: The first UK national drug formulary for children. Royal College of Paediatrics and Child Health. (The use of unlicensed medicines for licensed medicines for unlicensed applications in paediatric practice).
4. Guidance for the Purchase and Supply of Unlicensed medicinal Products. Notes for Prescribers and Pharmacists, NHS Pharmaceutical Quality and Assurance Committee 3rd edition June 2004.

**Appendix one – Patient information leaflet**

University Hospitals of Derby and Burton NHS Foundation Trust

# PATIENT INFORMATION

Use of Unlicensed Medicines

## What is this leaflet about?

You have been given this leaflet because a medicine you have been prescribed does not have a licence, known as a marketing authorisation, issued by the Medicine and Healthcare Products Regulatory Agency (MHRA). This leaflet is intended to reassure you that we have thought very carefully about the best medicine for you and to help answer any questions that you may have. Please talk to your doctor or pharmacist if there is anything further that you would like to know.

Pharmaceutical companies must hold a marketing authorisation, also known as a licence, for each medicine that they sell in the United Kingdom. The MHRA issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine.

## Why don't all medicines have licences?

There are a number of reasons why a medicine may not have a licence, or marketing authorisation, for example:

- It is currently undergoing clinical trials, but does not yet have a licence
- The medicine used to be licensed in the UK, but is no longer available
- It is only available from abroad and needs to be imported
- Usage of the medicine is low and it is too expensive or too difficult to have a clinical trial
- The medicine needs to be made specially

## Why have I been given an unlicensed medicine?

You have been prescribed an unlicensed medicine because no suitable licensed alternative is available to treat your condition. However, the person treating you will have thought very carefully about prescribing the most appropriate medicine for you and its use will be reviewed on a regular basis.

## Should I be worried about taking unlicensed medicines?

The prescriber will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your doctor or pharmacist about your concerns. They may be able to give you further information or help to put you in touch with a support group for your illness or condition.

If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should report this to your doctor or pharmacist.

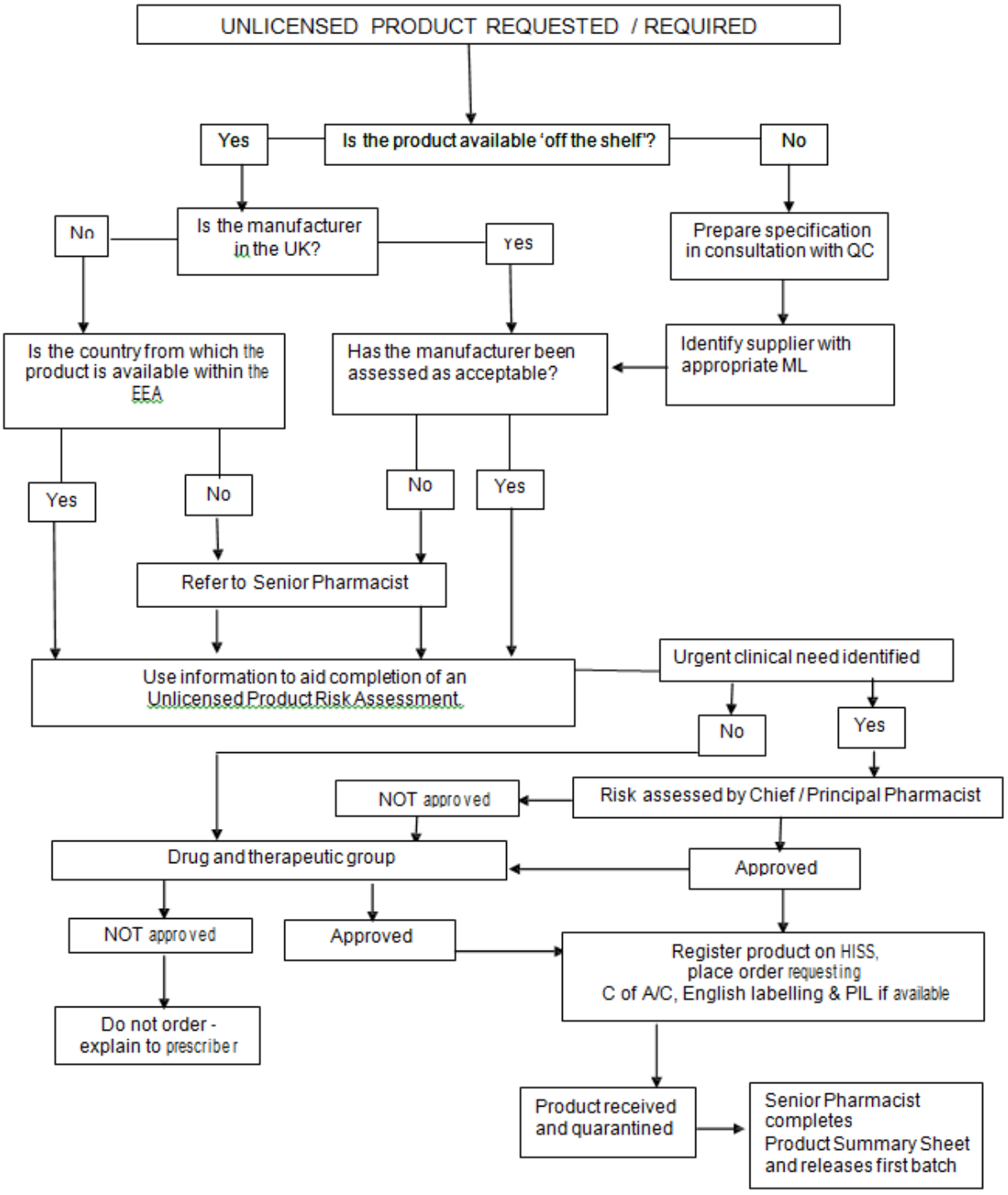
## What else do I need to know?

Sometimes it will take longer for the pharmacist to order in an unlicensed medicine. In which case, you will need to allow one or two weeks for the pharmacist to obtain further supplies of your medicine. You should bear this in mind, if you need to get a repeat prescription from your doctor.

## Where can I get more information?

If you would like to discuss any information contained in this leaflet, please speak to your pharmacist or contact your GP or Consultant. Alternatively you can contact the University Hospitals of Derby & Burton patient helpline on 01332 787980.

## Appendix Two – Unlicensed product decision tree – procurement



# Appendix Three – Pharmacy Risk Assessment Form - Unlicensed/Special Product

**Purchasing for Safety** [LOGISForm21]

## Risk Assessment Form - Unlicensed/Special Product

**PRODUCT** _____ **DATE** _____

*SOURCE - IMPORTED OR SPECIAL*

| **Details of Specials manufacturer - Logistics Technician** | | | |
|---|---|---|---|
| Name of Company | ✓ | | Score |
| Local Unit | | | 1 |
| NHS Specials Licensed Unit | | | 2 |
| Commercials Specials Manufacturer | | | 2 |
| Pharma Industry (named patient) | | | 0 |
| **Certification** | | | |
| Full analytical report available? | | Y | 0 |
| | | N | 4 |
| Certificate of Conformity? | | Y | 2 |
| | | N | 4 |

| **Details of Importer - Logistics Technician** | | | |
|---|---|---|---|
| Name of Company | ✓ | | Score |
| **Country of Origin** | | | |
| Mutual Recognition | | Y | 0 |
| No Mutual Recognition | | N | 3 |
| See appendix 1 for list | | | |
| Licensed in country of Origin | | Y | 0 |
| | | N | 3 |
| English SPC and/or PIL | | Y | 0 |
| | | N | 4 |
| English Label | | Y | 0 |
| | | N | 4 |
| **Certification** | | | |
| Full analytical report available? | | Y | 0 |
| | | N | 4 |
| Fully licensed with EMEA/PL number | | Y | 0 |
| | | N | 1 |

| **License Status - Logistics Technician** | ✓ | | Score |
|---|---|---|---|
| Is the Specials Manufacturer or Importer suitably Licensed for their activity? | | Y | 0 |
| | | N | 5 |
| Does the Trust have previous satisfactory experience with the supplier | | Y | 0 |
| | | N | 2 |
| Does the packaging have a produce license number relevant for the country of origin? | | Y | 0 |
| See K:\ORGANIZE\Logistics\Purchasing For Safety\Product licence numbers Version 2 7th Aug 2014[1].pdf | | N | 2 |
| Does the Supplier or MHRA place any restrictions on the use of this product? List here and ensure compliance: | | | |
| **Specification - Logistics Technician** | ✓ | | Score |
| BP/EP/USP Monograph | | | 0 |
| Other Pharmacopoeia Monograph | | | 1 |
| Manufacturer's specification only | | | 2 |
| No external specification available | | | 3 |
| Does the product contain material from human or animal origin? | | Y | 5 |
| | | N | 0 |
| **Route of Administration** - Product must be assessed for its intended use by Clinical Pharmacist | ✓ | | Score |
| Topical to Skin | | | 0 |
| Mucous membranes, broken skin or oral | | | 1 |
| Sterile Injectables | | | 5 |
| Complex calculation required to administer? | | Y | 5 |
| | | N | 0 |
| Complex manipulation required to administer? | | Y | 5 |
| | | N | 0 |
| Are active ingredient & excipients suitable? | | Y | 0 |
| If unsure please check with directorate pharmacist | | N | 5 |

| **Assessment Score =** | |
|---|---|
| **Low = 0 - 7** | |
| **Medium = 8 - 16** | |
| **High = 17 - 28** | |

| **Logistics Technician Sign Off** | |
|---|---|
| **Print Name** | |
| **Signature** | |
| **Designation** | |
| **Date** | |

| **Divisional Pharmacist Sign Off** | |
|---|---|
| **Print Name** | |
| **Signature** | |
| **Designation** | |
| **Approved for Purchase? Yes or No** | |
| **Date** | |

*When a product has been approved for Purchase the pharmacist takes responsibility for introducing the medicines into the Trust in a safe, efficient and timely manner*

**Appendix 1 - List of Mutally Recognised countries for Product Licences**

Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany,