

**Request and Risk Assessment for the use of Unlicensed Medicines**

This form should be completed by the Consultant with assistance from the ward/unit pharmacist each time a new unlicensed medicine is required. The completed form is to be submitted to the Drugs and therapeutic Committee for approval. In the case of urgent clinical need, the Chief Pharmacist and Chair of DTC may authorise the single use of a new unlicensed medicine outside of the DTC.

Before completing this form you must have read and understood the unlicensed medicines section of the medicines policy. **NB: Parts 1, 2, 3, 4 & 6 to be completed by Consultant, Part 5 to be completed by Pharmacy.**

**Part 1: Unlicensed Medicine Details**

Approved (Drug) name:

Proprietary (Brand) name if known:

Dose form: Strength:

Manufacturer (if known):

**Part 2: Patient Details**

Is this to be used for a single patient only?

**Single Patient Only**

Patient name: Ward/Unit:

NHS number: Site:

**Multiple Patients**

Approximate number of patients per year:

**Part 3: Clinical Details**

Indication: Frequency:

Dose range: Expected duration:

Route:

Why is an unlicensed medicine use being considered?

|  |  |
| --- | --- |
| 1. | Pharmaceutically equivalent licensed product temporarily unavailable **Yes / No** |
| 2. | Equivalent UK licensed product unsuitable (explain) |
| 3. | Other (give details) |

**Part 4: Clinical Evidence for Unlicensed Medicine**

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 any evidence to support its proposed administration schedule? Yes / No

Is the product licensed for the specific indication Yes / No / Not Known

in a different country

Are other centres in the UK using this medicine? Yes / No / Not Known

If yes, name:

Please summarise below any published evidence to support the use of the unlicensed medicine use and any previous clinical experience with medicine:

What are the risks to the patient of NOT using this medicine?

List any side-effects or toxic effects that have been reported?

Describe any monitoring required:

List any significant interactions:

List any contraindications and any other risks to the patient:

List any precautions, including precautions in use and pharmaceuticals precautions:

Is there a Patient Information Leaflet appropriate for intended use?

Yes\*/No/Not known (\*Please attach) and any special instructions

How will the patient obtain further supplies?

**Part 5: Procurement Details to be completed by Pharmacy**

Where is the medicine to be obtained from?

Describe any expected problems associated with continuity of supply:

What is the cost of the product?

List any additional / indirect costs involved in obtaining this medicine:

**Part 6: Details of person(s) completing form**

Consultant name:

SBU:

Contact number:

Email address:

Consultant signature:………………………………..…. Date:

Clinical pharmacist name:

Pharmacist signature:………………………..………… Date:

**Part 7: Outcome of Risk Assessment**

DTC approval Yes / No

Reasons if not approved:

Any restrictions on prescribing:

Name:

Signed by DTC Chair:……………………………….. Date: