

**Request Form for Use of New
Unlicensed Medicine or new off-label indication**

Appendix 1

The named product is an unlicensed medicine (or medicine to be used outside their licensed indications). Prescribing of an unlicensed medicine (or medicine to be used outside their licensed indications) is the responsibility of the prescriber. When procuring unlicensed medicines, the ordering pharmacist is considered to be the manufacturer and responsible as such. Prescribing and supply of unlicensed medicines (or medicines to be used outside their licensed indications) presents a **RISK to INDIVIDUAL PATIENTS, PRESCRIBERS and PHARMACISTS**, and by implication, to the Trust.

Prescribers are therefore reminded of the following:

- Unlicensed medicines (or medicines to be used outside their licensed indications) are **not** intended for routine, ongoing use.
- Where suitable licensed alternatives to unlicensed medicine (or medicine to be used outside their licensed indications) exist these **should always** be used in preference to unlicensed medicines (or medicine to be used outside their licensed indications)
- Whenever an unlicensed medicine (or medicine to be used outside their licensed indications) is prescribed, the prescriber is **PROFESSIONALLY ACCOUNTABLE** for his judgment in so doing and may be called upon to justify his actions.
- A General Practitioner is not obliged to prescribe an unlicensed medicine (or medicine to be used outside their licensed indications)
- Where this product has been assessed by the Drugs and Therapeutics Committee as 'high risk' (see Policy and Procedure for the Use of Unlicensed and off label Medicines) you must inform the patient or their representative of the status of this medicine to seek and obtain informed written consent on each occasion that the patient is treated with this product.

Product Name:.....

(International Non Proprietary Name)

Proprietary Name: (if known).....Manufacturer (if known)

Pharmaceutical Form:

Strength:.....

Indication:.....

Dose:..... Frequency:.....

Route:..... Duration of Treatment:.....

Why is use of this Unlicensed Medicine (or medicine to be used outside their licensed indications) being considered?

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Please outline the clinical evidence to support use of this product in this manner

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Name of requesting Consultant Signature.....

Date of request.....

Please send completed form to Pharmacy for the attention of the Formulary Pharmacist

Policy and procedure for the use of unlicensed and off-label medicines

Steve Bleakley Chief Pharmacist, rewritten March 2018