FORM C – Request to Use an Unlicensed Medicine

Liability for the use of a preparation which does not have a UK Market Authorisation, or use of a product out-with its UK Market Authorisation falls to NHS Lanarkshire.

Non-licensed categories:

a) Prescribing of a licensed medicine outwith the terms of its Marketing Authorisation.
b) Prescribing a product which is at the pre-marketing stage or is discontinued, for a named patient on compassionate grounds.
c) A drug not marketed in the UK, e.g. a 'pharmaceutical special' or it is imported from abroad at the request of a Consultant. In the case of imported medicines the supplying companies may require that separate paperwork be completed before a drug in this category can be supplied.
d) A medicinal preparation, which incorporates a laboratory chemical, which has no product licence and cannot be guaranteed to be of pharmaceutical quality
e) Living product for medical treatment.

Please submit your request for such a medicine by completing the section below and send it to the onsite Hospital Pharmacy Manager.

Section 1 : To be completed by the consultant assuming responsibility for the patient.

Patient Name:……. Ward/Clinic: …….

CHI Number: ……. Multiple Patients Yes/No

Drug Name			
Strength		**Formulation**	
Route & Dosage			
Indication			
Non-licensed category - a, b, c, d or e			
Reason why a licensed product not suitable			
Duration of therapy			
Side effects, adverse reactions, toxicity			
Other therapy already tried			
References to primary published work			

I undertake to report any adverse drug reactions to the Committee on Safety of Medicines via the yellow card scheme

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I attach a copy of the treatment protocol I will give to the patient to gain patient consent and I attach a copy of the signed patient consent form.

I undertake to discuss this medicine with the patient's General Practitioner who may be asked to continue to prescribe it in the community.

Consultant's Signature - …… Date .....

Please print name here ……

Section 2 – RISK ASSESSMENT (To be completed by pharmacy when product not licensed in the UK)

Unlicensed / Off-label use Consensus on use *Yes/ No*

Manufacturer Protocol *Yes/ No*

Evidence base

Risk category

Preparation/ Formula –

Manufacturer / supplier –

Grade of ingredients –
Formula reference –
Stability –

Report of Quality Assurance on non-pharmacopeial standard ingredients –

Potential harmful impurities –

Storage condition / shelf life –

Pharmacist signature ..... **Date** .....

In situations where there is not a clear agreement between the supplying pharmacy and the consultant requesting the unlicensed medicine this document will be presented at the Area Drugs and Therapeutic Committee for consideration and if approval is granted section 3 will be completed.

Section 3 – To be completed by the Chairman of the Drug and Therapeutics Committee

Date application received -

Recommendations -

Signature ..... **Date** .....
(Chairman of the Drug and Therapeutics Committee)