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:…Multiple patients …… **Ward/Clinic: …EPAS/Maternity**

CHI Number: ……. Multiple Patients Yes/~~No~~

Drug Name	Progesterone (Cyclogest)		
Strength	400mg	**Formulation**	vaginal pessaries
Route & Dosage	400mg BD PV		
Indication	Bleeding in early pregnancy with history of previous miscarriage		
Non-licensed category - a, b, c, d or e	a		
Reason why a licensed product not suitable	Currently no product licensed in the UK for this indication.		
Duration of therapy	**From 6 to 16 weeks gestation for prevention of miscarriage**		
Side effects, adverse reactions, toxicity	Potential side effects include: headache; dizziness; mood change; breast pain; constipation; vaginal soreness; oily discharge from the pessary. There are animal studies showing harmful effects on male babies' testes, and other hormone-producing glands (pituitary and adrenal) as well as an effect on brain development with progesterone use between 6-16 weeks. As these effects were seen in animals it is unknown whether this would be seen in human boys. The use of progesterone was considered safe by the PRISM trial as there was no increase in harmful effects for mothers or babies in the womb nor any increase in congenital abnormalities recorded in the babies born to mothers in the trial.		
Other therapy already tried	**Not applicable.**		
References to primary published work	**Lancet series of papers on miscarriage and NICE guideline on miscarriage/recurrent miscarriage.**		

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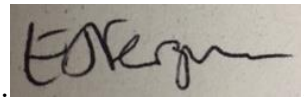
	Miscarriage matters: the epidemiological, physical, psychological, and economic costs of early pregnancy loss Siobhan Quenby, Ioannis D Gallos, Rima K Dhillon-Smith, Marcelina Podesek, Mary D Stephenson, Joanne Fisher, and others *The Lancet*, Vol. 397, No. 10285 Published: April 26, 2021 Full-Text HTMLPDF **Sporadic miscarriage: evidence to provide effective care** Arri Coomarasamy, Ioannis D Gallos, Argyro Papadopoulou, Rima K Dhillon-Smith, Maya Al-Memar, Jane Brewin, and others *The Lancet*, Vol. 397, No. 10285 Published: April 26, 2021 Full-Text HTMLPDF **Recurrent miscarriage: evidence to accelerate action** Arri Coomarasamy, Rima K Dhillon-Smith, Argyro Papadopoulou, Maya Al-Memar, Jane Brewin, Vikki M Abrahams, and others *The Lancet*, Vol. 397, No. 10285 Published: April 26, 2021 https://www.nice.org.uk/guidance/ng126

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

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 ..07/12/2023.....

Please print name here Evelyn Ferguson……

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: Treatment recommended by NICE (NG126) - Ectopic pregnancy and miscarriage: diagnosis and initial management (Aug 23). NICE recommendations based on based on evidence from PRISM and PROMISE trials.

Risk category

Preparation/ Formula – Cyclogest 400mg vaginal pessaries

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Manufacturer / supplier – L.D. Collins & Co. Ltd.

Grade of ingredients –
Formula reference –
Stability –

Report of Quality Assurance on non-pharmacopeial standard ingredients –

Potential harmful impurities –

Storage condition / shelf life – Do not store above 30°C / Shelf-life: 4years

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)