

NEW Unlicensed Medicines Policy and Process – November 2024

The previous NHS Lanarkshire Unlicensed Medicines Policy has expired and has been updated with a new policy and associated appendices, flowcharts and processes. This policy provides information on unlicensed medicines, off-label use of licensed medicines and the corresponding responsibilities of prescribers and pharmacy. It also discusses the processes prescribers should follow when considering the use of unlicensed medicines. It can be found here: [Unlicensed-Medicines-Policy | NHS Lanarkshire](#)

Key changes to the new unlicensed medicines policy are:

- ✓ All paperwork has been updated and streamlined for use across all locations in NHS Lanarkshire.
- ✓ The distinction between unlicensed and off-label medicines has been clarified along with the different processes required.
- ✓ A cost consideration element has been incorporated into the decision making process.
- ✓ The approval process has been clarified for acute & primary care
- ✓ Additional considerations have been incorporated for clinical areas including palliative care, paediatrics & mental health.
- ✓ A central R drive folder has been developed for use across all sites to allow sharing of key documents and consolidation and oversight of unlicensed medicines approval across the Board.

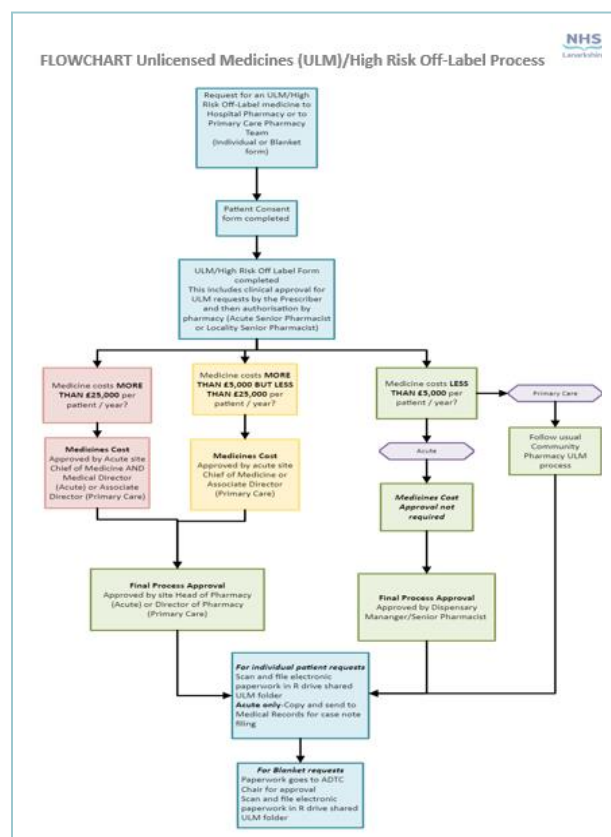
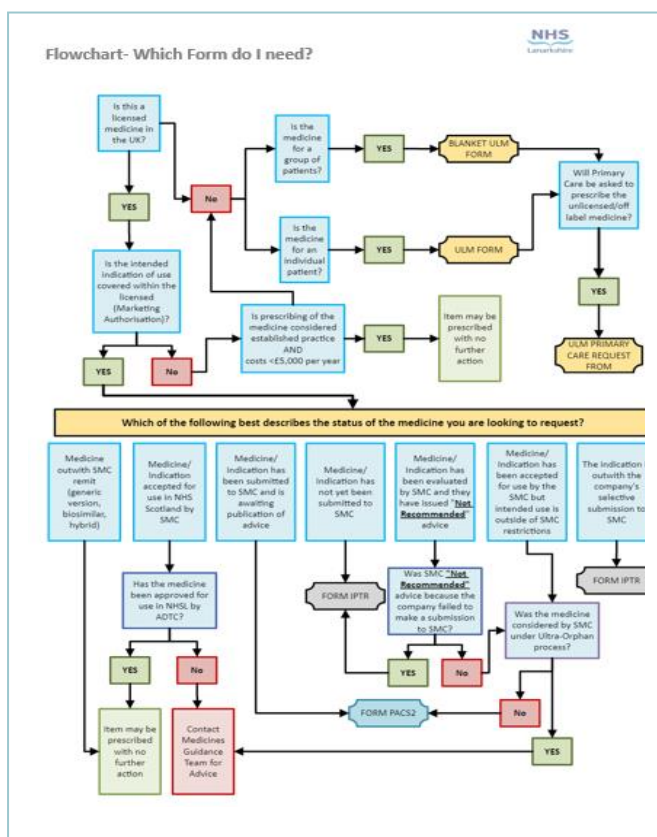


Associated Documentation

The documentation for unlicensed medicines has been updated. Some are updates of previous documents and others are completely new. They can all be found here - [Medicines Approval Process | Right Decisions](#):

New Document	Document it replaces
Flowchart – NEW 2024 Which Form Do I Need To Complete	The previous “Which Form Do I Need to Complete”
Flowchart – Unlicensed/High Risk Off-Label Medicines Process	No previous document
Appendix 1: Individual Unlicensed & High Risk Off-Label Medicine Application Form	Form C - Unlicensed Medicine Request
Appendix 2: Blanket Unlicensed & High Risk Off-Label Medicine Application Form	No previous document (Form C was previously adapted for blanket requests)
Appendix 3 - Prescribing Request to Primary Care for Unlicensed/High Risk Off-label Medicines	Form C PC - Prescribing Request to Primary Care for Unlicensed Medicine
Appendix 4: Criteria for clinical risk assessment of off-label medicines or specials	No previous document
Appendix 5: Patient Information Leaflet	No previous document
Appendix 6: Patient Consent to Unlicensed Medicine Use	Previous Patient Consent form
Appendix 7: Hospital Pharmacy Unlicensed Medicine Evaluation Form	Replaces various internal site specific acute forms
Appendix 8: Hospital Pharmacy Risk Assessment Form for an Unlicensed Medicine	Replaces various internal site specific acute forms

A ‘Frequently Asked Questions’ document that highlights expected enquiries has also been developed to assist teams throughout Lanarkshire. Two new flow charts have also been developed to guide teams through processes; an update to the existing “Which Form do I need to Complete” and a flowchart to illustrate the unlicensed/off-label medicines approval process. It is also important to highlight that whilst we have tried to capture most scenarios in the guidance, we cannot capture all. If any teams still have an outstanding query after referring to these resources and the new policy; please contact the Medicines Policy and Guidance team for further advice: medsguidance@lanarkshire.scot.nhs.uk.



What next:

- These changes will be communicated widely to teams across NHS Lanarkshire
- A central database will be developed to capture unlicensed medicines usage in one location
- An interim review of these new processes will take place within 12 months to continue to refine and streamline processes

Medicines Policy and Guidance Team

November 2024