

Medical, or non medical prescriber wishes to prescribe (within limits of competence) a medicine/medical device within NHS Lothian
Note: the same processes apply for medicines/medical devices available free of charge or via Early Access to Medicines Scheme (EAMS) ⌘

Is the medicine/medical device on the Formulary for the indication and patient group?

Yes

Prescribe

No

Is it (a) a licensed medicine being used within licence, (b) 'off-label' use of a licensed medicines, (c) an unlicensed medicine (ULM) (d) a food supplement being used for medical indication or (e) a medical device?

b,c,
d,e

See
Flowchart 2

WITHIN SMC REMIT ❖

a

OUTWITH SMC REMIT ❖

SMC full submission /resubmission accepted or accepted restricted

Submitted to SMC and awaiting assessment

Not yet submitted to SMC for approval or SMC not recommended because company did not submit to SMC

Following appraisal SMC Not recommended or use outwith SMC restriction

New Ultra-orphan pathway (from June 2018)

SMC not recommended advice ≥10 years

The medicine (or the new indication or use for a new patient group) received the marketing authorisation prior to 2002 is a generic or SMC have advised boards to follow local process (see separate guidance for paediatric licence extensions)

The product is a new strength, new formulation, or new presentation of an existing proprietary medicine already on the formulary (including biosimilars - see SMC guidance para 16 ❖), with no associated change to the, patient group for use, licensed indication or route of administration and the new product costs the same per patient or less.

ONE-OFF use in ONE PATIENT non-formulary request form ⌘

COMPLETE PACS2* ⌘

COMPLETE IPTR FORM* ⌘

COMPLETE PACS1 * ⌘

COMPLETE PACS2* ⌘

Contact the MMT for advice on the UMAR process

COMPLETE FAF2 ♠ and finance budget template

ONE-OFF use in ONE PATIENT non-formulary request form ⌘

ONE-OFF use in ONE PATIENT non-formulary request form ⌘

For new patients to be initiated on therapy* **SUBMIT COMPLETED PACS1, PACS2 or IPTR forms** ⌘ to PTR PANEL

USE in a PATIENT GROUP (collaborate with NHS Fife and NHS Borders to complete formulary applications and amendment request forms)

Submit accompanying treatment protocol/pathway/guideline to review group(s), e.g. relevant QIT or DTC and send copy with applications/forms noting review group(s) and approval or expected review date

COMPLETE FAF1 ♠ and finance budget template

COMPLETE FAF2 ♠ and finance budget template

COMPLETE Formulary amendment request form ♠

SUBMIT COMPLETED FAF1 ♠, FAF2 ♠, with accompanying finance budget templates and Formulary amendment request forms ♠ to prescribing@nhslothian.scot.nhs.uk

Flowchart 2 for Medicines Governance Applications and Forms

Medical/ non-medical prescriber wishes to prescribe a non-formulary medicine/medical device within NHS Lothian within one of the following categories.

Note: the same processes apply for medicines/medical devices available free-of-charge or via Early Access to Medicines Scheme (EAMS). ☞

