Which formulary application form (FAF) do I use to request changes to the East Region Formulary (ERF) for use of a medicine in a defined population?

NHS Borders NHS Fife NHS Lothian

Lead applicants proposing formulary inclusion of a medicine will be a clinician and supporting pharmacist from any of the East Region boards. Applicants to complete the form to reflect intended use and service implications (training, staffing, monitoring, impacts on clinical capacity in both secondary and primary care) relevant to clinical teams in each of the three boards and submit to Eos.prescribing@nhs.scot. The lead applicants must be two different individuals. Formulary applications require support of named clinical directors or equivalent medical managers in the three boards.

Medicine and indication	**Local board medicines governance process** (e.g. relevant local board Drug and Therapeutics Committee (DTC))	**ERF formulary application process**
Licensed use of medicine to be used in line with Scottish Medicines Consortium (SMC) accepted or accepted restricted advice (Medicine is in SMC remit)	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to East Region Formulary committee (ERFC) along with plans for local board approval e.g. name of DTC and expected date of review.	FAF1
Licensed use of a medicine that is not in SMC remit (Medicine is outwith SMC remit) or licensed use of a medical device prescribed in primary care and supplied on prescription	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to ERFC along with plans for local board approval e.g. name of DTC and expected date of review.	FAF2
Off-label use of a medicine or use of an unlicensed medicine or use of a food supplement for a medical indication	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to ERFC along with plans for local board approval e.g. name of DTC and expected date of review. Follow board medicines governance policy for approval of new unlicensed product. If the medicine/food supplement is already approved for use locally but this is a new indication or use in a new patient group undertake a risk assessment for the intended use.	FAF3
Paediatric licence extension with SMC accepted or accepted restricted advice for older age groups (Medicine is in SMC remit)	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to ERFC along with plans for local board approval e.g. name of DTC and expected date of review.	For advice contact Eos.prescribing@nhs.scot
Licensed use of medicine with an Ultra-orphan initial Assessment Report (UMAR)(Medicine is in SMC remit)	For advice email to BOR.Prescribing@borders.scot.nhs.uk [NHS Borders]; Fife Medicines Management Team [NHS Fife]; NHS Lothian Medicines Advice and Guidance Team [NHS Lothian]	For advice contact Eos.prescribing@nhs.scot
Licensed use of medicine with SMC not recommended advice > 10 years (Medicine is in SMC remit)	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to ERFC along with plans for local board approval e.g. name of DTC and expected date of review.	For advice and FAF4 contact Eos.prescribing@nhs.scot
A minor formulary change which is cost saving or cost neutral with no significant service impacts. If the change expands the defined population, includes a new indication or new route of administration a FAF form is required.	Associated prescribing materials (e.g. guideline, protocol and where appropriate shared care guidance) to be approved via local board medicines governance process. Include drafts for information to ERFC along with plans for local board approval e.g. name of DTC and expected date of review.	Formulary amendment form

- Note that generic, biosimilar or hybrid medicines are outwith SMC remit. SMC ‘not recommended’ advice for the originator medicine will no longer be applicable once generic or biosimilar medicines become available. Where there is a clinical need, the ERF will accept a FAF2 application to review the case for formulary inclusion. For further information on SMC remit see the document “Guidance on medicines outwith SMC remit” which can be found on the SMC website https://scottishmedicines.org.uk/making-a-submission/companies/
- For assistance in obtaining board clinical team contact BOR.Prescribing@borders.scot.nhs.uk [NHS Borders]; fife.fifemedicinesmanagement@nhs.scot [NHS Fife]; loth.prescribing@nhs.scot [NHS Lothian].
- In NHS Lothian board medicines governance polices and related resources are available here Safe Use of Medicines – Policy Online