

Guidance for Completing the Kent and Medway Joint Medicines Formulary – Formulary Amendment Request Form

General Guidance

The Formulary Amendment Request Form should be used to document all requests to the Kent and Medway Integrated Medicines Optimisation and Prescribing (IMaP) Group for any amendments to the Kent and Medway Joint Formulary to be recommended to the Integrated Medicines Optimisation Committee (IMOC).

Requests may include changes to formulary status, deletions, substitutions or temporary additions (e.g. due to shortages) as well as the inclusion of new formulations or new indications for medicines already listed on the Joint Medicines Formulary.

Please complete the form in full to avoid delay and return to the ICB medicines optimisation team kmicb.medicinesoptimisation@nhs.net

- Please complete **all** details – incomplete forms will be returned.
- Requests should be completed by the requesting clinician with support from the specialist or formulary pharmacist.
- The manufacturer/supplier (drug company) may provide information supporting the request – (this must be referenced appropriately), but the request **MUST** come from an appropriate applicant working within the local NHS (see above).
- Where possible electronic versions of any references and other supporting documents should be attached to the request (do not embed documents in the request, please send as separate attachments)
- Requests and any supporting guidelines/pathways etc should be in the final version or near to final version to allow for efficient discussion and decision making during the meeting. Do not submit documents containing comments or watermarks.
- All engagement with stakeholders should occur prior to submission of the request.
- Where amendments are complex, the SBAR form may be used to supplement the request form and provide additional detail.
- Requests should be submitted at least 4 weeks in advance of the IMaP meeting to allow for review and any critical amendments to be undertaken.
- The form should be submitted electronically as a **Word document** by e-mail to your Trust Formulary Pharmacist or for Primary care colleagues to kmicb.medicinesoptimisation@nhs.net
- Please ensure that the name of the medicine is included in the file name e.g. “Medicine” - KM Joint Formulary Amendment Request Form
- The applicant is expected to present the request at the IMaP meeting. They should present a maximum 5-minute summary of the evidence and be prepared to answer questions from the group members for a maximum 10 minutes.

- A decision will then be made by the IMaP to either recommend / not recommend the request to the IMOC. If recommended, this request will then be submitted to the IMOC for final approval.
- Any changes to papers requested by IMaP, prior to IMOC approval, are the responsibility of the applicant. Updated papers should be shared with the IMOC meeting organiser in accordance with meeting deadlines for papers.
- Information on the IMOC decision will be included in the minutes from the meeting and on a summary report which will be sent to the lead Healthcare Professional/Applicant within 2 weeks of the IMOC meeting.
- Each organisation is responsible for implementing the IMOC decision within their own organisation.

The following guidance explains how to complete each section of the Formulary Amendment Request Form

PART A

Part A is to be completed by the health care professional, requesting the amendment to the formulary.

1. Requesting Clinician, Pharmacist or Technician Details

Designation: State your job title.

Organisation: Enter the name of the NHS organisation you work for. The requestor must work within the NHS.

Declaration of interests: All applicants must provide a full and accurate Declaration of Interests to support transparent and unbiased decision-making. Please disclose any financial, professional, or personal interests that could reasonably be perceived to influence your request. This includes relationships with pharmaceutical companies, consultancy roles, sponsorships, research funding, gifts, or any other relevant affiliations. If no such interests exist, please tick to confirm that there are no conflicts of interest in relation to your request. Incomplete or omitted declarations may delay the assessment process.

2. About the Medicine

Medicine Details: Include the following exactly as they appear in the SPC:

- Medicine name (generic plus brand if branded generic* or biologic)
- Strength(s)
- Formulation
- Dose and frequency
- Route of administration
- Manufacturer
- Any special administration considerations (e.g., reconstitution, infusion time)

*NB: List prices for some 'branded generics' may be lower than the reimbursement price for equivalent generics. However, any cost savings achieved by their use may be unsustainable by the manufacturer and may not necessarily be cheaper, or in the best interests of the NHS in the longer term. There are a few circumstances when it is appropriate to prescribe a specific manufacturer's product (branded or generic). These include:

- drugs with a narrow therapeutic index
- certain modified- or controlled-release drugs
- certain administration devices
- multiple ingredient products
- biological drugs including biosimilars
- drugs with different licensed indications
- ensuring adherence to long-term medications, where differences in appearance between manufacturer's products might cause confusion and anxiety

3. Details of the Amendment Request

Change Required

Tick one of the following options:

- **Deletion:** removal from the formulary. The medicine will no longer appear at all on the formulary.
- **Change of status:** change to a different formulary classification e.g., Red → Amber, or Green → Grey
- **Temporary addition/substitution:** for shortages or service needs
- **New formulation:** for medicines already on formulary to add an additional formulation
- **New indication:** use for a new clinical condition or licensing change

Details & Reason for Change

Explain clearly:

- What change is needed
- Why the change is required (clinical need, safety, guideline update, shortages, service change, etc.)
- For temporary additions/substitutions include:
 - Proposed review date
 - Plan for reviewing the change
- Consider the evidence base where appropriate, e.g. for new indications or temporary additions/substitutions, and provide a summary of evidence supporting the change. Include:
 - National guidance (e.g., NICE, MHRA)
 - Clinical trial evidence where relevant
 - Local audit or service data (if available)
- For complex amendments, consider using the SBAR form to support with providing additional detail.

Supporting References

- All evidence must be provided via **hyperlinks or separate attachments**. Do not embed documents within the form.
- This section must be completed for any new indication requests
- List all references used, such as:
 - NICE Guidance
 - Clinical trial evidence
 - SPC/BNF

- Local audits

Cost Impact

Include **estimates** where possible:

- Anticipated number of patients
- Expected **cost pressure or cost saving**
- Primary care cost impact (use [Drug tariff](#))
- Secondary care cost impact
- Consider branded generics and sustainability of pricing







4. Formulary Amendments

Therapeutic Section

- Identify where the medicine will sit within the [Kent and Medway Joint Medicines Formulary](#) structure. Add a link to the webpage if it already exists. If a new page is required (e.g. new medicine class) state name for the new page and the parent section of the website.







Current formulary classification

Select the current status from the drop down.

 On Formulary Preferred	 On Formulary Second Line	 On Formulary Third Line
 Specialist Initiation	 Secondary Care Only	 Not Approved for Formulary

Proposed Formulary Classification

Select the proposed status from the drop down.



















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Guidance on the definitions can be found here: [Kent and Medway Formulary](#)

Formulary Annotations

Include:

- Which icons should accompany the formulary entry. Available icons are:

	Link to EMC website		Unlicensed Drug
	Link to NICE website		Brand Specific Prescribing Required
	Preparations to be initiated by Ophthalmology specialists only		Preparations classified as 'Controlled Drugs'
	Carbon footprint indicator		Blueteq required. Click icon to redirect to website to complete.
	High-Cost Drug		Available for purchase over the counter without a prescription.
	Cytotoxic Drug		Maidstone and Tunbridge Wells NHS Trust ONLY
	Drug subject to a shared care agreement		East Kent Hospital University Foundation Trust ONLY
	Unlicensed use		Dartford and Gravesham NHS Trust ONLY
	Supply/Restriction warning		Medway Foundation Trust ONLY

- The wording for any annotations to the formulary to support appropriate and safe prescribing e.g. warnings, prescribing restrictions (e.g., consultant-only, microbiology-only)

Impact on Other Medicines

Explain whether any:

- Existing medicines on the formulary need reclassification and what these changes are
- Medicines are replaced or removed
- Changes to existing formulary pages are required

Include all actions and information for the formulary team to make the necessary amendments.

5. Engagement

Stakeholder Engagement

Effective engagement is essential to ensure that formulary decisions reflect clinical practice, service models and patient needs across all Kent & Medway organisations. Requests that do not demonstrate comprehensive engagement will not be accepted.

Engagement must include all organisations and clinical areas where the medicine is/could be used. As the Kent & Medway Joint Medicine Formulary is system-wide, you must consult beyond your own organisation.

Stakeholders may include:

- Acute Trusts:** EKHUFT, DVH, MTW, MFT
- Primary care:** via the Kent and Medway Medicines Optimisation Group (KMMOG). Submissions requiring primary care input must be sent to the following mailboxes, which will arrange review and scheduling on the KMMOG agenda:
 - kmicb.eastkentprescribing@nhs.net
 - kmicb.dgscg.medman@nhs.net

- kmicb.wkmedman@nhs.net
- kmicb.medwayswale.meds@nhs.net
- **Community / specialist providers:** e.g. KCHFT, KMMH or other relevant commissioned services e.g. community dermatology
- **Relevant networks or MDTs:** e.g. condition-specific specialist groups, pathway oversight groups
- Any other service likely to be affected by implementation or change in practice

Record comments from all relevant providers including:

- Name, job role, and organisation of those consulted
- Summary of feedback received, capturing key themes, points of agreement or disagreement, concerns, and any variation between organisations
- Level of support or outstanding concerns
- Evidence that feedback has been considered or incorporated, demonstrating that changes have been made based on feedback, or the rationale for not adopting certain suggestions.

Requests must show that the engagement process has produced a Kent & Medway system-wide perspective, not an individual-organisation viewpoint, unless differences are due to commissioning arrangements.

Requests lacking full engagement will not be accepted.

External Organisations

Summarise:

- Pan-London guidance (if any)
- Neighbouring ICS positions

6. Implementation

Should patients prescribed the current product be considered for review

Select:

- Yes
- No
- Not applicable

If yes, choose the appropriate route:

- Specialist review of individual patients
- Specialist-led review programme
- Review by general practice during routine reviews

Provide details of:

- How patients will be reviewed
- Who will lead the review
- Timeframe and communication plan

Additional Implementation Considerations

Include anything that affects operational delivery and actions required for safe roll-out:

- ScriptSwitch messages for primary care
- Monitoring requirements
- Clinical communications
- Impact on service provision (e.g., extra blood tests, nurse time)
- Impact on primary care
- Deprescribing considerations
- Secondary care considerations:
 - Are there any expected implications when adding this medicines or its administration instructions to the ePMA system?
 - Are there any updates or revisions needed to existing pumps/driver drug libraries in the Trust?

PART B – To Be Completed by a Pharmacist

7. Request Reviewed By:

- Provide the reviewer's name, designation and organisation. This may be a formulary pharmacist or a specialist/senior pharmacist
- Whether any declarations of interest exist in relation to the request.

8. Independent Pharmacist Review:

Reviewing pharmacist's comments:

Provide:

- Critical appraisal of evidence
- Assessment of safety, cost-effectiveness and governance
- Suitability for GP prescribing (if requested)
- Risks, mitigations and practical implementation issues

Recommendation to committee: Final recommendation (support / do not support / support with conditions)