

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Document control

<b>Type of Document</b>	Terms of Reference
<b>Document Title</b>	Terms Of Reference, South East London Integrated Medicines Optimisation Committee (IMOC)
<b>Description:</b>	Sets out the governance and remit of the South East London Integrated Medicines Optimisation Committee
<b>Location:</b>	SEL Integrated Care Board website
<b>Publication date</b>	October 2024
<b>Last Review date</b>	August - September 2024
<b>Next Review due</b>	April 2025
<b>Consultation Body / Persons</b>	SEL Integrated Medicines Optimisation Committee members
<b>Consultation date</b>	August 2024
<b>Approval Body</b>	SEL IMOC ICB Executive Committee
<b>Approval date</b>	SEL IMOC – 15 <sup>th</sup> August 2024 (pending amendments) SEL IMOC Chair’s ratification: 27 <sup>th</sup> September 2024 ICB Executive – 9 <sup>th</sup> October 2024
<b>Readership / Audience:</b>	Members of SEL IMOC Stakeholders / partners in the SEL ICS Clinicians and Public as relevant
<b>Information Governance Class (Restricted or unrestricted)</b>	Unrestricted

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Version / Change History

<i>Version</i>	<i>Date</i>	<i>Author</i>	<i>Approving Committee / Group</i>	<i>Reason</i>
V22	August 2024	Assistant Director Integrated Medicines Optimisation	SEL IMOC ICB Executive Committee	Annual review of the Terms of Reference

#### Consultation History

<i>Consultation Body / Persons</i>	<i>Area of expertise</i>	<i>Date sent</i>	<i>Date returned</i>	<i>Comments</i>	<i>Changes made</i>
SEL IMOC members	Medicines Optimisation	August 2024	August 2024	Main changes are inclusion of: (i) membership in line with changes to ICB structure (ii) Learning disability in formulary application form and guideline development process (iii) Urgent Triage Panel process	

#### Appendices

<i>Appendix 1</i>	Member organisations and key relationships
<i>Appendices 2a-2c</i>	Process Diagrams for (i) new drug applications or indications, (ii) items not associated with new drug applications e.g. shared care requests and (iii) guidelines/protocols/pathways
<i>Appendix 3</i>	Application form for new drugs
<i>Appendix 4</i>	Request form for items not concerned with new drug applications to be discussed at IMOC
<i>Appendix 5</i>	Template for assessment of new drug requests – triage process
<i>Appendix 6</i>	Advice/decision recording
<i>Appendix 7</i>	Decision making categories and quadrant grid
<i>Appendix 8</i>	Declarations of Interest process
<i>Appendix 9</i>	<i>Urgent Triage Panel process for emergency situations</i>

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Introduction

The Integrated Medicines Optimisation Committee (IMOC) is a sub-committee of the Integrated Care Board's (ICB) Executive.

#### 1. Purpose

The areas of responsibility for the South East London Integrated Medicines Optimisation Committee (SEL IMOC) are:

- a. To provide a collective clinical leadership Committee to ensure co-operation and consistency of approach to medicines optimisation across the SEL Integrated Care System (ICS).
- b. To enable local clinicians to work together across the ICS to ensure that patients have safe and consistent access to medicines in the context of care pathways which cross multiple providers.
- c. To advise on implementation of best practice around medicines, including regional and national advice from NHS England, the National Institute for Health and Care Excellence (NICE) technology appraisals and guidelines to encourage rapid and consistent implementation
- d. To enable local NHS stakeholders and clinicians to exert a population approach to the prioritisation, improvement and development of healthcare delivery related to medicines.

#### 2. Scope

The IMOC will be the single point of entry for new medicines or new indications for all medicines. The IMOC will triage all new applications in SEL to ensure that applications are discussed in the most appropriate setting (see Appendix 5). This could include assessment by the IMOC or the IMOC will work with the SEL Joint Formulary Committee and Trust Drug and Therapeutic committees to make an assessment as appropriate.

Factors involved in the triage assessment include the following:

- The cost impact for medicines or end to end pathway cost associated with prescribing or administering the medicine is likely to be significant to the local health economy, noting financial thresholds in section 3.
- Where integrated working to maximise the benefit of the intervention is likely to have a high impact in improving the health of the SEL population and reducing inequalities
- An integrated approach to secure a change in the care pathway or model of care is required to facilitate access for our population to evidence based medicines.
- Where there is likely to be a high risk of challenge to decision making and a SEL wide approach would reduce this risk. It is likely that the SEL IMOC would wish to work with other ICS's in London and/or regional clinical networks as appropriate to further reduce the risk.

Devices and interventions are not considered by the committee. In exceptional cases, suitability for consideration by the SEL IMOC of devices that can be prescribed on an NHS FP10 prescription form will be via the triage panel process on a case-by-case basis.

The committee will have an overarching Chair and three vice-Chairs sought from the membership of the IMOC and will liaise closely with the local acute Trust Joint Formulary Committee via the membership.

The remit of the SEL IMOC will include considering recommendations made nationally by NHS England and, where appropriate, supporting implementation in line with the SEL IMOC processes.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### 3. Duties

The Integrated Medicines Optimisation Committee reports to the SEL Integrated Care Board's (ICB) ICB Executive.

#### Finance and Planning

The Integrated Medicines Optimisation Committee will use a prioritisation approach, taking account of the cost of the medicine and impact of the investment. The committee will consider the financial position of its stakeholder constituent organisations and the extent to which it is feasible to absorb any cost impact or if additional funding is required, also accounting for any substitution impact. The overall approach will be to incorporate robust horizon scanning as part of the ICS annual planning process through the Medicines Value Group, a possible exception to this being national guidance which wasn't anticipated. In an exceptional case where a medicine is felt to require additional funding, the committee will seek advice from the ICS Director of Planning and Chief Finance Officer on the best way to secure the committee's recommendation.

When considering formulary submissions or guidance that might impact financially (including NICE), the agreed financial limits that the IMOC will work to will be <£25,000 per 100,000 population per year impact per intervention considered. In line with the SEL ICB Schedule of Matters Delegated to Officers, the SEL IMOC has delegated authority to authorise new medicines with an estimated total yearly cost up to £25,000 per 100,000 population. Above this threshold, authorisation will be by the Executive Committee on the recommendation of the SEL IMOC. The IMOC will seek input in advance from finance leads for items that near the financial threshold. Note: The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's Technology Appraisals. For drugs recommended within NICE Technology Appraisals and being used within NICE criteria and where the total yearly cost is above £25,000 per 100,000 population per year – these will be highlighted to the Executive Committee for information only.

For managed entry of new medicines, if there is a higher than anticipated number of new drug submissions the IMOC will prioritise medicines with a financial impact to the ICS of >£20,000 per 100,000 population to help manage the workload.

In line with the Innovation report, the committee would not seek to duplicate NICE assessments or challenge an appraisal recommendation. It would support timely and planned implementation of NICE Technology Appraisals. To avoid duplication of workload it would take into account recommendations from other national bodies e.g. NHS England, Medicines and Healthcare products Regulatory Agency (MHRA) the Scottish Medicine Consortium, the European Medicines Agency (EMA) and the All Wales Medicines Strategy Group and the Accelerated Access Collaborative. Cancer drugs and those commissioned by NHSE would not be considered by the committee unless there is an impact on other locally commissioned services or medicines. At time of update, it is expected that some clinical services may move from NHSE/I specialised commissioning to ICS's and this would be expected to include any related medicines. These will be considered on a case by case basis as the changes are confirmed.

#### Appeals Process

Any appeals against SEL IMOC decisions should be directed to the Executive Director of Planning who will convene an appeal panel as required accountable to the Integrated Care Board (ICB). The Appeal Panel will be supported to discharge its responsibilities administratively through the SEL ICB corporate business function. Appeal requests must be submitted in writing to the Executive Director of Planning within 30 days of the date of issue of the decision.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

The appeals process gives applicants the right to appeal an IMOC decision if they feel that the process leading to the decision being made was not followed correctly. The Appeal Panel does not consider whether the decision was clinically right or wrong and cannot change the assessment criteria agreed by SEL ICS. The Grounds for an appeal against decisions made by the SEL IMOC are:

- (i) In reaching the original decision, the SEL IMOC did not follow its agreed decision making process as outlined in the Terms of Reference.
- (ii) The applicant can demonstrate that not all relevant evidence available at the time of review was taken into consideration at the time of the decision for whatever reason.

#### Notes:

1. The applicant cannot appeal against a decision just because they do not agree with the decision or because new evidence has come to light since the original decision was made. If new evidence is provided following a decision made by the SEL IMOC, the correct procedure is to resubmit for reconsideration of the decision by the committee.
2. The applicant cannot appeal against a decision because a neighbouring IMOC (or equivalent committee) came to a different decision.
3. The applicant will not be able to lodge an appeal if they did not attend the meeting where the application was considered.

The appeal panel will assess if the IMOC has followed its own processes accurately. The results of this appeal will be communicated directly to the appealing clinician and the IMOC, who will review the decision if required.

Proactive reviews of the IMOCs decision making processes will be carried out on an annual basis via scrutiny of individual examples.

#### Pharmaceutical Industry involvement

There may be occasions where pharmaceutical industry involvement may assist with the review process. This might be sought for budget impact modelling for example. Where pharmaceutical industry involvement has occurred in the review process this will be clearly recorded to ensure transparency.

#### Monitoring

In order to discharge its duties effectively, the committee may require the following information on a case-by-case basis:

- a. Comparative prescribing data in primary care and by Trust, including QIPP performance for specific areas under discussion on a South East London basis by the IMOC. Any continued data requirements should be for a pre-defined period and to support the monitoring of the IMOC.
- b. Data on cost effectiveness of drugs
- c. Comparative and cost data on expenditure by acute trust on high-cost drugs under the national NHS Payment Scheme (formerly the National Tariff).
- d. Minutes and recommendations from local formulary/DTC committees.
- e. Other cost or drug usage data from partners as required.

The committee will develop a work plan with specific objectives which will be reviewed regularly and formally on a 12-monthly basis. The workplan and review should assess the outputs of the committee against the benefits of the IMOC:

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

- a. An ability to assess medicines use across the whole care pathway and move beyond a simple assessment of one drug against another.
- b. A forum where a decision can be made about appropriateness of prescribing in different settings so that prescribing can take place in the right place. Shared care guidelines would be included in this.
- c. The costs of medicines can be assessed as part of the managed entry process. This can also incorporate a local reality check on NICE drugs and possible phased implementation of new medicines.
- d. The IMOC would be able to work in the “grey areas” i.e. clinical consensus can be gained where there may not be strong evidence for a medicine or there is a complex risk vs. benefits balance to be struck
- e. Reduce bureaucracy associated with management of tariff excluded drugs and Individual Funding Requests (IFRs).
- f. Transparency of QIPP savings – the IMOC could be explicit about potential shifts between medicines spend and subsequent investment or disinvestment in services/activity.
- g. Mapping of local need – using public health expertise we would be able to determine likely uptake of national guidelines locally and prioritise based on our local population.
- h. Consistency of access to medicines – we would enable Trusts to ensure consistency between clinicians in prescribing or recommendations to GPs to prescribe.
- i. Forecasting local spend on drugs and potential QIPP initiatives (using our local Medicines Information expertise to distill national horizon scanning information)
- j. Management of new drugs or indications “pre-NICE” and implementation planning.
- k. Monitoring of usage data and spend on medicines – highlighting where local uptake is higher or lower than expected

#### 4. Accountabilities, authority and delegation

The Integrated Medicines Optimisation Committee reports to the SEL Integrated Care Board’s (ICB) Executive Committee.

Within the Integrated Care System, the Integrated Medicines Optimisation Committee will also provide quarterly updates to the SEL Quality and Safeguarding Committee.

#### Collaborative arrangement

The SEL IMOC is a multidisciplinary clinical committee that is supported on a senior professional level by the SEL Integrated Pharmacy Stakeholder Group and the Pharmacy Leadership Team. Resources and leadership required across partner organisations will be reviewed on a regular basis by member organisations with the SEL IMOC retaining oversight.

The committee will be supported by Formulary Pharmacists in member acute and mental health Trusts, GSTT Medicines Information and member ICS Borough medicines management teams. A triage and horizon scanning process to support this will be provided by GSTT Medicines Information Department, supported by partner organisations.

***Nominated representatives are responsible for ensuring two-way reporting, implementation and feedback to the IMOC via relevant committees such as Drugs and Therapeutics Committees in member organisations***

Membership of the committee’s sub-groups to include consideration of patient engagement.



## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

Engagement with clinical groups and networks, especially if a formulary decision needs specific knowledge and expertise or has direct implications for a clinical practice area will be undertaken as required with:

- a. patients or patient representative groups
- b. local people and communities
- c. local clinical specialists
- d. relevant manufacturers of medicines, for example, when the company can offer additional evidence and insight that can assist with decision-making
- e. Other relevant decision-making groups.

Ensure stakeholder engagement is proportionate to the type of decision being made and the medicine being considered.

#### **5. Membership and attendance**

Each member is representative of a “constituency (e.g.: organisation)” and is accountable to the constituency for ensuring that representation reflects the view. Chairing of the meetings will be shared between the Chair and the three Vice Chairs on a rotational basis.

Any potential conflicts of interest should be declared, recorded and a report available for public scrutiny. In the case of committee members, if appropriate, they may be asked to leave the room during the decision-making process if a potential conflict of interest arises. The vice chair (or other non-conflicted member) should chair all or part of the meeting if the chair has an interest that may prejudice their judgement.

Members are responsible for ensuring representation – if they cannot attend a deputy must be arranged or comments given to the chair in advance of the meeting. An attendance rate of below 50% will be flagged to the chair for consideration.

Where appropriate the committee will invite and actively seek the views of appropriate Consultant and/or service leads for specific issues in order that decisions are made with full acknowledgement of specialist expertise and reflect the need of the local health economy.

Tenure of chairs and vice-chairs will be subject to review every 2 years. Chairs and vice chairs may continue long term with a review and must be supported by committee members to do so.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

<b>Core Membership – Voting membership (Reps as advised by Trusts/boroughs/organisations):</b>		
<b>NOTE:</b> for primary care borough Clinical Lead membership, nominated member may be a Primary Care Network (PCN) clinical director.		
<b>SEL ICS Organisation</b>	<b>Role</b>	<b>Votes allocated</b>
SEL ICB integrated/ collaborative Medicines Optimisation function	Chief Pharmacist	1
	2x Associate Chief Pharmacists	
	Assistant Director, Integrated Medicines Optimisation	
	Lead Pharmacist, Integrated Medicines Optimisation	
SEL ICB Place based Medicines optimisation function	2x Assistant Director for Medicines Optimisation (rotational basis)  6x GP Medicines Optimisation Clinical Lead (one for each SEL borough – Bexley, Bromley, Greenwich, Lambeth, Lewisham, Southwark)	6 (one vote per Place)
Overarching Committee Chair from a partner SEL NHS organisation	Local practicing clinician with an established interest in Medicines Optimisation	1
Guy's and St. Thomas' NHS Foundation Trust	Consultant lead/Chair of DTC (current vice-Chair)	1
	Pharmacist Lead (or delegated staff)	
King's College Hospital NHS Foundation trust	Consultant Lead	1
	Pharmacist Lead (or delegated staff)	
Lewisham and Greenwich NHS Trust	Consultant Lead	1
	Pharmacist Lead (or delegated staff)	
South London and Maudsley NHS Foundation Trust	Consultant lead (current vice-Chair)	1
	Pharmacist Lead (or delegated staff)	
Oxleas NHS Foundation Trust	Pharmacist Lead (or delegated staff)	1
Bromley Healthcare	Pharmacist Lead (or delegated staff)	1

<b>In attendance/optional (non-voting membership):</b>	
Patient and Public Voice representative	
NHS England (London Region)	Regional Chief Pharmacist Specialised commissioning Lead Pharmacist
Mental Health Trusts – Oxleas and SLaM and Bromley Healthcare	Specialist consultants and pharmacists to be invited as required.
ICS Finance	Director or Associate Director of Finance
South London Health Innovation Network (HIN)	Lead Pharmacist
SEL ICB	Clinical and Care Professional lead for Overprescribing
SEL ICB	Associate Director, Learning Disability & Autism
Specialist Expertise	Consultant Pharmacists as required – including but not limited to: Cardiovascular Disease, Diabetes, Respiratory, Older People, antimicrobial stewardship, palliative care



## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

Public Health Medicine	Public Health Consultant
Local Pharmaceutical Committee (LPC)	A nominated SEL LPC Community Pharmacist representative
Local Medical Committee (LMC)	A nominated SEL LMC GP representative
Primary care non-medical prescriber	Practice/PCN Pharmacist or nurse
SEL ICS	Senior Pharmacist, Integrated Medicines Optimisation Senior Pharmacy Technician, Integrated Medicines Optimisation SEL Business support (operational support)

Member's roles are:

- a. Contributing to and participating in the delivery of the committee's scope.
- b. Taking lead responsibility for bringing a clinical and operational perspective to decisions affecting medicines management services within their organisation
- c. Communicating decisions and issues between the committee and peers/colleagues.
- d. Interpreting national, professional and clinical guidance in relation to medicines management.
- e. Undertaking CPD in prescribing/medicines management.

Member responsibilities are:

- a. To be available to attend meetings lasting up to 2.5 hours on designated days
- b. To keep up to date and maintain an active interest on medicines management issues.
- c. Where appropriate, to be regularly involved in the prescribing process either as a current prescriber or undertake training to be a prescriber in the near future.
- d. To be an active participant of the committee and take responsibility for the decisions made.
- e. To represent the committee as required both internally and externally.
- f. To ensure that you represent the views of your peers in the directorate or uni-professional group that nominated you.
- g. To have regular access to a communication network with your peers which would allow you to:
  - i. assess and scope opinions on topics to be discussed
  - ii. bring relevant items to the attention of the committee
  - iii. communicate information out to colleagues from the committee
- h. To follow organisational corporate policies as appropriate (e.g. Working with Industry, Equal Opportunities, Data Protection etc.).
- i. To complete a declaration of interests on an annual basis and update as needed.

#### 6. Chair of meeting

The overarching Chair of the Committee is the Professor of Cardiovascular Clinical Pharmacology, King's College London and the Chair is supported by three vice-Chairs. The vice-Chairs will be nominated by the committee.

Chairing of the meetings will be shared between the Chair and the three Vice Chairs on a rotational basis. If the Chair is temporarily absent on the grounds of conflict of interest, a vice-Chair shall preside.

#### 7. Quorum and conflict of interest

At least 50% of core (voting) member organisations should be in attendance, with at least one each from primary care and an acute Trust. The committee must ensure that key members are present on a case-by-case basis depending on the agenda of an individual meeting.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

The committee agrees to enact its responsibilities as set out in these terms of reference in accordance with the Seven Principles of Public Life set out by the Committee on Standards in Public Life (the Nolan Principles).

All members will be asked to complete a Register of Interest annually and when changes are required, and declare conflicts of interest on agenda items as appropriate. The Declarations of Interests process for the committee is provided in Appendix 8 (pages 27 – 33).

**Note:** Employees of the ICB who are members of the IMOC will also be required to declare any interests they may have in accordance with the ICB's Conflict of Interest Policy (included within the Standards of Business Conduct Policy). Members will follow the process and procedures outlined in the policy in instances where conflicts or perceived conflicts arise.

#### 8. Decision-making

The SEL IMOC will be decision making for SEL ICS, which has agreed to be proactively engaged in the recommendations of the IMOC.

Recommendations of the IMOC and its sub-groups will be made by members by consensus discussion, or if necessary, by a majority vote of the core membership. In the case of a 50:50 split vote, the IMOC Chair will have the deciding vote. Each SEL ICS member organisation will receive one vote each. The overarching SEL IMOC Chair will also be allocated a single vote. Lay membership and specialists co-opted by the committee's sub-groups are advisory and non-voting. Recommendations will be recorded via the IMOC minutes.

Decision making criteria will be defined by a multi-criteria decision making tool which is agreed by IMOC members and shared with applicants, Appendix 7.

The committee will continually review its decision making processes based on the DH guiding principles and best practice as defined by the National Institute for Health and Care Excellence ([NICE](#)) and the [NHS Constitution](#).

Note: [Directions](#) issued by the Secretary of State for Health (2010) make it a statutory obligation for commissioners to make funding available within 3 months for medicines that have been recommended by a NICE technology appraisal, unless they are directed otherwise by the Secretary of State for Health.

#### 9. Frequency

Meetings of the IMOC will be held on monthly on the 3rd Thursday of every month, with sub-groups determining their meeting frequency individually.

All members will be expected to attend all meetings or to provide their apologies in advance should they be unable to attend.

Members are responsible for identifying a suitable deputy should they be unable to attend a committee meeting which needs to be agreed with the chair, and notified to the meeting secretariat, in advance.

Nominated deputies will count towards the meeting quorum if attendance has been agreed by the chair of the meeting.

#### 10. Reporting

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

Papers will be made available one week in advance of the meeting to allow members to discuss issues with colleagues ahead of the meeting. Members are responsible for seeking appropriate feedback.

The committee will report on its activities to the ICB Executive via minutes and any further agreed ICB reporting requirements.

The minutes of meetings shall be formally recorded for the purposes of a decision-making audit trail and assurance.

The IMOC will develop a local communication framework, in consultation with stakeholders, reviewed annually, to:

- disseminate targeted, concise information to other decision-making groups and key stakeholders, including patients and the public who need to know about the decision
- routinely communicate with neighbouring local formulary decision-making groups to share practice, particularly when there are cross-boundary patient flows
- anticipate media response to decisions.

IMOC documents will be published on the SEL ICB website, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes minutes of IMOC meetings, decision outcomes and associated decision outputs.

#### **11. Committee support**

Draft minutes will be circulated to members for committee review and comment and approval, together with an action log, within the agenda pack ahead of the next meeting. The minutes will be formally approved at the next meeting.

#### **12. Review of arrangements**

These Terms of Reference shall be reviewed by the committee on an annual basis, in the context of the self-assessment and any changing business requirements, with changes proposed approved by the ICB Executive.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### **Appendix 1. Partner Organisations & relationships, SEL IMOC**

Partner organisations signed up to the SEL Integrated Medicines Optimisation Committee are:

SEL boroughs of Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark  
King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, South London & Maudsley NHS Foundation Trust, King's College London).  
Lewisham and Greenwich NHS Trust  
Oxleas NHS Foundation Trust  
Bromley Healthcare NHS Trust

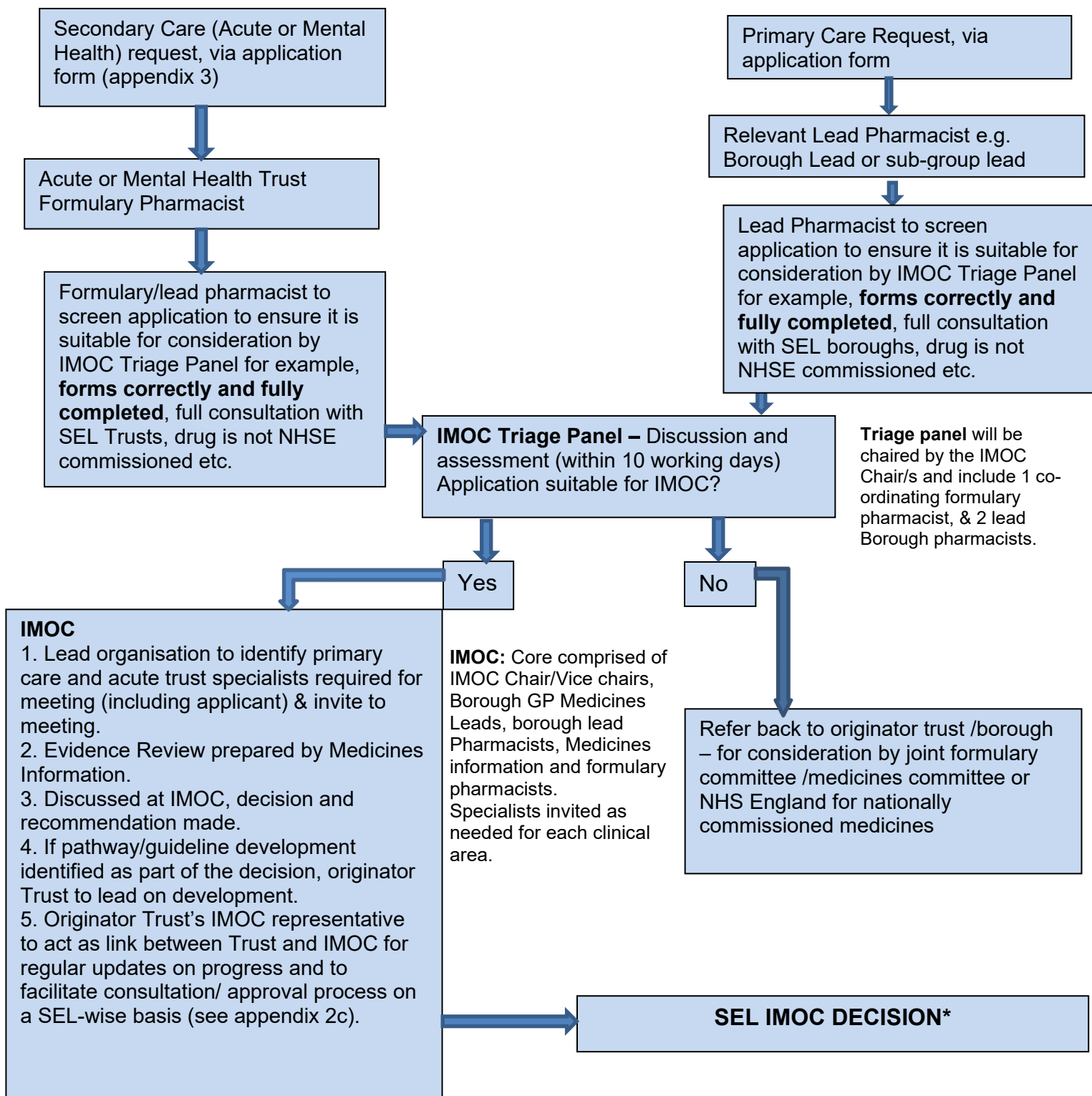
#### **Other key relationships:**

SEL Integrated Pharmacy Stakeholder Group and Pharmacy Leadership Team  
Medicines Information Services  
Public Health  
Clinical Effectiveness SEL (CESEL)  
Acute Provider collaborative (APC)  
ICB Executive  
ICS Medicines Safety Network  
ICS Antimicrobial Stewardship Network  
ICS Programme Boards as relevant  
ICS Medicines Value Group  
ICS Community Pharmacy Implementation Group  
Patients/public  
Borough Medicines Implementation Groups  
NHS England, London Area Team  
SEL Clinical and Professional Leadership Board  
Provider Trust Drug and Therapeutics Committees and Formulary Committees  
London Procurement Partnership – Medicines Optimisation Programme  
Other London ICS Integrated Medicines Optimisation Committees/Groups  
South London Health Innovation Network (HIN)  
London Individual Funding Request Panels  
Local Medical Committee (LMCs)  
Local Pharmaceutical Committees (LPCs)  
Local Professional Networks  
Local Authorities in SEL

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

**Appendix 2a. Process for new drug applications or indications. See Appendix 2b for issues not concerned with new drug applications**



Communicate to all IMOC members with rationale, position statement to include funding implications.

- Approved in-year (with Traffic Light) **OR**
- Declined

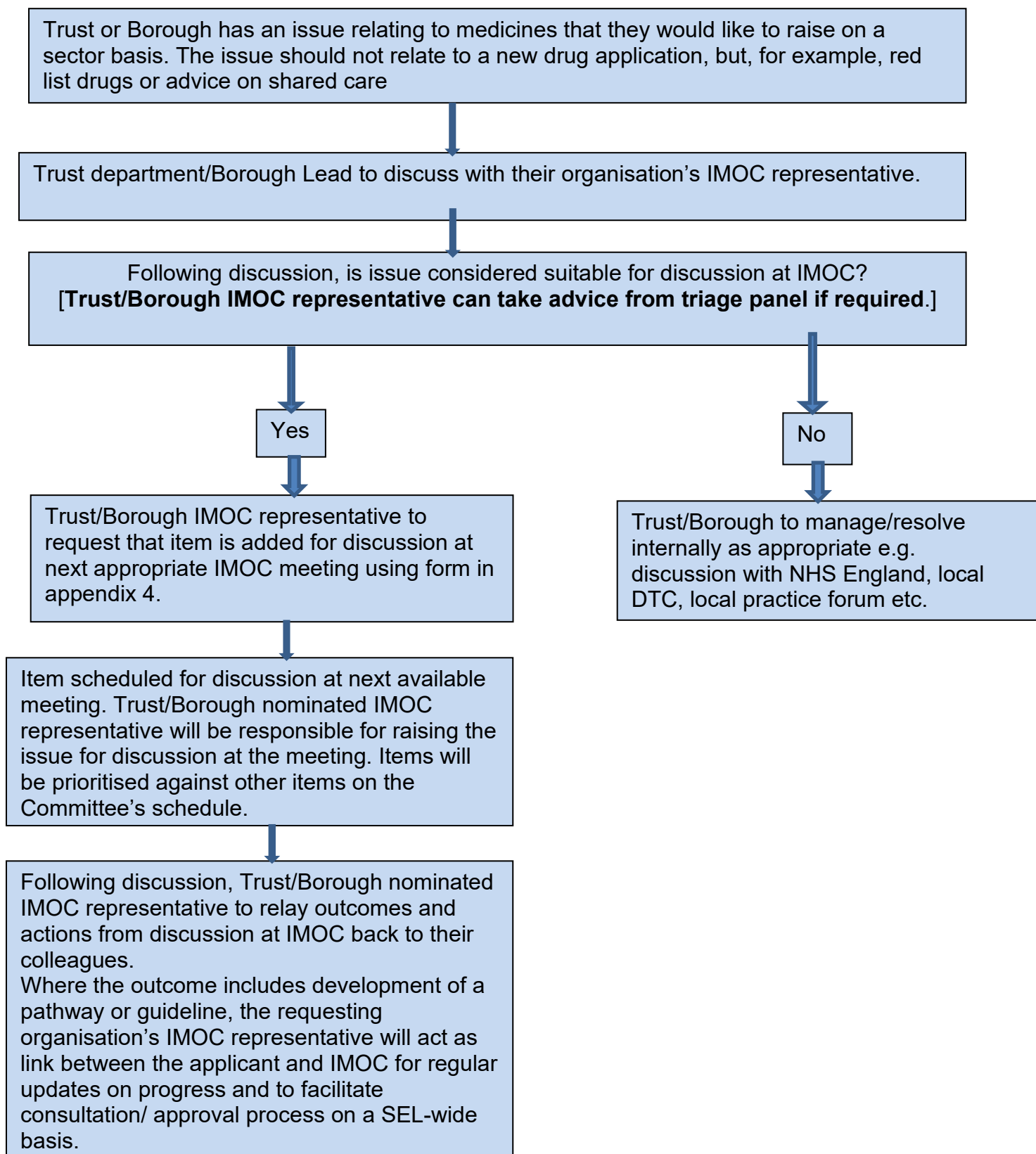
IMOC members to ensure decisions are disseminated and shared within their base organisation.

\* Financial implications of decisions should have been anticipated through horizon scanning as part of the annual planning process. If costs are unable to be absorbed despite substitution costs, or an unplanned NICE TA/other mandatory national guidance has been issued, then how to secure the recommendation will be discussed with both the ICS Director of Planning and CFO in advance of any decision.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 2b. Process Diagram for issues not concerned with new drug applications





## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 2c. Process flow for outputs such as pathways, guidelines, policies, protocols etc

**THINK OVERPRESCRIBING:** When developing new or reviewing existing IMOC guidance, the lead authors should include an Overprescribing section with links to nationally available (or existing SEL IMOC) deprescribing guidelines, where these are available.

**THINK LEARNING DISABILITY & AUTISM (LDA):** Consider offering reasonable adjustments for people with LDA (e.g. easy read materials, prescribing alternative medicine preparations for better compliance). For more information and support, please contact [LDAprescribingTeam@selondonics.nhs.uk](mailto:LDAprescribingTeam@selondonics.nhs.uk)

IMOC identifies pathway (e.g. as part of a drug submission), guideline (including shared care), policy/protocol etc development where no relevant IMOC sub-group exists.

Document, e.g. pathway, guideline (including shared care), policy/protocol developed through IMOC sub-Group

As part of the development process, the IMOC will identify a Lead Trust/Borough to develop the guideline/pathway/etc. For work relating to new drug submissions, this will be the organisation making the formulary submission. Nominated organisation reps for the IMOC to communicate development of the document, e.g. guideline/ pathway/policy to relevant individuals/teams within their base organisation.

- Lead authors to initially discuss at sub-Group meeting. This will be followed by email consultation via the sub-group membership. Consultation should include the whole membership to ensure views from different sectors /base organisations are considered.
- The consultation will also be circulated to the overarching IMOC membership (IMOC team can support circulation).
- Consultation should cover a sufficient period of time and be for a minimum period of at least **10 working days**. Comments tracker will be used to log and respond to comments.
- Sub-Group representatives will be responsible for sharing the draft document with relevant individuals or groups at their base organisation as deemed appropriate.

- Lead Trust/Borough nominated IMOC representative to feedback to applicant and agree who within their organisation will develop the document (“authors”).
- The IMOC representative will be responsible for acting as link between the author and IMOC for regular updates on progress and to facilitate the document consultation/ approval process on a SEL-wide basis.

Once drafted, the document will be consulted on with IMOC membership. Consultation should cover a sufficient period of time and be for a minimum period of at least **10 working days**. Comments tracker will be used to log and respond to comments. For the consultation, IMOC representatives will be responsible for sharing the draft document with relevant individuals or groups at their base organisation as deemed appropriate.

- Lead author to consider consultation feedback and make amendments where appropriate.
- Where the authors do not make amendments based on feedback, a clear rationale should be provided in the comments tracker for not amending the document.
- Lead author must share the final draft of the document with the sub-Group for sign-off / approval **before** presentation to IMOC.
- **Nb:** for some guidance, the IMOC may agree that a wider consultation is not necessary, for example review of existing guidance with minor changes.

**Nb:** for some guidance the IMOC may agree that a wider consultation is not necessary, for example review of existing guidance with minor changes.

Lead author to consider consultation feedback and make amendments where appropriate. Where the authors do not make amendments based on feedback, a clear rationale should be provided in the comments tracker for not amending the document.

Final version of document to be presented to IMOC for approval. Changes to be considered and made by authors if requested by IMOC prior to approval.

**Ratification by SEL IMOC**

Communicate to all IMOC members and upload onto IMOC website.

**It is the responsibility of nominated SEL organisation IMOC members to ensure the output e.g. guideline/pathway/policy/protocol is disseminated and shared within their organisation. This may be through their DTC, Borough groups, directorate teams etc.**

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 3. Application form for new drug applications.

Application form for the use of a new medicine or existing medicine for a new indication. **Please note: this submission will NOT be accepted by formulary teams if any sections of the form are left incomplete.**

1. APPLICANT DETAILS		
Name:	Trust/Organisation:  Specialty and Job Title:	Email:  Contact Number:
2. MEDICINE DETAILS		
Name (generic and brand), Strength & Form:		
Dose:	Intended duration of treatment:	
Licensed indication:		
Intended indication for use: <b>Note: Only one indication per application form will be considered.</b>		
Starting criteria for the medicine:		
Stopping criteria:		
3. COMMISSIONING ROUTE FOR THE MEDICINE		
Is the medicine excluded from the national tariff (PbR excluded)? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes: who is the responsible commissioner for the medicine? <input type="checkbox"/> ICBs <input type="checkbox"/> NHS England		
If no: is the medicine part of a national specialised service? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Are services relating to this formulary application commissioned by local authorities (for example, alcohol misuse, smoking cessation, sexual health)? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>* If yes, please ensure you have documented (e.g. email) support from all 6 SEL Local Authorities for this application*</b>		
4. EVIDENCE TO SUPPORT APPLICATION		
List below and append key supporting references:		
Outcomes anticipated from the medicine (include patient orientated outcomes as priority).		

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

<p>Summarise any experience of using this medicine for the proposed indication (e.g. from local Trust approval for individual patients):</p>
<b>5. FORMULARY IMPLICATIONS</b>
<p>Detail below the proposed place in therapy and append a proposed treatment guideline:</p>
<b>6. OVERPRESCRIBING</b>
<p>In South East London the ambition is to reduce overprescribing in line with the <a href="#">National overprescribing review report</a> recommendations. Please describe:</p> <ul style="list-style-type: none"> <li>The circumstances under which this medicine may be reviewed with a view to deprescribe if no longer appropriate and</li> <li>If inclusion of this medicine may result in other medicines the patient is prescribed for their condition being deprescribed</li> </ul>
<b>7. LEARNING DISABILITY &amp; AUTISM (LDA)</b>
<p>In line with reducing health inequalities and improving access to medicines in our local population, please advise if there are any reasonable adjustments that can be considered as part of this application for people with LDA requiring this treatment. Reasonable adjustments, such as providing easy read materials or prescribing alternative medicine preparations may enhance their understanding as well as improve medication compliance. For more information, please contact: <a href="mailto:LDAprescribingTeam@selondonics.nhs.uk">LDAprescribingTeam@selondonics.nhs.uk</a></p>
<b>8. COMPARISONS</b>
<p>Describe below how the medicine compares with existing treatment options:</p>
<p>Indicate which medicine may be removed from the formulary if this is added:</p>
<p>Comparative efficacy with existing formulary options:</p>
<p>Comparative safety with existing formulary options:</p>
<p>Advantages for the patient over existing therapies/interventions</p>
<p>Cost comparison with existing treatment or standard of care/intervention:          Include costs across the whole health economy and your impression of the most appropriate prescriber (GP/Consultant/All). <b>Please note that in line with the Committee's Terms of Reference, submissions with a cost &gt;£25,000 per 100,000 population (or ~£500K for the whole of SEL) will be subject to further scrutiny and therefore it may take longer for a decision to be made.</b>          Please confirm if the estimated cost per 100,000 population is a substitution or an additional cost:</p>
<p>Hospital Activity Impact: Please provide detail on how addition of this medicine to the formulary will impact on:</p> <ul style="list-style-type: none"> <li>Outpatient appointments:</li> </ul>

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

- Follow up requirements e.g. monitoring:
- Continued prescribing:
- Day case attendances (e.g. to administer the medicine):
- Inpatient stay:

What will the Primary Care Activity Impact be (in terms of continued prescribing/follow up appointments and monitoring):

#### 9. POPULATION SIZE

Specify number of patients with this condition per annum **at your Trust** and what percentage of these patients are from South East London:

- Specify number of patients with this condition who would receive this drug per annum at your Trust:
- Specify anticipated likely **number of patients per annum per 100,000 of general population**:
- Where other Trusts in SEL wish to also have this medicine available for use, please specify patient numbers specifically for SEL population **at each Trust**:

#### 10. RISK ASSESSMENT

*Detail below any potential risk issues that may arise with administration of this medicine. Please also suggest ways of reducing such risks:*

#### 11. SHARED CARE ARRANGEMENTS

Is the medicine intended for GPs to continue care?  Yes  No

If yes, after what time period should care be transferred to GPs?

If yes, a shared care protocol may necessary if agreed by the committee (please append examples if these are available):

#### 12. ENVIRONMENTAL IMPACT/SUSTAINABILITY

*Detail below how this application impacts on the environment/supports and promotes environmental sustainability*

#### 13. CONSULTATION WITH COLLEAGUES AT OTHER TRUSTS IN SOUTH EAST LONDON (THE SUBMISSION WILL NOT BE ACCEPTED IF THIS SECTION HAS NOT BEEN COMPLETED)

Please tick the boxes below to ensure you have consulted with **all** Trusts in South East London:

Guy's and St. Thomas' NHS Foundation Trust

Names of individuals consulted at GSTfT **and add a summary of their opinions:**

King's College Hospital NHS Foundation Trust (Denmark Hill and PRUH sites)

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

Names of individuals consulted at KCH <b>and add a summary of their opinions:</b>	<input type="checkbox"/>
Lewisham and Greenwich Hospitals NHS Trust	
Names of individuals consulted at LGT <b>and add a summary of their opinions:</b>	<input type="checkbox"/>
Oxleas NHS Foundation Trust	
Names of individuals consulted at Oxleas <b>and add a summary of their opinions:</b>	<input type="checkbox"/>
South London and Maudsley Hospital NHS Foundation Trust	
Names of individuals consulted at SLaM <b>and add a summary of their opinions:</b>	<input type="checkbox"/>
Where the drug is commissioned through Local Authorities (LA), please provide email confirmation to your formulary pharmacist from each SEL LA representative that this submission is supported by the LA.	

#### 14. CONFLICTS OF INTEREST

As part of the application process, all applicants are required to complete the attached Declaration of Interest form (DoI). Formulary submission forms will **not** be accepted without a completed DoI form. The DoI form will be provided to you with the application form by your Trust formulary/Borough lead pharmacist. Please contact your Trust formulary/Borough lead pharmacist if you have not been provided with the DoI form.

#### 15. DECLARATION

This submission form has been completed by a clinician(s) and not by a pharmaceutical industry representative:

This submission has been discussed with and is agreed by the Clinical Director/Prescribing Lead:

#### Final Checklist:

- Application form **fully** completed
- Supporting documents to append:
  - References
  - Treatment Protocol/Guideline

Signature of requesting Consultant/GP..... Print

Name..... Date.....

Signature of Clinical Director/GP Integrated Care Board Lead..... Print

Name..... Date.....

Division.....

Signature of Service General Manager.....

**Terms Of Reference**  
**South East London Integrated Medicines Optimisation Committee**

Print Name..... Date.....

Division.....

**PLEASE EMAIL ANY QUERIES, COMPLETED FORMS AND SUPPORTING DOCUMENTS TO  
(Trusts to add their email address)**

**NOTE:** Electronically sent forms are acceptable where this has been agreed within your organisation. Please contact your Trust Formulary Pharmacist if you are unsure about arrangements within your Trust.

**\*\*\*INCOMPLETE FORMS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO THE  
REQUESTING CONSULTANT\*\*\*\***



## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Request for an item to be discussed at the SEL Integrated Medicines Optimisation Committee (not relating to a full formulary application)

**This form should be fully completed and submitted to the relevant Trust lead formulary pharmacist/sub-group lead pharmacist for review.** They will share it with the SEL IMOC team, who may also review and comment. The final form will be scheduled at the next most convenient IMOC meeting depending on competing priorities.

<b>Trust or SEL Borough making request</b>	
<b>Directorate within Trust making request</b>	
<b>Nature of request</b>	Shared care <input type="checkbox"/> Re-categorisation – red to amber <input type="checkbox"/> Re-categorisation – amber to green <input type="checkbox"/> Formulary switch – unlicensed to licensed <input type="checkbox"/>  Other <input type="checkbox"/> <b>Please state:</b>
<b>Drug and indication</b>	
<b>(i) Is this a high cost drug (tariff excluded drug)?</b> <b>(ii) If yes, is this an ICS attributed medicine or local authority attributed drug?</b> <b>If not ICS attributed, please discuss with NHSE.</b>	(i)  (ii)
<b>Background - provide background information on why the Trust/Borough would like this request to be considered by the IMOC.</b> <b>For historical requests, please provide usage (items and spend) and outcome data for the last 3 years to support the request.</b>	<b>For shared care requests please also include information on place in therapy, patient numbers and how often the patient will be seen by the specialist – refer also to the “to share or not share care” flowchart available <a href="#">here</a>.</b>
<b>Summarise discussion with other Trusts (or Boroughs if this request is originating from primary care) in SEL.</b>	Has this request been discussed with other Trusts (KCHFT, GSTFT, LGT, SLAM, Oxleas, and BHC) in SEL? <b>Y / N</b>  <b>IF YES:</b> Please detail name/organisation and response: GSTFT: KCHFT: LGT: SLAM: OXLEAS: Boroughs in SEL (for requests originating from SEL Integrated Care Board):  <b>IF NO:</b> Please detail why this request doesn't apply to other Trusts/ICB.
<b>Please add any key points in relation to consideration of:</b> (i) Overprescribing/deprescribing elements in line with the National Overprescribing review (ii) Learning Disability and Autism elements- are there any are any reasonable adjustments that can be considered for people with LDA requiring this treatment (iii) How this request impacts on the environment/supports and promotes environmental sustainability	

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

<p>Number of patients anticipated at <u>each trust</u> supporting this request. Numbers of patients estimated across SEL</p>	
<p>(i) What is the cost of treatment per patient?  (ii) What is the total estimated cost per year for the number of patients identified – total and SEL  (iii) What is the estimated cost per 100,000 population for SEL? <b>This must be provided.</b>  (iv) For switches, please also provide comparator costs.  (iv) Is the cost in (iii) additional or a substitute?  (v) How is the cost impact expected to change over time, year on year (over the next 3 years)?  Please provide estimates if year-on-year increase estimated</p>	<p>(i)  (ii)  (iii)  (iv)  (v)</p>

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

**Appendix 5. Template for Assessment of new drug requests – to be completed by triage panel members as part of the triage process.**

Date:

Submission:

Assessor/s:

	Criteria	Yes	No
1.	Submission relates to an intervention which is commissioned nationally or a cancer therapy		
1.	There is NICE guidance for this intervention in the past OR due within the next 12 months	<b>Unless implementation</b>	
2.	Submission has been subject to a business planning decision in previous local service development processes.	<b>Unless this is roll out.</b>	
3.	Submission is for funding and use within secondary care only		
4.	Submission is evidenced by published data		
5.	Submission relates to an intervention that is included in the RMOC work plan		

**The IMOC would not be an appropriate route for any answer which relates to a grey box.**

**Priority for consideration at the IMOC should be given to:**

	Criteria	Ranking (1= low, 3 = high)
1.	Where the cost impact (saving or cost pressure) for medicines or end to end pathway cost associated with prescribing or administering the medicine is likely to be significant to the local health economy. Highest priority is those where the cost impact is likely to be >£20,000 per 100,000 population for SEL health economy (include medicines and activity costs). Lowest priority are submissions with cost impact <£5,000 per 100,000 population.	
2.	An integrated approach to secure a change in the care pathway or model of care is required to facilitate access for our population to evidence based medicines.	
3.	Where integrated working to maximise the benefit of the intervention is likely to have a high impact in improving the health of the SEL population and reducing inequalities	
4.	Where there is likely to be a high risk of challenge to decision making and a SEL wide approach would reduce this risk. It is likely that the SEL IMOC would wish to work with other ICS's in London and/or the London Regional Medicines Optimisation Committee and/or regional clinical networks as appropriate to further reduce the risk.	
<b>TOTAL (out of max 12 points)</b>		

**Low priority submissions may be referred back to local decision making forums (e.g. Trust formulary committees or Borough Medicines Groups) if timely agenda space cannot be found.**

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 6. Advice/Decision Recording

Mtg Date	Drug	Indication	IMOC Outcome*	Hospital restrictions	Specialty/ Prescribing Restrictions	Ex Tariff	Funding route	Shared Care?	Shared care protocol required Y/N

\*Approved in-year with Traffic Light  
OR Declined

#### Traffic Light System for Approved Drugs:

<b>Grey</b>	Medicines not normally recommended for prescribing	
<b>Red</b>	Medicines which should be prescribed by specialists only (normally secondary care or mental health trust only).	Further restrictions within the term "specialist" and groups of patients may be required on a case by case basis
<b>Amber</b>	<p>Prior agreement must be obtained by the specialist from the primary care provider before prescribing responsibility is transferred. Note: Shared care may not always be required for amber categorised medicines, for example, if it a short course of medication or the patient number is &lt;2/100,000 population. In these cases the specialist should ensure appropriate and sufficient individualised communication to the GP.</p> <p>There are 3 categories of AMBER in SEL:</p> <p>Amber 1. Recommendation by a specialist, but is considered non-urgent and therefore could be started in primary care at the discretion of the GP after the GP's consideration.</p> <p>Amber 2. Initiation by a specialist, then continuation in primary care under an individual management plan. In some cases, stabilisation for a specified time may be required and this will be detailed on the formulary or in the IMOC formulary recommendation</p> <p>Amber 3. As above, requiring shared/transfer of care document</p>	Where shared care guidance is necessary, the shared care guidance must have been agreed by the relevant secondary care trust DTC and approved by the IMOC.
<b>Green</b>	Medicines suitable for routine use and can be prescribed within primary and secondary care within their licensed indication*/agreed criteria for use. Primary care prescribers take full responsibility for prescribing.	*in accordance with nationally recognised formularies, for example the BNF, BNF for Children, Medicines for Children or Palliative Care Formulary

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 7. Integrated Medicines Optimisation Committee decision making - categories and quadrant grid.

Standard criteria applied for decision making should include\*:

- patient safety
- clinical effectiveness
- cost effectiveness or resource impact
- strength of evidence
- place in therapy relative to available treatments
- national guidance and priorities
- local health priorities
- equity of access
- stakeholder views

\* NICE Medicines Practice [Guideline](#) - Developing and updating local formularies, October 2015

The IMOC will use the following quadrant grid to inform and provide some insight into how it reaches its decisions. Instead of using the descriptive terms “appropriate”, “restricted use” and “inappropriate” (which are sometimes misused), the following categories will be used:

**Green** - suitable for prescribing in primary care

**Amber (1, 2 or 3)** - suitable for restricted prescribing under defined conditions

**Red** - not suitable for prescribing in primary care

**Grey** - cannot be recommended for prescribing because of inadequate evidence for efficacy and/or safety

The drug will be given a Green, Amber (1, 2 or 3), Red or Grey rating reflecting how far along the horizontal axis the strength of the evidence is considered to lie, and whether its place in therapy (on the vertical axis) is considered to be relatively low or high:

Place in therapy in primary care

<b>Amber</b> Higher place Strong evidence of benefit but some concerns over safety	<b>Green</b> Higher place Strong evidence of benefit and safety
<b>Grey</b> Lower place Weak evidence of benefit and safety	<b>Red</b> Lower place Strong evidence of benefit but significant concerns over safety

**Strength of evidence for efficacy/concerns over safety** →

Adapted from  
<https://ccq.centreforoptimisation.nhs.uk/download/8974fb9e54e39426be730da63e3bbeeb/MTRAC-Categories-Explanation.pdf>

**For the strength of the evidence for efficacy and safety, include the following:**

1. Design of available studies according to standard hierarchy I to V (systematic reviews, RCT, uncontrolled or non-randomised trials, abstracts, opinions, etc.). Quantity and quality of studies (JADAD score, intention-to-treat analysis, power calculation, etc.) Were there comparisons with other drugs? Was the comparator chosen appropriate?
2. What was the size of the effect seen with the drug, compared with the control?
3. Was the outcome used to assess benefit appropriate?
4. How safe was the drug in trials? What adverse events were reported? What % patients stopped treatment because of drug-related adverse events? How safe is the drug in intended use over a realistic time-frame?

**For the place of the drug in therapy in primary care include the following :**

1. Is there a need for this drug in primary care (are there other options available)?
2. Is there a need for specialist supervision or monitoring?
3. How likely is it that prescribing will occur in primary care?
4. Is there relevant NICE guidance?
5. Is cost a consideration? Are there any cost-effectiveness and quality-of-life data?

South East London Integrated Medicines Optimisation Committee Terms of Reference. Page 25

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### **Decision making where the evidence base is less robust:**

There will be occasions where the Committee will be required make decisions on areas where the evidence base is less robust but there is a clear need for the intervention in a clearly defined cohort of patients. In this situation, the Committee will take the following additional factors (to those on the previous page) into account to aid its decision making:

- (i) Rarity of the condition (which will impact on the quality of the evidence available)
- (ii) Specialist tertiary centre management (e.g. following failure of standard lines of therapy)
- (iii) Risks/benefits of treating vs. not treating
- (iv) Potential to reduce IFR workload by assessing proposed medicines use in a small clearly defined cohort
- (v) Taking forward research trials has been considered by the applicant but is not possible or the patient cohort is excluded from current research trials.

Decisions made by the Committee in these circumstances will initially be time limited to enable the applicant to collate outcome data for reporting back to the Committee after an agreed timeframe. This data will also help contribute to the evidence base.

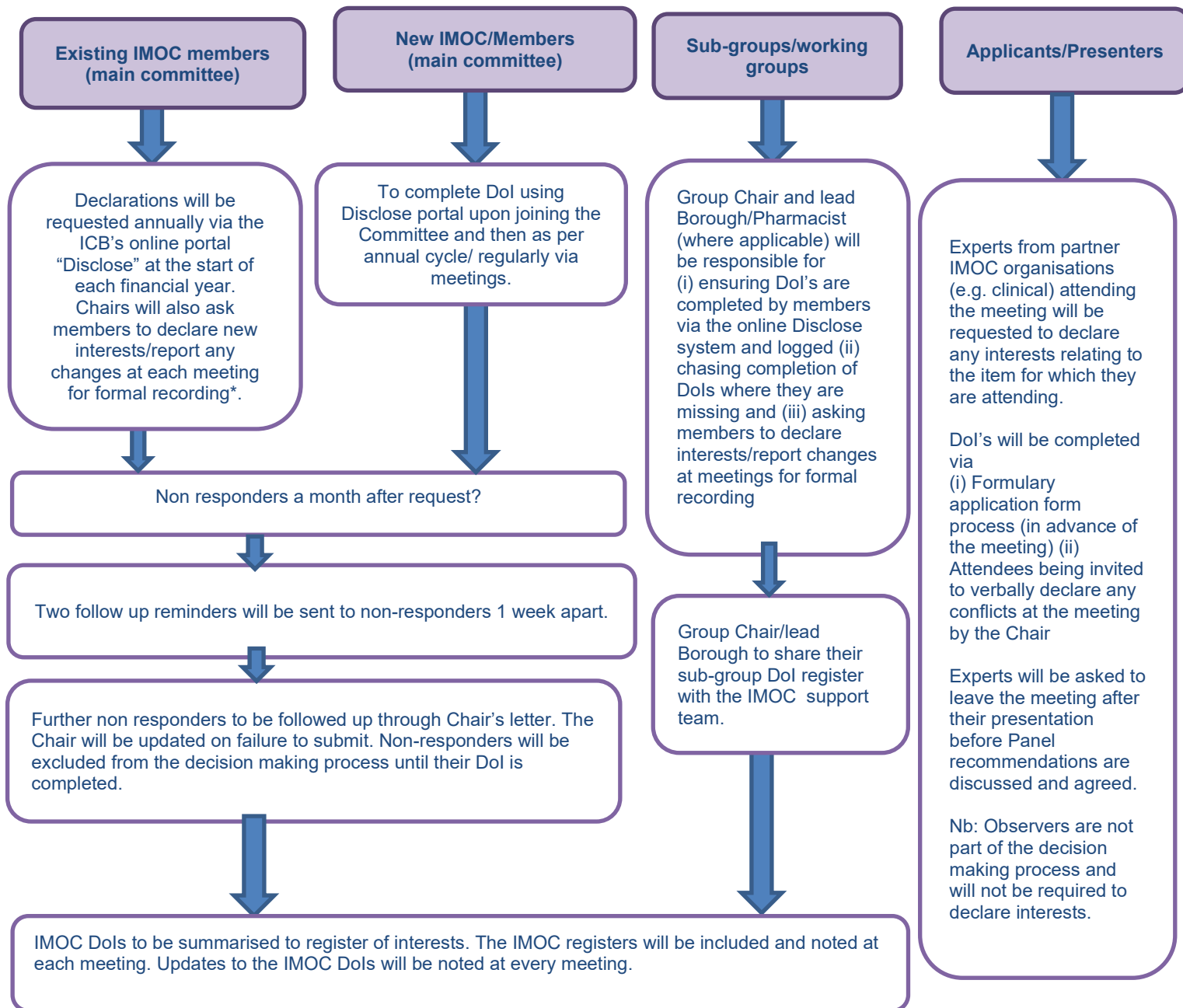


## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 8. Declaration of Interests (DoI) process.

#### Outline process for declaration of interests for SEL IMOC members and sub-groups



**\*Note:**

A Committee member who is any doubt as to whether they have an interest which should be declared, or whether to take part in the proceedings, should ask the Chairperson for guidance. The Chairperson has the power to determine whether or not a member with an interest shall take part in the proceedings. Further detail on the mitigating actions to be taken should conflicts arise can be found in the DoI form on pages 29 - 30.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

**Note: The IMOC has agreed that unsigned completed DoI forms can be returned electronically as long the form is returned from the member's NHS email address. The form must be dated.**

## SEL INTEGRATED MEDICINES OPTIMISATION COMMITTEE: DECLARATION OF INTERESTS

The following guidelines apply to **members of** the South East London Integrated Medicines Optimisation Committee (SEL IMOC) and to members of **any Sub-Groups** of the South East London Integrated Medicines Optimisation Committee. **Members of the main SEL IMOC and its sub-groups make their declarations using the online portal "Disclose"**.

These guidelines also apply to **applicants** wishing to make a formulary submission to the IMOC. Formulary applicants must make their declarations using the form on pages 4 – 6 of this DoI guidance.

### TYPES OF INTEREST TO BE DECLARED

If members or formulary applicants have interests not specified in the following notes, but which they believe could be regarded as influencing their advice they should be declared.

#### A PERSONAL INTEREST

A personal interest involves payment to the members personally. The main examples are:

- a) **Consultancies:** any consultancy, directorship, position in or work for the pharmaceutical industry, which attracts regular or occasional payments in cash or kind.
- b) **Fee-Paid Work:** any work commissioned by the pharmaceutical industry for which the member is paid in cash or kind.
- c) **Shareholdings:** any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

#### A NON-PERSONAL INTEREST

A non-personal interest involves payment, which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:

- a) **Fellowships:** the holding of a fellowship endowed by the pharmaceutical industry.
- b) **Support by the Pharmaceutical Industry:** any payment, other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to a member personally, but which does benefit his/her position or department e.g.
  - i. A grant from a company for the running of a unit or department for which a member is responsible;
  - ii. A grant or fellowship or other payment to sponsor a post or a member of staff, in the unit for which a member is responsible. This does not include financial assistance for students;

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

- iii. The commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

#### DECLARING AN INTEREST

- a) Members of the South East London Integrated Medicines Optimisation Committee should use the online Disclose system to inform the Committee when they are appointed of their current **personal** and **non-personal interests**.
- b) Only the name of the company and nature of the interest is required; the amount of any salary, fees, shareholding, grant etc need not be disclosed to the Committee.
- c) Members will be invited to complete their online Declarations of Interests annually for **personal** and **non-personal** interests. Members will also be invited to inform the Committee of any relevant changes in their **personal** interests at the time of the change.
- d) Applicants making a new drug submission to the South East London Integrated Medicines Optimisation Committee are required to complete the Declarations of Interest form on pages 4 - 6 of this DoI document as part of the formulary application process.
- e) Personal gifts of more than £25 in value from a commercial source need to be declared, as do several smaller gifts, individually worth less than £25, but in total worth over a £100 from the same or closely related source in a 12-month period (Department of Health Standards, November 2000).

### DECLARATION OF INTERESTS AT COMMITTEE SUB-GROUP MEETINGS AND PARTICIPATION BY MEMBERS AND FORMULARY APPLICANTS

Members and formulary applicants are required to declare relevant interests at Committee or Sub-Group meetings, and to state whether they are personal or non-personal interests and whether they are specific to the product under consideration.

A member who is any doubt as to whether he or she has an interest which should be declared, or whether to take part in the proceedings, should ask the Chairperson for guidance. The Chairperson has the power to determine whether or not a member with an interest shall take part in the proceedings.

- a) A Committee or sub-group member or formulary applicant must declare a **personal specific interest** if he or she has **at any time** worked on the product under consideration and has personally received payment for that work, in any form, from the pharmaceutical industry.  
The member shall take no part in the proceedings as they relate to the product, except, at the Chairperson's discretion to answer questions from other members. If the interest is no longer current, the member may declare it as a **lapsed personal specific interest**.
- b) A Committee or sub-group member or formulary applicant must declare a **personal non-specific interest** if he or she has a **current personal interest** in the pharmaceutical company concerned which does not relate specifically to the product under discussion.

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

The member shall take no part in the proceedings as they relate to the product, except, at the Chairperson's discretion, to answer questions from other members.

- c) A Committee or sub-group member or formulary applicant must declare a **non-personal specific interest** if he or she is aware that the department for which he or she is responsible for has at any time worked on the product but the member has not personally received payment in any form from the pharmaceutical industry for the work done.

The member may take part in the proceedings unless he or she has personal knowledge of the product through his or her own work or through direct supervision of other people's work, in which case he or she should declare this and not take part in the proceedings (except to answer questions).

- d) A Committee or sub-group member or formulary applicant must declare a **non-personal non-specific interest** if he or she is aware that the department for which he or she is responsible is **currently** receiving payment from the pharmaceutical company concerned which does not relate specifically to the product under discussion.

The member may take part in the proceedings unless, exceptionally, the Chairperson rules otherwise.

- e) If a Committee or sub-group member or formulary applicant is aware that a product under consideration is or may become a **competitor** of a product manufactured, sold or supplied by a company in which the member has a **current personal interest**, he or she should declare the interest in the company marketing the rival product.

The member should seek the Chairperson's guidance on whether to take part in the proceedings.

## RECORD OF INTERESTS

A record is kept by the relevant Chairperson of:

- a) Names of members who have declared interests on appointment, as the interest first arises or through the annual declaration, and the nature of the interest.
- b) Names of members who have declared interests at meetings, giving dates, names of relevant products and companies, details of the interest declared and whether the member took part in the proceedings. Chairs of Sub-Groups will be responsible for ensuring Declarations of Interests for members of their Sub-Groups are up to date.
- c) Information about interests declared by members will be published each year and circulated with the Committee agenda.
- d) The Register of Interests will include declarations for the 2 previous years.

Terms Of Reference

South East London Integrated Medicines Optimisation Committee

**South East London Integrated Medicines Optimisation Committee (SEL IMOC)**

**ANNUAL DECLARATIONS OF INTERESTS IN THE PHARMACEUTICAL INDUSTRY FOR FORMULARY APPLICANTS**

- This form is effective from October 2024
- Applicants making a formulary submission to the Committee are required to complete this form as part of the formulary application process. Please ensure any lapsed interests over the last 2 YEARS are also declared.

Name: *(please print)*

*Under the guidance of the Code of Practice on Declaration of Interests, I wish to declare to the Chairperson of the South East London Integrated Medicines Optimisation Committee that my only interests in the pharmaceutical industry are as follows: -*

Interest type	I have an interest to declare (please tick):	
	YES	NO
<b>Current Personal Interests (see pages 1-3 for definitions)</b>		
These include (not exhaustive):		
(i) Consultancies		
(ii) Fee paid work		
(iii) Shareholdings		
(v) other – if yes, please state in next section		
<b>Non Personal interests (see pages 1-3 for definitions)</b>		
These include (not exhaustive):		
(i) Fellowships		
(ii) Support by the Pharmaceutical Industry		
(iii) Other – if yes, please state in next section		

**If the answer is YES for any of the above, please provide further detail on the next two pages, then date and sign (or add name if sending by NHS email) on page 6 and return to the appropriate recipient as per information on page 6.**

**If NO for all answers, please date and sign (or add name if sending by NHS email) the form on page 6 and return to the appropriate recipient as per information on page 6.**

### Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### CURRENT PERSONAL INTERESTS\*

Name of Company	Nature of Interest (e.g. shares, fees, consultancy, salary, grants etc.)	Is the interest specific or non-specific?

\*Please state if your interest is limited to a particular product or group of products

#### NON-PERSONAL INTERESTS (which have arisen during the last 12 months)

Name of Company	Nature of Interest	Is interest current? (yes or no)	Is the interest specific or non-specific?



**Terms Of Reference**  
**South East London Integrated Medicines Optimisation Committee**

**ANY ADDITIONAL INFORMATION:**

<b>Date:</b>	
--------------	--

<b>Signature:</b>	
-------------------	--

**Please return the completed DoI form via email to your Trust formulary pharmacist or, for primary care formulary applications, your Borough Chief Pharmacist.**

## Terms Of Reference

### South East London Integrated Medicines Optimisation Committee

#### Appendix 9 – Urgent decision-making in emergency situations through the Triage Panel

There will be critical circumstances where urgent and rapid decision making will be required by the Committee, this includes emergency situations arising from external circumstances, such as a pandemic. In these situations, the IMOC's Triage Panel will provide the decision making process through a virtual process. The following principles will apply:

- The principles outlined in these Terms of Reference on decision making will be applied to urgent interim decisions made by the Triage Panel.
- Where an item relates to an area covered by an IMOC sub-group, the sub-group will have reviewed, and the Chair will have approved the request/recommendation being made to the IMOC Triage Panel. Rapid consultation with the IMOC membership should also be considered, if the urgency of the request allows this.
- To facilitate a timely decision-making process, the Triage Panel will be requested to consider the request (after sub-group approval, where appropriate) and feedback within and up to 3 working days and to confirm whether they approve the request. The exact deadline will be determined on a case-by-case basis and should be no more than 3 working days.
- In order for Triage Panel approval, a quorate response will be required - 5/8 of the Triage Panel membership (excluding the IMOC chair) should respond to confirm their approval. This quoracy level will be adjusted during periods of significant leave, such as summer break. In the event that a quorate response is not achieved in the maximum timeframe of 3 working days the timeframe may be extended to accommodate a consensus approval by the Triage Panel.

Note: Triage Panel responses must clearly state if the Triage Panel member either (i) approves the request, (ii) approves the request pending amendments or (iii) Does not approve the request.

- After confirmation of the Triage Panel position, the IMOC Chair will be asked to ratify the decision.
- Any urgent decisions made by the Triage Panel will be interim. Approval will usually be for 3 - 6 months and subject to review after this period lapses.