

**NHS South East London Integrated Care Board
Integrated Medicines Optimisation Committee
Terms of Reference**

FINAL DRAFT – 1 June 2022

1. Introduction

The Integrated Medicines Optimisation Committee (IMOC) is a sub-committee of the Quality and Performance Committee.

2. 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 NICE guidelines and technology appraisals and advice from Regional Medicines Optimisation Committee (RMOCs)* 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.

3. 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 the London Regional Medicines Optimisation Committee 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 of prescribable devices by the IMOC will be via the triage 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.

*National Regional Medicines Optimisation Committees (RMOC) were launched by NHS England in July 2017. Although there are four committees, the RMOCs operate against a single framework, with each group being part of a greater national system. The London RMOC published an [addendum](#) to the national operating model in June 2020, this sets out how the Committee will operate at a regional level. The RMOCs make recommendations, pursue actions, and co-ordinate activities related to any aspect of Medicines Optimisation. The remit of the SEL IMOC will include considering the recommendations made by the RMOC system and, where appropriate, supporting implementation in line with the SEL IMOC processes.

4. Duties

Finance and Planning

The Integrated Medicines Optimisation Committee will use a prioritisation approach, taking account of 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 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 impact per intervention considered. In line with the SEL CCG 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 Commissioning Strategy 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. This arrangement will be reviewed once the governance structures for finance in the Integrated Care System have been agreed. It is anticipated that within the ICB structure, authorisation will transition to the Planning & Finance Committee.

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 CCGs of >£20,000 per 100,000 population to help manage the workload.

In line with the recent 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. RMOG, 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 NHS E/I 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 and will be 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.

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 excluded from the national tariff (formerly Payment by Results excluded [PbRe] drugs).
- 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:

- 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

5. Accountabilities, authority and delegation

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

Within the Integrated Care System, the Integrated Medicines Optimisation Committee will also provide quarterly updates to the SEL Clinical and Care Professional Board.

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 a patient representative (sourced via local Healthwatch organisations).

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.

6. 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 is 2 years with the possibility of a further 2 years. The chair may continue after this time but must be supported by Committee members to do so and the arrangement will be subject to ongoing review every 2 years.

SEL ICS Organisation	Role
Core Membership – Voting membership (Reps as advised by Trusts/boroughs/organisations):	
NOTE: for primary care membership (GP/Pharmacist), nominated member may be a Primary Care Network (PCN) clinical director.	
Bexley Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (Borough or PCN)
Bromley Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (or delegated staff)/ (Borough or PCN)
Greenwich Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (or delegated staff) (Borough or PCN)
Lambeth Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (or delegated staff) (Borough or PCN)
Lewisham Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (or delegated staff) (Borough or PCN)
Southwark Borough	GP Medicines Optimisation lead or PCN Clinical Director Pharmacist Lead (or delegated staff) (Borough or PCN)
SEL ICS (Planning directorate - borough hosted medicines function)	Chief Pharmacist
	Lead Pharmacist for the SEL IMOC
Guy's and St. Thomas' NHS Foundation Trust	Consultant lead/Chair of DTC (current vice-Chair)
	Pharmacist Lead (or delegated staff)
King's College London/ Guy's and St. Thomas' NHS Foundation Trust	Professor of Cardiovascular Clinical Pharmacology, King's College London/ Honorary Consultant Physician (Overarching Committee Chair)
King's College Hospital NHS Foundation trust	Consultant Lead
	Pharmacist Lead (or delegated staff)
Lewisham and Greenwich NHS Trust	Consultant Lead
	Pharmacist Lead (or delegated staff)
South London and Maudsley NHS Foundation Trust	Consultant lead (current vice-Chair)
	Pharmacist Lead (or delegated staff)
Oxleas NHS Foundation Trust	Pharmacist Lead (or delegated staff)
Bromley Healthcare	Pharmacist Lead (or delegated staff)
Community Pharmacy	Community Pharmacist

In attendance (non-voting membership – may receive agenda packs for information only):	
NHS England & Improvement - London Region	Medical Director (Receives IMOC agenda packs for information only)

NHS England & Improvement (London Region)	Regional Chief Pharmacist Specialised commissioning pharmacists
SEL ICS (Quality)	Director of Quality
Specialist Pharmacy Service	Professional Lead for Medicines Information (London)
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
Specialist Expertise	Consultant Pharmacists as required – including but not limited to: Cardiovascular Disease, Diabetes Respiratory, Older People, antimicrobial stewardship, palliative care
Lay member (via sub-groups)	Nominated by Healthwatch
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
SEL ICS	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.

Members 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.

7. Chair of meeting

The meeting will be chaired by the Professor of Cardiovascular Clinical Pharmacology, King's College London. The deputy chair will be a nominated by the committee.

At any meeting of the group, the chair if present shall preside. If the chair is absent, the deputy chair shall preside. If the chair is temporarily absent on the grounds of conflict of interest, the deputy chair shall preside.

8. Quorum and conflict of interest

The quorum of the group is at least 50% of core members, 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.

The group 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).

Group members will 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.

9. Decision-making

Where a decision is required, it is expected that this will be reached by consensus. Where a vote is required to decide a matter, each core member may cast a single vote. In the event of equal votes, the chair will have a casting vote.

10. Frequency

Meetings of the IMOC will be held on monthly on the 3rd Thursday of every month, with sub-groups meeting as needed.

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 committee chair.

11. Reporting

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

The group will report on its activities to the Quality and Performance Committee via minutes and any further agreed ICB reporting requirements.

The minutes of meetings shall be formally recorded and reported to the Quality and Performance Committee for the purposes of 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 ICS 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.

12. Committee support

The meeting secretariat will ensure that draft minutes are shared with the chair for approval within three working days of the meeting. Draft minutes with the chair's approval will be circulated to members for committee approval, together with an action log, within the agenda pack for the next meeting. In the event the next meeting is cancelled, the draft minutes will be circulated by email to members for review.

13. Review of Arrangements

The committee shall undertake a self-assessment of its effectiveness on at least an annual basis. This may be facilitated by independent advisors if the committee considers this appropriate or necessary.

These terms of reference shall be reviewed by the group chair and ICB chair on an annual basis, in the context of the self-assessment and any changing business requirements, with changes proposed for approval to the Quality & Performance 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 (Guys and St Thomas's NHS Foundation Trust, Kings College Hospital NHS Foundation Trust, South London & Maudsley NHS Foundation Trust, Kings 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
London Regional Medicines Optimisation Committee (RMOC) and subgroups (London Formulary & Medicines Group, AMR Group, Medicines Value Group)

Medicines Information Services

Public Health

Clinical Effectiveness SEL (CESEL)

ICS Quality and Performance Committee

ICS Medicines Safety Group

ICS Antimicrobial Stewardship Network

ICS Programme Boards as relevant

ICS Medicines Value Group

Borough Medicines Implementation Groups

NEL Commissioning Support Unit

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)

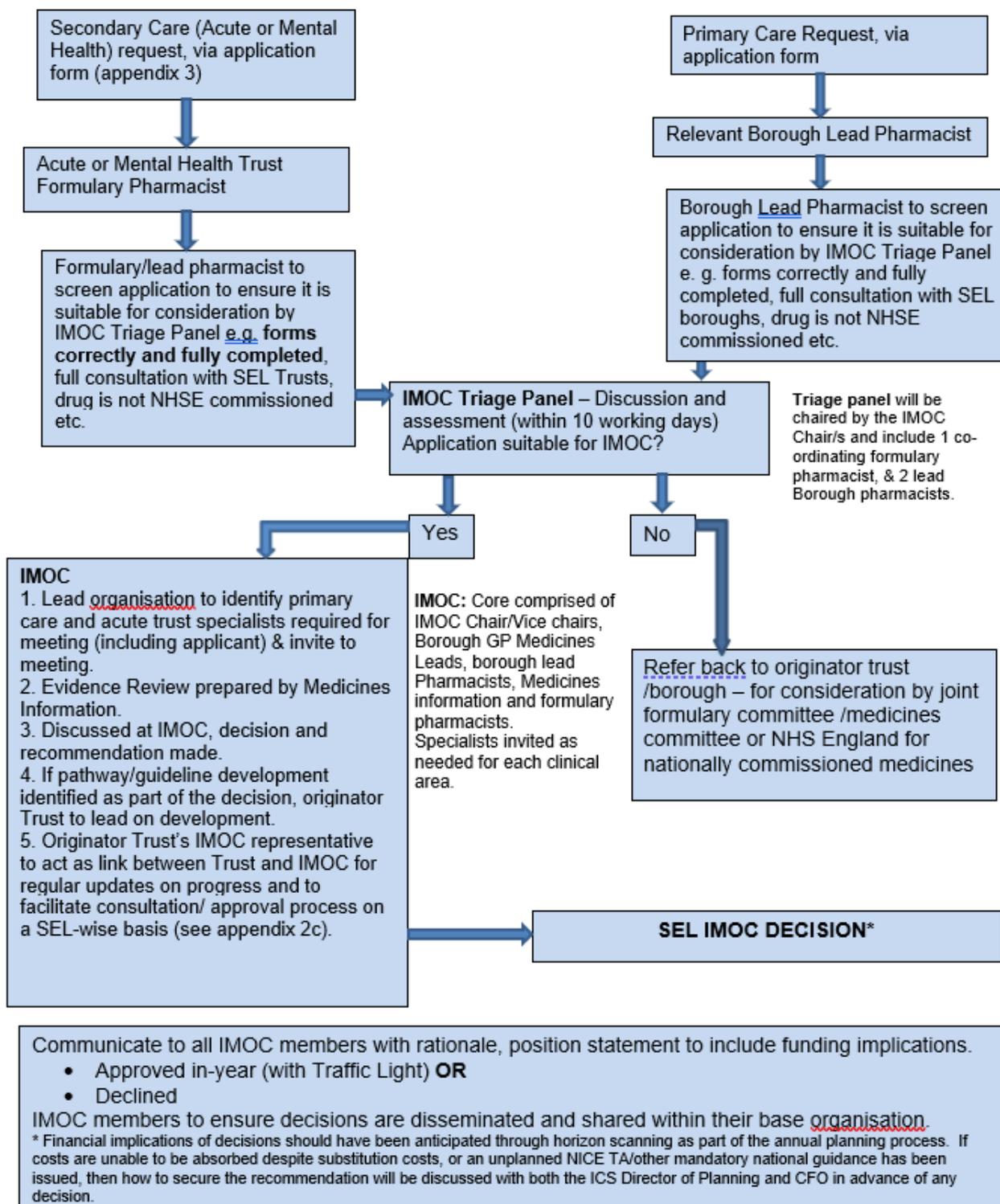
Local Pharmaceutical Committees (LPCs)

Local Professional Networks

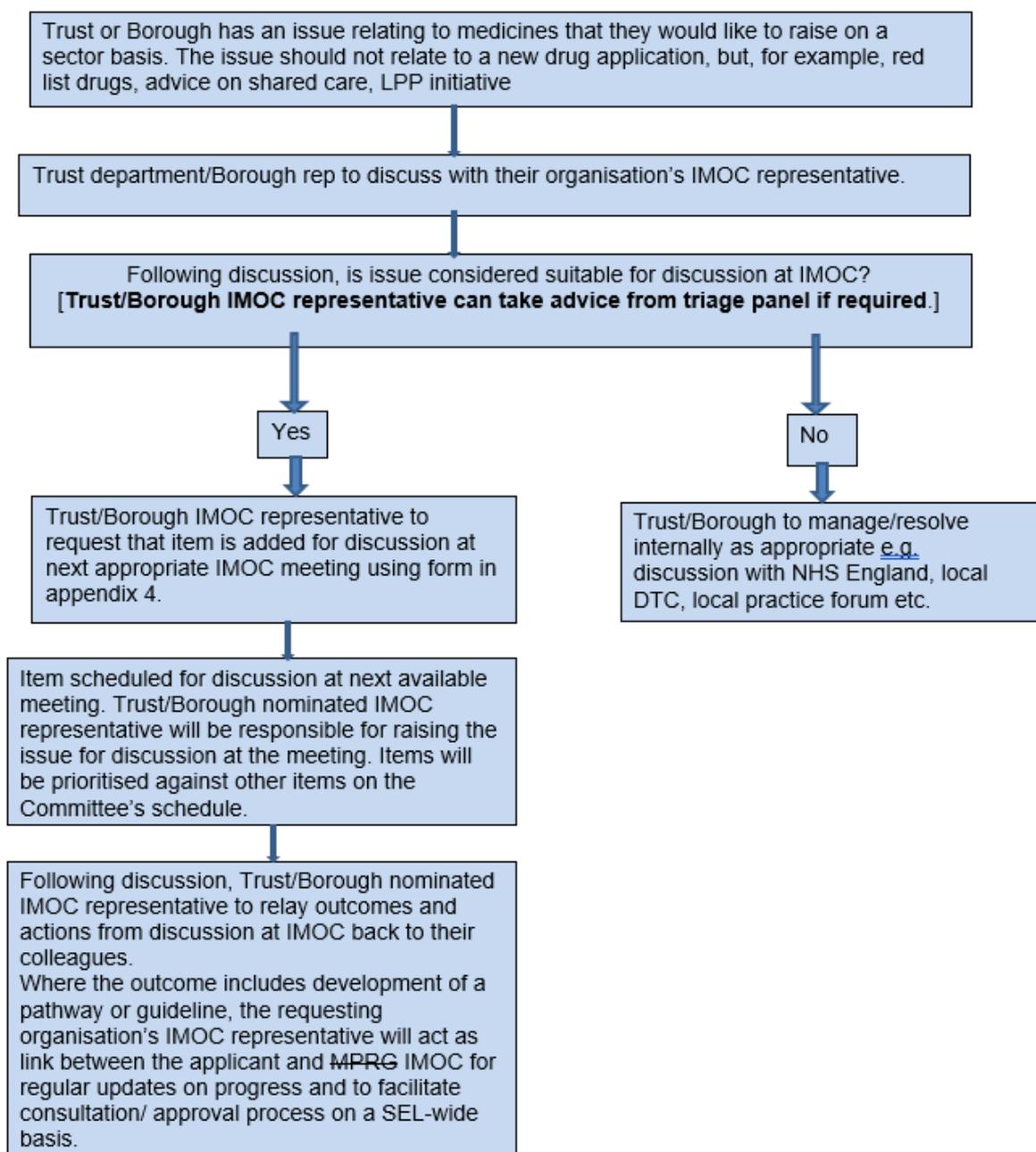
Local Authorities in SEL

Patients/public

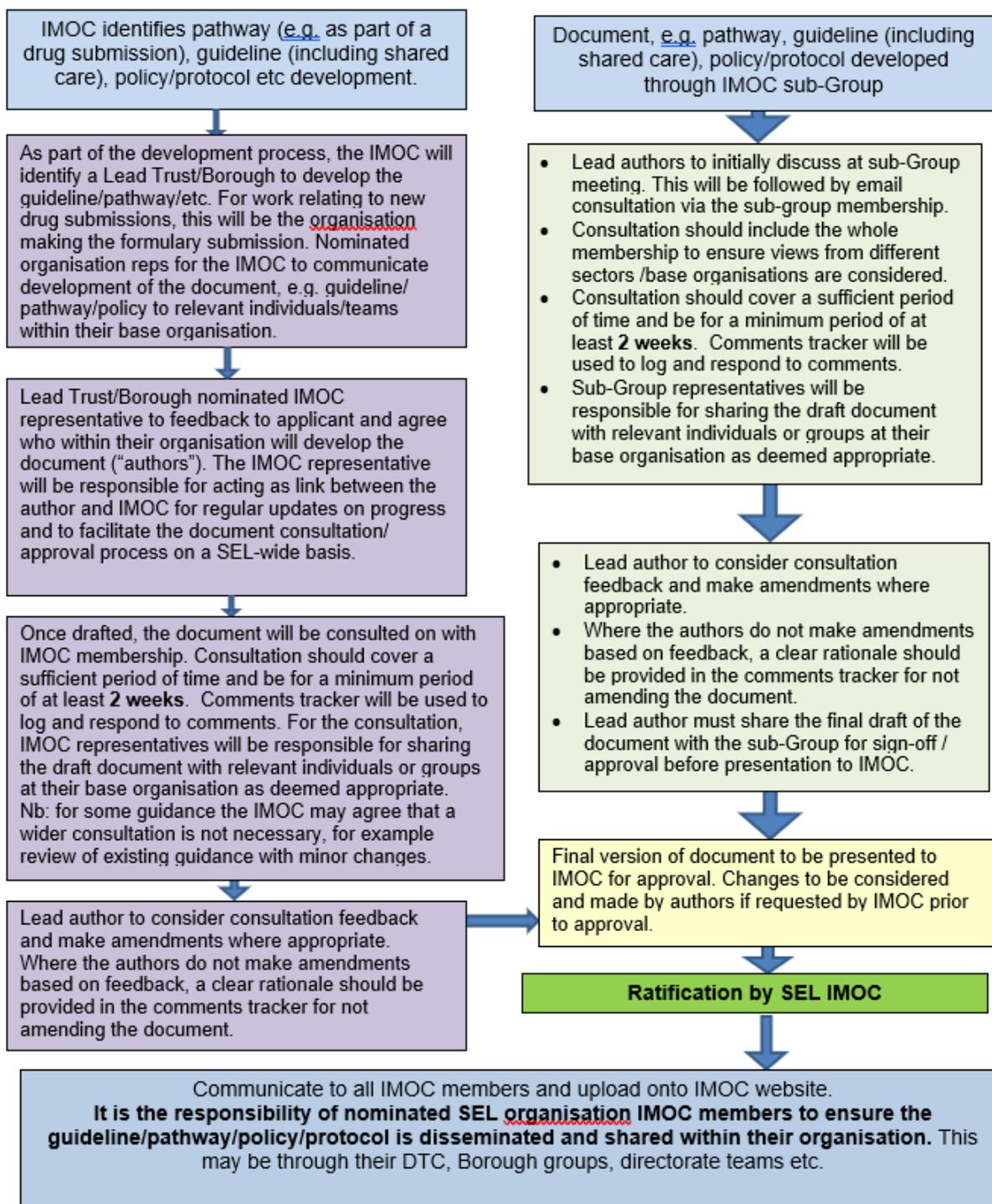
Appendix 2a. Process for new drug applications or indications. See Appendix 2b for issues not concerned with new drug applications



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



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



Appendix 4. 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 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: Note: Only one indication per application form will be considered.		
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"/> CCGs <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		
* If yes, please ensure you have documented (e.g. email) support from all 6 SEL Local Authorities for this application*		

4. EVIDENCE TO SUPPORT APPLICATION
List below and append key supporting references:
Outcomes anticipated from the medicine (include patient orientated outcomes as priority).
Summarise any experience of using this medicine for the proposed indication (e.g. from local Trust approval for individual patients):
5. FORMULARY IMPLICATIONS
Detail below the proposed place in therapy and append a proposed treatment guideline:
6. COMPARISONS
Describe below how the medicine compares with existing treatment options:
Indicate which medicine may be removed from the formulary if this is added:
Comparative efficacy with existing formulary options:
Comparative safety with existing formulary options:
Advantages for the patient over existing therapies/interventions
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). Please note that in line with the Committee's Terms of Reference, submissions with a cost >£25,000 per 100,000 population (or ~£475K for the whole of SEL) will be subject to further scrutiny and therefore it may take longer for a decision to be made.
Please confirm if the estimated cost per 100,000 population is a substitution or an additional cost:
Hospital Activity Impact: Please provide detail on how addition of this medicine to the formulary will impact on: <ul style="list-style-type: none"> • Outpatient appointments: • 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):

7. 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**:

8. RISK ASSESSMENT

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

9. 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):

10. ENVIRONMENTAL IMPACT/SUSTAINABILITY

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

11. 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)
 Names of individuals consulted at KCH **and add a summary of their opinions:**

Lewisham and Greenwich Hospitals NHS Trust
 Names of individuals consulted at LGT **and add a summary of their opinions:**

Oxleas NHS Foundation Trust
 Names of individuals consulted at Oxleas **and add a summary of their opinions:**

South London and Maudsley Hospital NHS Foundation Trust
 Names of individuals consulted at SLaM **and add a summary of their opinions:**

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.

12. 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/CCG lead pharmacist. Please contact your Trust formulary/CCG lead pharmacist if you have not been provided with the DoI form.

13. 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

Appendix 4

Request for an item to be discussed at the SEL Integrated Medicines Optimisation Committee (not relating to a new drug submission)

This form should be fully completed and submitted to [your lead formulary pharmacist/borough lead pharmacist to share with the SEL IMOC team](#). The item will be scheduled at the next most convenient meeting depending on competing priorities.

Trust or SEL Borough making request	
Directorate within Trust making request	
Nature of request	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"/> Please state:
Drug and indication	
(i) Is this a tariff excluded drug? (ii) If yes, is this an ICS attributed medicine or local authority attributed drug? If not ICS attributed, please discuss with NHSE.	(i) (ii)
Background - provide background information on why the Trust/Borough would like this request to be considered by the IMOC. For historical requests, please provide usage (items and spend) and outcome data for the last 3 years to support the request.	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 here.
Summarise discussion with other Trusts (or Boroughs if this request is originating from primary care) in SEL.	Has this request been discussed with other Trusts (KCHFT, GSTFT, LGT, SLAM, Oxleas, and BHC) in SEL? Y / N IF YES: Please detail name/organisation and response: GSTFT: KCHFT: LGT: SLAM: OXLEAS: Boroughs in SEL (for requests originating from SEL CCG): IF NO: Please detail why this request doesn't apply to other Trusts/CCGs.
Number of patients anticipated at <u>each trust</u> supporting this request.	
(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? This must be provided.	(i) (ii) (iii) (iv)

(iv) For switches, please also provide comparator costs. (iv) Is the cost additional or a substitute?	(v)
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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	Unless implementation	
2.	Submission has been subject to a business planning decision in previous local service development processes.	Unless this is roll out.	
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.	

TOTAL (out of max 12 points)	
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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.

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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:

Grey	Medicines not normally recommended for prescribing	
Red	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
Amber	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 <2/100,000 population. In these cases the specialist should ensure appropriate and sufficient individualised communication to the GP.	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.
	There are 3 categories of AMBER in SEL:	
	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.	
	Amber 2. Initiation by a specialist, stabilisation for a specified time, then continuation in primary care under an individual management plan.	
	Amber 3. As above, requiring shared/transfer of care document	
Green	Medicines suitable for routine use and can be prescribed within primary and secondary care within their licensed indication*/agreed criteria for use.	*in accordance with nationally recognised formularies, for example the BNF, BNF for Children, Medicines for

Primary care prescribers take full responsibility for prescribing.	Children or Palliative Care Formulary
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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:

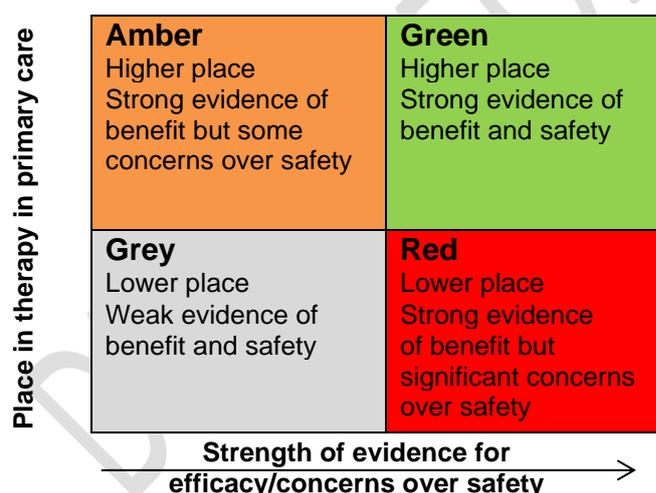
Green - suitable for prescribing in primary care

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:



Adapted from

<https://ccg.centreforoptimisation.nhs.uk/download/8974fb9e54e39426be730da63e3bbbeb/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?

Decision making where the evidence base is less robust:

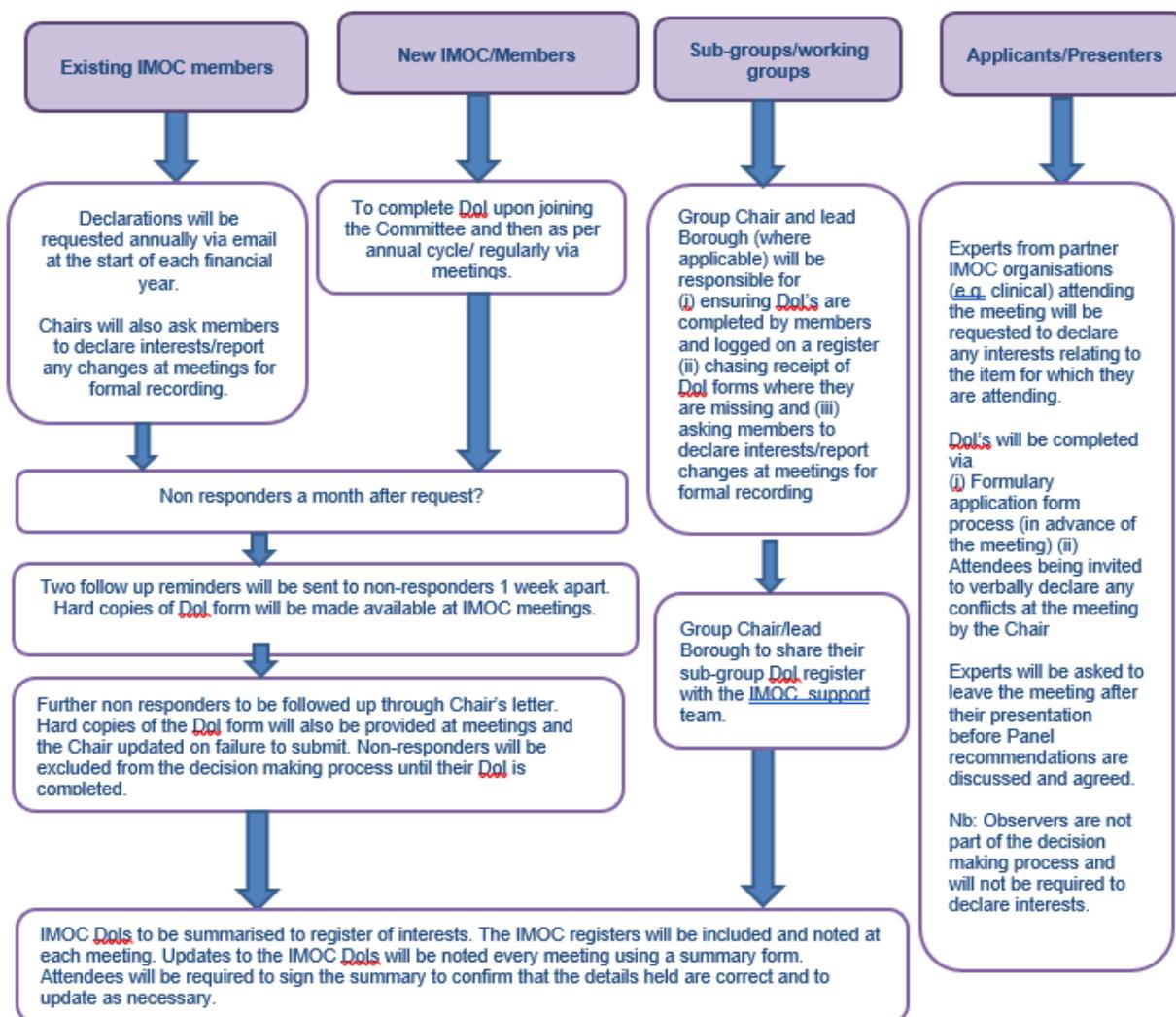
There will be occasions where the Committee will be required make decisions on areas where the evidence base is less robust but there is a clear need for the intervention in a clearly defined cohort of patients. In this situation, the Committee will take the following additional factors (to those on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

Appendix 8. Declaration of Interests (DoI) process and Declaration Form.

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



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 and to members of any Sub-Committees/Groups of the South East London Integrated Medicines Optimisation Committee. The guidelines also apply to applicants wishing to make a formulary submission to the IMOC.

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

DECLARING AN INTEREST

- a) Members of the South East London Integrated Medicines Optimisation Committee should inform the Committee in writing 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 a Declarations of Interests form 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 a Declarations of Interest form 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 MEETINGS AND PARTICIPATION BY MEMBERS AND FORMULARY APPLICANTS

Members and formulary applicants are required to declare relevant interests at Committee or Sub-Committee/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 in 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 Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

- a) A 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 Chairman'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 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.

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

- c) A 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 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 Chairman rules otherwise.

- e) If a 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 Chairman's guidance on whether to take part in the proceedings.

RECORD OF INTERESTS

A record is kept by the Chairman of:

- a) Names of members who have declared interests to the Committee 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 Committee or Sub-Committee/Group 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-Committees/Group will be responsible for ensuring Declarations of Interests for members of their Sub-Committees/Groups are up to date.
- c) Information about interests declared by members to the Committee will be published each year and circulated with the Committee agenda.
- d) The Register of Interests will include declarations for the 2 previous years.

South East London Integrated Medicines Optimisation Committee (SEL IMOC)

ANNUAL DECLARATIONS OF INTERESTS IN THE PHARMACEUTICAL INDUSTRY

- IMOC members will be required to complete this form at the beginning of each financial year (April). Lapsed interests covering the last 2 YEARS should also be declared. Members will be required to update their interests at every meeting through the year. This form is for the financial year **1st April 2022 to 31st March 2023**.
- 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)*

If you are not a member of the SEL IMOC but are a member of a Sub-Committee or sub-group of the SEL IMOC, please state the name of this Sub-Committee/Group:

Sub-Committee/Group:

Under the guidance of the Code of Practice on Declaration of Interests, I wish to declare to the Chairman 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
Current Personal Interests (see pages 1-3 for definitions)		
These include (not exhaustive):		
(i) Consultancies		
(ii) Fee paid work		
(iii) Shareholdings		
(v) other – if yes, please state in next section		
Non Personal interests (see pages 1-3 for definitions)		
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.

ANY ADDITIONAL INFORMATION:

Date:	<input type="text"/>
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Signature:	<input type="text"/>
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Please return the completed DoI form via email to the most appropriate recipient:

Category	Where the form should be returned to
DoI form for IMOC member	LAMCCG.medicinesoptimisation@nhs.net
DoI form for IMOC sub-group member	Return the form to your sub-group Chair
DoI for formulary applicant	Return the form to your Trust formulary pharmacist or, for primary care applications, your Borough Chief Pharmacist

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