

Document control

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South East London Integrated Medicines Optimisation Committee

Version / Change History

Ver	sion	Date	Author	Approving Committee / Group	Reason
V21		April 2023	Lead IMOC Pharmacist on behalf of the SEL IMOC	SEL IMOC SEL Quality and Performance Committee	Annual review of the Terms of Reference

Consultation History

Consultation Body / Persons	Area of expertise	Date sent	Date returned	Comments	Changes made
SEL IMOC members	Medicines Optimisation	February 2023	March 2023	As per comments log change is inclusion o overprescribing in for application form and development process	f mulary guideline
Finance leads	Finance	April 2023	July 2023	Amendments require delegation schedule delegated financial re IMOC back to the origof up to £25,000 per population. As part of escalation route char Planning and Finance Committee to the Exe Committee. Escalation to NICE Technology will be highlighted for only.	to re-set the emit of the ginal figure 100,000 f this, the nged from ecutive ons relating Appraisals
SEL corporate Governance Team	Governance	April 2023	June 2023	IMOC main committed groups set up on onling system. These members now record declaration appendix 8 updated to this.	ne Disclose pers can ons online –

Appendices

Appendix 1	Member organisations and key relationships
Appendices 2a-2c	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
Appendix 3	Application form for new drugs
Appendix 4	Request form for items not concerned with new drug applications to be discussed at IMOC
Appendix 5	Template for assessment of new drug requests – triage process
Appendix 6	Advice/decision recording
Appendix 7	Decision making categories and quadrant grid
Appendix 8	Declarations of Interest process

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South East London Integrated Medicines Optimisation Committee. A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust



South East London Integrated Medicines Optimisation Committee

Introduction

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

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 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.

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 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 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.

*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

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group being part of a greater national system. The London RMOC published an <u>addendum</u> 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.

3. Duties

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.

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 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 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 – 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 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. RMOC, 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



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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.

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- 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

4. 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.



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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.

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 is 2 years with the possibility of a further 2 years. The chair and vice chairs 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.

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SEL ICS Organisation	Role
Core Membership – Voting mer	nbership (Reps as advised by
Trusts/boroughs/organisations	
NOTE: for primary care borough Network (PCN) clinical director.	membership, nominated member may be a Primary Care
Bexley Borough	GP Medicines Optimisation lead or PCN Clinical Director
-	Pharmacist Lead (or delegated staff)/ (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 -	Chief Pharmacist
borough hosted medicines function)	Lead Pharmacist for the SEL IMOC
Guy's and St. Thomas' NHS	Consultant lead/Chair of DTC (current vice-Chair)
Foundation Trust	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	Consultant Lead
Foundation trust	Pharmacist Lead (or delegated staff)
Lewisham and Greenwich NHS	Consultant Lead
Trust	Pharmacist Lead (or delegated staff)
South London and Maudsley	Consultant lead (current vice-Chair)
NHS Foundation Trust	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
Primary care non-medical prescriber	Practice/PCN Pharmacist or nurse

In attendance (non-voting membership – may receive agenda packs for information only):		
NHS England & Improvement -	Medical Director	
London Region	(Receives IMOC agenda packs for information only)	
NHS England & Improvement	Regional Chief Pharmacist	
(London Region)	Specialised commissioning pharmacists	
SEL ICS (Quality)	Director of Quality	

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Specialist Pharmacy Service	Professional Lead for Medicines Information (London)
Mental Health Trusts – Oxleas	Specialist consultants and pharmacists to be invited as
and SLaM and Bromley	required.
Healthcare	
ICS Finance	Director or Associate Director of Finance
South London Health Innovation	Lead Pharmacist
Network (HIN)	
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.

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:
 - 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.

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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.

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).

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 25 – 31).

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. 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 copted by the Committee 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: <u>Directions</u> 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 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.



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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

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 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.

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 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.

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.

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).

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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)

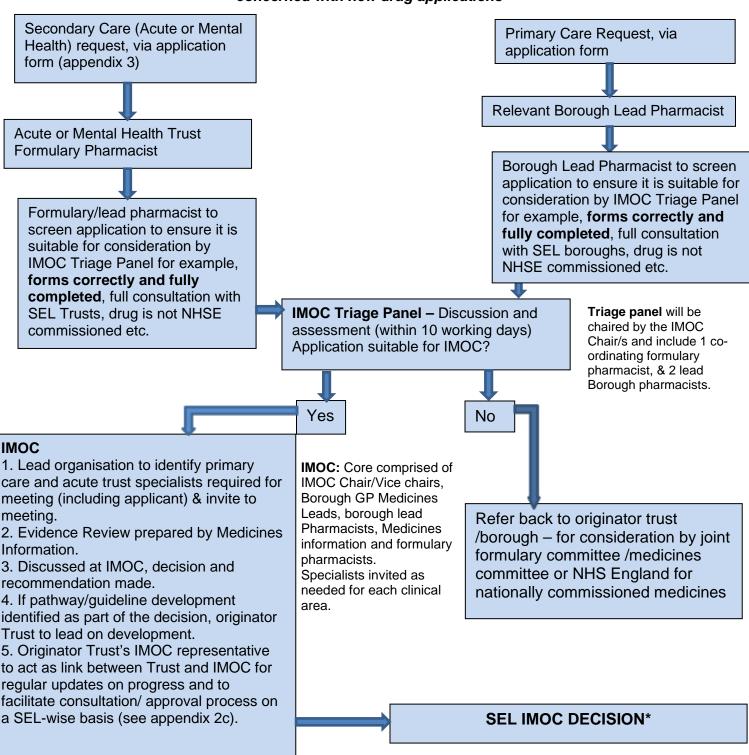
Local Professional Networks

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



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.



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

Trust or Borough has an issue relating to medicines that they would like to raise on a sector basis. The issue should not relate to a new drug application, but, for example, red list drugs, advice on shared care, LPP initiative Trust department/Borough rep to discuss with their organisation's IMOC representative. Following discussion, is issue considered suitable for discussion at IMOC? [Trust/Borough IMOC representative can take advice from triage panel if required.] Yes No Trust/Borough IMOC representative to Trust/Borough to manage/resolve request that item is added for discussion at internally as appropriate e.g. next appropriate IMOC meeting using form in discussion with NHS England, local appendix 4. DTC, local practice forum etc. Item scheduled for discussion at next available meeting. Trust/Borough nominated IMOC representative will be responsible for raising the

meeting. Trust/Borough nominated IMOC representative will be responsible for raising the issue for discussion at the meeting. Items will be prioritised against other items on the Committee's schedule.

Following discussion, Trust/Borough nominated IMOC representative to relay outcomes and actions from discussion at IMOC back to their colleagues.

Where the outcome includes development of a pathway or guideline, the requesting organisation's IMOC representative will act as link between the applicant and IMOC for regular updates on progress and to facilitate consultation/ approval process on a SEL-wide basis.



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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.

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.

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 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.

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



- 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 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.

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.

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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:		Email:
	Specialty and Job Ti	tle:	Contact Number:
2. MEDICINE DETAILS			
Name (generic and brand), Stre	ngth & Form:		
Dose:		Intended dura	ation of treatment:
Licensed indication:			
Intended indication for use: Note	e: Only one indication	on per applic	ation form will be considered.
Starting criteria for the medicine	:		
Stopping criteria:			
3. COMMISSIONING ROL	TE FOR THE MI	EDICINE	
Is the medicine excluded from the	ne national tariff (PbR	excluded)?	☐ Yes ☐ No
If yes: who is the responsible commissioner for the medicine? ICBs NHS England			
If no: is the medicine part of a national specialised service? Yes No			
Are services relating to this formulary application commissioned by local authorities (for example, alcohol misuse, smoking cessation, sexual health)? Yes No			
* If yes, please ensure you have documented (e.g. email) support from all 6 SEL Local Authorities for this application*			
4. EVIDENCE TO SUPPO	RT APPLICATIO	N	
List below and append key supp	orting 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):			



South East London Integrated Medicines Optimisation Committee

5. FORMULARY IMPLICATIONS

Detail below the proposed place in therapy and append a proposed treatment guideline:

6. OVERPRESCRIBING

In South East London the ambition is to reduce overprescribing in line with the <u>National overprescribing</u> review report recommendations. Please describe:

- The circumstances under which this medicine may be reviewed with a view to deprescribe if no longer appropriate and
- If inclusion of this medicine may result in other medicines the patient is prescribed for their condition being deprescribed

7. 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 ~£500K 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:

- 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):

8. 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:

patients are from South East London:	
· Specify number of patients with this condition who would receive this drug per annum	n at your Trust:
· Specify anticipated likely number of patients per annum per 100,000 of general per	opulation:
 Where other Trusts in SEL wish to also have this medicine available for use, please numbers specifically for SEL population at each Trust: 	specify patient
9. RISK ASSESSMENT	
Detail below any potential risk issues that may arise with administration of this medicine suggest ways of reducing such risks:	e. Please also
10. SHARED CARE ARRANGEMENTS	
Is the medicine intended for GPs to continue care?	
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 appenthese are available):	d examples if
11. ENVIRONMENTAL IMPACT/SUSTAINABILITY	
Detail below how this application impacts on the environment/supports and promotes e sustainability	nvironmental
12. CONSULTATION WITH COLLEAGUES AT OTHER TRUSTS IN S LONDON (THE SUBMISSION WILL NOT BE ACCEPTED IF THIS 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:	

South East London Integrated Medicines Optimisation Committee Terms of Reference. Page 18



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.

LA.
13. 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.
14. 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
Signature of Clinical Director/GP Integrated Care Board Lead Print
Name
Division
Signature of Service General Manager
Print Name
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*****



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 after review. The item will be scheduled at the next most convenient meeting depending on competing priorities.

	ng on competing priorities.	
Trust or SEL Borough making request		
Directorate within Trust making request		
	Shared care •	
	Re-categorisation – red to amber	
	Re-categorisation – amber to green	
Nature of request	Formulary switch – unlicensed to licensed	
Wature or request		
	Other	
	Please state:	
Drug and indication		
(i) Is this a tariff excluded drug?	(i)	
(ii) If yes, is this an ICS attributed medicine or	(ii)	
local authority attributed drug?	(")	
If not ICS attributed, please discuss with NHSE.	For shared care requests please also include information on place	in
Background - provide background information	therapy, patient numbers and how often the patient will be seen by	
on why the Trust/Borough would like this	specialist – refer also to the "to share or not share care" flowchart	
request to be considered by the IMOC.	available <u>here</u> .	
For historical requests, please provide usage		
(items and spend) and outcome data for the last		
3 years to support the request.		
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, GST 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 Integrated Caboard):	
	IF NO:	
	Please detail why this request doesn't apply to other Trusts/ICB.	
Number of patients anticipated at <u>each trust</u> supporting this request.		
(i) What is the cost of treatment per patient?	(i)	
(ii) What is the total estimated cost per year for	(ii)	
the number of patients identified – total and SEL		
(iii) What is the estimated cost per 100,000	(iii)	
population for SEL? This must be provided.		
(iv) For switches, please also provide	(iv)	
comparator costs.		
(iv) is the cost additional or a substitute?	(v)	



South East London Integrated Medicines Optimisation Committee

<u>Appendix 5. Template for Assessment of new drug requests – to be completed by triage panel</u> 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	Unless	
	OR due within the next 12 months	implementation	
2.	Submission has been subject to a business planning	Unless this is	
	decision in previous local service development	roll out.	
	processes.		
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)	

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.



Appendix 6. Advice/Decision Recording

Mtg Date	Drug	Indication	IMOC Out- come*	Hospital restrict- ions	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. 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, 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 Amber 3. As above, requiring shared/transfer of care document	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.
Green	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

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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

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:

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

Strength of evidence for efficacy/concerns over safety Adapted from

https://ccg.centreformedicinesoptimisatio n.co.uk/download/8974fb9e54e39426be7 30da63e3bbeeb/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)?
- 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?

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South East London Integrated Medicines Optimisation Committee. A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust

^{*} NICE Medicines Practice Guideline - Developing and updating local formularies, October 2015



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:

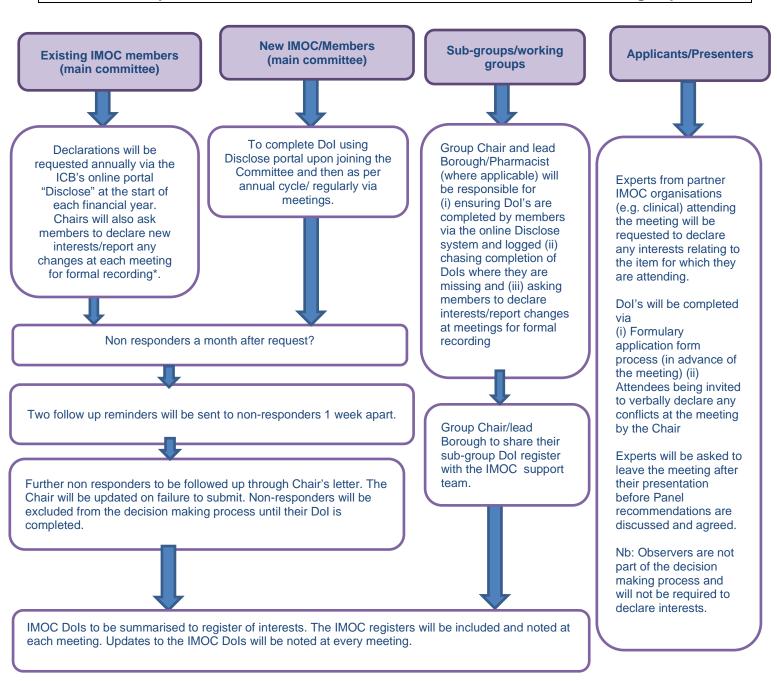
- (i) Rarity of the condition (which will impact on the quality of the evidence available)
- (ii) Specialist tertiary centre management (e.g. following failure of standard lines of therapy)
- (iii) Risks/benefits of treating vs. not treating
- (iv) Potential to reduce IFR workload by assessing proposed 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.

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 Dol form on pages 28 - 29.

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Note: The IMOC has agreed that unsigned completed Dol 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 Dol 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:

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South East London Integrated Medicines Optimisation Committee. A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust



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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 Dol 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.



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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.



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 for the financial year 1st April 2023 to 31st March 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	
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.



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?

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?

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



ANV	Тוחח	INIEOE	ΜΔΤΙΩΝ:

Date:		Signature:	

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