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EXPERT REVIEW COMMITTEE OF THE NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE TERMS OF REFERENCE

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Contents

1. Abbreviations

EML	-	Essential Medicines List
ERC	-	Expert Review Committee
HTA	-	Health Technology Assessment
NDoH	-	National Department of Health
NEMLC	-	National Essential Medicines List Committee
PTC	-	Pharmaceutical and Therapeutics Committee
STGs	-	Standard Treatment Guidelines

2. Purpose

The National Essential Medicines List Committee (NEMLC) is a non-statutory committee constituted in terms of the National Drug Policy (1996)[1] and appointed by the Minister of Health. The primary objective of the NEMLC is the selection of medicines to be used in the public sector, based on a structured, unbiased and robust decision-making framework with considerations of public health relevance, clinical need, safety, efficacy, effectiveness, affordability, and implications for practice.

The Expert Review Committee (ERC) is a standing subcommittee of the NEMLC, constituted to support the NEMLC to develop and review an essential medicines list (EML), together with the therapeutic interchange database, to guide clinical practice in all public sector health establishments and inform procurement of essential medicines in the public sector. The EML is prepared across three levels of care, i.e. primary, secondary, and tertiary/quaternary, and is accompanied where possible by standard treatment guidelines (STGs).

The ERC develops and maintains evidence-based tools for the development and review of STGs for acceptance by the NEMLC, with subsequent peer review by identified stakeholders. Following ratification of the STGs by the NEMLC, the ERC provides technical support in the finalisation of each chapter for publication. In addition, the ERC prepares draft policies for review by the NEMLC when called upon.

[1] National Department of Health, 1996. *National Drug Policy.* Pretoria: National Department of Health.

3. Authority to Act

The ERC is a subcommittee of the NEMLC and is appointed by the Minister of Health. The NEMLC and its ERC do not have any delegated powers to act on behalf of, or to commit, the Minister of Health or Government to any actions.

4. Functions

4.1. The functions of the ERC include, but are not limited to:

- supporting the NEMLC with scoping, topic prioritisation and question development for evidence reviews;
- performing evidence retrieval and synthesis to inform recommendations for amendments to the STGs and EML; and
- providing technical support to the NEMLC for the drafting of the STGs and EML and finalisation for publication.

4.2. The list of topics for review by the ERC is carried out according to a project plan developed by the EDP Oversight Group in consultation with the ERC, based on the priority topic list approved by the NEMLC. Evidence Working Groups are convened as required in alignment with the prioritisation and project plan approved by the NEMLC. The NEMLC and its ERC may be requested to provide review and input into other documents, including but not limited to the NEMLC therapeutic interchange database, tender specifications, circulars, as well as ideal health facility frameworks and NDoH Programme Guidelines and Policies, with respect to medicines and guidelines.

5. Composition of ERC

5.1. The ERC, including its co-chairpersons, is appointed by the Minister of Health for a period not exceeding four years. South African citizens or permanent residents are eligible for appointment, and preference for appointment to the ERC, especially for the role of co-chairpersons, may be given to previous members of NEMLC and its ERCs to retain institutional knowledge and facilitate a smooth transition between committees. Members of the ERC are participants in their individual capacity and do not represent any constituency, organisation, or sector.

Core Members

5.2. The ERC is composed of 10 to 20 core members responsible for scoping and appraisal of analyses across a wide range of topic areas and have experience in the review process. This includes experts across all levels of care with expertise in one or more of the following:

- Bioethics;
- Clinical practice guideline development;
- Clinical pharmacy;
- Clinical research;
- Epidemiology;
- Evidence-based medicine/ health technology assessment (HTA);
- Health economics/ pharmacoeconomics;
- Medicine safety;
- Pharmacology;
- Pharmaceutical and Therapeutics Committees (PTCs);
- Public sector clinical practice*;
- Rational medicines use; and
- Public health and/or policy.

*A balance of public sector clinical practice expertise across a broad range of topics and methodological expertise is required. Experts currently working within other sectors who have extensive clinical practice expertise in the public sector with awareness of public sector population needs and service conditions may also be included as core members.

Subject Matter Expert Members

5.3. Subject matter experts are appointed by the Minister of Health, based on the ERC Technical Project Plan, to contribute towards a specific area. These members are required to attend ERC meetings on an ad hoc basis, depending on the project plan.

Co-Opted Members

5.4. Additional experts may also be co-opted onto the ERC and appointed by the Chief Director: Health Products Procurement to serve on one or more Evidence Working Groups for a specific technical skill.

5.5. Subject matter experts and co-opted members do not contribute to the quorum or decision-making of the ERC.

ERC Evidence Working Groups

5.6. ERC Evidence Working Groups may be convened by the ERC to conduct reviews within a NEMLC topic area based on the ERC technical project plan. Existing core and subject matter expert members of the ERC as well as NEMLC members with expertise in the specific topic area, as well as additional co-opted members, may be assigned to the Evidence Working Group by the EDP Oversight Group. The ERC Terms of Reference apply, although meeting quorum is not required for decision-making. Subject matter experts or core members lead the Evidence Working Groups.

5.7. Meeting notes, including recommendations and action points are to be documented as a record of the ERC Evidence Working Group discussions. Deliverables produced by the Evidence Working Group are to be presented by the Evidence Working Group Lead or designated individual.

Appointment of Members

5.8. Applicants with relevant expertise are invited to apply for appointment to the ERC in their individual capacity by the NDoH. Conflicts of interest declared are considered when assessing eligibility for appointment. At the completion of their term of office, members of the ERC may re-apply for appointment.

5.9. Core and subject matter expert members are appointed by the Minister of Health. Co-opted members are appointed by the Chief Director: Health Products Procurement.

6. Code of Conduct

All members are expected to:

- act with the highest professional and ethical standards at all times;
- adhere to the norms and standards related to integrity, ethics, professional conduct and anti-corruption in the public service, in accordance with the Public Service Act (1994)[2];
- make themselves available for skills and ethics training provided or facilitated by the NDoH;
- make themselves available for meetings, punctually and for the duration of the scheduled meeting time;

[2] Government of South Africa, 1994. *Public Service Act No. 103 of 1994.* Pretoria: National Department of Health.

- notify the EDP Oversight Group at least 24 hours before the meeting, if unable to attend for the full duration of the scheduled meeting time;
- indicate their inability to attend any meeting in writing to the EDP Oversight Group, in good time with the reasons for non-attendance;
- be informed and prepared for the meeting by reading the agenda and meeting documents prior to the meeting;
- respect and value each member's perspective and contribution;
- regard the views expressed by individual members of the ERC as confidential;
- contribute to deliberations in an informed, rational and respectful manner, and collectively contribute to the outcome;
- refrain from accepting remuneration from the pharmaceutical industry or interest groups for preparing applications or submissions to the NEMLC;
- declare all potential interests, in accordance with Section 13.3;
- communicate and respond timeously to requests for information from other ERC members, the EDP Oversight Group and co-chairpersons;
- only share information with stakeholders whom they represent with the written approval of the NDoH; and
- for core members, to make decisions together solely in the interest of the public, taking joint responsibility for decisions made, as a reflection of the entire ERC.

7. Remuneration

The ERC of the NEMLC is categorised as a B1 Committee and members are remunerated according to the agreement between the NDoH and National Treasury, in accordance with the rates stated in Chapter 20 of the National Treasury Regulations[3]. This includes remuneration for members not employed on a full-time basis by the public sector for their time spent in meetings. Travel and accommodation costs for in-person meetings are arranged by the NDoH, if required.

8. Termination of Membership

8.1. Membership of the ERC will be terminated when:

- the Minister of Health, in the public interest, terminates the membership;
- a member resigns from the committee, in writing;

[3] Government of South Africa, 2001. *Treasury Regulations for Departments, Constitutional Institutions and Public Entities, Issued in Terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999).* Pretoria, South Africa.

- a member is suspended for misconduct; or
- a member fails to attend two or more meetings without an apology deemed to be of sufficient merit. Apologies are evaluated by the co-chairpersons, and if necessary, discussed at the next quorate meeting of the ERC.

8.2. Membership may be reviewed if there is a lack of contribution towards discussions of the ERC. Membership is also reviewed upon any member's change in employment, as well as a conflict of interest, and may be terminated in accordance with these terms of reference or at the discretion of the Minister of Health, following recommendation by the EDP Oversight Group and the co-chairpersons.

8.3. Any abstention of a member from the ERC for a prolonged period of time, such as due to sabbatical or illness, is managed on a case-by-case basis. Where necessary, the member may be temporarily or permanently replaced to ensure that the required skills are maintained on the ERC at the discretion of the Minister of Health on recommendation by the co-chairpersons.

9. Roles of ERC Members

All members of the ERC are expected to:

- contribute to the decision-making process of the ERC, including relevant experience and skills to the committee;
- make full and considered contributions to the debates and decision-making processes of the committee;
- strengthen clinical guideline alignment and promote the standardisation of guideline development and HTA processes;
- actively participate in at least one Evidence Working Group at all times during their term of office, where feasible;
- present at the NEMLC when called upon; and
- ensure timely turnaround of technical documents, submitting to the EDP Oversight Group at least 7 days before a scheduled meeting of the ERC and 10 days before a scheduled meeting of the NEMLC, where possible.

10. Role of the Co-Chairpersons

10.1. The co-chairpersons should be conversant with the principles of evidence-based medicine and/or HTA. Clear lines of communication between the co-chairpersons and the EDP Oversight Group are essential.

10.2. The co-chairpersons' responsibilities are to:

- preside at all meetings of the ERC, where possible;
- conduct ERC meetings in accordance with a project plan;
- assist the EDP Oversight Group to prepare the agenda before meetings, and to review the minutes after meetings;
- facilitate the committee's discussion of technical documents to arrive at consensus;
- encourage participation from all members of the ERC;
- advise the committee on policy, administrative and regulatory matters;
- sign all meeting governance documents, where possible;
- provide advice and guidance when called upon by the EDP Oversight Group; and
- present the recommendations of the ERC as core members of the NEMLC.

10.3. If one of the co-chairpersons resigns before the end of the term of office, a new co-chairperson may be appointed by the Minister of Health. The other co-chairperson will act as sole chair in the interim.

11. Role of the EDP Oversight Group

Functions of the EDP Oversight Group, provided by the NDoH, include but are not limited to:

Secretariat Functions

- developing and maintaining a project plan for the review and maintenance of the publications of the NEMLC and ERC;
- overseeing governance processes of the NEMLC and ERC;
- convening the meetings and making all the necessary logistic arrangements for the meetings; and
- maintaining a record of the decisions taken, and communication and dissemination of information to promote transparency.

Policy and Technical Functions

- supporting the prioritisation of topics for review by the NEMLC and ERC;
- facilitating the proper functioning of the committees, providing technical support including development of technical documents, and facilitating training of committee members;
- advising the committees on policy, administrative and regulatory matters;
- compiling minutes of the meetings and finalising drafts in consultation with the chairpersons;
- coordinating and facilitating any research that is required for the committee to perform its functions;
- managing the dissemination of the STGs and EML, including developing the technical content of communication materials, including the NEMLC bulletin, webinars and circulars;
- maintaining the EML and therapeutic interchange database;
- monitoring the use of medicines in accordance with the STGs; and
- supporting medicine stock-out mitigation as well as query management and resolution.

12. Decision-Making Process

12.1. The lead of each Evidence Working Group presents the assessments and proposed updates to the core members of the ERC, who appraise the assessments and provide recommendations to the NEMLC. Only core ERC members are involved in decision-making. The Evidence Working Group Lead may be required to present the recommendations to the NEMLC on behalf of the ERC, together with the co-chairpersons.

12.2. Decisions of the ERC are preferably taken by consensus rather than by voting, and decisions must be explicitly stated by the co-chairpersons. Where a consensus cannot be reached at a meeting, a mechanism for voting is decided by the ERC members present, including agreement on the number and nature of questions, as well as the platform on which the vote is conducted. No abstentions are permitted, and a decision is taken within one week of the ERC meeting. The co-chairpersons have casting votes.

12.3. If conflicts arise between members of the ERC, members should seek the advice of the co-chairpersons, whose decisions are binding. If the co-chairpersons are unable to agree on a course of action, they should consult the remaining ERC members by consensus. The decision of the ERC is binding on both co-chairpersons. If any member of the ERC is concerned that the situation is damaging to the reputation of the ERC, they should report those concerns to the ERC members and/or the EDP Oversight Group. If necessary, the EDP Oversight Group may report those concerns to the ERC on behalf of the member. If the working relationship between co-chairpersons breaks

down or is perceived to have broken down, these concerns should be reported to the EDP Oversight Group, who will consider them together with the NEMLC co-chairpersons and Director: Affordable Medicines Directorate.

12.4. Documents may be sent to the ERC for review, comment and/or approval electronically, with a specified date for comments to be submitted, after which no further comments will be considered. An extension of the comment period may be requested by members prior to the original specified date.

13. Meetings of the ERC

13.1. The ERC usually meets monthly, based on the project plan developed by the EDP Oversight Group and approved by the NEMLC. The co-chairpersons are required to attend a meeting with the EDP Oversight Group prior to each ERC meeting to discuss the agenda.

13.2. Members and other attendees may not:

- nominate representatives to attend meetings in their absence;
- allow non-members to listen to or attend the meetings unless approved by the co-chairpersons;
- automatically transcribe or record meetings of the NEMLC and its ERC. This is permitted for the EDP Oversight Group to enable efficiencies in the preparation of the official meeting minutes.

Conflict of Interest and Confidentiality

13.3. Members are required to abide by declaration of interest requirements in accordance with the Affordable Medicines Directorate Conflict of Interest Policy[4]. Non-specific interests must be declared prior to appointment to the ERC, on an annual basis thereafter, or as the need arises, and updated prior to each meeting of the committee where needed. Declarations of non-specific interests are applicable to both the NEMLC and its ERC and should be made at the first committee to which the member is appointed. In addition, specific interests must be declared where applicable by members and other meeting participants prior to each meeting and noted verbally at the meeting. NEMLC members involved in the assessment and/or appraisal of a topic are also required to complete the specific interest declaration form before the relevant NEMLC meeting. Declarations of non-specific interests made on appointment and annually are applicable to the NEMLC and its ERC and should

[4] Affordable Medicines Directorate, 2020. *Affordable Medicines Directorate Conflict of Interest Policy*. Pretoria: National Department of Health.

be assessed by the chairpersons of the first committee to which the member is appointed. The co-chairpersons' conflicts of interest are managed and counter-signed by the Chief Director Health Products Procurement or designated official.

13.4. All members of the ERC and EDP Oversight Group, co-opted members and other meeting participants are required to abide by confidentiality requirements in accordance with the NEMLC Confidentiality Guideline[5]. Declarations of confidentiality are applicable to both the NEMLC and its ERC and should be made at the first committee to which the member is appointed.

Quorum

13.5. A quorum of members must be present before the meeting can proceed. The quorum requirement is over 50%, calculated from the number of core members appointed to the committee. This excludes the EDP Oversight Group, subject matter experts, co-opted members and ad hoc attendees. A register of appointed members is maintained by the EDP Oversight Group.

Agenda

13.6. A draft agenda is determined by the EDP Oversight Group, finalised in consultation with the co-chairpersons and circulated electronically before each meeting. Any issues to be addressed must be raised ahead of the ERC meeting with the co-chairpersons, through the EDP Oversight Group, to ensure inclusion on the agenda, where necessary.

Minutes

13.7. The minutes of ERC meetings are circulated to all members within 10 working days after each meeting, where possible. All members should return any comments or proposed amendments to the minutes prior to the next meeting. A standing item on each ERC meeting agenda is the consideration of previous minutes. Adoption of the minutes, after any correction, is moved by a proposer and a seconder from within the core ERC and recorded as such. The corrected minutes are signed by:

- The co-chairpersons;
- A proposer; and
- A seconder.

[5] Affordable Medicines Directorate, 2021. *NEMLC Confidentiality Guidance Document.* Pretoria: National Department of Health.

Other Meeting Attendees

13.8. Other stakeholders such as National Department of Health (NDoH) Programme representatives may also be invited to attend ERC meetings and provide presentations and opinions on an ad hoc basis, following approval by the co-chairpersons of the ERC prior to the meeting.

14. Communication and Publications

14.1. Except for the use of formal communication such as through the NEMLC Bulletin, only the NDoH may represent the views and decisions of NEMLC and its ERCs to external stakeholder groups. Documents pertaining to the NEMLC and ERCs, including presentations and review documents should be drafted on NDoH approved templates.

14.2. All publications emanating from the work of the NEMLC and its ERC must accurately represent the original source documents and any subsequent contributions. It is essential that ethical standards and confidentiality obligations are always upheld and that authors are duly acknowledged, in accordance with the Guideline on Publications Emanating from Work Conducted by the NEMLC (Draft)[6].

15. Procedure for the Review of the STGs and EML

The National Standards for Evidence-Informed Decision-Making to Develop Trustworthy Health Care Guidance Products (Draft)[7] provides the framework and the Evidence-Informed Decision-Making Manual for the STGs and EML[8] guides the specific procedure for reviewing the STGs and EML. The Health Technology Assessment Methods Guide[9] steers the approach to gathering and producing evidence. The ERC proposes recommendations to the NEMLC.

[6] National Department of Health, 2021. *Guideline on Publications Emanating from Work Conducted by the NEMLC (Draft)*. Pretoria: National Department of Health.

[7] National Department of Health, 2025. *National Standards for Evidence-Informed Decision-Making to Develop Trustworthy Health Care Guidance Products (Draft).* Pretoria: National Department of Health.

[8] National Department of Health, 2025. *Evidence-Informed Decision-Making Manual for the STGs and EML (Draft).* Pretoria: National Department of Health.

[9] National Department of Health, 2021. *Health Technology Assessment Methods Guide to Inform the Selection of Medicines to the South African National Essential Medicines List*. Pretoria: National Department of Health. (accessed from https://www.knowledgehub.org.za/system/files/elibdownloads/2021-07/3.%20HTA%20Methods%20Guide_draft_v1.2_14Jun21.pdf)

16. Review of the ERC Terms of Reference

The Terms of Reference of the ERC are reviewed on appointment of a new ERC or as required.

17. Related Documents

Related documents include, but are not limited to, the following:

- Conflict of Interest Policy[10];
- Expert Review Committee Terms of Reference[11];
- Guideline on Publications Emanating from Work Conducted by the NEMLC[12];
- Health Technology Assessment Methods Guide[13];
- Confidentiality Guideline[14];
- National Policy for Lodging an Appeal Against a Medicine-Related Decision of the National Essential Medicines List Committee[15];
- National Standards for Evidence-Informed Decision-Making to Develop Trustworthy Health Care Guidance Products[16];
- Evidence-Informed Decision-Making Manual for the STGs and EML[17] and
- Therapeutic Interchange Policy[18].

[10] Affordable Medicines Directorate, 2020. *Affordable Medicines Directorate Conflict of Interest Policy*. Pretoria: National Department of Health.

[11] National Department of Health, 2025. *Expert Review Committee Terms of Reference (Draft).* Pretoria: National Department of Health.

[12] National Department of Health, 2021. *Guideline on Publications Emanating from Work Conducted by the NEMLC (Draft)*. Pretoria: National Department of Health.

[13] National Department of Health, 2021. *Health Technology Assessment Methods Guide to Inform the Selection of Medicines to the South African National Essential Medicines List*. Pretoria: National Department of Health. (accessed from https://www.knowledgehub.org.za/system/files/elibdownloads/2021-07/3.%20HTA%20Methods%20Guide_draft_v1.2_14Jun21.pdf)

[14] Affordable Medicines Directorate, 2021. *NEMLC Confidentiality Guideline.* Pretoria: National Department of Health.

[15] National Department of Health, 2023. *National Policy for Lodging an Appeal Against a Medicine-Related Decision of the National Essential Medicines List Committee*. Pretoria: National Department of Health.

[16] National Department of Health, 2025. *National Standards for Evidence-Informed Decision-Making to Develop Trustworthy Health Care Guidance Products (Draft).* Pretoria: National Department of Health.

[17] National Department of Health, 2025. *Evidence-Informed Decision-Making Manual for the STGs and EML (Draft).* Pretoria: National Department of Health.

[18] National Department of Health, 2021. *Therapeutic Interchange Policy*. Pretoria: National Department of Health.