NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE: Terms of Reference

20 JULY 2023

Contents

Abbreviations

EML	-	Essential Medicines List
ERC	-	Expert Review Committee
MAC-AMR	-	Ministerial Advisory Committee on Antimicrobial Resistance
MEC	-	Member of the Executive Council
NDoH	-	National Department of Health
NEMLC	-	National Essential Medicines List Committee
PTC	-	Pharmaceutical and Therapeutics Committee
SAHPRA	-	South African Health Products Regulatory Authority
STG	-	Standard Treatment Guideline
TB	-	Tuberculosis
TOR	-	Terms of Reference

Purpose

The National Essential Medicines List Committee (NEMLC) is a non-statutory, advisory committee constituted in terms of the National Drug Policy (1996) 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. The NEMLC develops and reviews an essential medicines list (EML) for use in the public sector, accompanied where possible by standard treatment guidelines (STGs). The STGs and EML are prepared for three levels of care, i.e. primary, secondary, and tertiary/quaternary care.

Authority to act

The NEMLC is an advisory committee to the Minister of Health and does not have any delegated powers to act on behalf of, or to commit, the Minister or Government to any actions.

Composition of NEMLC

The NEMLC is appointed by the Minister of Health for a period not exceeding three years. The minimum number of core members is thirty (inclusive of the nine provincial representatives). The co-chairpersons of the NEMLC are also appointed by the Minister of Health.

Representation of Groups Within the NEMLC

The following groups must be represented within the core membership of the NEMLC:

- Adult medical specialists within the public sector or academia
- Paediatric medical specialists within the public sector or academia
- Medical practitioners with experience at the primary health care level in the public sector
- Ministerially Advisory Committee on Antimicrobial Resistance (MAC-AMR)
- Provincial pharmaceutical services department, nominated by the relevant Member of the Executive Council (MEC) responsible for Health in each province
- Pharmaceutical services: South African Military Health Services
- Pharmaceutical services: Department of Correctional Services
- Medical Research Council
- Council for Medical Schemes
- South African Health Products Regulatory Authority (SAHPRA)
- Medical Schools
- Pharmacy Schools
- Nursing Schools

Ex-Officio Members of the NEMLC

Ex-Officio members nominated by the relevant Deputy Director-General must include, but are not limited to, one person representing each of the following directorates in the National Department of Health (NDoH):

- Nursing Services
- Non-communicable Diseases
- Emergency Medical Services
- Nutrition
- Pharmacoeconomic Evaluation
- Primary Healthcare
- Tuberculosis (TB)
- Drug-Resistant TB, TB and HIV
- National Pharmacovigilance
- Women's, Maternal and Reproductive Health
- Child, Youth and School Health
- Communicable Diseases
- District Services
- Tertiary Hospital Services

Expertise required on the NEMLC

Applicants with relevant expertise are invited to apply for appointment to the NEMLC in their individual capacity. The following areas of expertise must be represented within the core membership of the NEMLC:

- clinical pharmacology
- clinical pharmacy
- rational prescribing
- health economics/pharmaco-economics
- evidence-based medicine
- public health
- bioethics

Preference may be given to previous members of NEMLC and its Expert Review Committees (ERCs), in order to retain institutional knowledge. Applicants for appointment to the NEMLC may be contacted for a telephonic interview if deemed necessary and declared conflicts of interest will be considered when assessing eligibility for appointment. At the completion of their term of office, members of the NEMLC may re-apply for appointment.

Convening of Subcommittees

Subcommittees may be convened, as required, by the Minister of Health, NDoH or co-chairpersons of the NEMLC to conduct background analysis and prepare guidance and recommendations for review by the NEMLC on specific topics that may arise. These subcommittees may comprise members of the NEMLC, members of the ERCs, and others (e.g. stakeholders with expertise in the question at hand). Any subcommittee(s) will be chaired by the co-chairpersons of the NEMLC or designated person(s).

Non-members may be invited to attend subcommittee meetings and provide presentations as required on approval by the co-chairpersons prior to the meeting. The process for the management of declarations of interest and confidentiality will follow the standard NEMLC process, and these Terms of Reference (TOR) will apply.

Reports, with supporting documents, will be prepared by a subcommittee following each meeting, and will be shared with the NEMLC electronically or presented at its next meeting, either for ratification or information purposes.

NEMLC Subcommittee on COVID-19 Therapeutics

The NEMLC Subcommittee on COVID-19 Therapeutics, chaired by a member of the NEMLC, will be created to provide specific patient-focused evidence-based recommendations to the NEMLC to support the inclusion of selected medicines for the prevention and treatment of COVID-19 in the STGs and EML as well as other related COVID-19 guidelines and material. The NEMLC Subcommittee on COVID-19 Therapeutics will be responsible for new reviews as well as updating reviews previously performed by the MAC on COVID-19 Therapeutics, on request from the NEMLC. Criteria for review or updating of previous reviews may include new evidence on cost, availability, registration, efficacy or safety concerns.

Proposed recommendations to the NEMLC will be provided in a rapid medicine review format within 4 weeks and ratified for publication by the NEMLC within 6 weeks of the commencement of review, depending on the urgency required. Rapid reviews will be shared electronically to the NEMLC for review and approval, with ad hoc meetings convened if further discussion is required.

Expert Review Committees (ERCs)

ERCs, chaired by a member of the NEMLC, will be created for the following levels of care:

- Primary Health Care and Adult Hospital Level;
- Paediatric Hospital Level; and
- Tertiary/Quaternary Hospital Level.

For the primary and secondary levels of care, the EML will be accompanied by STGs aimed at promoting the rational use of essential medicines. For the Tertiary/Quaternary level of care, the list will be supported by medicines reviews that summarise the evidence base used during the selection process. These reviews will be made available to Pharmaceutical and Therapeutics Committees (PTCs) to guide the development of local formularies and rational use strategies.

Code of Conduct

Members are expected to:

- avail themselves for meetings, punctually and for the whole of the scheduled meeting time;
- indicate their failure to attend any meeting in writing to the secretariat, in good time with the reason as to why they are unable to attend;
- act with the highest professional and ethical standard at all times;

- contribute to debate in an informed and rational way and take decisions solely in the interest of the public;
- regard the views expressed by individual members of the NEMLC as confidential;
- respect and value each member's perspective and contribution;
- make decisions together and take joint responsibility for decisions made;
- be informed and prepared for the meeting by reading the agenda and meeting documents; and
- share appropriate information with stakeholders who they represent.

Termination of Membership

Membership of the NEMLC will be terminated when:

- the Minister of Health, in the public interest, terminates the membership;
- a member resigns from the committee, in writing (in the case of provincial or National Department of Health programme representatives, a nomination for a replacement member must be submitted);
- a member is suspended for misconduct; or
- a member fails to attend 2 or more meetings, without an apology deemed to be of sufficient merit (apologies will be evaluated by the co-chairpersons, and if necessary discussed at the next quorate meeting of the NEMLC).

If leave of absence is approved by the co-chairpersons, membership will be suspended for the assigned period of time and the member will not be included in quorum calculations.

Membership will be reviewed upon any member's change in employment or resignation from a current position, and may be terminated in accordance with the TOR or at the discretion of the Minister of Health.

Roles of NEMLC Members

All members of the NEMLC are expected to:

- contribute their relevant experience to the committee;
- make full and considered contributions to the debates and decision making processes of the committee; and
- facilitate communication through the relevant administrative structures and provide technical support to these bodies in preparing submissions that are in compliance with the guidelines for submission.

Representatives on the NEMLC are required to share appropriate information between stakeholders whom they represent and the NEMLC, including distribution of draft STGs and EML for comment as well as the NEMLC Bulletin.

Representatives from the Provinces

The provincial representatives are responsible for the communication of information between the NEMLC and the provincial administration, as well as contributing to the medicine selection process by providing insight into the practice implications at provincial and institutional level.

In addition to any roles assigned to provincial representatives by the province, these members are expected to:

- contribute toward the technical activities of the committee, where relevant;
- provide mentorship and build capacity at the provincial and local PTCs;
- facilitate and provide technical support to the provincial PTC when compiling submissions in response to:
  - call for comment notices; and
  - chapter/medicine reviews.
- actively engage in the dissemination and implementation of the STGs and EML at the local level.

Representatives from Correctional Services and Military Health Services

The representatives are responsible for contributing to the medicine selection process by providing insight into the implications of decisions on Correctional Services and Military Health Services.

Representative from the South African Health Products Regulatory Authority (SAHPRA)

The representative is responsible for contributing to the medicine selection process by providing insight into the regulatory implications of decisions.

Representative from Medical Research Council

The representative is responsible for contributing to the medicine selection process by providing insight into the research implications of decisions.

Representative from Council for Medical Schemes

The representative is responsible for the provision of clinical and professional input as the country progresses towards National Health insurance.

Representatives from Academia (Medical, Pharmacy and Nursing Schools)

Representatives are responsible for strengthening the collaboration with academic institutions and facilitating rational medicines use in accordance with the STGs and EML.

Representative from the MAC-AMR

The representative from the MAC-AMR is responsible for guiding the selection of antimicrobials on the EML based on antimicrobial stewardship considerations.

Representatives from the National Department of Health Clinical Programmes

The representatives are responsible for contributing to the medicine selection process by providing insight into the programmatic implications of decisions, as well as ensuring alignment between programmatic guidelines and the STGs and EML.

The representatives are expected to:

- contribute toward the technical activities of the committee;
- nominate content experts, where relevant;
- ensure that selection of medicines during programmatic guideline development is in accordance with EML principles;
- provide peer review of chapters/medicines from the STGs and EML, and identify any differences with programme guidelines;
- provide evidence-based advice whenever an STG requires further review or amendment; and
- advocate the EML at the national and local level and actively engage in its dissemination and implementation.

Role of the Co-Chairpersons of the Committee

The co-chairpersons should both be conversant with the principles of evidence-based medicine. Clear lines of communication between the co-chairpersons and the secretariat are essential.

The co-chairpersons' responsibilities are to:

- preside at all meetings of the NEMLC, where possible;
- conduct NEMLC meetings in accordance with a project plan;
- facilitate the committee's discussion of technical documents to arrive at consensus;
- develop and maintain policies and guidance documents for the review of the STGs and EML; and

- advise and consult with ERCs, Department of Health Clinical Programmes, provincial PTCs, reviewers and stakeholders on medicines selection processes.

The co-chairpersons will:

- assist the secretariat to prepare the agenda before meetings, and to review the minutes after meetings;
- review and sign letters on behalf of the committee regarding decisions of the committee;
- consult with chairpersons of the ERCs and other NDoH Guideline Committees to ensure consistency in guidelines;
- advise the committee on policy, administrative and regulatory matters, and
- co-sign all meeting governance documents, where possible.

If one co-chairperson resigns before the end of the term of office, a new co-chairperson should preferably be elected from within the NEMLC. The remaining co-chairperson will continue as sole chairperson until the appointment of a new co-chairperson by the Minister of Health.

Decision-Making Process

Decisions of the NEMLC will preferably be taken by consensus, rather than by voting. Where a consensus cannot be reached at a meeting, a mechanism for voting will be decided by the NEMLC members present, including agreement on the number and nature of questions as well as the platform on which the vote will be made. No abstentions will be permitted and a decision will be taken within one week of the NEMLC meeting. Ex-officio members do not have voting rights. The co-chairpersons will have the casting vote, with one vote between them.

If conflicts arise between members of the NEMLC, members should seek the advice of the co-chairpersons, whose decisions will be binding. If the co-chairpersons are unable to agree on a course of action, they should seek the advice of the chairpersons of the ERCs and if that does not resolve the issue, then they should consult the remaining NEMLC members by consensus. The decision of the NEMLC will be binding on both co-chairpersons. If any member of the NEMLC is concerned that a situation is damaging to the reputation of the NEMLC, they should report those concerns to the secretariat. If necessary, the secretariat may report those concerns to the NEMLC 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 secretariat, who will consider and advise the NEMLC.

Role of the Secretariat

The secretariat will be provided by the Essential Drugs Programme and will:

- develop and maintain a project plan for the review and maintenance of the publications of the committee;
- convene the meetings and make all the necessary logistic arrangements for the meetings;
- facilitate the proper functioning of the committee;
- advise the committee on policy, administrative and regulatory matters;
- compile minutes of the meeting and finalise the draft in consultation with the co-chairpersons of the committee (draft minutes will be circulated within 20 working days after each meeting; minutes will be adopted at the beginning of each meeting);
- co-ordinate and facilitate any research that is required for the committee to perform its functions;
- in consultation with the ERCs, compile the technical documents to be tabled at the NEMLC meetings (these documents are to be received by all NEMLC members at least 7 days prior to the scheduled meeting, where possible); and
- maintain a record of the decisions taken to promote transparency.

Meetings of the NEMLC

The NEMLC will meet at least four times a year based on the project plan developed by the secretariat. Members may not nominate representatives to attend meetings in their absence.

Conflict of Interest and Confidentiality

Members are required to abide by declaration of interest requirements in accordance with the Affordable Medicines Directorate Conflict of Interest Policy. Non-specific interests must be declared prior to appointment to a NEMLC, on an annual basis thereafter or as the need arises and updated prior to each meeting of the committee where needed. In addition, specific interests must be declared where applicable by members and other meeting participants prior to each meeting. Declarations of non-specific interests made on appointment and annually are applicable to both NEMLC and its ERCs, and should be assessed by the chairperson of the first committee to which the member is appointed. Specific interests are declared prior to each meeting, where applicable. The co-chairpersons' conflicts of interest will be managed and counter-signed by the Director: Affordable Medicines or designated official.

Members and other meeting participants are required to abide by confidentiality requirements in accordance with the NEMLC Confidentiality Guideline. Declarations of confidentiality also are

applicable to both NEMLC and its ERCs and should be made at the first committee to which the member is appointed.

Quorum

A quorum of members must be present before the meeting can proceed. The quorum requirement is at least 50% + 1, calculated from the number of members appointed to the committee. Ex-officio members do not form part of the quorum.

Agenda

A draft agenda will be determined by the secretariat and finalised in consultation with the co-chairpersons of the NEMLC, as well as chairpersons and vice-chairpersons of the ERCs. The agenda will be driven by the matters arising from the previous meeting and attainment of milestones of the project plan.

Minutes

The minutes of NEMLC meetings will be circulated to all members within 20 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 NEMLC meeting agenda will be the consideration of previous minutes. Adoption of the minutes, after any correction, will be moved by a proposer and a seconder, and recorded as such. The corrected minutes will be signed by:

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

Medicine Reviews

The Health Technology Assessment Methods Guide[1] will steer the approach to gathering and producing evidence on clinical efficacy, safety, effectiveness and affordability, as well as additional factors considered in the evidence-to-decision framework, such as equity, feasibility and cost-effectiveness.

[1] 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)

Procedure for the Review of the STGs and EML

Consultation with stakeholders is an integral part of the review process. Primary stakeholders include the provincial PTCs, the various clinical programmes of the NDoH and relevant health professional associations and societies. A call for comment notice will be issued for all interested stakeholders to provide written comment and recommendations regarding the review of the EML using the prescribed format. A motivation form for the inclusion of medicines onto the EML must be provided by stakeholders, including provincial PTCs. The NEMLC will develop and maintain the necessary submission forms and guidelines.

The ERCs will perform the review of the EML, and where appropriate, the STGs. Completed chapters, together with the supporting medicine reviews and explanatory memoranda, will be circulated to NEMLC members at least 14 days prior to each meeting, where possible. The chairperson of the relevant ERC will present the chapter and a brief discussion of the technical considerations of any additions or deletion of medicines. Following the presentation of each chapter the co-chairpersons of the NEMLC will invite comment in order to determine whether the peer review process has arrived at consensus that the chapter is of sufficient quality for circulation to external stakeholders. If such consensus is reached, a resolution will be moved by a proposer and seconder. If the resolution is accepted by consensus, the chapter and supporting documents will be circulated to all relevant parties for comment by a predetermined date. The secretariat will compile all comments for presentation to the ERC for consideration. After consensus is reached within the ERC, an edited version of the completed chapters together with supporting medicine reviews will be presented to the NEMLC for final ratification, before publication.

Meetings and Communication with Stakeholders

Only the co-chairpersons may represent the views and decisions of NEMLC to external stakeholder groups. The primary point of contact will be the secretariat. It is envisaged that the secretariat will meet with stakeholders:

- after any call up notice for information (in order to clarify administrative aspects, such as the evidence requirements);
- for clarification of information supplied by a stakeholder;
- to communicate and clarify queries posed by an ERC; or
- to implement resolutions of the NEMLC.

Feedback from communications between the secretariat and stakeholders will be provided to the NEMLC and/or ERCs, preferably in writing.

Where extraordinary circumstances merit, members of the NEMLC and/or the relevant ERC may meet with external stakeholders, with the secretariat present, in order to:

- clarify substantive queries or responses where all reasonable written responses have failed to resolve the matter under review; or
- attend to matters of urgent public health interest.

Brief minutes should be maintained of all meetings with stakeholders. All information received in writing shall be recorded in the Essential Drugs Programme registry.

Note – The various major clinical programme clusters of the NDoH are ex-officio members of the NEMLC and are not considered external stakeholders, hence these rules do not apply.