health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE
Terms of Reference

8 SEPTEMBER 2025

Contents

1. Abbreviations

EML	-	Essential Medicines List
ERC	-	Expert Review Committee
HTA	-	Health Technology Assessment
MEC	-	Member of the Executive Council
NAGI	-	National Advisory Group on Immunisation
NDoH	-	National Department of Health
NEMLC	-	National Essential Medicines List Committee
PTC	-	Pharmaceutical and Therapeutics Committee
SAHPRA	-	South African Health Products Regulatory Authority
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 NEMLC develops and reviews 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).

3. Authority to Act

The NEMLC is appointed by the Minister of Health to develop the STGs and EML. It does not have any other delegated powers to act on behalf of, or to commit, the Minister of Health or Government to any actions.

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

4. Functions

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

- providing oversight of the NEMLC and ERC processes to ensure clinical governance;
- approving topics for review, scoping and question development;
- reviewing proposed recommendations and technical documents provided by the ERC and ratification thereof; and
- ratifying amendments to the STGs and EML.

4.2. The NEMLC may be requested to provide review and input into other documents, including but not limited to the NEMLC therapeutic interchange database, tender specifications, circulars, ideal health facility frameworks, as well as National Department of Health (NDoH) Clinical Programmatic Guidelines.

5. Composition of NEMLC

5.1. The NEMLC, including its co-chairpersons, is appointed by the Minister of Health for a period not exceeding four years. The minimum number of core members is twenty-one. South African citizens or permanent residents are eligible for appointment and the NEMLC is intended to be representative of the geographic and demographic diversity of South Africa, in keeping with the principles of equity of care. Preference for appointment to the NEMLC, especially for the role of co-chairpersons, may be given to previous members of NEMLC and its ERCs in order to retain institutional knowledge and facilitate a smooth transition between committees.

<u>Core Members</u>

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

- Co-Chairpersons of the ERC;
- Provincial Departments of Health. The representative from each province must be nominated by the relevant Member of the Executive Council (MEC) and must be a member of the Provincial Pharmaceutical and Therapeutics Committee (PTC), if constituted. The representative should be responsible for management of the provincial formulary, and be able to contribute to key areas of decision making incorporated in the evidence-to-decision framework, such as feasibility and acceptability; and
- Experts representing all levels of care, including the co-chairpersons, 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;
- 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.

Ex-officio Members

5.3. The following groups must be represented within the ex-officio membership of the NEMLC:

- Representatives from NDoH Programmes. These individuals may be nominated by the relevant Deputy Director-General and must include, but are not limited to, one person representing each of the following directorates and chief directorates in the NDoH:
  - Communicable Diseases;
  - District Health Services;
  - Environmental Health and Port Health Services;
  - Health Promotion, Nutrition and Oral Health;
  - HIV and AIDS and STIs;
  - Hospitals and Tertiary Health Services;
  - Maternal, Child and Women's Health;
  - Non-communicable Diseases;
  - Nursing Services;
  - Sector-Wide Procurement;
  - TB Control and Management; and
  - Trauma, Violence and Emergency Medical Services.
- Council for Medical Schemes;

- Ministerial advisory committees related to the selection of essential medicines and guideline updates, including but not limited to the National Advisory Group on Immunisation (NAGI);
- Pharmaceutical services: Department of Defence and Military Veterans;
- Pharmaceutical services: Department of Correctional Services; and
- South African Health Products Regulatory Authority (SAHPRA).

5.4. Ex-officio members may attend NEMLC meetings on an ad hoc basis depending on the meeting agenda to accommodate their other NDoH or organisational commitments and are expected to partake in discussions pertaining to their directorate. They do not contribute to quorum or decision-making.

Appointment of Experts

5.5. Applicants with relevant expertise are invited to apply for appointment to the NEMLC in their individual capacity by the NDoH. Applicants for appointment to the NEMLC may be required to participate in an interview if deemed necessary. Conflicts of interest declared are considered when assessing eligibility for appointment. At the completion of their term of office, members of the NEMLC may re-apply for appointment.

5.6. External experts may be co-opted by the co-chairpersons of the NEMLC to contribute towards a specific topic for a limited period. Co-opted members are appointed by the Director: Affordable Medicines Directorate and do not contribute to decision-making of the NEMLC or count towards quorum.

Clinical Editors

5.7. Clinical editors may be appointed to review the STGs for accuracy, including appropriate coding, dosing, units, safety issues, definitions, terminology, readability, interpretation, and other content-related correctness.

5.8. The Essential Drugs Programme (EDP) Oversight Group may request clinical editing of a chapter of the STGs, in accordance with the Guideline for the Clinical Editing and Formatting of the National STGs and EML[2].

[2] Affordable Medicines Directorate, 2024. *Guideline for the Clinical Editing and Formatting of the National STGs and EM (Draft)L*. Pretoria: National Department of Health.

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)[3];
- 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;
- 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 NEMLC 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;
- communicate and respond timeously to requests for information from other NEMLC members, the EDP Oversight Group and co-chairpersons;
- only share confidential information 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 NEMLC.

7. Remuneration

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[4]. 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

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

[4] 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.

for in-person meetings are only arranged for expert members and nominated representatives of other Ministerial Advisory Committees if required.

8. Termination of Membership

8.1. 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 NDoH Programme representatives, a nomination for a replacement member must be submitted);
- 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 NEMLC.

8.2. For ex-officio members who have been nominated to be members of the NEMLC, the nominating authority will be notified of the intention to terminate the membership. 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.

8.3. Membership may be reviewed if there is a lack of contribution towards discussions of the NEMLC. 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.

9. Roles of NEMLC Members

9.1. All members of the NEMLC are expected to:

- contribute to the decision-making process of the NEMLC based on their specific membership role, including relevant experience and skills to the committee;
- make full and considered contributions to the debates and decision-making processes of the committee;
- facilitate approved 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; and

- strengthen clinical guideline alignment and promote the standardisation of guideline development and HTA processes.

9.2. In addition, 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 Provincial Pharmaceutical Services

9.3. The provincial representatives are responsible for the communication of information between the NEMLC and the provincial administration, the timely dissemination and implementation of the decisions through provincial PTCs, as well as contribution to the medicine selection process.

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

- contribute toward the technical activities of the NEMLC, 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; and
- be responsible for the dissemination, implementation, monitoring, feedback regarding implementation of the STGs and EML at the local level; and
- provide insight into the practical implications of decisions, as well as feedback to the NEMLC on implementation.

Representatives from the NDoH Programmes

9.5. The representatives are responsible for contributing to the medicine selection process during the review and updating of the STGs and EML, as well as facilitating the improved collaboration between the NEMLC and NDoH Programmes.

9.6. The NDoH Programme representatives are expected to:

- contribute toward the technical activities of the NEMLC;
- nominate content experts, where relevant;
- ensure that selection of medicines during programmatic guideline development is in accordance with EML principles and aligned to NEMLC recommendations for specific medicines;

- provide peer review of chapters/medicines from the STGs and EML, identify any differences with NDoH Clinical Programmatic Guidelines and support the engagement process towards guideline alignment;
- provide evidence-based advice whenever a guideline requires further review or amendment;
- advocate for the EML at the national and local level and actively engage in its dissemination, implementation, monitoring and evaluation; and
- provide insight into the programmatic and procurement implications of decisions, as well as feedback to the NEMLC on implementation.

Representative from Council for Medical Schemes

9.7. The representative is responsible for facilitating formal stakeholder engagement between the NDoH and the Council for Medical Schemes, as well as providing clinical and professional input as the country progresses towards National Health insurance.

Representatives from the Department of Correctional Services and Department of Defence and Military Veterans

9.8. The representatives are responsible for the timeous dissemination and implementation of decisions, as well as contributing to the medicine selection process by providing insight into the implications of decisions on the Department of Correctional Services and Department of Defence and Military Veterans.

Representative from the Ministerial Advisory Committees, including the NAGI

9.9. The representatives from the ministerial advisory committees are responsible for guiding the selection of medicines related to their fields of expertise, including vaccines for the NAGI. Representatives are also responsible for facilitating the improved collaboration between the NEMLC and ministerial advisory committees.

Representative from the SAHPRA

9.10. The representative is responsible for facilitating formal stakeholder engagement between the NDoH and SAHPRA, as well as contributing to the medicine selection process by providing insight into the regulatory implications of decisions.

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 NEMLC, where possible;
- conduct NEMLC 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 NEMLC;
- advise and consult with the ERC, NDoH Programmes, Provincial PTCs, reviewers and stakeholders on medicines selection processes and to ensure consistency with NDoH Clinical Programmatic Guidelines;
- review and sign letters on behalf of the committee regarding decisions of the committee;
- advise the committee on policy, administrative and regulatory matters;
- sign all meeting governance documents, where possible; and
- provide advice and guidance when called upon by the EDP Oversight Group.

10.3. If one of the co-chairpersons 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 continues as sole chairperson until the appointment of a new co-chairperson by the Minister of Health.

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 co-chairpersons;
- coordinating and facilitating any research that is required for the committees 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. Core members are required to make decisions for the NEMLC, while ex-officio members are required to provide insights into the practical implications and advise the NEMLC.

12.2. Decisions of the NEMLC 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 NEMLC members present, including

agreement on the number and nature of questions as well as the platform on which the vote is made. No abstentions are 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 together will have the casting vote.

12.3. If conflicts arise between members of the NEMLC, 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 NEMLC members by consensus. The decision of the NEMLC is binding on both co-chairpersons. If any member of the NEMLC is concerned that the situation is damaging to the reputation of the NEMLC, they should report those concerns to the NEMLC members and/or the EDP Oversight Group. If necessary, the EDP Oversight Group 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 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 NEMLC 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 NEMLC

13.1. The NEMLC meets at least four times a year either virtually or in-person, based on the project plan developed by the EDP Oversight Group. The co-chairpersons of the NEMLC and ERC are required to attend a meeting with the EDP Oversight Group prior to each NEMLC 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;
- automate transcribing and recording of meetings of the NEMLC. This is permitted for the EDP Oversight Group to enable efficiencies in the preparation of the official meeting minutes.

13.3. 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.

13.4. 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)[5].

Conflict of Interest and Confidentiality

13.5. Members are required to abide by declaration of interest requirements in accordance with the Affordable Medicines Directorate Conflict of Interest Policy[6]. Non-specific interests must be declared prior to appointment to NEMLC, 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 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 be assessed by the co-chairpersons of the first committee to which the member is appointed. The co-chairpersons' conflicts of interest are managed and counter-signed by the Director: Affordable Medicines Directorate or designated official.

13.6. All members of the NEMLC 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[7]. 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.

[5] National Department of Health, 2021. *Guideline on Publications Emanating from Work Conducted by the NEMLC (Draft)*. Pretoria: National Department of Health.
[6] Affordable Medicines Directorate, 2020. *Affordable Medicines Directorate Conflict of Interest Policy*. Pretoria: National Department of Health.
[7] Affordable Medicines Directorate, 2021. *NEMLC Confidentiality Guidance Document.* Pretoria: National Department of Health.

Quorum

13.7. 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, ex-officio and co-opted members, as well as adhoc attendees. A register of appointed members is maintained by the EDP Oversight Group.

Agenda

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

Attendance of Non-Members

13.9. Only non-members who have been involved directly in the development of content to be discussed during an agenda item may be invited to attend NEMLC or ERC meetings and provide presentations as required on approval by the co-chairpersons prior to the meeting. Non-members are only permitted to attend the meeting for the specific agenda item. The process for the management of declarations of interest and confidentiality follows the standard NEMLC process, with declarations received at least three days before the meeting.

Minutes

13.10. The minutes of NEMLC meetings are 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 is the consideration of previous minutes. Adoption of the minutes, after any correction, is moved by a proposer and a seconder from within the NEMLC and recorded as such.

13.11. The corrected minutes are signed by:

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

14. 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)[8] provides the framework and the Evidence-Informed Decision-Making Manual for the STGs and EML[9] guides the specific procedure for reviewing the STGs and EML. The Health Technology Assessment Methods Guide[10] steers the approach to gathering and producing evidence. In addition, the NEMLC may be required to review donation applications being considered by the NDoH involving medicines that are not on the EML.

15. Meetings and Communication with Stakeholders

15.1. Except for the use of formal communication such as through the NEMLC Bulletin, only the NDoH may represent the views and decisions of NEMLC to external stakeholder groups. The primary point of contact is the EDP Oversight Group. It is envisaged that the EDP Oversight Group 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.

15.2. Feedback from communication between the EDP Oversight Group and stakeholders is provided to the NEMLC and ERC, preferably in writing. Where extraordinary circumstances merit, members of the NEMLC and/or ERC may meet with external stakeholders, with the EDP Oversight Group 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.

15.3. Abridged minutes containing a high-level overview of discussions and action points should be maintained of all meetings with stakeholders and may be shared with external stakeholders as

[8] 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.

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

[10] 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)

agreed by the EDP Oversight Group. All information received in writing shall be recorded by the EDP. The NDoH Programme representatives are not considered external stakeholders, hence these rules do not apply.

16. Review of the NEMLC Terms of Reference

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

17. Related Documents

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

- Affordable Medicines Directorate Conflict of Interest Policy[11];
- Expert Review Committee Terms of Reference[12];
- Guideline on Publications Emanating from Work Conducted by the NEMLC[13];
- Health Technology Assessment Methods Guide[14];
- NEMLC Confidentiality Guidance Document[15];
- National Policy for Lodging an Appeal Against a Medicine-Related Decision of the National Essential Medicines List Committee[16];
- National Standards for Evidence-Informed Decision-Making to Develop Trustworthy Health Care Guidance Products[17];
- Evidence-Informed Decision-Making Manual for the STGs and EML[18] and
- Therapeutic Interchange Policy[19].

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

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

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

[14] 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)

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

[16] 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.

[17] 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.

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

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