health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC)

Confidentiality Guidance Document

A code of practice for the National Essential Medicines List Committee and members of the technical expert review committees

Background

Confidentiality and transparency are not mutually exclusive and a balance needs to be struck between managing risk whilst maintaining the appropriate degree of transparency required for sound technical decision-making and protection of constitutional rights.

A risk is any event that affects the performance and viability of the review program and/or its external stakeholders. In terms of leaked information the risk broadly translates into:

- loss of credibility
- decisions are made externally based on draft material
- reluctance of members to participate in the process and/or loss of momentum of the review
- negative impacts upon the procurement process of the government
- negative business consequences for various parties including suppliers

In addition to the product of the review which is within the public domain any member of the public may utilise the avenue of the Promotion of Access to Information Act ("PAIA"), provided such requests are reasonable and have been made in compliance with the administrative procedures that makes provisions for such access.

1. Introduction

This code of practice guides the National Essential Medicines List Committee (NEMLC) members, members of the expert review committees and any working groups that the committee may, from time to time, establish as to the circumstances in which they should maintain confidentiality regarding the decisions of the committee and its source documents.

2. Scope and definitions

2.1 Scope

This code applies to:

- The Chairperson and NEMLC members.
- Members of expert review committees appointed by the Minister. This also includes co-opted members and members of any working groups that the NEMLC may, from time to time, establish.

2.2 Definitions

In this Code:

- "Pharmaceutical industry" means companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicines as defined in the Medicines and Related Substances Act (Act 101 of 1965) that are, or may be, used by state institutions, as well as trade associations representing companies involved with such products.
- "Professional organisations" refers to colleges, health professional associations and societies, and universities.
- "Members" includes the NEMLC and all its expert review committees.
- "Administrative unit" is a department or organisation with which the member has an employment relationship with managerial responsibilities.
- "Employees" refers to full and part time employees of the NDoH.
- "Confidential business information" commercial or financial information considered to be confidential because disclosure may:
  - Impair the Government's ability to obtain necessary information in the future; or
  - Cause substantial harm to the competitive position of the individual or business entity which provides the information.
- "Proprietary information" is information or data belonging to an owner or proprietor, who may have exclusive rights to the manufacture and sale of a specific item.
- "Trade secret" is any formula, pattern, device, or information that is used in business which provides a competitive advantage.
- "Sensitive information" Information or data in which disclosure, loss, misuse, alteration, or destruction may adversely affect national security or other government interest.
- "Promotion of Access of Information Act" or "PAIA" Section 32(1)(a) of the Constitution of the Republic of South Africa Act, No. 108 of 1996 provides that everyone has a right of access to any information held by the state and any information held by another person that is required for the exercise or protection of any rights. The Promotion of Access to Information Act, No. 2 of 2000 is the national legislation which was enacted to give effect to the constitutional right of access to information.
- "Internal stakeholders" are those subcommittees or task teams constituted by the NEMLC with established terms of reference.
- "External stakeholders" refers to all stakeholders that have not been designated as internal or who have been granted access to the documentation in terms of a resolution of the NEMLC.

3. Types of information that are considered confidential

The following is intended as a guide to the types of information and situations which should remain confidential. Where a member or employee is uncertain as to whether information should be disclosed to an external party he or she should seek guidance from the chairperson of the NEMLC, or National Department of Health secretariat. Alternatively, the interested party should be referred to the National Department of Health's information officer appointed in terms of PAIA and the relevant manual published by this officer. Further guidance as to implementation of PAIA such as grounds for refusal can be found at http://www.doj.gov.za/paia/paia.htm.

Different types of confidential information can be envisaged and the following list, which is not exhaustive, is provided as guidance.

- Identity of a reviewer of a specific chapter, the review of the EML follows a process of consensus seeking around evidence based principles and hence the decision of the committee is that of a collective and not an individual. Disclosure of an individual's identity poses certain risks which include;
  - Exposure of the review processes to potential undue pressures from external stakeholders and parties with vested interests which may:

        - Discredit the objectivity and impartiality of the review process.
        - Introduce conflict of interests as contemplated in the relevant policy on this matter.
    - In addition, disclosure of the individual's identity may negatively impact upon that reviewer's willingness to participate in future reviews.
- Although the EML process does not routinely utilise information that may be considered propriety any such information that is supplied to the committee should enjoy the protection of the appropriate level of confidentiality.
- Leaked information poses a specific list of risks as it may, for example:
    - Prolong the review process through the introduction of subjective information by individuals with a vested interest prior to the finalisation of the evidence based consensus process.
    - Provide a competitor a business advantage to a potential supplier in which case it would be considered a trade secret.
    - Have a negative impact upon the Department of Health's ability to generate competition and hence obtain the best price for a pharmaceutical commodity and it would therefore be considered confidential business information.
    - Have a negative impact upon the government actualising a public health outcome in which case this information would be deemed sensitive information.
    - Be implemented as policy prior to finalisation of the consensus seeking process.

Leaked information is any information that an individual has access to which is not in the public domain. This includes all documents that are actively being reviewed by NEMLC or its Expert Review Committees, unless approved for external consultation as contemplated in the terms of reference. In its resolution of acceptance of a technical document the NEMLC should declare the level of confidentiality and for documents approved for consultations and the scope of the consultation.

4. Position of the chairperson

The Chairperson of the NEMLC is the individual responsible for compiling information to be communicated to the information officer for disclosure in terms of any approved PAIA application. The NEMLC chairperson may consult with the secretariat or the chairman of the relevant Expert Review Committees in the compilation of such documentation. The affected committee should be informed of such disclosure and should be furnished with a copy for their reference. The nature, but not necessarily the details of communication with internal and external stakeholders, should be declared as part of the proceedings of the affected committee. In meetings with stakeholders on technical matters the relevant chairperson of the technical committee will act as the spokesperson supported by any member of the committee who has agreed to such a meeting and members of the secretariat. The secretariat may meet with stakeholders to discuss matters that are of a procedural or administrative nature or to clarify a technical matter which requires expertise available in the secretariat provided that the member of the secretariat has been present in the relevant deliberations.

5. Maintenance of confidentiality

Committee members should be provided with a copy of the confidentiality policy and upon review must sign a confidentiality agreement:

- on appointment, and
- annually

using the format provided in **appendix A**

The committee secretariat will provide the member with the policy and ensure that the confidentiality agreement has been received upon appointment and then annually.

All source documentation must comply with relevant copyright provisions and should remain confidential unless approved by the NEMLC. During the review strict confidentiality must be maintained on all draft documents until consensus have been reached at the level of the NEMLC that such a document may be released for consultation or public consumption. Members of the technical committee must note that consensus and approval by the sub committee does not lift the confidentiality restriction until such time as the NEMLC has pronounced on the matter. A reviewer may however consult with experts in accordance with the terms of references and in consultation with the relevant committee. Where such consultation requires the disclosure of any significant sections of technical documents the recipient must sign a confidentiality agreement using the format provided in **appendix A.** When the restriction is lifted the expert should be informed of such.

For the purposes of confidentiality the restriction refers to information contained in the document whether it is disclosed verbally, electronically or as a hard copy.

The maintenance of confidentiality also requires procedural safeguards. Final minutes tabled at the NEMLC should not identify the names of individuals although the working version may have transient reference to individuals using initials in order to track contributions that are outstanding. Although the minutes adopted by the technical committee may have residual reference to these initials their removal is considered mandatory and administrative.

All materials related to the review process must be stored in a secure manner to prevent unauthorised access. They must be transmitted using secure carriers and technologies. When documentation is no longer required, it must be destroyed using a secure method such as burning or shredding or returned to the secretariat for destruction.

When a member is faced with a request for information by an external stakeholder which he or she feels has merit or is in the interest of public health they should consult the chairperson of the relevant Expert Review committee who in turn will refer the matter to the chairperson of the NEMLC unless the aforementioned has delegated such powers.

A copy of the confidentiality policy should be available to any member of the public who expresses an interest in accessing information or where they are of the opinion that the agreement has been transgressed.

6. Handling of disclosure of confidential information

A determination should be made as whether the disclosure was:

- outside of the provisions of this policy, or
- inadvertent, or
- clearly in disregard of this policy.

Furthermore discussion should be lead with respect to the harm or potential harm such a disclosure may have held for the review process, individuals who have contributed or the government.

The chair in consultation with the committee may rule that:

- The member reviews the policy and discusses its provisions with the chairperson and signs a new confidentiality agreement.
- The member takes corrective measures in order to prevent further inadvertent disclosures.
- The member is excluded from participation of meetings and/or consultation.

7. Record of agreement

The secretariat should keep a record of:

- names of individuals who signed agreements on appointment, as the need first arises or through the annual process.
- names of individuals 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.

8. Publication

Information regarding this policy and agreements with members may be made available to third parties if compelled in terms of the Rules of Court pursuant to litigation or by virtue of the provisions of the Promotion of Access to Information Act, 2000 (Act 2 of 2000). The latter requires the protection of personal information and contains procedures which require consultation with the person to whom the information relates. Therefore in the event of compulsory disclosure, this will not take place without prior consultation with the affected party.