



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Affordable Medicines Directorate

Conflict of Interest Policy

1. Introduction

This policy outlines the principles and process of identifying and managing actual, potential or perceived conflict of interest of individuals involved in any committee operating under the auspices of the Affordable Medicines Directorate (AMD) of the National Department of Health (NDoH).

It deals with the identification, declaration, assessment and management of any interest/s of an individual, which may conflict with the duties and/or decision making of a committee, such that the individual concerned may not be independent, objective and impartial in relation to such duties.

Decisions taken by committees could have a substantial impact on the health and well-being of South Africans as well on the spending of public funds. There may also be direct or indirect consequences of these decisions which may include, but are not limited to, changes in clinical practice, utilisation and uptake of medicines, systems and/or technologies, supply chain considerations, integrity of master data and perceived validation of prior research.

The interests of all individuals who could influence the decisions or duties of a committee must be identified, declared, assessed and managed, to as far as possible, prevent any advice or recommendation made by a committee being challenged on the basis of an actual or perceived conflict of interest of individuals involved. The personal interests of any member or other meeting participant, should not take precedence over the interests of public health.

Appropriate management of actual, potential or perceived conflict of interest protects the reputation and integrity of committees by helping to ensure their impartiality and independence. This helps to ensure that the advice and recommendations provided reflect the highest standards of professionalism and minimise risk to the NDoH.

Implementation and adherence to this policy will assist in confirming that the work done by committees is transparent, and that decisions taken are balanced, credible, independent of bias, and of a high ethical standard.

2. Abbreviations and Definitions

2.1. Abbreviations

AMD	Affordable Medicines Directorate
COI	Conflict of Interest
DOI	Declaration of Interest
NDoH	National Department of Health

2.2. Definitions

Assessor of interest means the person who is responsible for the assessment of the conflict of interest or potential conflict of interest of an individual.

Chairperson means the person elected, appointed or nominated in accordance with the terms of reference of the relevant committee.

Commercial entity means any commercial company, organisation, individual, group or association that has or may have a direct or indirect interest in the decisions and work undertaken by a committee, and includes legal or natural persons who (i) own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant commercial entity; (ii) are controlled by; or (iii) are under common control of a commercial entity and includes non-profit entities, as well as researchers and research organisations such as universities.

Committee means any committee which operates under the auspices of the AMD.

Conflict of interest means any financial or other interest or undertaking that could directly or indirectly compromise the performance of an individual's duties in a committee, or the reputation of a department within the public service in its relationship with its stakeholders.¹

Co-opted expert means an individual with particular expertise in a specific field who performs a technical review and/or provides input to a committee whether verbally or in writing, regardless of whether or not such input is provided in terms of a contract signed with such person.

Immediate family member means an individual within the close family circle or first degree relative of a natural person such as a sibling, parent, child, partner or spouse.

Interest means any direct or indirect investment or involvement in an undertaking.

Member means an individual appointed to a committee in accordance with the terms of reference of such committee.

Meeting participant means an individual temporarily included and/or co-opted, as well as observers or any other individuals attending any meeting of a committee.

Personnel means individuals employed by the NDoH.

Vice-Chairperson means the person elected, appointed or nominated in accordance with the terms of reference of the relevant committee.

3. Purpose of the policy

The purpose of this policy is to protect the integrity of decision-making of committees operating under the auspices of the AMD, through the identification, declaration, assessment, management and disclosure of any interest/s of individuals which relate to the work of committees. It provides for the management of actual and potential conflict of interest, and where appropriate, recusal or exclusion of individuals from involvement in discussions and/or decision making.

4. Scope of the policy

This policy applies to chairpersons, all committee members, other meeting participants as well as personnel involved in the management and technical activities of a committee and includes

¹ Section A(1) Notice 865 of 2009 The Public Service Commission Rules of the Public Service Commission: Managing Conflicts of Interest identified through the Financial Discloser Framework for Senior Managers

any other individual present at any meeting of a committee or involved in any way with the work of such committee.

5. Categorisation of Interests

When identifying and managing interests, it is important to determine both the nature and type of interest of an individual to enable effective, consistent and transparent management thereof.

Interests may be categorised as specific or non-specific. A **non-specific interest** is one where the actual or potential conflict relates to a general area of interest or involvement of an individual. A **specific interest** relates to a situation where the actual or potential conflict of interest of an individual relates directly to a matter under consideration by a committee.

The distinction between 'specific' and 'non-specific' interests determines the process and timing of addressing any actual, potential or perceived conflict of interest.

5.1. Types of interests

An interest may also be categorised based on whether or not an individual derives personal or non-personal benefit, and then categorised further based on whether or not he/she derives a financial benefit therefrom. (Refer Appendix 1)

5.1.1. Personal and non-personal interests

An interest is considered to be "personal" if the individual or an immediate family member of such individual gained, or currently gains, monetary or other value in their personal capacity from an interaction with any commercial entity that has or may have an interest in the activities of the committee. Personal interests include but are not limited to, financial gain, personal opinions, research interests or any other interests.

An interest is considered to be "non-personal" if an individual is employed by or contracted to an organisation or institution that gained, or currently gains monetary or other value from an interaction with any commercial entity, which has or may have an interest in the activities of the committee and decisions made by the committee.

5.1.2. Financial interests

Personal and non-personal interests can be divided further into financial or non-financial interests.

Financial interests include any arrangement or relationship where there is the opportunity for financial gain or benefit from a commercial entity by the individual or one of his/her immediate family members, or an organisation where the individual was employed, or to which he/she was contracted in at least the past four years or is expected to be employed or contracted in the next year. This period may be extended if the person declaring an interest believes that it is necessary to declare any interest or potential interest outside this period. This includes interests of a monetary or economic nature that are foreseen as possible or probable, including signed or anticipated contractual arrangements with commercial entities.

Personal financial interests include but are not limited to:

- Any employment, consultancy, directorship, or other position with a commercial entity which attracts regular or occasional payments in cash or kind, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;
- Financial interests in a commercial entity by an individual or his/her immediate family member;
- Any payments for service or research made to an individual or his/her immediate family member in at least the past four years or expected to be made in the next one year, by a commercial entity;
- Any investments (include shares, equity or bonds) in a commercial entity held by the individual, where the individual has control over the selection of shares/composition of the fund, but excludes unit trusts and pension funds in which the individual has no control over the related investments;
- Intellectual property rights (e.g. patents, patents in which the individual has a financial interest, copyrights, and royalties from such rights);
- A financial interest in a substance, technology or process to be considered in, or otherwise related to, the subject-matter of the meeting or work of the committee;
- Any expenses or hospitality provided by a commercial entity; or
- Any research grants, travel imbursements or consulting arrangements sponsored by a commercial entity, other than the employer of the individual concerned, including the NDoH, a Provincial Department of Health or any other organisation.

Non-personal financial interests involve payments or other financial benefits made in the past to a department or organisation by which the individual is employed or to whom he/she is affiliated, but which is not received personally, e.g. commercial grants, sponsored fellowships, funds for a post, unit, consultancy services, travel or research.

5.1.3. Non-financial interests

Personal non-financial interests include but are not limited to:

- any clear opinions an individual may hold, or published statements in which he/she expressed a clear opinion on a matter under review as a result of a research project, evidence review, or association with a society, charity, advocacy group, academic institution or any other organisation related to the specific and non-specific areas of focus of the committee;
- any reputational risks to the individual in relation to the matter under consideration;
- personal areas of interest;
- representation on boards, research bodies, statutory bodies, committees or other bodies undertaking the development of other guidelines; or
- access to classified or proprietary information that the individual cannot disclose to the committee.

Non-personal non-financial interests refer to any published statements or official positions held by the organisation by which the individual is employed or to which he/she is contracted, or association, charity or advocacy group of which the individual is a member; where a clear opinion about the intervention under review has been expressed, which may be perceived to alter behavior and of which the person declaring an interest is aware.

6. Declaration of Interests

Each member or other meeting participant must identify and declare all interests prior to a meeting of a committee. When an individual is uncertain as to whether an interest should be declared, he or she should seek guidance from the Director: AMD or the chairperson or vice-chairperson of the relevant committee.

Non-specific interests must be declared prior to appointment to a committee, on an annual basis thereafter or as the need arises and updated prior to each meeting of the committee.

In addition, specific interests must be declared by members and other meeting participants prior to each meeting of a committee in accordance with a time frame determined by the Director: AMD, in consultation with the chairperson or vice-chairperson of a committee.

The importance of declaring interests and the potential consequences of non-disclosure should be discussed in detail with prospective members of a committee prior to appointment or nomination, and with members of a committee on an annual basis. Identification of a conflict of interest will not necessarily prohibit membership or involvement in a committee, but will allow the opportunity to manage conflicts identified appropriately.

Any person requested by a committee to provide information/input that will inform decision-making must declare his/her interests and await a ruling thereon by the relevant assessor of interest before any work is started. This process must be repeated for each request received.

Interests should be declared and documented by all members and other meeting participants by completing a declaration of interest form.

The secretariat of the committee must provide a summary of declaration of interests by members and other meeting participants to the Director: AMD.

7. Assessment of Interests

Assessment of all non-specific declarations of interest must be conducted prior to appointment of members onto a committee and on an annual basis. An assessment of all declarations of interest (specific and non-specific) must be conducted prior to each meeting of a committee. Assessments must be performed in accordance with Appendix 1 to determine if a COI exists and if so, the level of significance. Table 1 provides details of the persons responsible for the assessment of interest of various categories of person.

Table 1: Responsible individuals in assessment of interests

Person declaring interest	Assessor of Interest
Prospective member of a committee	Director: AMD or persons responsible for selection or appointment of members of a committee
Member of a committee	Chairperson or vice-chairperson of relevant committee
Meeting participant (who is not a member of the committee)	Chairperson or vice-chairperson of relevant committee
Chairperson	Director: AMD or appointee as specified in the terms of reference of the committee

Person declaring interest	Assessor of Interest
AMD Personnel	Director: AMD
Director of AMD	DDG: NHI

The persons responsible for the assessment of interest may refer a matter related to declaration of interest to the relevant committee for discussion. The interest declared may also be discussed further with the declarer thereof, to obtain more insight or information. Final responsibility for the classification, and management of COIs, rests with the assessor of interest as provided in Table 1. The Director: AMD may consult with the DDG: NHI as needed on interests declared by prospective committee members, committee members or meeting participants.

7.1. *Classifying interests*

The individual/s responsible for assessment of interest will evaluate the declarations of interest and classify each interest accordingly.

An interest can be classified as ‘no conflict’; ‘insignificant’; ‘potentially significant’, or ‘clearly significant’. Appendix 1 details the steps to categorise each interest declared, timeframes for declaration, assessment of significance and management according to significance.

The classification will be recorded with a written statement, explaining the reason/s for such classification, and signed by the person/s responsible for the assessment.

8. Management of declared interests

The management of interests includes the recording and monitoring of interests, the actions taken to manage COIs, as well as the management of non-compliance with this policy (See Appendix 1).

Due to the specific duties of the chairpersons of committees, all their interests should be carefully considered and documented before appointment.

8.1. *Recording of interests*

All declared interests of the chairperson, members and other meeting participants should be collated by the secretariat. Non-specific interests that may be relevant at a specific meeting must be noted in the agenda for discussion at that meeting. Receipt of declarations of interest prior to commencement of a committee meeting should be recorded in the minutes, as well as the actions taken to manage any COIs identified. All new interests and COIs should be added to the record of declared interest at the start of any meeting, and should be included as part of the meeting documentation. Conflicts should be addressed prior to proceeding to other agenda items.

8.2. *Monitoring Conflict of Interests*

Non-specific and specific interests and classified COIs need to be carefully considered by the assessor/s of interest during the planning of committee activities, as COIs may compromise activity prioritisation of the committee. Before meetings that involve formulation of the committee’s project plan, specific interests should be declared and reviewed. In addition, the

record of declared interests should be reviewed for all non-specific and specific interests declared previously. Details regarding who proposed and seconded potential committee activities should be recorded in the minutes.

Once the project plan has been finalised, responsible individuals (Table 1) should assess declared non-specific interests against the project plan, and document any identified COIs that may be relevant to a particular matter.

All interests and COIs relevant to any committee activity must be recorded in the record of declared interests and then reviewed the day before each meeting by the assessors of interest. At the beginning of the meeting, as an agenda item, all newly declared interests and COIs, should be discussed with the committee led by the responsible individual. The agenda should allow for the chairperson, vice-chairperson, AMD personnel or committee members to raise any concerns related to any previously declared interests or COIs.

8.3. *Actions for managing Conflicts of Interests*

When an interest has been declared and a COI has been identified, the following actions can be carried out by the responsible individual (See Table 1), to manage the COI:

1. No COI

No action required.

2. Insignificant COI

Member or other meeting participant may participate in all applicable facets of meeting provided his/her interests are recorded and he/she provides an undertaking that conflicts or relationships will not bias or influence his/her involvement in committee activities.

3. Potentially significant COI, but expert insight would benefit decision

Member or other meeting participant should have limited involvement or recuse themselves from the particular agenda item, review, appraisal, or decision of committee. The management of potentially significant COI is decided upon by the responsible assessors of interest.

4. Clearly significant COI

Member or other meeting participant should recuse themselves and be excluded from participation in decision making relating to the agenda item in question. The management of clearly significant COI is decided upon by the responsible assessors of interest.

The affected person shall be given the opportunity to clarify his/her position, where after the assessor of interest shall make a decision in the absence of the affected person. Where a clearly significant conflict of interest is likely to recur, despite the mitigating measures applied on previous occasions, the assessor of interest should consider whether it is appropriate for such member to continue to serve on the committee, and make a decision accordingly.

In terms of interests declared by co-opted experts or advisors which are deemed to be significant, the responsible assessor of interest will determine if the work should still be delivered by that individual or whether alternate arrangements should be made.

8.4. Process to manage non-compliance with this policy

Potentially significant and clearly significant COI should be discussed prior to proceeding further with the agenda items of a meeting to determine if a specific member(s) or other meeting participant should be recused from decision-making. This should be managed by the chairperson and documented by the secretariat.

In the event that an individual has failed to declare an interest, a written explanatory statement about the non-disclosure must be provided by the individual and the matter must be investigated by the responsible individual to determine:

- Whether the lack of disclosure was intentional;
- The significance of the undisclosed interest (according to the classification above); and
- If the declared interest directly affected any review, appraisal, recommendation, decision or activity of the committee.

During such an investigation, the member or other meeting participant must recuse him/herself from all committee activities until the investigation is concluded.

On conclusion of the investigation the following actions may be taken in accordance with the terms of reference and in line with applicable legislation.

9. Record and Publication of Declared Interests and Conflicts of Interests

A record of the declared interests and COIs shall be kept at the NDoH including:

- Names of individuals who declared interests on appointment, as the interest first arose or through the annual declaration, and the nature of such interest;
- Names of individuals who have declared interests at meetings - giving dates, names of relevant products and companies, details of the interest declared, whether the member or other meeting participant took part in the proceedings and resulting action that took place regarding management of the COI.

Information disclosed on this form should be included in the minutes of each meeting and may be made available to third parties or disclosed pursuant to a requirement or request by operation of any applicable law, regulation or court order.

Summarised annual declarations of interest should be published on the NDoH website. A rolling form of specific COIs declared at each meeting, as well as changes to non-specific COIs, should also be maintained by the Committee Secretariat and published on the NDoH website.

Where a technical document is developed for the committee and published, such as a medicine review, the individual/s responsible for the document should have relevant summarised declarations of interest included as part of the document.

10. Roles and Responsibilities

Individual	Roles and Responsibilities
Assessor/s of Interest	<ul style="list-style-type: none"> • Ensure that the declarations of interest of members and other meeting participants have been received upon appointment, annually and at each committee meeting; and • Assess the potential COI declared by an individual in line with this policy.
Committee Secretariat	<ul style="list-style-type: none"> • Administer declaration of interest forms and ensure that the declarations of interest of members and other meeting participants have been received upon appointment, annually and at each committee meeting, as applicable; • Record, store and publish declarations of interest in line with this policy; • Declare their own actual and potential COIs; and • Ensure recusal of committee members and meeting participants occurs (as appropriate) during decision-making and adequate documentation of such action.
Committee members and other meeting participants	<ul style="list-style-type: none"> • Declare all potential interests in line with this policy before appointment to a committee, annually and at every committee meeting, as applicable.
Senior Management of AMD	<ul style="list-style-type: none"> • Assess and manage potential interests of members prior to joining a committee, as well as declaring their own actual and potential COIs, as outlined in section 7.

11. Related Documents

- Terms of reference of committees operating under the auspices of AMD
- National Essential Medicines List Committee Declaration of Interests Guidance Document (also applicable to Expert Review Committees)
- Confidentiality Guideline for committees operating under the auspices of AMD

12. Sources

1. National Department of Health. Declaration of Interests Guidance Document: A code of practice for the National Essential Medicines List Committee, members of technical expert review committees [Internet].
2. Office of the President. 1997. Public Service Commission Act (Act No. 46 of 1997). Pretoria, South Africa. 3.
3. Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med* [Internet]. 2015 Oct 6 [cited 2017 Sep 21];163(7):548. Available from: <http://annals.org/article.aspx?doi=10.7326/M14-1885>
4. Canadian Agency for Drugs and Technologies in Health (CADTH). Conflict of Interest Guidelines for CADTH - Expert Committee and Panel Members [Internet]. 2016 [cited 2017 Sep 21]. Available from: https://www.cadth.ca/sites/default/files/corporate/CADTH_COI-Guidelines-Committ-Panels_e.pdf

5. Scottish Medicines Consortium. Code of practice on declarations of interest [Internet]. 2017 [cited 2017 Sep 21]. Available from: https://www.scottishmedicines.org.uk/files/about/CODE_OF_PRACTICE_ON_DECLARATIONS_OF_INTEREST_updated_March_2017.pdf
6. National Institute for Health and Care Excellence (NICE). Policy on Conflicts of Interest [Internet]. 2014 [cited 2017 Sep 21]. Available from: <https://www.nice.org.uk/media/default/about/who-we-are/policies-and-procedures/code-of-practice-for-declaring-and-managing-conflicts-of-interest.pdf>.
7. Parrish A, Blockman M. Who will guard the guards? Medical leadership and conflict of interest in South African healthcare. SAMJ [Internet]. 2014 [cited 06 October 2017]; 104 (11): 757 – 758. Available from: <http://www.samj.org.za/index.php/samj/article/view/8546/6317>.
8. Frybourg S, Remuzat C, Kornfeld A & Toumi M. Conflict of interest in Health Technology Assessment decisions: case law in France and impact on reimbursement decisions. 2015. *Journal of Market Access & Health Policy* [Internet]. 2015 [cited 2017 Oct 06], Vol. 3 (1).
9. Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Chapter 2, Principles for Identifying and Assessing Conflicts of Interest Washington (DC): National Academies Press (US); [Internet] 2009 [cited 2017 Oct 6]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK22937/>
10. Australian Government Department of Health Therapeutic Goods Administration, Conflicts of interest and confidentiality obligations “Guidance for TGA advisory committee members”. Version 2.0, May 2018

Appendix 1. Overview of interests to declare and strategies to manage conflicts of interest



