

MEDICINES CONTROL COUNCIL



POLICY ON MANAGEMENT OF POTENTIAL CONFLICT OF INTEREST NOVEMBER 2011

1 INTRODUCTION

Section 6(4) of the Medicines and Related Substances Act 101 of 1965, "The Medicines Act" states as follows:

"A member of the Medicines Control Council or of a committee appointed in terms of section 9 shall declare his or her commercial interests related to the pharmaceutical or health care industry, which interests shall include, but shall not be limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind, and shall recuse himself or herself from any discussion or decision-making to which the said interests relate or may relate."

The MCC is responsible for scientific evaluation of medicinal products and related substances for human and veterinary use. The MCC also regulates the conduct of clinical trials and licences manufacturers, wholesalers and distributors of medicines. The MCC also advises the Minister on the classification of medicines and their control.

The MCC has a significant impact on the protection and promotion of human and animal health. The MCC may, acting in terms of section 9 (1) (b) of the Medicines Act and subject to the approval of the Minister appoint expert committees and working groups to assist it in its work. Once these bodies have been established, the MCC – acting in terms of section 9(3) of the Medicines Act, may appoint their members.

Integrity and high standards of professional conduct by all involved in the work of the MCC (such as members, expert committee members, sub-committees, working groups, expert consultants and secretarial support) are critical to maintain the independence of the MCC and its reputation.

Members of the MCC and its expert committees have been appointed on the basis of their expertise such as the assessment of medicinal products for human and animal use and their legal expertise as well as their integrity to provide advice in the public interest. Owing to their skills, expertise and experience as well as the nature and mandates of their institutions of primary employment, it is possible that members of the MCC and its expert committees have, or may have had some association with the pharmaceutical or health care industry.

1 **Introduction - continued**

Conflict of interest policies are designed to protect the integrity of decision-making processes through disclosure, transparency and where appropriate, recusal (or in exceptional circumstances, exclusion). As the MCC must ensure that decisions are taken and perceived to be taken solely on the basis of evidence and in the public interest, such a policy is clearly required.

2 **SCOPE**

The policy applies to:

- Members of Council
- The Chairpersons of Expert Technical Committees appointed by the MCC including ad hoc members and members of any working groups and/ or task teams that the MCC may, from time to time, establish and
- Members of the secretariat who by virtue of their support functions are involved in the work of the MCC and its structures.

3 **DEFINITIONS**

Unless the context indicates otherwise, the following words and phrases used in this document have the following meanings:

- Company means business that is involved with medicines or acts as an applicant
- Healthcare industry means businesses that are involved in health care and includes Clinical Research organisations
- “Pharmaceutical industry” means companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicines as defined in the Medicines Act as well as trade associations representing such companies, partnerships or individuals.
- “Professional organisations” refers to colleges, health professional associations and societies, universities, research institutions, “Affected person” means any person to whom this policy applies
- “secretariat” refers to employees of the National Department of Health (NDoH) who provide technical or administrative support to the MCC and its structures.

“Direct interest in a company” includes, but is not limited to:

- Employment with a company
- Consultancy with a company
- Strategic advisory role for a company
- Financial interests in a company, including but not limited to:
 - The holding of shares or bonds, (except share holdings through general mutual funds or similar arrangements where the person holding interest has no control over the selection of shares).
 - Compensation, fees, honoraria and /or salaries paid directly to an individual by the relevant company; and,
 - Reimbursement by the relevant company of expenses associated with conference or meeting attendance (e.g. accommodation and travel costs)

3 **Definitions - continued**

- A proprietary interest in a substance, technology or process
- Expert witness in a court of law in a case involving the relevant company
- Employment, consultancy, directorship, or any other work completed or position held during the past five years, whether or not paid, in or for any commercial entity which has an interest in the subject matter of the meeting or area of work, or an ongoing negotiation concerning prospective employment or other association with the commercial entity
- Payment or other financial support covering any period within the past five years, or an expectation of financial support for the future, from a commercial entity with an interest in the subject matter of the relevant meeting or area of work, including but not limited to grants, fellowships and the financing of posts
- Access to classified or proprietary information concerning or relevant to the subject matter of the relevant meeting or area of work; and
- Direct involvement in the development of a medicine that is the subject matter of the relevant meeting or area of work.

Indirect interest in a company includes but is not limited to:-:

- Principal investigator in a clinical trial of relevance to the MCC's or Expert Committee's mandate
- Investigator in a clinical trial of relevance to the MCC's or Expert Committee's mandate
- Individual's institution receives a grant or other funding from a pharmaceutical company (e.g. sponsoring of a research chair at a university department or an organization receives funding for research work and the individual is employed by such an organization, is a volunteer or representative of such organization and receives no personal gain).
- Involvement in research work for a company
- Family interests, in which a spouse, child, parent sibling or other close relative if the latter resides in the same household as the member, employed (or applies for employment) by a party that may have an interest in the subject matter of the meeting or work of relevance to the MCC's or Expert Committee's mandate.

4 **PURPOSE**

Conflict of interest policies are designed to protect the integrity of decision-making processes through disclosure and transparency and, where appropriate, recusal.

5 **PRINCIPLES OF THE POLICY**

5.1 Robustness

Direct versus indirect interest

- a. The focus is more on direct interests leading to the highest risk level and resulting in restricted involvement in the Council's activities.
- b. Indirect interests leading to an intermediate risk level with mitigating strategies to balance limiting involvement in the council's activities and accessing the best expertise on a particular scientific matter.

5.2 Efficiency

Conflicts of interest are categorised into three groups namely: direct interests, indirect interests and no interests. Direct interests are assigned the highest risk level (level 3), indirect interests an intermediate risk level (level 2) and no interests the lowest risk level (level 1).

5.3 Transparency

A record shall be kept at the NDoH of:

- a. Names of affected who have declared interests on appointment, as the interest first arises and/or through the annual declarations well as the nature of the interest;
- b. Names of affected persons who have declared interests at meetings giving dates, names of relevant medicines and companies, details of the interest declared and whether the member took part in the proceedings.
- c. The level of interest of each affected person.
- d. The list of MCC members, expert committee members and secretariat shall be published on the MCC website.

6 DECLARATION OF INTERESTS

Each affected person shall before or at the first MCC or committee meeting he or she attends each year of the period of tenure of such member submit to that body's chairperson, a list of his or her direct and indirect interests, in companies in the pharmaceutical or health care industries.

The Chairperson and an evaluation advisory group nominated by the MCC shall determine whether such conflict:

- a. Is direct
- b. Indirect
- c. Requires a cooling - off period and
- d. The nominated expert or member of the secretariat shall be advised of the assessment outcome accordingly.

In addition, an affected person shall, with reference to any particular item on the agenda of an MCC or committee meeting, make full disclosure of his or her direct or indirect interest in companies in the pharmaceutical and/or health care industry whose medicines or operations are the subject matter of any agenda item.

Having made such a disclosure:

- The affected person shall be given the opportunity to take a decision.
- If there is no recusal or only a partial recusal, the MCC or relevant committee will deliberate with the affected person out of the room.
- If there is no consensus, the majority decision will be taken.
- If there is no majority, the chairperson has a casting vote.

7 DUTIES OF CHAIRPERSONS

- a. The Chairperson of MCC and the Chairpersons of the expert committees or working groups will ensure that the declarations of conflict of interest of members have been received upon appointment and then annually.
- b. The registrar of medicines shall ensure that the declarations of conflict of interest of the secretariat members have been received upon appointment and then annually.
- c. The Chairperson of Council shall ensure that all conflicts declared are evaluated and a determination is made whether they are indirect, direct or require a cooling-off period.
- d. If the expert committee chair is unsure on the management of any potential conflict the matter should be referred to MCC for a decision.

8 PUBLICATION

Information provided will be treated confidentially and only disclosed where required and requested, in accordance with the provisions of the Promotion of Access to Information Act (Act 2 of 2000).

The Policy will be published in the Government gazette and on the MCC website.

MEDICINES CONTROL COUNCIL



GUIDE FOR COMPLETING THE FORM

The form needs to be completed in the person's own handwriting and certified by a Commissioner of Oaths. Answering "Yes" to a question on this form does not automatically disqualify or limit participation of a member in a Medicines Control Council activity.

DECLARATION OF INTEREST OF COUNCIL, COMMITTEE, WORKING GROUP & STAFF MEMBER

SURNAME AND NAME:	
POSTAL ADDRESS:	
RESIDENTIAL ADDRESS:	
POSITION:	
NAME OF DEPARTMENT:	
TELEPHONE NO:	
E-MAIL ADDRESS:	

EMPLOYMENT AND CONSULTING

Within the past 5 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?

- 1a Employment Yes No
- 1b Consulting, including service as a technical or other advisor Yes No

RESEARCH SUPPORT

Within the past 5 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes No

- 2b Non-monetary support valued at more than R10 000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes No
- 2c Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work Yes No

INVESTMENT INTERESTS

Do you have current investments (valued at more than R100 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

- 3a Stocks, bonds, stock options, other securities Yes No
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company) Yes No

INTELLECTUAL PROPERTY

Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

- 4a Patents, trademarks, or copyrights (including pending applications) Yes No
- 4b Proprietary know-how in a substance, technology or process Yes No

PUBLIC STATEMENTS AND POSITIONS (during the past 5 years)

- 5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes No
- 5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work? Yes No

ADDITIONAL INFORMATION

- 6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage? Yes No
- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes No
- 6c Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this MCC meeting or work? Yes No
- 6d Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes No

Nos. 1 – 4: Type of interest, question number and category (e.g. Intellectual Property 4.a copyrights) and basic descriptive details	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)
Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details				

CONSENT TO DISCLOSURE

By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product

DECLARATION: I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the Chairperson of MCC or Expert Committee and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

DATE: _____ SIGNATURE: _____

PLACE: