



MEDICINES CONTROL AGENCY

THE GAMBIA

Policy on External Experts and Declaration of Interests

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1 INTRODUCTION

- 1.1. The Medicines Control Agency (MCA) may seek advice from external experts in its decision-making processes of regulatory functions and activities such as product registration, authorisations, licensing, supervision, etc as deemed appropriate for the Agency.
- 1.2. External experts may/can be involved in expert committees, working groups and other scientific and technical meetings.
- 1.3. The Medicines and Related Products Act, 2014 stipulates in Part II, Section 4 (e) that the Agency shall foster co-operation between the Agency and other institutions or organizations and other stakeholders.
- 1.4. The Medicines and Related Products Regulations, 2020 requires in Part XIV, Section 86 that staff of the Agency, member of the Board or a member of a committee shall declare any interests related to any medicine or related product, which may be relevant to any decision-making and that a person who has an interest in a matter for consideration shall disclose the nature of that issue in writing and is disqualified from participating in any deliberations in respect to any decision-making on that matter.

2 PURPOSE AND SCOPE

- 2.1. This policy provides guidance on the selection of individual external experts to ensure the quality of work.
- 2.2. It sets out the practice for experts on direct and indirect interests, and the necessity to declare them in order to avoid and manage potential competing interests. In addition, it covers the question of confidentiality and discretion.
- 2.3. The policy applies to MCA staff involved in the appointment and management of external experts and the persons servicing as external experts.
- 2.4. It relates to the handling of competing interests of experts involved in activities carried out by the Agency in the context of the effective regulation and control of medicines and related products.
- 2.5. The application of this policy supports the proper functioning of the Agency in the performance of its roles and responsibilities.
- 2.6. This policy does not apply to ethical behaviour and conduct of MCA staff, as this is covered in the MCA Code of Ethics and Conduct Policy.

3 RESPONSIBILITIES

- 3.1. The Executive Director (ED) of MCA recruits, selects and appoints external experts with approval of the Governing Board, as required for the functioning of the Agency, and determines the tenure.
- 3.2. The Governing Board may recommend the services of advisers and selected experts.

- 3.3. The ED, in cooperation with the Governing Board, evaluates the Declaration of Interest (DOI) and assigns the interest level.
- 3.4. The external experts provide scientific and technical expertise to the Agency's activities as required.
- 3.5. An external expert is required to submit an up-to-date curriculum vitae (CV) and to sign the DOI and a Confidentiality Agreement before any of the activity begins.

4 RECRUITMENT AND SELECTION OF EXTERNAL EXPERTS

- 4.1. Experts may be recruited from public or private bodies or entities (i.e. government, industry and interested parties like universities or colleges, health facilities, other organisations including statutory bodies, pharmaceutical companies or any other source).
- 4.2. Any expert shall be required to have an appropriate degree and to be qualified by training and experience in regulatory affairs, medicines and related products evaluation with respect to quality, safety or efficacy, inspections, risk management, pharmacovigilance, clinical trials or quality control as needed, for the activities to be carried out.
- 4.3. Experts will be made aware of vacancies by publication on the MCA website, advertisements or through stakeholders.
- 4.4. Interested experts will be required to apply in writing, explicitly indicating in the cover letter their area of expertise and interest in relation to the vacancy, and to provide their CV and the DOI.
- 4.5. MCA selects and appoints external experts in accordance with its written procedures and the MCA Service Rules, and the recommendations of the Governing Board.

5 DURATION AND TERMINATION OF SERVICE

- 5.1. The duration of appointment depends on their functions and may last for a limited time for a certain activity in e.g. a working group or as an adviser, or for a longer period as e.g. an expert committee member.
- 5.2. The conditions of appointment will be detailed in a contract or agreement between the MCA and the expert and the required duties will be specified in the contract, agreement or terms of reference.
- 5.3. Premature termination of the service on either side must be expressed in writing as early as possible.

6 CONFLICTING INTERESTS

- 6.1. This policy is designed to avoid potentially compromising situations that could undermine or otherwise affect the work of the expert or activity in which the expert is involved with MCA. Consequently, the scope includes any interest that could reasonably be perceived to affect the functions that the expert is performing for the MCA.

- 6.2. Different categories (types) of interests are possible as highlighted below. However, it should be emphasised that some of the definitions cannot address all the various scenarios which may exist.
- 6.3. Any potentially conflicting interest must be declared by the external expert.

Conflict of Interest

- 6.4. Conflict of interest means any interest by an MCA expert that may affect or reasonably perceived to affect the expert's objectivity and independence in providing advice to the Agency.

Direct Interest

- 6.5. The conflict could involve personal financial gain, such as employment, consulting income or honoraria, a business interest, such as a partnership or joint venture; an investment, such as stocks or bonds; financial support for research from the private sector given directly to the expert or to his or her university or research institution; or an intellectual property interest, such as a patent or copyright.
- 6.6. A conflict could also arise where an expert's participation in an activity accords him or her access to proprietary information or gives the expert a commercial competitive advantage.

Interest of Others

- 6.7. A conflict of interest could also be created by interests of others who may, or may be perceived to, unduly influence the expert's views. A typical example is where an expert's work could affect or be affected by interests held by the expert's family, rather than the expert personally. Accordingly, relevant interests of the expert's immediate family members must be declared. In this policy family members include the expert's spouse, parents and children. "Spouse" includes a partner with whom the expert has a similar close personal relationship.
- 6.8. In addition, if the expert is aware that the outcome of the activity would benefit or adversely affect other parties with whom the expert has substantial common interests (whether personal, professional or financial), disclosure of those affected interests is also necessary. Examples of other parties include the expert's employer or close professional colleagues.

Public statements and positions

- 6.9. An expert's independent judgment could also be affected by public statements made and positions held which can cause a conflict of interest. For example, an expert may have taken a definite position related to the same product or subject matter by providing testimony as part of a regulatory or judicial process. The expert may serve on a board or hold an office in an organisation that has taken a position, on the subject, and he or she is expected to represent or defend it.

7 DECLARATION OF INTEREST

- 7.1. Generally, an analysis of a conflict of interest must be performed whenever MCA relies on the governance or independent advice of an expert in order to take a decision. In such cases, a Declaration of Interest (DOI) Form must

be completed whenever an expert is asked to serve in a governance or advisory role in a personal capacity and not as representative of his or her institution.

- 7.2. Where the expert is engaged under a contract or agreement or is serving on a voluntary (unpaid) basis or provides scientific and technical advice that is the basis for decision-making by the Agency, the basic rule is to request a DOI Form whenever the work involves;
 - (i) an assessment or analysis intended to lead to the development of recommendations, norms, guidelines or policies or
 - (ii) an evaluation of a product, compound, organism, process or methodology. In these circumstances, the DOI Form must be completed by the expert and evaluated by the Agency, before the activity begins.
- 7.3. A Declaration of Interest is not required if an expert is invited purely to "observe" and does not participate in the formulation of recommendations or advice, or is a representative of industry and other interest groups not invited to make an assessment or to give advice as an independent expert or is a Governing Board member invited because he or she is representing an organisation.
- 7.4. All completed DOI Forms will be kept confidential and will only be used to evaluate whether an expert's declared interest constitute a real, potential or apparent conflict of interest. The form itself is a working document of the Agency and should not be distributed or made public, also to protect legitimate privacy concerns of the experts. DOI Forms should be retained for at least ten (10) years consistent with procedures for the retention of confidential documents.

8 EVALUATION OF THE INFORMATION DISCLOSED

- 8.1. The DOI Form consists of a series of questions requesting disclosure of any interest relevant to the subject of the work to be performed or to be discussed at a meeting in which the expert has been invited to participate. If the expert answers any question in the affirmative, he/she is asked to supply further details at the end of the form.
- 8.2. An affirmative answer in the DOI Form does not automatically disqualify the expert. Rather, affirmative answers are screened by the Agency to determine if a potential conflict of interest exists. The MCA will request from the expert an updated curriculum vitae (CV) and will evaluate the responses in the DOI Form in conjunction with information in the expert's CV, since one may provide relevant information that is not apparent from the other.
- 8.3. The evaluation is to determine whether the expert may participate in the activity at all or whether the expert may do so but only under certain conditions.
- 8.4. The following actions should be undertaken to ensure that an appropriate and robust evaluation takes place:
 - the nature and value of the interest e.g. financial, investment, intellectual property;

- academic / intellectual vs. financial;
 - number of relevant interests declared on the DOI Form;
 - personal vs. non-personal (department or institution) nature of the declared interest;
 - if non-personal, the position and role of the expert in the department or institution;
 - the relevance and specificity of the declared interest in view of the subject matter of the meeting or work to be undertaken;
 - the timeliness of the declared interest;
 - whether the interest relates to an expert's family member or other party;
 - whether the interest could be attributed to a professional bias reflected repeatedly as part of expert testimony in a regulatory or judicial proceeding or by reason of the expert's office.
- 8.5. A conflict of interest evaluation essentially involves full consideration of the contribution, tasks and function of the expert as well as the availability of alternative experts with the required expertise to weigh the nature, type and magnitude of the expert's interest and therefore the degree to which the interest may be reasonably expected to influence the expert's judgment against the adequacy of measures/options available to protect the independence and integrity of the decision-making process.
- 8.6. If it is concluded that a declared interest is potentially significant, one of the following three options, or a combination of those options, may be considered to determine under what conditions, if any, the expert may participate in the activity or meeting:
- **Conditional Participation:** Where the expert's interest is relatively minor the expert's involvement in the meeting or work must be publicly disclosed.
 - **Partial Exclusion:** This would limit the expert's involvement, either by excluding the expert from that portion of the meeting or work where a conflict of interest has been identified and/or excluding the expert from participating in the decision-making process.
 - **Total Exclusion.** Here, the expert is excluded from the meeting or work altogether, where the nature of the conflict of interest is too significant vis-à-vis the overall objective, or where limiting the expert's involvement to only a portion of the meeting or work is not feasible.
- 8.7. In general, a useful approach is to assess the situation through the eyes of a hypothetical "reasonable person on the street". If an appropriately well informed person might reasonably conclude that the work or proceedings as a whole might be tainted, or could be unfair or unduly influenced by the expert's interest in the outcome, then the expert's involvement should be excluded or limited (rather than merely disclosed).

9 PUBLIC DISCLOSURE

- 9.1. As stated above, if an expert declares an interest that leads the Agency to either conditionally approve his/her participation in a meeting or work or to

partially exclude him/her from a meeting or activity, then the MCA must make a public disclosure of that interest to meeting or work participants as well as in the final report, relevant publication or work product emanating from such meeting or activity.

- 9.2. Public disclosure of an expert's interest does not eliminate the conflict of interest but rather mitigates it by making others aware of the interest thereby enabling them to exercise an appropriate degree of critical assessment about the views or recommendations that are made by that expert.
- 9.3. The following are examples of interests that must be publicly disclosed:
 - financial interests and investments (stocks, compensation or otherwise);
 - financial support for research activities provided by the private sector directly to the expert or indirectly to his/her university or research institution;
 - patents or other form of intellectual property that are held by an expert or that he/she is a beneficiary of and that relate to the subject matter of the meeting or activity;
 - consultancies, employment relationships or other external professional activities as well as the name of the entities with whom the expert has or has had a relationship as well as a general statement of the duration of such relationship, if known;
 - "speaking" fees from, or sponsored participation in, lectures, symposia and seminars.

10 CONFIDENTIALITY AND USE OF OFFICIAL INFORMATION

- 10.1. The protection of personal data and intellectual property and respect of confidential information is an essential part of the relationship between the Agency and stakeholders. The MCA recognises that experts have access to confidential information.
- 10.2. Experts are advised to exercise care when answering questions so as not to supply information to third parties where this information is not public. Discretion should be exercised when discussing professional work with third parties, including family and friends, and with colleagues or third parties in a public place, e.g. restaurant, public transport. Common sense must be applied regarding indirect questions seeking to obtain information.
- 10.3. Experts have a life-long duty of confidentiality even after they have ceased their relationship with the MCA. This covers all information of the kind covered by the obligation of professional secrecy. Once a document or information has been made public, the duty of confidentiality ceases only to the extent of the information released into the public domain.

11 REFERENCES

- WHO Guidelines for Declaration of Interests (WHO Experts), 850 E LEG, June 2010

- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts, EMA/626261/2014, Rev. 1, October 2016
- The European Medicines Agency Code of Conduct, EMA/385894/2012 rev.1, June 2016
- MCA Service Rules, version 2, April 2021

12 DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	07 December 2020	New document
2	31 January 2022	Change of title; requirements for external experts included

Signature:
Executive Director

Date: