



Agencija za  
kvalitetu i  
akreditaciju  
u zdravstvu

## **Agency for Quality and Accreditation in Health Care**

Department for Development, Research and Health Technology Assessment

# **A Code of Practice for declaring and dealing with conflicts of interest in HTA process**

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This Document presents a combination of the following published documents which are adapted to Croatian setting: A Code of Practice for Declaring and Dealing with Conflicts of Interest (NICE), Form for Disclosure of Potential Conflict of Interest (IQWiG), and Guidelines for Authors of CADTH Health Technology Assessment Reports, The Canadian Agency for Drugs and Technologies in Health (CADTH), 2003.

The document is available from the Agency's website, [www.aaz.hr](http://www.aaz.hr)

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# **I CONFLICT OF INTEREST GUIDELINES**

## **Purpose of the Guidelines**

These guidelines are intended to ensure that all persons involved in the process of producing HTA reports, as well as other HTA documents, disclose any real or perceived conflict of interest situations.

## **Scope**

Conflict of interest guidelines apply to all individuals working on HTA process (HTA Assessment, Committee Appraisal and HTA Reports, as well as other HTA documents (all staff, consultants, contractors, collaborators, committee members, ad hoc groups, authors and reviewers of Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment), whether financial compensation has been or will be provided by Agency for Quality and Accreditation in Health Care.

## **Responsibility**

It is the joint responsibility of the Agency Director and the Assistant Director for HTA to ensure that all relevant parties complete a conflict of interest statement for each HTA project undertaken. It is the responsibility of the Assistant Director for HTA to ensure that such statements are accurately reflected in the published report and are also recorded in the project files (except for the amount of compensation, which remains confidential).

## **Compliance**

All relevant parties must comply with these conflict of interest guidelines as they ensure the integrity and impartiality of Agency and allow stakeholders to have confidence in Agency's objectivity. This policy requires individuals to make a thorough disclosure of real, potential or perceived conflicts of interest, specific and/or non-specific, financial, family and non-financial. Such conflicts may preclude participation in a particular project, but will not necessarily restrict participation in other projects.

## Description of Type of Conflict of Interest

Conflicts of interest (current or within the past three years, mentioned below) (*Specific* - for product under current evaluation and *Non-specific* – for other product, unrelated to the matter under consideration) are considered to be:

<b>Type of Conflict of Interest</b>
<b>1 Personal financial <i>specific</i></b>
2 Personal financial <i>non-specific</i>
<b>3 Personal family <i>specific</i></b>
4 Personal family <i>non-specific</i>
<b>5 Non-personal financial <i>specific</i></b>
6 Non-personal financial <i>non-specific</i>
<b>7 Personal non-financial <i>specific</i></b>

**Personal financial interest (1 and 2):** a current or within the past three years personal payment from manufacturer or owner or industry or sector of products; any consultancy, directorship, position in or work for healthcare industry that attracts regular or occasional payments in cash or in kind; any free-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind; any shareholdings, or other beneficial interest, in shares of a healthcare industry that are either held by the individual or for which the individual has legal responsibility; expenses and hospitality provided by a healthcare industry company including that required for accommodation, meals and travel to attend meetings and conference; funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No interests exist in the case of accrued pension rights from earlier employment in the healthcare industry.

**Personal family interest (3 and 4):** Same as personal financial interest but applicable to family members.

**Non-personal financial interest (5 and 6):** payments or other benefit that benefits a department or organization for which an individual has managerial responsibility, but which is not received personally; the holding of a fellowship endowed by the healthcare industry; any payment or other support by the health industry that does not convey any

financial or material benefit to an individual personally but might benefit him or her like a grant from a company for the running of a unit or department for which a member is responsible, a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is responsible; the commissioning of research or other work by or advice from, staff who work in a unit for which the member is responsible.

**Personal non-financial (7) interest in a topic under consideration might include, but is not limited to;** a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review; a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence; holding office in a professional organization or advocacy group with direct interest in the matter under consideration, other reputation risk in relation to an intervention under review.

## **II WHEN SHOULD INTERESTS BE DECLARED AND WHAT ACTION IS REQUIRED?**

It is inappropriate for the Chair and members of the Agency Board, the Chair of its HTA Advisory or Appraisal Committees and Working Group, the Agency Director, Assistant Director for HTA or other employees, or the employees of the national and international academic or scientific collaborating centers which take a part of assessment, to have **any current personal** interest. Nor should they accept *direct* expenses or hospitality from the healthcare industries, as reimbursement for the reasonable and proportional costs involved in travel, accommodation and associated subsistence, for attending conferences at which they have been asked to speak or otherwise play a formal role. Such expenditure should be determined in accordance with the Agency's and organizations' speaking engagements policy and through organizations common donation funds without specifying the purpose of such donation; established committees will decide on priorities and purposes for this donations amount).

Appendix A sets out for each group, when a declaration of interest should be made. Appendix B summarizes the action which should be taken, when interest are declared at Advisory or Appraisal committee meetings.

*- ON APPOINTMENT*

The chair, the other board members, and employees of the Agency must declare all categories of interests on appointment, and then annually. This also applies to the chairs and members of the Agency HTA Advisory or Appraisal committee, other bodies and the staff of the national and international academic or scientific collaborating centers which take part in assessment process.

All people mentioned above should divest themselves of their personal financial interests on appointment, or as soon as is practical thereafter, but no more than 3 months after.

The declaration of personal family interests by a member or employee will not bar his or her employment or appointment to the Board or other body. When this personal family interest may have a bearing on specific aspects of the work of the employee at the Agency or at the national and international academic or scientific collaborating centers which take part in assessment, then the employee should discuss this with line manager who will set up appropriate arrangements to ensure that the interest does not conflict with the employee's duties.

Any uncertainty about potential conflicts of members of any bodies on appointment should be resolved at the discretion of the relevant chair and recorded in the letter of appointment. Members with conflicts that could be regarded as prejudicing their contribution to the discussion should be excluded from the group or committee. It is recognized that individuals may have some interaction with the healthcare industry and, while this should be declared, it does not necessarily preclude membership of an advisory body.

*- AT HTA Advisory or APPRAISAL COMMITTEE and other HTA BODY MEETINGS*

Members and other individuals covered by this Code who are attending to take part in the meeting should declare relevant interests at each body meeting and at appeal panels and state into which of the following categories they believe the interest falls.

A person with personal financial specific or personal family specific interest shall take no part in the proceedings as they relate to the intervention or matter and will normally leave the meeting until this matter has been concluded.

A person with personal financial non-specific interest- may take part in the proceedings unless, exceptionally, the chairs rules otherwise.

A person with non-personal financial specific interest or personal family non-specific interest may take part in the proceedings unless personal knowledge of the intervention or matter either through own work, or through direct supervision of others peoples work. In either of these cases person should declare this interest and not take part in the proceedings except to answer questions.

A person with non-personal financial non-specific interest may take part in the proceedings unless, exceptionally, the chair rules otherwise.

For personal non-financial interest the chair of the body shall determine, on a case-by case basis, whether person should take part in the proceedings.

#### SPECIAL NOTES ON COMPETITOR INTERVENTIONS

If a member is aware that an intervention or matter under consideration is, or may become, a competitor of an intervention developed, manufactured, sold or supplied by a company in which the member has a current personal financial or personal family interest, such person should declare an interest in the company marketing the rival intervention. The member should seek the Chairman's guidance on whether to take part in the proceedings.

#### - *IN EVIDENCE PUBLICATIONS*

Where an individual covered by this Code is responsible *for authoring*, in whole or part, of an HTA Report or other HTA documents, such individual must declare any interests in accordance with this Code.

### **III RECORD OF INTEREST AND THEIR PUBLICATION**

A record is kept at the Agency of:

Names of individuals who have declared interest on appointment, as the interests first arise or through the annual declaration and the nature of the interest; Names of individuals who have declared interests at meetings giving dates, names of relevant

interventions and companies, details of the interest declared and whether the member took part in the proceedings.

Information about any interests declared under this Code will be made publicly available on the Agency's website, in the form of a statement of annual declarations, through the minutes of advisory bodies or in guidance publications (except amount of compensation).

### **Appendix A: When is it necessary to declare an interest?**

	<b>Declaration on appointment</b>	<b>Annual declaration</b>	<b>Declaration at HTA Advisory or Appraisal Committee meeting</b>	<b>Declaration in evidence publication</b>
Agency Board chair and members	Yes	Yes	Does not participate	Does not author evidence publications
Agency employees	Yes	Yes	Yes	Yes
Agency HTA Committee chair	Yes	Yes	Yes	Does not author evidence publications
Agency HTA Committee member	Yes (except ad hoc groups)	Yes (except ad hoc groups)	Yes	Yes
Academic and scientific employee which takes part in assessment	Yes	Yes	Yes	Yes
Evidence contractor	Discuss with Agency	Not relevant	Yes	Yes
Expert advisor	Not relevant	Not relevant	Yes	Yes

## Appendix B: Declaring interest at an Advisory body meeting

Type of interest	See Page	Action
1 Personal financial specific	2	Declare and withdraw
2 Personal financial non-specific	2	Declare and participate (unless, exceptionally, the chair of the Advisory body rules otherwise)
3 Personal family specific	2	Declare and withdraw
4 Personal family non-specific	2	Declare and participate (unless, exceptionally, the chair of the Advisory body rules otherwise)
5 Non-personal financial specific	2	Declare and participate, unless the individual has personal knowledge of the intervention or matter either through own work, or through direct supervision of others peoples work. In either of these cases person should declare this interest and not take part in the proceedings except to answer questions.
6 Non-personal financial non-specific	2	Declare and participate (unless, exceptionally, the chair of the Advisory body rules otherwise)
7 Personal non-financial specific	2	Declare – action is at discretion of the chair of the Advisory body

## Appendix C: Definition of terms

*Professional Organizations:* refers to the public health professional associations, bodies and societies, universities, or any other bodies with whom the Agency has a contractual relationship or with whom the Agency is considering entering a contractual relationship

*Advocacy Group:* organizations whose functions include speaking for and on behalf of individuals and groups with an interest in health or health-related matters of the kind on which Agency issues guidance

*Members:* all members of the committees and groups

*Employees:* full and part-time on contract employees of the Agency

*Family members:* a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible

*Expert advisor:* clinical, patient or other expert invited to attend and take part in an Agency HTA meeting

*Evidence contractor:* organizations that the Agency contracts, directly or indirectly, to supply part of evidence

**Appendix D:**

**Agency for Quality and Accreditation in Health Care**

Department for Development, Research and Health Technology Assessment

**Form for disclosure of potential conflict of interest in Health  
Technology Assessment (HTA) process**

HTA project name and number:

**CONFLICT OF INTEREST STATEMENT**

All individuals working in the whole or in part of HTA process; on HTA assessment and HTA reports, as well as other HTA documents, Advisory or Appraisal Committee (all Agency staff, consultants, contractors, collaborators, committee members, ad hoc groups, authors and reviewers of Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment) are required to declare an interest that might be a conflict, or be perceived as conflict of interest.

Please indicate whether you have current or have had, within the past three years, any of the following affiliations with companies that manufacture health technology (products) which are *Specific* (for product under current evaluation) and *Non-specific* (for other product, unrelated to the matter under consideration):

<b>Type of interest*</b>	<b>Yes</b>	<b>No</b>
<b>1 Personal financial <i>specific</i></b>		
<b>2 Personal financial <i>non-specific</i></b>		
<b>3 Personal family <i>specific</i></b>		
<b>4 Personal family <i>non-specific</i></b>		
<b>5 Non-personal financial <i>specific</i></b>		
<b>6 Non-personal financial <i>non-specific</i></b>		
<b>7 Personal non-financial <i>specific</i></b>		

**\*Description of Conflict of Interest type:**

Conflicts of interest (current or within the past three years, mentioned below), *Specific* - for product under current evaluation and/or *Non-specific* – for other products, unrelated to the matter under consideration, are considered to be:

**Personal financial interest (1 and 2):** a current or within the past three years, personal payment from manufacturer or owner or industry or sector of products; any consultancy, directorship, position in or work for healthcare industry that attracts regular or occasional payments in cash or in kind; any free-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind; any shareholdings, or other beneficial interest, in shares of a healthcare industry that are either held by the individual or for which the individual has legal responsibility; expenses and hospitality provided by a healthcare industry company including that required for accommodation, meals and travel to attend meetings and conference; funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No interests exist in the case of accrued pension rights from earlier employment in the healthcare industry.

**Personal family interest (3 and 4):** Same as personal financial interest but apply on family members.

**Non-personal financial interest (5 and 6):** current or within the past three years, payments or other benefit that benefits a department or organization for which an individual has managerial responsibility, but which is not received personally; the holding of a fellowship endowed by the healthcare industry; any payment or other support by the health industry that does not convey any financial or material benefit to an individual personally but might benefit him or her like a grant from a company for the running of a unit or department for which a member is responsible, a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is responsible; the commissioning of research or other work by or advice from, staff who work in a unit for which the member is responsible.

**Personal non-financial (7) interest in a topic under consideration might include, but is not limited to;** a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review; a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence; holding office in a professional organization or advocacy group with direct interest in the matter under consideration, other reputation risk in relation to an intervention under review.

**If yes to any of the above, please describe below, including approximate amount of compensation (the amount of compensation will be confidential):**

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Date

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Name and Signature