

Conflict of Interest Policy

DNDi POLICIES

December 2015

DNDi
Drugs for Neglected Diseases initiative

I. Context and objective

DNDi's mission is to improve the health of people suffering from neglected diseases by developing new drugs or new formulations for these patients. Acting in the public interest, DNDi is part of a small ecosystem, working closely with the founding partners, private industry, academia, public bodies and authorities, and other not-for-profit organizations. In this context, the purpose of the Conflict of interest Policy (the "Policy") is to contribute to stakeholders' trust in DNDi's operations and support integrity in decision-making. It is not to avoid all conflicts, but rather to help identify, reduce and address situations that bear of conflict of interest. This policy brings more clarity on the principles set in DNDi by-laws (Section VI, art. 34 to 36) and replaces DNDi Guidance paper on Conflicts of interest (2007). It shall be considered in relations with other policies guiding the conduct of DNDi Members at DNDi, in particular:

- DNDi Code of Practice for the Scientific Advisory Committee
- DNDi Internal control system
- DNDi Procurement policy
- DNDi HR policy and framework
- DNDi Fraud and Corruption Prevention policy
- DNDi Research Misconduct policy
- DNDi Policy for Scientific and Clinical External Communications

This policy applies to DNDi Members, as defined in Section II. Acceptance of any collaboration with DNDi entails a commitment to assign priority to the needs and goals of DNDi. Each DNDi Member must be alert to the possibility that outside obligations, financial interest or employment relationships run the risk of compromising their objectivity.

When a DNDi Member has significant interests in a company, organization or institution external to DNDi, or receives compensation, funding, or other assistance from entities external to DNDi, whose activities are connected to DNDi activities, there is the potential for the creation of a conflict of interest.

DNDi has always been committed to the highest possible standards of openness, honesty and accountability, and is determined to maintain a culture of transparency. Based on the same standards, DNDi Members shall also declare COI to third parties when interacting with them on behalf of DNDi.

II. Scope and definitions

"DNDi members", shall mean: any member of the Board of Director, regional governing bodies, consultative bodies set upon DNDi By-laws (e.g. Scientific Advisory Committee, Audit Committee, etc.), the Executive team, and all DNDi staff members as well as close consultants.

“Associated Person” shall mean, in relation to a DNDi member: immediate family members and emotional ties (spouse, parents, children, siblings, mother-, father-, brothers- and sisters-in-law and anyone who shares his/her home...)

“Covered Individual” shall mean any DNDi member and Associated person.

“Conflict of Interest” (or “COI”) refers to situations in which an interest or activity may compromise, or have the appearance of compromising, an individual’s professional judgment in performing actions in the best interest of DNDi. A COI arises when:

- the Covered Individual has a Financial Interest in relation to an entity with which DNDi has negotiated or is negotiating a contract or other arrangement, or which could benefit or be adversely affected as a direct result of DNDi’s action on a particular matter;
- any other interest, personal or professional, could directly and significantly affect the activity performed by the Covered Individual.

“Financial Interest” consists of one or more of the following interests of the Covered Individual, that reasonably appear to be related to his/her responsibilities:

- salary or other payments for services (e.g. consulting fees or honoraria) received from external entities;
- equity interests (e.g. stocks, stock options or other ownership interests) in external entities;
- intellectual property rights and interests (e.g. patents, copyrights, royalties);
- Any sponsored travel.

as further characterized in the Interest Disclosure Form.

The term does not include:

- Income from investment vehicles, such as mutual funds and retirement accounts (as long as the Covered Individual does not directly control the investment decisions made in these vehicles);
- Sponsored travel from government, academic institution, medical center or a research institute affiliated with an academic institution.

III. Procedure

Where facts known to a person reasonably suggest an actual, potential or apparent conflict of interest, the DNDi Member is expected to disclose the situation in good faith consistent with the spirit and objectives of this Policy.

III.1 – Disclosure

Interest Disclosure Forms shall be completed for all DNDi Member at the following time:

- when this Policy will be implemented
- upon the initiation of the relationship with DNDi;

- annually, to confirm or update the previous Interest Disclosure Form;
- on an ad-hoc basis (as soon as becoming aware of any actual, potential or apparent COI, or upon explicit request);

a) Implementation of the Policy

This Policy prevails on existing initiatives and provisions relating to conflict of interest across DNDi.

Interest Disclosure Forms shall be completed for all DNDi Members within six months after Board approval of the Policy in accordance with the procedure described below.

b) Initiation of the relationship with DNDi

At the start of relationship with DNDi (ie new contract for employee or consultant, official designation as member of a committee), each DNDi Member shall complete and submit Interest Disclosure Form that lists his/her known COI:

- Committee membership (Board, SAC, Audit committee, ad-hoc committee) to the Chair of the relevant committee; Chairs should report to the Secretary when the position exists, or to an official member of the relevant committee and a director of the Executive team
- Staff and close consultants to the Human Resources department.

DNDi Members with no COI to disclose should also complete the Interest Disclosure Form and indicate the absence of COI.

c) Renewal of Declarations

On a yearly basis, all staff and close consultants will be request to confirm and/or update the previous Interest Disclosure Form to the HR department.

For committee members, at the beginning of each meeting, as a standing agenda item, the Chair will remind attendees to comply with the Policy. At the renewal of the mandate, a member will confirm and/or update his/her previous Interest Disclosure Form.

d) Ad-hoc Declaration

As soon as becoming aware of any actual, potential or apparent COI, or upon explicit request, a DNDi Member must declare the COI:

- For the staff, to its line management and/or the Operations Director,
- For the committee members, to the Chair of the committee and/or the Director/Head in charge of the committee.

If such situation occur in the course of a meeting or in an unexpected manner that do not enable the DNDi Member to fill the Interest Disclosure Form, he/she has to disclose verbally the situation.

The DNDi Member involved in the COI may acknowledge the situation and recuse him/herself without going through the process of the review.

III.2 – Review

The Interest Disclosure Form will be reviewed by a COI Review Committee. It will be composed by a minimum of two persons, as followed:

- For the staff's or close consultants' declarations: minimum two Directors (one from the line management, and one from the Operations department);
- For the committee members' declarations: at least the Chair of the committee and a Director of the Executive team.
- For the Chair: the Secretary when the position exists, or an official member of the relevant committee and a director of the Executive team.

The COI Review Committee will determine whether a COI actually or potentially exists or appears to exist. The COI Review Committee may invite any other relevant person (e.g. legal counsel, procurement officer, project manager, etc.) for advice.

As a good practice, specific leaders will be part of this COI Review Committee when the type of interest falls into their field/scope of intervention. In particular:

- Finance leadership, when the COI implies financial considerations;
- R&D leadership, when the interest is linked to R&D;
- Regional leadership, when the interest is linked to their region;
- HR leadership, when the interest is linked to human resources;
- etc.

Furthermore, the COI will be assessed and managed in conformity with any applicable law and relevant funder's or partner's requirements.

III.3 – Measures

After review, the COI Review Committee will specify the actions to be taken to manage the conflict(s). Such actions may include, without limitation:

- a. Abstention to participate in the debate (e.g. leaving the room, call...)
- b. Abstention to participate in the decision-making process
- c. Severance of relationship that creates the conflict;
- d. Public disclosure of the COI (e.g. when presenting or publishing the research);
- e. Disclosure of the COI to stakeholders (e.g. partners, staff, committee members, etc.);
- f. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the COI;
- g. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the project affected by the COI;
- h. Modification of the research/purchase/funding/partnership plan;
- i. Any other measure required by DNDi funders or partners.

If appropriate, the COI Review Committee may determine that additional interim measures are necessary between the date of disclosure and the completion of review.

In a case of a **verbal disclosure** (i.e. in meeting situation), the Chair of the meeting will take appropriate measures (in particular a. and b. listed above). It is recommended that he/she consults a committee member to make the decision. Such decision will be reported in the minutes of the meeting.

The COI Review Committee will give an opportunity to the DNDi member to be involved in the determination of a COI and of appropriate corrective actions, if any. However, final decision will be made by the COI Review Committee.

Decision made under this Policy by the COI Review Committee, shall be communicated to the DNDi Member in the form of a written statement that sets forth the basis for the decision.

In the event DNDi identifies a COI that was **not disclosed** timely by the DNDi Member, the COI Review Committee will complete a retrospective review of the activities of the Covered Individual to determine whether the activities, conducted during the time period of the non-compliance, was biased. Corrective action may be taken, as well as any disciplinary measures pursuant to HR Policy or relevant committee rules.

III.4 – Miscellaneous

Confidentiality & Disclosure - Except to the extent required by law, the information disclosed will be kept confidential and will be shared only with those who have a need to know under this Policy. The DNDi Member should know, however, that DNDi may be required to report the existence of a COI to funders, partners or any other third parties pursuant to applicable law, regulations, guidelines or policies.

Implementation - Regular trainings and discussions with teams will also be organized to raise awareness around COI stakes for DNDi.

Archiving: For staff, the HR department will maintain records relating to this Policy (e.g. initial/annual Interest Declaration Forms, specific COI documentation and related measures...), for 10 years from disclosure. For committee members, the administrative support of the committee will maintain the records (e.g. Executive & Board assistant for Board matters, R&D assistant for SAC, Finance Director for Audit Committee).

III.5 – Gifts and services

As a general principle, DNDi discourages the exchange of gifts. DNDi Members and Associated Person may not receive or offer any gift or anything else of significant value (e.g. services) for the purpose of influencing directly or indirectly, the action of DNDi or of the recipient.

Gifts received from vendors, suppliers, consultants and partners must be declined or given to DNDi or shared with DNDi generally, and if acknowledgement is appropriate, acknowledged on behalf of

DNDi. This Policy is not intended to prohibit normal business practices, such as meetings over meals, corporate items given to participants in meetings and conferences, or token hosting gifts, as long as they are of nominal and reasonable value (less than EUR 50) and promote DNDi's legitimate business interests.

The exchange of gifts should also consider local custom and be in line with applicable laws and regulations. If a DNDi Member believes there is an appropriate reason to make an exemption to this Policy for a specific situation, he/she should declare to his/her line management Director or Chair of the committee (and for Chairs/Executive director, to another Committee member as described above).

IV. Exhibit – Interest Disclosure Form

Policy version control

Title	DNDi Conflict of Interest Policy (COI)	
Written by	Head of legal, Finance Director, Operations Director	
Validated by / Date	- Extended Executive Team - Audit committee	23 th October 2015 9 th November 2015
Approved by / Date	Board of Directors	
Distribution list	- Board, SAC and Committees - Staff and Close consultants	

Revision History

Version	Reasons and Changes	Date
Version 0.1	Draft for discussion – ICS Project	Aug. 2014
Version 0.2	Reviewed for presentation to Extended Executive Team and Audit Committee	Nov. 2015
Version 1.0	Board Validated version	1 st Dec. 2015

INTEREST DISCLOSURE FORM

1/ PERSONAL INFORMATION

Family Name, First Name : _____ Title or position : _____
Legal Entity : _____

As: Board of Directors SAC Other committee: _____
 Employee Consultant Expert

2/ EMPLOYMENT AND/OR CONSULTING

Have you or any Associated Person, within the past year, received a remuneration exceeding EUR 5'000 from as external entity with an interest related to the subject matter of your work at DNDi ? Please also disclose any current negotiation for future work.

2 a - Employment YES / NO
2 b - Consulting YES / NO

3/ RESEARCH SUPPORT

Have you or any Associated Person, within the past year, received support from an external entity or with an interest related to the subject matter of your work at DNDi ? Please also disclose any current negotiation for future work.

3 a - Research support, including grants, collaborations, sponsorships, other funding: YES / NO
3 b - Non-monetary support valued at more than EUR 500 overall within the past year YES / NO
 (including equipment, facilities, paid travels, etc.)

4/ INVESTMENT INTERESTS

Do you, or any Associated Person, have current investments (valued at more than EUR 5'000*) in a commercial entity with an interest related to the subject matter of your work at DNDi ? Please also include indirect investments through trust or holding companies, and exclude mutual funds or pension funds or similar structures that are broadly diversified.

4 a – Stock, bonds, stock options, other securities YES NO
4 b – Commercial business interests (e.g. JV, partnerships) YES NO

** value of the stock in non-publicly traded entities at the last sale price recognized by the entity (not at the share price originally paid by the Covered Individual)*

5/ INTELLECTUAL PROPERTY

Do you, or any Associated Person, have any current intellectual property rights that might be enhanced or diminished by the outcome of your work at DNDi

5 a – Patents, trademarks or copyrights YES NO
5 b – Property know-how in a substance, technology or process YES NO

