

Rules on Conflict of Interests

Version 01.09.2010

A Preamble

ESCAMP is an incorporated charitable association under German law with headquarters in Freiburg im Breisgau, Germany. The work of ESCAMP is carried out by the management board, other ESCAMP members, employed staff, and cooperating experts and advisors. The key objective of all ESCAMP activities is to develop scientific assessment criteria for anthroposophic medicinal products (AMPs) in view of appropriate regulation within the European Union. To attain this objective in the most efficient way, no conflicts of interests should interfere. At the same time, the knowledge and expertise of different stakeholders, e. g. manufacturers of AMPs is needed (such as data concerning pharmacology, pharmacovigilance, any unpublished pre-clinical or clinical research etc.). Therefore, the ESCAMP management board has adopted a set of rules (hereinafter "Rules on Conflict of Interests" or "Rules") to safeguard an independent structure and objectivity of the work of ESCAMP. These Rules help to identify and subsequently address (potential) conflicts of interests and avoid that any conflicts of interests would arise in the future.

B Application

The Rules on Conflict of Interests shall apply to all ESCAMP members, all members of the management board and their deputies, all members of working groups operating within the ESCAMP organisation (hereinafter called "Members" or "Member") as well as all persons employed by ESCAMP e. g. as consultants or experts (hereinafter called "Employees" or "Employee").

Any financial support shall only be accepted by ESCAMP as long as the funding is not subject to conditions that could affect the independence of ESCAMP.

C Definitions

Section 1 Conflict of Interests

A conflict of interest exists if:

- a) a personal interest of a Member or Employee collides with the objectives of ESCAMP; or
- b) an interest related to a party to which the Member or Employee is connected, including economic relationship, influences the ESCAMP work conflicting with the objectives of ESCAMP; or
- c) a company-related interest of a Member or Employee (e.g. a cooperating expert working in an industry) affects the unbiased, independent or objective exercise of his or her duties within ESCAMP.

Section 2 Interested Person

An Interested Person is any Member or Employee who represents any interest which is inconsistent with the ESCAMP objectives in such a way that this Member or Employee is not capable of performing his or her work for ESCAMP independently or of making impartial decisions concerning ESCAMP, because one of the conditions laid down in Section 1 are fulfilled.

D General Rules

Section 3 Key Principle

(1) All conflict of interests shall be strictly avoided within ESCAMP. Any Member or Employee who is active for ESCAMP shall, within the scope of his or her activities as a Member respectively Employee, pursue exclusively the objectives laid down in the ESCAMP Constitution (German: "ESCAMP Satzung").

Members and Employees shall confirm this by signing receipt and acceptance of the Rules on Conflict of Interests. Members and Employees shall also fill in a Public Declaration of Interests, which shall be renewed annually.

- (2) If a (potential) conflict of interests cannot be avoided, Members or Employees shall immediately inform the ESCAMP management board thereof in accordance with Section 5 of these Rules, indicating both the content and the nature of the (potential) conflict of interests.
- (3) Either the Interested Person or any other person suspecting a conflict of interest of a Member or Employee may make the aforementioned notification.
- (4) Any notification made under these rules will be treated confidentially and shall not be disclosed to any other (third) party that is not directly involved, or who is not a member of the ESCAMP management board.

Section 4 Personal Interests

When setting up co-operations relating to ESCAMP activities, only the ESCAMP interests may be considered. If any relationship between an involved third party and a Member exists, the ESCAMP management board shall be notified thereof pursuant to the procedure mentioned in Section 3 of these Rules. The aforementioned personal relationship may not make the Member an Interested Person as defined in Section 2 of these Rules.

E Procedures

Section 5 Key Rules of Procedure

- (1) The ESCAMP management board shall be informed of any potential conflict of interests of any Member or Employee in writing.
- (2) If the ESCAMP management board has been notified of a potential conflict of interests, it shall determine whether a Member or Employee is an Interested Person and decide to take appropriate action (hereinafter called "Decision"). The Decision made by the ESCAMP management board on a notified conflict of interests shall be recorded in the minutes of the board meeting. The aforementioned Decision shall be marked as confidential, and shall only be disclosed in accordance with Section 3, paragraph 4 of these Rules.
- (3) The Decision shall be taken unanimously or on the basis of a simple majority.
- (4) In all cases the Member or Employee who may qualify as an Interested Person has the right to be heard by the ESCAMP management board on the reported conflict of interests before the ESCAMP management board takes any Decision.

(5) In case of urgency, the ESCAMP management board may render the Decision outside the regular board meetings. The votes will be cast via e-mail or facsimile. The aforementioned votes of the board members are recorded. The votes are confidential information and treated pursuant to the procedure laid down in Section 3, paragraph 4 of these Rules.

Section 6 Exclusion from Voting and Cooperation

If the Decision concerns a member or a deputy member of the ESCAMP management board, this member will be excluded from casting any vote on the Decision. The member excluded from the vote shall not be deemed as a person entitled to vote. An Employee assessed as an Interested Person shall be excluded from the cooperation.

Section 7 Representation and Disclosure of Information

- (1) An Interested Person may neither represent ESCAMP, nor disclose any information in the (suggested) capacity of Member or Employee, in any manner related to a conflict of interests that has been determined as such in a Decision of the ESCAMP management board.
- (2) The ESCAMP management board may explicitly lay down in its Decision a detailed description of the limitations of a Member's authorities as mentioned in Section 7, paragraph 1 of these Rules.
- (3) An Interested Person will be held fully liable for damages resulting from an infringement of Section 7 of these Rules.

F Final Provision

Section 8 Commencement and Availability of Rules on Conflict of Interest (1) A copy of these Rules on Conflict of Interests has been made available to all ESCAMP Members and Employees. All Members and Employees of ESCAMP declare to accept these Rules.

- (2) These Rules on Conflict of Interests take effect as of 1 September 2010.
- (3) The Rules on Conflict of Interests shall be placed on the ESCAMP website.
- (4) The Public Declaration of Interest of all Members and Employees shall be placed on the ESCAMP website.
- (5) The management board shall review these Rules within 3 years of their adoption.