

OFFICE OF NEW DRUGS

Management of the PTCC Education Subcommittee

CONTENTS

PURPOSE

BACKGROUND

OBJECTIVE

ORGANIZATION

RESPONSIBILITIES

PROCEDURES

EFFECTIVE DATE

PURPOSE

- This MAPP describes the roles and responsibilities of the Pharmacology and Toxicology Coordinating Committee (PTCC) Education Subcommittee, as well as the structure and function of the subcommittee, the procedures for designating members to serve on the subcommittee, the responsibilities of those designated to serve on the subcommittee, and the subcommittee procedures.
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BACKGROUND

- The PTCC Education Subcommittee has been established to: (1) define and prioritize the scientific educational needs of pharmacology/toxicology reviewers, (2) help develop educational efforts to meet these needs, and (3) review those efforts and assure that their quality is high. The educational activities may include formal courses, individual lectures or lecture series, seminars, workshops, electronic courses on tapes, and CD ROM interactive disks or other computer-based learning tools. The subcommittee is responsible for scientific training for new reviewers, as well as for satisfying the continuing educational needs of senior reviewers. The subcommittee is also responsible for assuring pharm/tox representation on the new reviewer's
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workshop steering committee and for coordinating input to the workshop steering committee. The recommendations of the Education Subcommittee are presented for endorsement to the parent PTCC. Because all scientific educational activities in the Center for Drug Evaluation and Research (CDER) fall within the purview of the Center's Committee for Advanced Scientific Education (CASE), all pharmacology and toxicology educational activities derived from the PTCC Education Subcommittee will be coordinated with the Center's CASE.

OBJECTIVE

- The objective of the PTCC Education Subcommittee is to maximize the scientific competency of CDER pharmacology and toxicology review staff.
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ORGANIZATION

Oversight

- The PTCC provides oversight for the PTCC Education Subcommittee.

Membership

- **Chairperson and Co-Chairperson:** The Education Subcommittee Chairperson and Co-Chairperson are selected by the subcommittee, generally from existing members, and approved by the PTCC. One of the two officers will be a pharmacology/toxicology team leader or supervisor and therefore, a full voting PTCC member. Selection of chair and co-chair candidates is based on interest in developing continuing educational curricula and a demonstrated willingness to actively participate in committee endeavors. The chair and co-chair are to serve for a 2-year term. The subcommittee will select a new chair and co-chair at the end of the terms or upon resignation of either of the officers. Terms may be extended beyond the 2-year period, with the approval of the subcommittee members and the PTCC and with the agreement of the current officers.
- **Members** - Voting members of the PTCC Education Subcommittee include the Chair, Co-Chair, and the appointed members from CDER. Members should be chosen to serve based on their qualifications, expertise, and interest in developing educational curricula; their workload and abilities to participate

in the activities of the committee; and their supervisors' concurrence. There should be an effort to (1) diversify the voting membership by including reviewers from each Office of Drug Evaluation (ODE) and from different review divisions within the ODEs and (2) include pharm/tox scientists from non-Office of New Drugs (OND) review, research, training, or compliance divisions. Committee membership should be kept small and will consist of at least 10 voting members. One pharmacology/toxicology OND reviewer member will also serve on the CDER CASE as liaison for coordination of activities and communication between the two committees.

Nominated members will be selected by the chair and co-chair and by a majority vote of the Education Subcommittee membership. The consensus by majority vote of the PTCC is required for each appointed voting membership. Voting membership on committees should normally be rotated periodically (generally every 2 years). When desirable, based on expertise or experience, a member's term may be extended. Subcommittee membership should be reviewed annually by the PTCC. A member who does not attend three consecutive meetings may be dropped from the subcommittee membership unless the chair or co-chair is informed of extenuating circumstances.

To facilitate productivity of the committees, invitations to guests and the use of smaller ad hoc working groups to address specific issues should be encouraged.

- **Executive Secretary** - Either of the Co-Chairs may act as Executive Secretary or appoint either a full-time or part-time Executive Secretary to the PTCC Education Subcommittee.
- **Other Participants** - Nonvoting members will include two representatives from the Office of Training and Communications (OTCOM) to maximize educational guidance input and to facilitate efficient operational support for pharm/tox educational activities. The representatives from OTCOM will be selected by that office's Division of Training and Development, with concurrence of the Chair and Co-Chair. Also with concurrence of the Chair and Co-Chair, other nonvoting members, nonvoting observers, and consultants from other Divisions/Centers/Committees may be included in the activities of the PTCC Education Subcommittee to facilitate cross-Center and/or Agency interactions.

RESPONSIBILITIES

The PTCC Education Subcommittee will:

- Review and prioritize the specific scientific education needs of new pharmacology and toxicology reviewers, as well as meet the continuing scientific education needs of all pharmacology and toxicology reviewers.
- Develop formal and informal scientific learning opportunities for pharmacology and toxicology reviewers.
- Coordinate formal courses and arrange for recording them to be used by reviewers as needed (e.g., on interactive CD ROMs).
- Coordinate educational activities with CASE and with CDER's OTCOM.
- Coordinate with the PTCC Retreat Subcommittee to assist with the development of educational programs held at retreats.
- Assure pharm/tox representation on the new reviewer's workshop steering committee and coordinate input to the workshop steering committee.

The Chair and Co-chair of the PTCC Education Subcommittee will:

- Schedule and conduct meetings of the committee as required to fulfill the committee's objectives.
- Prepare an agenda and distribute it to the committee members before each committee meeting.
- Ensure that copies of all records of committee meetings and other deliberations of the committee are recorded and placed in a file maintained by the Executive Secretary for the PTCC Education Subcommittee.
- With the assistance of the committee members, create and maintain a Task List for the committee describing major tasks the committee is undertaking, projected milestones and completion dates, and the current status of each project.
- Report semiannually to the PTCC on the activities of the committee. In preparation for each of these semiannual meetings, the Co-Chairpersons should provide to the PTCC at least a week before the meeting an updated

Task List, a summary of achievements since the last report to the PTCC, a projection of activities for the next 6 months, and a list of issues for which PTCC input is needed.

The Executive Secretary will:

- Arrange and organize meetings. Issues to be brought before the PTCC Education Subcommittee should be directed to the attention of the Executive Secretary, who will attempt to schedule them in consultation with the co-chairs of the PTCC Education Subcommittee.
- Distribute documents.
- Assure that files of committee activities are maintained.
- Prepare brief minutes of each meeting and distribute them to the committee members. Minutes also should be filed electronically on the designated shared drive under the subdirectory established for the PTCC Education Subcommittee.

The CASE representative will:

- Coordinate between CASE and the PTCC Education Subcommittee, and report to each committee as appropriate.

The Members of the PTCC Education Subcommittee will:

- Regularly attend meetings and review materials before the meetings, and have a general willingness to participate in committee activities. Committee members missing three consecutive meetings without an excused absence may be replaced by the Co-Chairpersons.
- Perform other responsibilities identified by the Chairperson and Co-Chairperson. Members have the right to accept or reject the designated responsibilities.

PROCEDURES

- **Meetings** of the PTCC Education Subcommittee should be held at least quarterly, and as needed.
 - **Voting** – A majority of the voting members of the PTCC Education Subcommittee must be present for voting on issues to occur. If unanimous agreement is not reached on an issue brought to the committee for a vote, areas of disagreement should be documented in the meeting minutes.
 - **Communications Between the PTCC Education Subcommittee, the PTCC, and CASE** - The activities of the PTCC Education Subcommittee will be communicated to the PTCC and to CASE regularly and in a timely manner.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.