
PROGRAM DESCRIPTION

OFFICE OF NEW DRUGS

**Management of the CDER Pharmacology/Toxicology Coordinating Committee and
Its Associated Subcommittees and Working Groups**

Table of Contents

PURPOSE.....1
RESPONSIBILITIES.....2
PROCEDURES.....5
ORGANIZATION.....7
EFFECTIVE DATE.....8
ATTACHMENT 1 — Recommendation for the
Creation of a CDER PTCC Subcommittee or
Working Group.....9

PURPOSE

This MAPP describes:

- The role and responsibilities of the Pharmacology/Toxicology Coordinating Committee (PTCC) and its associated subcommittees
- The procedures to be used for establishing pharmacology/toxicology subcommittees
- The structure and function of the PTCC subcommittees, working groups, and scientific interest groups
- The procedures to be used in designating members to serve on such subcommittees
- The responsibilities of the subcommittee members

RESPONSIBILITIES

The PTCC is responsible for:

- Providing advice on policy for the pharmacology and toxicology discipline in the Office of New Drugs (OND), and chartering subcommittees focused on pharmacology/toxicology subdisciplines.
- Providing recommendations to the OND Associate Director for Pharmacology and Toxicology on the development of guidance documents, including guidances for industry, policy and/or procedure documents, concept papers, and other communications needed to ensure high-quality regulatory reviews and evaluations and to promote consistency across the Center for Drug Evaluation and Research (CDER).
- Advising the OND Associate Director for Pharmacology and Toxicology and office of drug evaluation (ODE) associate directors on recommended pharmacology/toxicology policy on technical issues in CDER.
- Serving as a forum for scientific evaluations and discussion involving pharmacology/toxicology issues with the goal of ensuring consistency across divisions and offices.
- Documenting pharmacology/toxicology practices and policies through prescribed means and coordinating, facilitating, and monitoring the efforts of the PTCC subcommittees, including advising on subcommittee objectives, structure, function, membership, and member responsibilities; assigning topics; establishing new subcommittees as appropriate; and reviewing and approving any final subcommittee documents before transmission to CDER management for clearance. The establishment and function of PTCC subcommittees must be clear to ensure effective use of staff resources and to ensure that subcommittee activities are consistent with Food and Drug Administration (FDA) regulations and policies.
- Recommending good review practices for pharmacology/toxicology reviewers.
- Serving as a repository for committee and subcommittee recommendations, decisions, and actions.
- Promoting and coordinating training, professional development, workshops, and other intramural and extramural activities related to pharmacology/toxicology issues.

The OND Associate Director for Pharmacology and Toxicology is responsible for:

- Serving as Chair of the PTCC, and as such, advising CDER management on pharmacology/toxicology policy issues
- Developing CDER positions on International Council for Harmonisation guidances for industry related to pharmacology/toxicology with input from the PTCC
- Ensuring that the PTCC decision making processes are fair and transparent, in keeping with other Center policy
- Facilitating PTCC meetings, approving agendas, assigning action items and timelines, and defining responsibilities of the PTCC
- Providing concurrence on any products produced by the PTCC or a subcommittee
- Approving the establishment of new PTCC subcommittees and working groups

The ODE Associate Directors for Pharmacology and Toxicology are responsible for:

- Advising the OND Associate Director for Pharmacology and Toxicology on PTCC and related policy issues
- Ensuring consistency with existing PTCC policies and practices through written and oral advice to pharmacology and toxicology reviewers, team leaders, and supervisors; ODE division directors; or ODE office directors

The Executive Secretary is responsible for:

- Organizing and scheduling meetings of the PTCC and distribution of the proposed agenda
- Distributing documents
- Maintaining files of committee activities
- Preparing minutes (meeting minutes will be made available to every committee member) and filing the minutes on a shared drive or internal Web page
- Maintaining a list of active and inactive subcommittees and working groups, and membership in the subcommittees and working groups

Subcommittees are responsible for:

- Reviewing technical issues and monitoring scientific developments in specialty areas, and keeping the PTCC informed about these issues and developments.
- Serving as an expanded forum, beyond the core PTCC membership, for scientific and technical discussions within their areas of expertise related to pharmacology/toxicology issues. Subcommittees, when requested, can provide scientific and technical feedback or consults to review divisions on issues in their areas of expertise. Requests for such feedback, and the products of such discussions, should be shared with the appropriate ODE associate director.
- Participating, as requested by the PTCC or the OND Associate Director for Pharmacology and Toxicology, in the development of CDER guidance and procedures related to matters within their areas of expertise.
- Collecting and analyzing data and disseminating outcomes through public presentations and manuscripts.
- Planning workshops as assigned.
- Effectively communicating their work to the PTCC and within CDER.

PTCC Chairs and Co-Chairs of Subcommittees are responsible for:

- Ensuring that the subcommittees are addressing the needs of the PTCC and CDER.
- Ensuring that subcommittee discussions do not impinge on the regulatory responsibilities of review divisions.
- Reporting to the PTCC periodically to describe the status of any tasks in which they are engaged and to obtain PTCC input and direction. In preparation for each meeting, the chairs should provide to the PTCC, in advance of the meeting, a summary of issues to be discussed.
- Developing proposed time frames for completion of projects and forwarding the time frames to the PTCC for concurrence. The PTCC may recommend amendment of the priorities of the projects assigned, as necessary.
- Scheduling and conducting subcommittee meetings as required to fulfill subcommittee objectives. The co-chairs or subcommittee designees may convene and chair meetings in the absence of the chairs.

- Ensuring that an agenda is prepared and distributed to the subcommittee members in advance of each subcommittee meeting.
- Ensuring that brief minutes of each meeting are prepared and distributed to the subcommittee members. Minutes also should be filed electronically on the designated shared drive or Web page under the subdirectory established for each subcommittee.
- With the assistance of the subcommittee members, creating and maintaining task lists for the subcommittees describing major tasks the subcommittees are undertaking, projected milestones and completion dates, and the current status of each project as appropriate.

Members of Subcommittees are responsible for:

- Actively participating in subcommittee activities
 - Regularly attending the meetings of the subcommittees for which they are the designated representatives
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PROCEDURES

- Meetings — PTCC meetings should be held monthly, with additional meetings scheduled as needed.
- Minutes — All PTCC meetings will result in minutes documenting issues presented to the PTCC membership, and announcing committee decisions and rationales. Copies of the minutes will be distributed to PTCC members.
- Establishment of subcommittees or working groups
 - Suggestions for the creation of new subcommittees, including ad hoc working groups that may report to the PTCC or a subcommittee directly, should be made in writing to the PTCC by a primary reviewer or supervisor in CDER (see Attachment 1).

Each suggestion should be accompanied by a brief statement of the proposed objectives of the subcommittee, and may include the names of persons who might serve on the subcommittee as members and as chair and co-chair, the expected frequency of meetings, and the subcommittee's expected life (e.g., 3 months, on-going).

- The PTCC will determine whether the subcommittee should be established and will notify pharmacology/toxicology reviewers and other affected CDER staff of the creation of a new pharmacology- and toxicology-related subcommittee. A list of current subcommittee members will be maintained by the PTCC Executive Secretary.
- Additions to the membership or changes in the objectives of a subcommittee should be submitted to the PTCC for concurrence.
- Disbandment of subcommittees or working groups
 - A subcommittee shall be disbanded when:
 - It reaches the end of its scheduled lifetime
 - It has fulfilled its objectives
 - The PTCC determines the subcommittee is not fulfilling a necessary function in the Center
 - Every year, the PTCC shall review the list of subcommittees to determine whether any of the subcommittees on the list should be disbanded or the membership or chair changed. If, after discussions with the chair of the subcommittee, it appears that a subcommittee no longer performs a useful function, the PTCC shall issue a notice that the subcommittee will be disbanded.
- Communications between PTCC and CDER pharmacologists/toxicologists
 - The activities of the PTCC will be communicated to the pharmacology/toxicology reviewers through distribution and electronic filing of the minutes of the PTCC meetings
 - CDER pharmacologists/toxicologists may raise issues to the PTCC by bringing them to the attention of:
 - Their supervisor or team leader
 - A subcommittee chair
 - An ODE associate director
 - The OND Associate Director for Pharmacology and Toxicology

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- Any PTCC member
 - The PTCC Executive Secretary
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ORGANIZATION

The following descriptions and explanations should be applied on a general basis.

- **PTCC**
 - **Chair** — The PTCC Chair is the OND Associate Director for Pharmacology and Toxicology or a designated representative
 - **Executive Secretary** — The Chair may act as Executive Secretary, or appoint either a full-time or part-time Executive Secretary to the PTCC
 - **Members** — Members of the PTCC include the Chair, all ODE associate directors for pharmacology and toxicology, and all supervisory pharmacologists and toxicologists, team leaders, or designees
 - **Other participants** — With concurrence of the PTCC Chair, observers and consultants from other divisions or offices in CDER may be included in the activities of the PTCC
- **Subcommittees and working groups**

Other structures may be used to accomplish the mission of the PTCC, as determined by the PTCC itself and the OND Associate Director of Pharmacology and Toxicology.

Subcommittees

- **Chair and co-chair** — The PTCC will select a chair and co-chair for each subcommittee, taking into account candidates' expertise and interest in the subject matter of the subcommittee, and their organizational and management skills. Chairs and co-chairs should be selected with the goal of achieving broad representation across OND. Each chair should serve for a 3-year term. However, the PTCC will evaluate a chair's position annually and may decide to reduce or extend the term in 1-year increments. At least one of the individuals serving as the chair or co-chair for each subcommittee should be a member of the PTCC. The PTCC will consider individuals for chair or co-chair recommended by the members of the subcommittee.

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- **Membership** — Members from pharmacology/toxicology review and management staff in OND should be chosen to serve on subcommittees based upon their qualifications, expertise and interest in the subject matter of the subcommittee, their workload, and the demands on their time caused by membership on other subcommittees. Adjunct members may be selected from pharmacology/toxicology research staff in CDER or from other review disciplines (e.g., statistics). Ad hoc members from other FDA centers, with the concurrence of the PTCC, may be invited to participate in discussions of particular scientific issues on an as-needed basis.

In general, membership should be kept small, with approximately one member from each review division when practical, to facilitate efficient operation of each subcommittee. If a larger discussion forum is desired, a scientific interest group separate from the PTCC subcommittee should be formed (see below). Membership should be from different divisions and not over representative of a single division or office.

Generally, membership on subcommittees should be rotated periodically. When desirable, based on expertise or experience, a member's term may be extended. Defined term limits are restricted by the expertise of the current pharmacology/toxicology staff available within the Center. Subcommittee membership should be reviewed annually by the PTCC.

Working groups

- Smaller ad hoc working groups (usually five to seven members) may be established to facilitate work on a short-term project not being addressed by a standing subcommittee. Working groups may have a similar structure to subcommittees. A working group should focus on a specific topic and generally have a limited operational time.
- **Scientific interest groups**
 - Occasionally, scientific interest groups may be formed to discuss discipline-specific scientific issues that do not have an effect on regulatory policy. Because these groups do not discuss regulatory issues, they are not covered by this MAPP.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

**ATTACHMENT 1 — Recommendation for the Creation of a CDER PTCC
Subcommittee or Working Group**

1. **Name of Subcommittee:**

2. **Objectives:**

3. **Proposed Composition:**

Chair:

Co-Chair:

Membership:

4. **Meeting Frequency:**

5. **Completion Date:**

Concur: _____ Nonconcur: _____

Chair, PTCC

Date