PHARMACOLOGY AND TOXICOLOGY

MANAGEMENT OF CDER PHARMACOLOGY/TOXICOLOGY COORDINATING COMMITTEE

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PURPOSE This guide describes:

- The role and responsibilities of the Pharmacology and Toxicology Coordinating Committee (PTCC);
- The procedures to be used for establishing pharmacology/toxicology committees in the Center for Drug Evaluation and Research (CDER);
- The structure and function of the various committees;
- The procedures to be used in designating members to serve on such committees; and
- The responsibilities of those designated to serve on such committees.

BACKGROUND

CDER pharmacology committees have been established to develop guidelines for use by sponsors and applicants, to address emerging technical problems, and to address management issues (see Attachment A). These committees perform most effectively if the objectives of the committee and the responsibilities of its members are clearly defined. The work of each committee should also be effectively communicated both within and outside

CDER. The establishment and function of pharmacology committees must be clear to ensure effective utilization of staff resources and consistency between CDER management views and agency regulations and policies. To achieve these various objectives, CDER has established a coordinating committee, the PTCC.

ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There may be some fluctuation in implementation due to workload demands:

- **PTCC**

  1. **Chair** - The PTCC Chair is the Assistant Director for Pharmacology and Toxicology, Office of Review Management or a designated representative.

  2. **Executive Secretary -** The Chair may act as Executive Secretary, or appoint either a full-time or part-time Executive Secretary to the PTCC.

  3. **Members** - Voting members of the PTCC include the Chair, Office of Drug Evaluation Supervisory Pharmacologists or designees and expert members at-large as needed.

  4. **Other Participants -** With concurrence of the PTCC Chairperson, non-voting observers and consultants from other Division/Centers or Federal government organizations may be included in the activities of the PTCC to facilitate cross Center and/or agency interactions.

- **Subcommittees and Working Groups**

  1. **Chair and Co-Chair** - The PTCC will select a Chairperson and a co-Chair for each Subcommittee, taking into account expertise and interest in the subject matter of the committee workload, and organizational and management skills. Chairs and co-Chairs should be distributed with the goal of achieving broad representation between the Offices of Drug Evaluation (ODE), ORR and other interested offices.

     Each Chairperson should serve for a two-year term. The PTCC may, however, evaluate a Chair's position annually and may, in unusual circumstances, decide to reduce or extend the term in one-year increments.

  2. **Membership** - Members should be chosen to serve on committees based upon their qualifications, expertise and interest in the subject matter of the committee, their workload, and the demands on their time caused by

membership on other committees.

Invitations for representation should be offered to the ODEs, ORR and other interested CDER Offices or FDA Centers as appropriate to the committee goals and expertise desired.

Membership should be kept small (10 or fewer members on core Subcommittees) to facilitate efficient operation of each subcommittee.

Membership on committees should normally 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. Committee membership should be reviewed annually by the PTCC.

To facilitate productivity of the committees, the use of smaller ad hoc working groups (5 to 7 members) to address specific issues should be encouraged.

RESPONSIBILITIES

- **The PTCC is responsible for:**

1. Providing advice on a consultative basis on pharmacology/toxicology issues in CDER and issues outside of the Center/Agency/Department that may involve CDER;

2. Coordinating resolution of pharmacology/toxicology issues in CDER;

3. Developing policy on pharmacology/toxicology issues in CDER and making policy recommendations to agency management;

4. Documenting pharmacology/toxicology policies through prescribed means;

5. Serving as liaison between pharmacology/toxicology working-level groups and management in the agency;

6. Serving as the primary decision-making body for scientific evaluations and decisions involving pharmacology/toxicology issues that cross divisions, offices and Centers;

7. Coordinating, facilitating and monitoring the efforts of the pharmacology/toxicology subcommittees including: establishing committee structure, function and membership; assigning of topics; reviewing and

approving final committee products before transmission to CDER management for clearance;

8. Establishing and implementing Good Review Practices (GRP) standards for the pharmacology/toxicology review groups;

9. Serving as repository for committee recommendations, decisions and actions; and

10. Promoting and coordinating training, research, professional development, workshops and other intramural and extramural activities related to PT issues.

- **The Executive Secretary is responsible for:**

1. Arranging and organizing meetings. Issues to be brought before the PTCC should be directed to the attention of the Executive Secretary who will attempt to schedule them in consultation with the Chair of the PTCC;

2. Distributing documents;

3. Maintaining files of committee activities;

4. Preparing minutes [meeting minutes will be made available to every committee member. Minutes shall be filed on the X: drive under X:\PTCC\MEET\YEAR-MONTH-DAY (Example: PTCC\MEET\94-04-04)]; and

5. Ensuring the accuracy of PTCC documents.

- **Subcommittees are responsible for:**

1. Serving as a source of advice and assistance to PTCC in responding to CDER staff on matters pertaining to pharmacology reviews that are within their areas of expertise;

2. Developing, as needed, policies and procedures related to matters within their areas of expertise;

3. Preparing responses, as needed, to questions from the pharmaceutical industry within their areas of expertise. However, all such consultations, regardless of origin, should come through the PTCC before a Subcommittee initiates work; and

4. With approval from PTCC, establishing working groups on specific issues

bringing in additional expertise as necessary.

- **Chairs of Subcommittees are responsible for:**

  1. Reporting to the PTCC twice a year to describe the status of any tasks in which they are engaged and to obtain PTCC input and direction;

  2. Developing proposed time frames for completion of projects and forwarding them to PTCC for concurrence. The PTCC may amend the priorities of the projects assigned, as necessary;

  3. Obtaining input on policy documents from the PTCC prior to review by or "negotiations with" organizations outside of CDER or FDA (e.g., trade associations);

  4. Scheduling and conducting meetings of the committee as required to fulfill the committee's objectives. The co-Chair shall call and run meetings in the absence of the Chairperson;

  5. Preparing an agenda and distributing it to the committee members in advance of each committee meeting;

  6.. Preparing brief minutes of each meeting and distributing them or notifying the members and co-chairs of the PTCC of their existence by including them in the Program Update which is sent to all pharmacology reviewers, Division Directors, Office and Center Managers. Minutes also should be filed electronically on the designated shared drive under the subdirectory established for each of the Subcommittees;

  7. Ensuring that copies of all records of committee meetings and other deliberations of the committee are placed in a file maintained by the Executive Secretary for PTCC;

  8. With the assistance of the committee members, creating and maintaining 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; and

  9. Reporting semi-annually to the PTCC on the activities of the committee. In preparation for each meeting, the Chairperson should provide to the PTCC at least a week in advance of the meeting, an updated Task List, a summary of achievements since the last report to the PTCC, a projection of activities for the next six months, and a list of issues for which PTCC input is needed.

- **Members of Subcommittees are responsible for:**

1. Representing their Division's/Office's views on issues considered by the committees that pertain to their areas of responsibility;

2. Communicating with their Division\Office management about the deliberations of the committees; and

3. Regularly attending the meetings of the committees for which they are the designated representatives. If a member cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the Chairperson.

PROCEDURES

- **Meetings** of the PTCC should be held at least monthly or as needed.

- **Voting** - At least 75% of the voting members of the PTCC 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 PTCC minutes.

- **Reports** - All PTCC meetings will result in reports documenting issues presented to the PTCC membership, and announcing committee decisions and their rationale. Copies of the reports will be distributed to PTCC members and the original reports will remain with the Committee Chairperson and/or the Executive Secretary. Recommendations made by the PTCC will be delivered to the person or organization which sponsored the discussion for their disposition and action.

- **Establishment of Committees** - Suggestions for the creation of new committees, including ad hoc working groups that may report to PTCC directly or to a Subcommittee, should be made in writing (see Attachment B) by a reviewer or first-line or higher level supervisor in CDER to the PTCC.

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

  The PTCC will determine whether the committee should be established and will notify pharmacology reviewers and other affected CDER staff of the creation of a new pharmacology-related committee. A list of current committee members will be maintained by PTCC.

Changes in the membership or objectives of a committee should be submitted to the PTCC for concurrence.

- **Disbandment of Subcommittees or Working Groups** - A committee shall be disbanded when:

  1. It reaches the end of its scheduled lifetime;

  2. It has fulfilled its objectives; or

  3. The PTCC determines the committee is not fulfilling a necessary function in the Center.

  Every six months, the PTCC shall review the list of committees to determine whether any of the committees on the list should be disbanded or the membership or chairpersons changed. If, after discussions with the chairperson of the committee, it appears that a committee no longer performs a useful function, the PTCC shall issue a notice that the committee will be disbanded.

- **Dispute Resolution** - One of the primary functions of the PTCC is to serve as a forum for dispute resolution for pharmacology issues that arise in the Divisions or in one of the Subcommittees. The chair of the PTCC is responsible for bringing upper management perspective to resolution of disputes involving pharmacology and toxicology issues. If the PTCC cannot reach agreement on a particular issue, the issue should be brought to the attention of Center management for resolution.

- **Communications Between CDER Pharmacologists/Toxicologists and Management**

  1. The activities of the PTCC will be communicated to the Office Directors, Division Directors, Supervisory Pharmacologists and Pharmacology Reviewers through distribution and electronic filing of the minutes of the PTCC and subcommittee meetings.

  2. CDER pharmacologists may raise issues to the PTCC by bringing them to the attention of:

     a. Their Supervisory Pharmacologist;

     b. A Subcommittee Chairperson;

     c. Any PTCC member; or

     d. The Executive Secretary of the PTCC.

EFFECTIVE DATE

This guide is effective upon date of publication.

Attachment A

PHARMACOLOGY SUBCOMMITTEES AND WORKING GROUPS

Committee	Status
Carcinogenicity Assessment	Active
Herbals	Active
Inactive Ingredients	Active
Stereochemistry/Stereoisomer	Reactivate
Genotoxicity	Active
General Safety Pharmacology	Active
Clinical Pathology	Active
Infotechnological	Active
Immunotoxicology	Active
Toxicokinetic	Inactive
Dose Selection	Inactive
Reproductive Toxicology	Active
Structure-Activity	Inactive
Good Review Practices (GRP)	Active
GRP - Reviewer Training	Active
GRP - Review Format	Active
6/12 Month	Active
Neurotoxicology	Reactivate

Attachment B

RECOMMENDATION FOR THE CREATION OF A CDER PTCC SUBCOMMITTEE OR WORKING GROUP

1. **Name of Committee:**

2. **Objectives:**

3. **Composition:**

   Chairperson:

   Co-Chair:

   Membership:

4. **Meeting Frequency:**

5. **Completion Date:**

   Concur:_____ Non-Concur:_____

   _____ _____
   Chairperson, PTCC Date

   Concur:_____ Non-concur:_____

   _____ _____

Co-Chairperson,PTCC Date