PROGRAM DESCRIPTION

OFFICE OF MEDICAL POLICY

Center for Drug Evaluation and Research Medical Policy Council

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PURPOSE

This document describes the organization, membership, responsibilities, and procedures of the Medical Policy Council (MPC) in the Center for Drug Evaluation and Research (CDER or Center). The MPC is a component of the Medical Policy and Program Review Council (MPPRC) which functions under two authorities: this MAPP and a Charter specific to OND Program Review Council (PRC). The applicable MAPP is determined by the specific topic/decision brought to the MPPRC meeting. To promote efficiency in operations and because there is overlap in membership, the meetings of the MPC will be held in concert with the meetings of the PRC). The joint meeting will be referred to as the Medical Policy and Program Review Council (MPPRC). Topics are identified on the joint meeting agenda as a policy (i.e., MPC) or a program issue (i.e., PRC).

The MPC will provide senior support to the Center on medical policy development, including:

- Leadership oversight and medical policy management for the Center
- Attention to and management of essential Center cross-cutting medical policy issues
- Advocacy for the activities of the MPC and its working groups
- Communication to both internal and external stakeholders on the medical policy decisions made by the Council

BACKGROUND

The MPC, acting under this MAPP, provides a senior-level forum to establish medical policy in CDER and its application to the new drug applications (NDA), investigational new drug applications (INDs), abbreviated new drug applications (ANDAs), and biosimilars and biologic review processes. MPC will help ensure that medical policy is implemented in a consistent manner throughout the Center.

The MPC will meet on a regular basis to consider medical policy issues that are complex or precedent setting and require senior management input.

Although the issue discussed by the MPC may have been triggered by a specific product, if policy is established by MPC (acting under this MAPP), this policy will be applied to all similar products.

For the purposes of the MPC, medical policy generally concerns broad issues related to application of statute or regulation to new situations or situations where application has been unclear or inconsistent. Policy issues may involve health care professional and patient labeling, human subject protections, counterterrorism drug development (such as application of the animal rule (21 CFR 314.600)), prescription drug promotion, good clinical practice, and novel drug development pathways, among others. Programmatic issues discussed under the PRC may include approvability or other challenging scientific/regulatory issues, as identified by the review team, team leaders, or divisional or office leadership across the Center.

To be considered by the MPC, a medical policy issue typically would meet one or more of the following criteria:

- A novel medical policy issue requiring input from senior management
- A medical policy issue on which CDER has not taken a consistent position
- An existing medical policy position that should be reconsidered in light of scientific or regulatory advances
- A medical policy that may be triggered by a specific product, but that will be applicable to other products (note that the specific product review issue will generally be managed under the PRC charter; however, typically a working group is initiated which is expected to bring to MPPRC (acting under this MAPP) recommendations for new policy/guidance).
- Strategies for implementation of a new medical policy

RESPONSIBILITIES

MPC

- Directs the development of policy, regulations, and guidances that have cross-CDER implications intended to communicate and implement consistent standard policies and procedures related to medical policy for internal and external use (e.g., IND drug development application review, post-approval management, labeling)
- Establishes and oversees subcommittees and working groups on medical policy to accomplish specific assessments and projects
- Reviews work products (e.g., documents and recommendations) of subcommittees and working groups on cross-CDER medical policy before circulating for clearance
- Promotes and coordinates internal and/or external communication of medical policy decisions when appropriate
- Develops Agency-wide communications on medical policy decisions when appropriate

MPC Members (related to their organizational units)

- During discussions, represent their organizational unit's views on issues under consideration by the MPC
- Identify relevant stakeholders and their concerns to the medical policy issue under discussion
- Nominate representatives from their organization's unit to participate in working groups to implement activities deemed necessary by the Council to meet goals and objectives
- Identify agenda items
- Attend meetings regularly

MPC Chair

- Provides leadership and direction to the MPC
- Promotes involvement and balanced participation of all members
- Reviews proposals and determines selection and prioritization of issues for consideration in conjunction with Council members when appropriate
- Provides mediation and has decision authority on the final Council recommendations if consensus is not reached within the Council
- Reviews nominations for the office and division directors and deputy directors and medical officer positions on the Council

Project Manager

- Reviews and prioritizes proposed agenda items for consideration by the Chair
- Schedules meetings and communicates agenda and any background material prior to each meeting
- Drafts and disseminates the meeting minutes
- Holds subcommittees and working group members accountable for completion of tasks
- Follows up on assignments and action items assigned to members

- Prepares documents and papers as directed by the Chair
- Serves as a primary point of contact for the MPPRC, subcommittees, and/or working groups
- Maintains the rosters of the subcommittees and/or working groups
- Maintains a repository that includes meeting notes, a log and status of issues discussed and actions assigned, and copies of Council decisions and actions

Subcommittees

- Establish a MAPP detailing the organization, membership, roles and responsibilities, and procedures of the subcommittee for Council approval
- Confirm objectives with the Council and projected life span of subcommittee
- Provide quarterly updates to the Council of subcommittee activities
- Provide work products to the Council in a timely manner
- Respond to questions from the Council on specific issues
- Advise and assist the Council in responding to Agency staff and other queries

Working Groups

- Develop project plans that include timelines and update MPC at regular intervals as designated by MPC
- Confirm working group objectives, goals, and due dates with the Council
- Define working group member responsibilities
- Provide work products to the Council in a timely manner
- Respond to questions from the Council on specific issues
- Advise and assist the Council in responding to Agency staff and other queries

The Individual and/or Office Seeking MPC Evaluation

- Submits a Proposal to the Project Manager for consideration by the Chair
- If the Proposal is accepted:
  - Provides a brief, focused (usually 3 to 5 pages) background document to the Project Manager at least 1 week before the scheduled MPC meeting. The background document (see attachment 2) should provide all the necessary information to understand the medical policy issue to be discussed. The background document should also include questions for the panel members to consider and provide resolution.
  - Identifies a lead from the office seeking MPC evaluation.
  - Submits to the Project Manager a proposed list of attendees representing viewpoints on the medical policy issue to be discussed.
- No later than 1 year after the MPC meeting was held, addresses any action items assigned that do not have a different due date based on statutory or other organizational need

PROCEDURES

1. Identification of issues

- Medical policy issues may be submitted by any Center staff member. The medical policy issue may be triggered by product-specific discussion and review; this review would generally be held under the PRC charter. If the discussion at the MPPRC meeting suggests that the issue has broad policy implications, typically a working group is initiated to develop recommendations, and these are brought to MPPRC (under this MAPP) for discussion and agreement.

- Medical policy issues may be developed from issues raised by the medical product industry, academia, political bodies, or other interested parties and brought to the attention of Center staff. MPC will consider whether opening a docket would be useful for soliciting outside stakeholder input on medical policy issues.

2. Proposals for discussion at an MPC meeting should be no more than one or two paragraphs to include the following:

   - The medical policy issue to be resolved
   - The trigger that raised the medical policy issue
   - The date by which a response is needed

3. The Chair will review proposed medical policy issues and select and prioritize issues for consideration, with appropriate input from Council members. If the proposal is not selected to be reviewed by the Chair or cannot be reviewed by the Council by the date specified, the Project Manager will provide an explanation of the Council's decision to the requester by email. Reconsideration by the Council of such decisions can be requested.

4. If the proposal is selected, a pre-meeting may be scheduled between the Chair and the individual or office seeking Council evaluation to assist in refining the medical policy issue to be discussed.

5. The medical policy issue will be summarized in a Medical Policy Council background document (see attachment 2) prepared by the requester and submitted at least 7 days in advance of the meeting.

6. A MPPRC meeting will be convened.

   - Experts from CDER and Agency staff will be sought and invited to participate in the discussion at the Chair's discretion.

   - The requester will provide a brief overview of the medical policy issues at the beginning of the meeting.

- Decisions will be established through deliberation among all parties attending the Council meeting, reaching resolution through consensus.

- If the Council reaches a resolution to the medical policy issue brought to its attention at the scheduled meeting:

  - The Council will determine the appropriate internal and external communication for the medical policy reached and any action items recommended. This could include, but is not limited to, the following:

    - Decisional Memorandum
    - MAPP (new or revision to current MAPP)
    - Guidance (new, revision to current guidance, or addendum to current guidance)
    - Publication in an appropriate journal

    Until such documents are drafted and distributed, the Council will determine the appropriate communication strategy to disseminate decisions to CDER staff.

    - If the Council believes that a current MAPP, guidance, or other document conveys the medical policy discussed at the meeting adequately, the Council may determine that training for CDER staff on the medical policy issue may be needed. The Council may recommend that the Division of Learning and Organizational Development develop and implement such training. If the policy included in the current MAPP, guidance, or other document requires further clarification, the Council may implement a communication strategy to explain the medical policy described.

    - The Council may establish a working group to explore the question further and draft the communication document.

- If the Council does not resolve a medical policy issue at the scheduled meeting:

  - The Council may establish a working group to explore the question further and return to the Council with recommendations for Council discussion on how to proceed; and
  - The Council may identify specific questions/concerns for an individual and/or office to research and provide answers, returning to the Council at a future meeting for further discussion.

- If the Council establishes a working group, lead offices will be identified and included in the action items.

- If the Council establishes a subcommittee, a charter will be adopted for the subcommittee.

- Medical policy and action items will be archived in an electronic database accessible to all CDER staff.

7. If the requester identifies concerns or challenges in implementing the medical policy decision reached, the requester can ask that the Council reconsider the decision.

    - Requests for reconsideration must be accompanied with an explanation on how implementing the medical policy established by the Council would affect CDER decisions.

    - The Council, at the discretion of the Chair, may respond to the request for reconsideration using one of the following two options:

        - The Chair, with appropriate input from Council members and experts from CDER, may respond to the request in writing.
        - The agenda item may be re-introduced to the Council at a future meeting, with the additional material in support of the request.

    - The request for reconsideration and the response will be archived with the initial medical policy decision reached.

8. The Chair will meet with appropriate CDER staff to debrief on the Council meeting and to coordinate action items when needed.

9. Action items that do not have a due date based on statutory or other organizational need will be addressed no later than 1 year after the Council meeting was held. The Project Manager is responsible for tracking action items and following up with the lead contact(s).

AUTHORITY

The MPC will have the following authority:

- Establish medical policy for issues brought before the MPC
- Establish subcommittees
- Establish working groups
- Provide direction and feedback to subcommittees and working groups
- Ratify subcommittee and working group recommendations

ORGANIZATION

Membership

The CDER Medical Policy Council includes the following:

- Chair: Director, Office of Medical Policy
- Members:
  - Center Director
  - Deputy Center Director for Clinical Science
  - Deputy Center Director for Science Operations
  - Deputy Center Director for Operations
  - Director, Office of New Drugs
  - Director, Office of Surveillance and Epidemiology
  - A Director from Office of Biostatistics
  - Director, Office of Clinical Pharmacology
  - Director, Office of Pharmacovigilance and Epidemiology
  - Deputy Director, Office of New Drugs
  - A staff member from the Office of New Drugs Policy
  - A staff member from the Oncology Center of Excellence
  - Up to four staff from the Office of New Drugs review divisions to participate on the Council for a 2-year term
  - (Ad Hoc) Office of Generic Drugs: Deputy Director for Clinical and Regulatory Affairs; Associate Director for Clinical Affairs; and a representative from OGD Policy

Any Council member may send a representative to participate on his or her behalf when the member is unavailable for the Council meeting.

CDER Executive Committee members will be advised on Council meeting agendas and will be invited by the Council to attend and/or send a representative with expertise within their offices on the medical policy issue to be discussed.

Nominations for Office of New Drugs staff members will be provided by the Director, Office of New Drugs, to the Council Chair for consideration. If possible, the OND office and deputy directors, the division director, and the medical officer representatives should represent a cross-section of OND.

Office of Generic Drug representatives are routinely invited to MPC meetings for informational awareness. For agenda items more directly impacting the generic drugs program, OGD representatives and subject matter experts will be invited to join discussions.

The Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and any other relevant office within the Agency will be

invited by the MPC to send a representative to attend those meetings of known interest at the discretion of the Chair.

Subcommittees
Subcommittees may be established by MPC to perform ongoing activities and work products with oversight by the Council. These subcommittees typically perform ongoing activities that are more detailed and/or directed to a specific medical policy issue.

Subcommittees will have an extended life span. Subcommittees will be disbanded when they have successfully completed their goal or their purpose no longer meets the goals of the Council.

Working Groups
Working groups may be established and directed by the MPC to facilitate work on a short-term project not being addressed by a standing subcommittee.

Working groups will have a limited life span. The working groups will adjourn when they have successfully completed their goal or additional work is not required as determined by the MPC.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
03/19/13	Initial	n/a
09/16/15	1	1. Establishes subcommittees and procedures.
		2. Clarifies the Council's advisory role in making recommendations.
		3. Clarifies the decision-making role of review divisions/offices.
		4. Updates responsibilities and procedures and establishes a time frame for seeking Council evaluation.
		5. Updates name of the Division of Learning and Organizational Development.
		6. Updates MAPP in current template.
09/06/17	2	1. Updates Responsibilities section
		2. Updates Membership list
02/11/21	3	1. Clarify MPC versus Program Review purpose and roles and responsibilities and Editorial Changes

ATTACHMENT 1

The following are examples of medical policy issues and challenges that the CDER Medical Policy Council may address:

1. Labeling implications of prescription drug-use related software.

2. Demonstration of contribution of components for fixed-dose combination products and labeling implications.

3. Standards for use of the animal rule.

4. Approval of products that may benefit the community but not the individual (e.g., combinations to prevent emergence of microbial resistance, transmission blocking vaccines, interventions to reduce transmissibility of tuberculosis).

5. Standards of evidence for prophylaxis where efficacy may not be testable in humans (e.g., prevention of anthrax, countermeasures to prevent poisoning).

6. Assessing requests for breakthrough therapy designation.

7. Approaches to novel clinical trial designs, including new biostatistical analysis methods proposed by sponsors or applicants.

8. Life Cycle Management and impact on generic drug products.

ATTACHMENT 2

CDER Medical Policy Council
Background Document Template

Purpose - The CDER Medical Policy Council background document is a *stand-alone* document of a medical policy issue(s) that requires resolution from the CDER Medical Policy Council. It should convey the medical policy issue to be resolved, the trigger that raised the medical policy issue, and the date by which a response is needed. The document should follow the CDER Style Guide, be no more than three to five pages, and provide all the necessary information to understand the medical policy issue to be discussed.

Introduction - Provide an overview of the medical policy issue to be resolved.

Background - Describe scientific, clinical, and regulatory areas that address the medical policy issue to be resolved. If applicable, include any areas and issues that have been raised; the regulation, MAPP, and/or guidance that has an impact on the medical policy issue; any considerations and advice already provided in discussions with the sponsor; and any other important aspect, such as previous advice and precedent given to other sponsors or staff, that would affect the resolution to be reached. The information should contain ideas, including any differing opinions, on how the medical policy should be implemented.

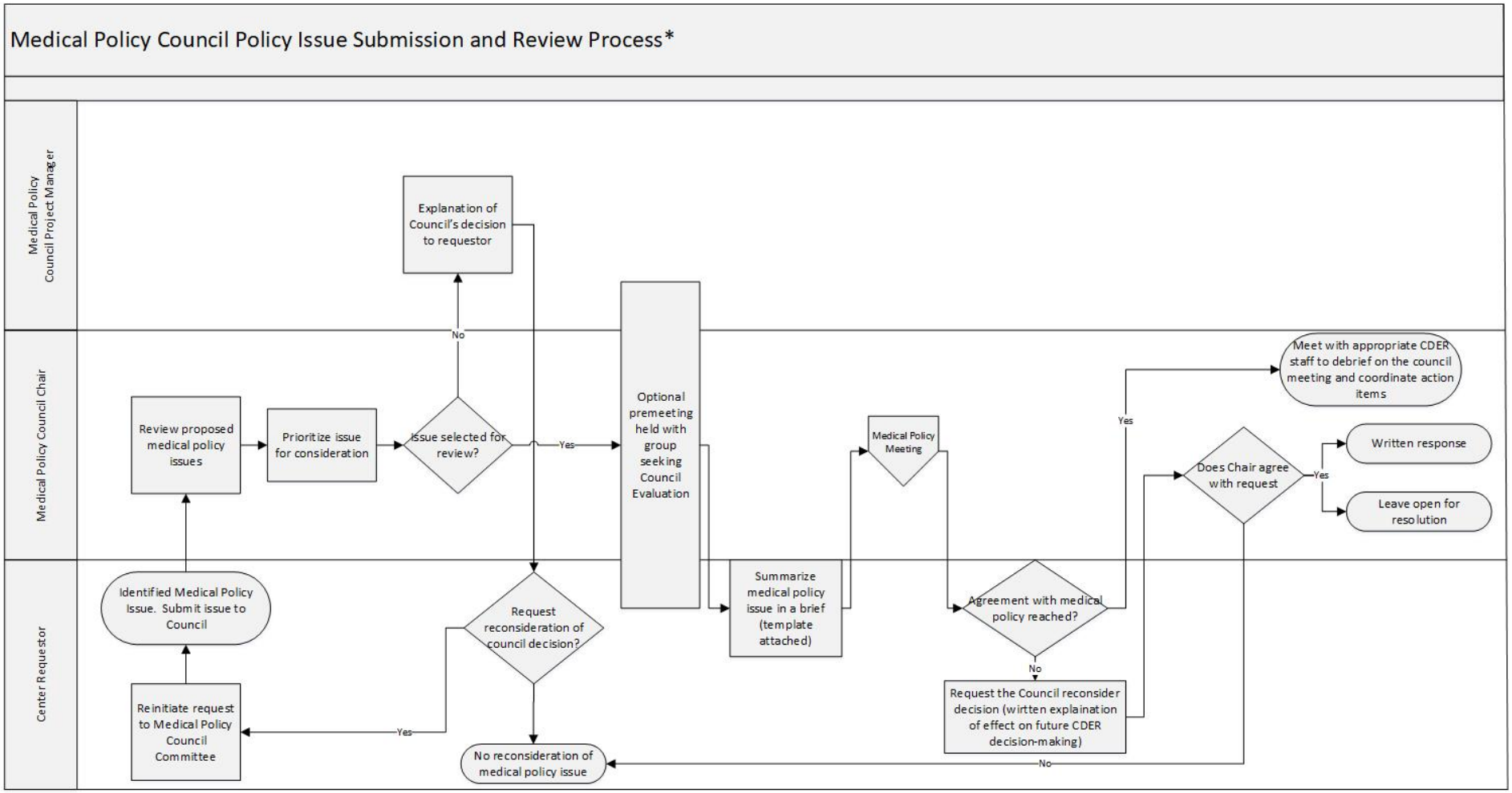
Questions to be Considered by the Council - List the questions that the Council should consider in response to the medical policy issue to be resolved. The questions should be general, applying to all drugs and/or biological products or a group of drugs and/or biological products. Questions should not be product-specific.

It is recommended that the questions include options with the preferred outcome highlighted, if possible.

Presentation - Provide all presentation materials to be used by the individual or an identified lead from the Office seeking Committee evaluation. The presentation will be limited to no more than 10 minutes and may only reference materials provided in the background document or attachments (see Attachments - below). A PowerPoint presentation is not required.

Attachments - Attach any additional background material, such as reviews, guidance, MAPPs, or regulations. Attachments are not required, but such attachments are supplementary to the Council background document.

ATTACHMENT 3



ATTACHMENT 4