PROGRAM DESCRIPTION

OFFICE OF MEDICAL POLICY

Center for Drug Evaluation and Research Medical Policy Council

Table of Contents

PURPOSE **1**
BACKGROUND **1**
RESPONSIBILITIES **2**
PROCEDURES **4**
AUTHORITY **7**
ORGANIZATION **7**
EFFECTIVE DATE **8**
CHANGE CONTROL TABLE **9**
ATTACHMENT 1 10
ATTACHMENT 2 11
ATTACHMENT 3 12
ATTACHMENT 4 13

PURPOSE

This document describes the organization, membership, responsibilities, and procedures of the Medical Policy Council in the Center for Drug Evaluation and Research (CDER or Center).

The CDER Medical Policy Council (the Council) 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
- Advocacy for the activities of this Council and its working groups
- Communication to both internal and external stakeholders on the medical policy decisions made by the Council

BACKGROUND

The Council provides a senior-level forum to establish medical policy in CDER and its application to the new drug applications (NDA), biosimilars and biologic review processes, as well as other CDER programs, including abbreviated new drug applications. The Council will help ensure that medical policy is implemented in a consistent manner throughout the Center.

The Council 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 Council may have been triggered by a specific product, the policy established by the Council will be applied to all similar products. Product-specific recommendations will be referred to the appropriate review division and/or office for follow-up and implementation.

For the purposes of this Council, medical policy generally concerns one or more of the following: (1) Clinical evidence of effectiveness or safety, (2) clinical study/trial design, (3) health care professional and patient labeling, (4) prescription drug promotion, (5) human subject protection, (6) bioresearch monitoring, (7) good clinical practice, (8) counterterrorism drug development (such as in the application of the animal rule; 21 CFR 314.600), and (9) postmarketing surveillance.

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

- A novel medical policy issue requiring senior management input
- A medical policy issue on which CDER seems to have taken inconsistent positions
- An existing medical policy position that should be reconsidered in light of scientific or regulatory advances
- A complex safety management issue requiring senior management input
- A medical policy that may be triggered by a specific product, but that will be applicable to other products
- Strategies for implementation of a new medical policy

RESPONSIBILITIES

The Council

- Directs the development of policy, regulations, and guidances intended to communicate and implement consistent standard policies and procedures related to medical policy for internal and external use
- 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 medical policy before they are circulated for clearance
- Promotes and coordinates internal and/or external communication of medical policy decisions when appropriate
- Develops Agencywide communications on medical policy decisions when appropriate

Council Members (related to their organizational units)

- Represent their organizational unit's views on issues under consideration by the Council
- 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

Council Chair

- Provides leadership and direction to the Council
- 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 decision authority on issues that cannot reach consensus 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 focal point for the Council, 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 the Council at regular intervals as designated by the Council
- 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 Council 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 Council 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 Council 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 Council 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. Although the medical policy issue may be triggered by product-specific discussion and review, the medical policy issue presented to the Council will not be product-specific.

   - 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. The Council will consider whether opening a docket would be useful for soliciting outside stakeholder input on medical policy issues.

2. Requests to discuss a proposed medical policy issue at a Council 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.

6. A Council 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 10-minute 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 Council will have the following authority:

- Establish medical policy
- 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
  - Director, Office of New Drugs
  - Director, Office of Surveillance and Epidemiology
  - Director, Office of Biostatistics
  - Director, Office of Clinical Pharmacology
  - An office deputy director from the Office of New Drugs
  - A division or deputy director from a review division of the Office of New Drugs to participate on the Council for a 2-year term

- A medical officer from a review division of the Office of New Drugs to participate on the Council for a 2-year term

Ad Hoc

Office of Generic Drugs

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

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 division director and medical officer 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.

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 Council to send a representative to attend those meetings of known interest at the discretion of the Chair.

Subcommittees

Subcommittees may be established by the Council 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 Council 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 Council.

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
01/31/2018		1. Non-substantial change to add 1 OND member

ATTACHMENT 1

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

1. Obstacles to development of a non-inferiority margin (e.g., historic data outdated or historic data unavailable on current endpoint, or efficacy data unavailable on proposed comparator or non-inferiority margin undefined when new drug must be used in combination with other active agents).

2. Obstacles to development of an appropriate control regimen (e.g., the new product has already been adopted by the medical community as the standard of care for a new off-label indication).

3. Ethical obstacles to studying a drug in a high prevalence area where a drug may not be deployed in the future (e.g., malaria prophylaxis).

4. Standards for use of the animal rule.

5. Approaches to new indications proposed by sponsors; principles in deciding on medical relevance.

6. 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).

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

8. Defining surrogate endpoints (e.g., when does a surrogate become a validated clinical endpoint?).

9. Assessing requests for breakthrough therapy designation.

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

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.

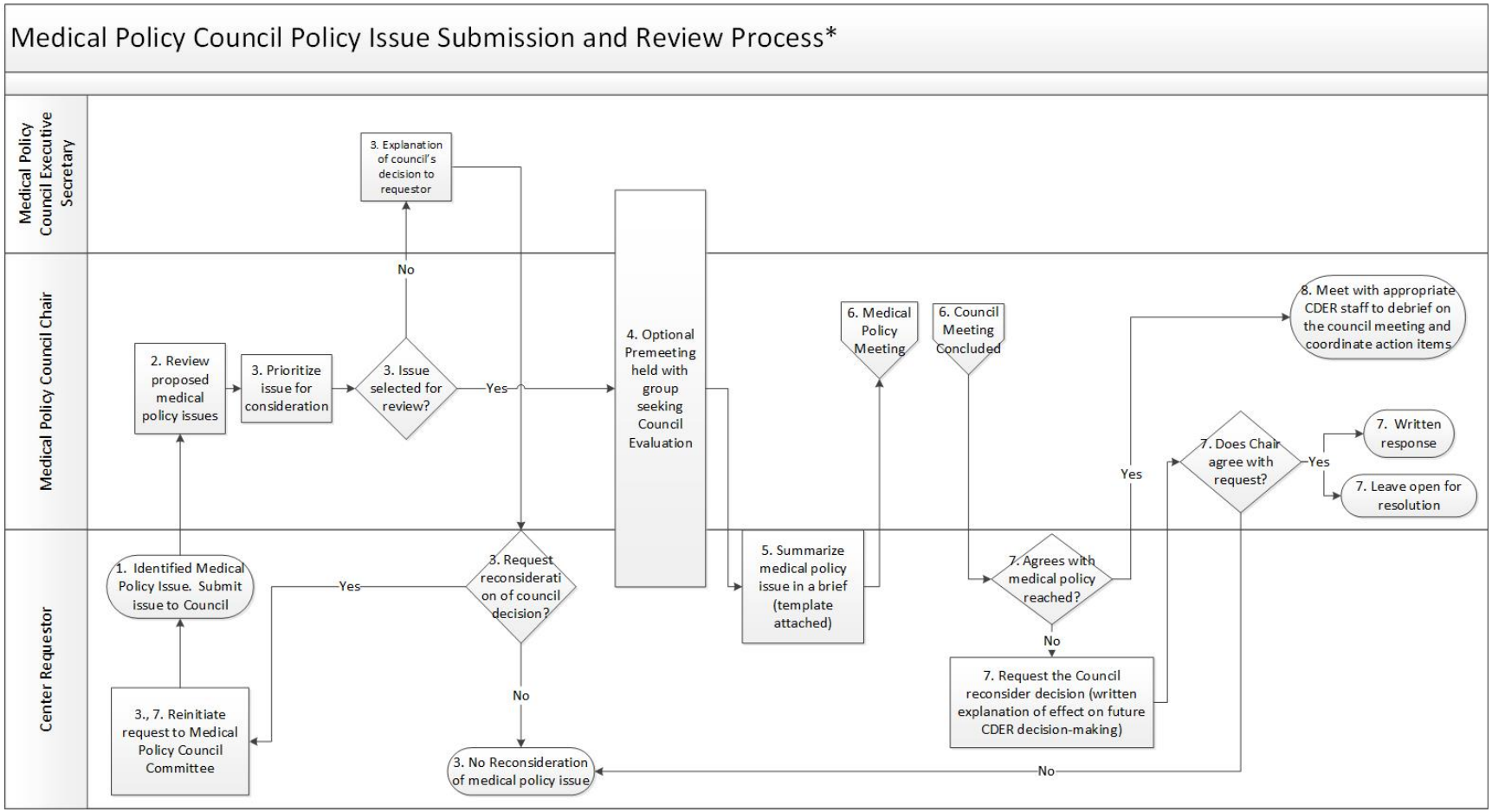
Questions to be Considered by the Council - List the questions that the Council should consider in response to the medical policy issue to be resolved. The questions should be general, applying to all drugs and/or biological products or a group of drugs and/or biological products. Questions should not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

Procedures for Medical Policy Council Meeting