

## BYLAWS

### PHARMACEUTICAL & MEDICAL DEVICE LABELING COMMITTEE OF THE INSTITUTE OF PACKAGING PROFESSIONALS

#### **Article I**      **Purpose**

The Pharmaceutical & Medical Device Labeling Committee (P&MDLC) of The Institute of Packaging Professionals is organized to study labeling issues related to pharmaceutical and medical device packaging operations. The primary objective is to study the technical advances as well as Regulatory issues in labeling facing its membership. The information solicited by the Committee at the meetings will be restricted to the scientific and technical aspects of pharmaceutical labeling.

#### **Article II**      **Committee Responsibilities to The Institute of Packaging Professionals**

The Committee will participate in The Institute of Packaging Professionals as deemed necessary and beneficial by the Committee. The Committee will work with the Technical Council (TC) through its representative on the TC and develop all written reports that the Committee deems beneficial. Participation in seminars will be at the discretion of the Committee.

#### **Article III**      **Membership**

Member Company Requirements:

- 1) Must be involved in research, development and/or manufacture of pharmaceuticals, biologics and/or devices/combination products which fall under the regulated Labeling provisions of the US Food and Drug Administration.

Company Representatives:

Note: Corporations that have multiple independent operating companies are allowed representatives for each independent operating company providing the company and individual meet the membership requirements below:

1. Be a member, in good standing, of The Institute of Packaging Professionals (preferably corporate representative).

2. Be closely affiliated with the labeling process specific to content and production artwork associated with commercial packaging operations for products which are supported by a New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or 510K filing by the company. This suggests Regulatory, Package Engineering, Package Design, Graphic Artists, Quality Control or any group involved with creating, designing and/or evaluating labeling and labeling systems for the pharmaceutical or medical device company the member represents.
3. Be well informed about pharmaceutical/medical device labeling and the package operations of their companies so that they are able to discuss subjects and contribute at Committee meetings.
4. Be recognized by his/her company as The Institute of Packaging Professionals member or alternate to the Committee. The individual applying for membership must obtain his/her immediate supervisor's signature on the membership application to prove management recognition and support of the individual and company commitment.
5. Be willing and interested in accepting subcommittee assignments or Committee office.
6. Be aware that the P&MDLC is a technical committee appointed as a Charter Unit of the Institute of Packaging Professionals.

The member company shall designate a primary Representative

The member company is expected to have representation at all meetings. Unless otherwise arranged in advance with Vice-Chair, a maximum of 2 attendees (e.g., 2 company representative's or-1 company representative and a company guest) from each company shall be permitted at each meeting. The member company is also expected to be as generous in sharing ideas and creating projects as eliciting answers or solutions to problems.

Individual Membership is based on individual and company. If current member changes company, a new application must be submitted and approved for his/her replacement.

#### **Article IV Honorary Membership:**

Retiring Committee members may be offered honorary membership if the following criteria have been met:

The retiring member has served as Chairperson and has been an active and contributing committee member for 5 years or more.

Honorary membership includes an open invitation to attend committee meetings. The honorary member is obligated to avoid conflict of interest and exercise professional

discretion. If an Honorary Member accepts employment from an organization that does qualify for membership on the Committee, the privilege of attending and receiving benefit from meetings must be suspended for the duration of employment. Honorary members must maintain membership in the Institute of Packaging Professionals. Honorary members must attend at least 1 meeting each calendar year to continue to receive committee mailings.

**Article V**      **Membership Application Procedures**

New Members qualifying under Article III may be elected following application to the membership and a subsequent majority vote on their behalf. The application and election procedure will be as follows:

The Secretary will review any applications received for membership (both regular member and alternate) for membership requirements as stated previously under Article III and review with the Chairperson and Vice-Chairperson of the Committee. Any questions regarding the application will be researched by the officers.

Upon approval by the executive committee, the Secretary will present the application to the full committee electronically for voting. Active members (one per Member Company) will vote by responding electronically either accepting or rejecting the application. A simple majority is required to approve a membership application. Once approved, the Secretary will notify the new member. The new member will then be able to attend the next committee meeting and subsequent meetings with full membership status.

Alternate members are not automatically elected to full membership upon departure of the regular member. When such vacancy occurs, an alternate member may submit an application to become the regular member by meeting the requirements of Articles III and V of the Bylaws of this Committee.

**Article VI**      **Alternates**

Each company should establish, in advance, an alternate who can attend meetings and in the absence of either regular member, will vote for the member and represent the member company when necessary. The alternates must submit an application as well as meet the qualifications of Article III. All alternates must be sponsored by the members from their companies. The member must sign the alternate's application to show recognition and support of the application.

If no alternate exists within the company that meets all of the requirements of Article III, an alternate may be assigned who would be considered the member's logical in-house back up.

**Article VII   Guests**

By invitation, a limited number of guests may attend an official Pharmaceutical & Medical Device Labeling Committee Meeting provided the matter is cleared by the Vice-Chairperson. It may at times also be necessary to limit the meeting to only members because of space constraints by the Host. This will be communicated by the Vice-Chairperson.

**Article VIII   Executive Officers**

The Committee activities and meetings will be managed by the Executive officers comprised of, a Chairperson, Vice-Chairperson, Secretary, and Meeting Coordinator. The Chairperson is elected by the general committee membership. The remaining Executive officers are appointed by the newly elected Committee Chairperson and approved by vote of the general committee membership. Officers must be Committee members (not alternate members). Collectively the officers form the Executive Committee.

**Article IX   Election of Committee Chairperson**

The Executive officers shall serve the role of Nominating body for the election of the Committee Chairperson. Members interested in serving as Committee Chairperson or Executive officers will submit their names to the Executive Committee at the Fall meeting for voting on during the Spring meeting. The Executive Committee will also solicit members to serve as officers from within the general committee membership.

Nominees for Committee Chairperson will be presented electronically by ballot to the general committee members by the Secretary a minimum of 30 days prior to the Spring meeting. The Chairperson shall be elected to office by a majority vote of the general committee members. The remaining committee officers will be proposed by the newly elected Chairperson during the Spring meeting as a motion to the general committee and approved per Article XII by the general committee members.

The Institute of Packaging Professionals Technical Council shall be notified by mail of the election of new officers by the outgoing Chairperson immediately following the Spring meeting.

**Article X   Term of Office**

The term for the officers will be two (2) years. In the event that an incumbent must leave the Executive Committee and surrender the office, the following procedure applies:

- Incumbent Chairperson resigns – The Vice Chairperson will temporarily fill the vacant Chairperson position. The Executive Committee will call for nominations from the general committee membership by e-mail. The Secretary will subsequently prepare a ballot including the nominees and submit the ballot for vote to the general committee

membership during the next regularly scheduled meeting or electronically prior to next meeting based on Executive Committee activity.

- Incumbent Vice Chairperson, Secretary or Meeting Coordinator resigns: The Chairperson and remaining Executive Committee members will appoint an interim replacement officer for the position vacated and notify the general committee membership via e-mail. The appointment will be formally proposed as motion at the next regularly scheduled meeting and approved per Article XII by the general committee members.

## **Article XI    Duties of the Officers**

### **A. Executive Committee – Officers**

1. Work together in planning meetings, arrangement, host, and communications with The Institute of Packaging Professionals and handling of the Pharmaceutical & Medical Device Labeling Committee meeting.
2. Certification that each Committee member complies with individual membership qualifications to be continually reviewed and enforced by the Executive Committee.

### **B. Duties of Chairperson**

1. Preside at all Committee meetings. Assign members to subcommittees to outline and develop special projects.
2. Handle outside inquiries regarding Pharmaceutical & Medical Device Labeling Committee activities using discretion in giving information immediately or referring inquiries to the Committee at its next regular meeting.
3. Manage and oversee the activities of all subcommittees and assure that their activities are consistent with the P&MDLC's Mission Statement (Attachment A) and Bylaws.

### **C. Duties of the Vice-Chairperson**

1. Preside at Committee meetings during question and answer programs – presenting members' questions for discussion.
2. Assists the Secretary.

3. Provides oversight and coordination with IoPP regarding the P&MDLC website. Submits updates to IoPP relative to website content changes as required.

No later than 45 days prior to a Committee regular meeting, submit to members details as to host, meeting place, transportation and pertinent detail regarding scheduled activities of host. Included is the request for members to indicate if they plan to attend and questions they want to submit for discussion at the meeting.

4. No later than 15 days prior to a Committee regular meeting, submit to members the final details of the meeting, transportation details, a final agenda and the questions submitted by the membership for discussion.

**D. Duties of Secretary**

1. Prepare minutes of Committee meeting and distribute to members.
2. Maintain a membership attendance chart reflecting attendance at least eight (8) of the previous meetings. This chart will be distributed to each member at the time of mailing the meeting notice.
3. Record retention – maintain a permanent record of membership lists, meeting host, location, and date. Maintain a record of meeting minutes for 3 years, on a running basis.
4. At the beginning of each official meeting of the Committee, read aloud for all present the antitrust compliance statement. (Attachment B)
5. Administer new member applications and review with the Chairperson and Vice-Chairperson as described in Article V.

**F. Duties of Meeting Coordinator**

1. Lead the P&MDLC meeting planning activities
  - a. Arrange with the membership for an Organizational Presentation by two member companies per meeting.
  - b. Arrange for two P&MDLC related presentations per meeting from member companies or suppliers with technical labeling expertise.
  - c. Coordinate with the host company to ensure that the meeting room and audio-visual equipment is set up to the needs of the Committee and presenters.

**Article XII**    **Standard Voting Procedures**

If at any time during a meeting a discussion or decision requires a vote by the committee, a member may motion to put the discussion to a vote, with a “second” from the floor. Unless otherwise specified in the Bylaws, a decision will be taken from a simple majority vote as the standard. In certain instances, the Executive Committee may at their discretion require a two-thirds majority vote on a given matter.

As previously stated, only one elected member or his/her alternate can vote on Committee matters, unless otherwise designated by the elected member. In any case only a single vote can be cast per company.

A vote of Committee members may be necessary prior to the next regularly scheduled meeting. This may be accomplished by e-mail.

**Article XIII**    **Meetings**

The number of regularly scheduled meetings of the Committee will be as follows:

Spring Meeting – March or April

Fall Meeting – September or October

As needed, additional meetings may be called at the discretion of the Chairperson.

**Article XIV**    **Bylaws**

From time to time, these Bylaws will require amendment to accommodate changes to the Committee’s internal environment and the environment of the Pharmaceutical and Medical Device Industries, which the Committee serves.

The procedure will be as follows:

The Chairperson shall appoint a standing subcommittee consisting of the Vice Chairperson and at least two (2) members to review and update the Bylaws. The term of subcommittee members will be two years on a rotating basis. The purpose of this subcommittee is to present proposals as warranted by our changing environment (both internal and external) to amend the Bylaws of this Committee. It is also recognized that from time to time individual members of the Committee might present to the standing subcommittee proposed amendments to the existing Bylaws. It will be the responsibility of this subcommittee to present to the officers of the Committee a written recommendation of any proposed amendment. The officers will present this written recommendation to the Committee at large during any regular scheduled meeting.

The committee shall discuss the amendment, revise, if necessary, the wording or intent of the amendment and shall table the amendment for the next regularly scheduled meeting. These discussions and final wording of the amendment will be documented in the minutes of the meeting as a proposed change.

At the next regularly scheduled meeting, the amendment shall be further discussed and voted upon as it was written and documented in the minutes. Seventy-five percent (75%) of the member companies must be present at the meeting or be represented by proxy.

The motion to approve the amendment must carry by a two-thirds majority of the voting members of the Committee.

The IoPP Bylaws shall prevail in situations not addressed by the P&MDLC Bylaws.

#### **Article XV    Code of Conduct**

All P&MDLC officers, members, and their guests are expected to conduct the business of the Committee in a respectful, courteous, ethical, professional and objective manner. Discussions and debate are encouraged to arrive at prudent decisions for the benefit of the P&MDLC, its members, and the packaging community in general.

#### **Performance Improvement Process**

If during the course of conducting the business of the P&MDLC, the behavior of a member(s) is observed to be out of compliance with the Code of Conduct, then the following steps will be taken:

1. The officers will have a conversation with the individual(s) involved in an attempt to clarify the situation, and obtain an apology(s) or retraction(s) as indicated, or obtain restitution in the event that property damage is involved. A record of this conversation will be made and kept on file by the Recording Secretary.
2. If no resolution of the situation is completed as a result of the conversation, then the next step is for the Chairperson to write a letter describing the situation, and requesting a written apology, retraction and/or restitution from the individual(s) involved. This letter(s) will be sent via certified mail with return receipt to assure that the delivery of the letter(s) to the recipient(s) was accomplished. A copy of the letter will be forwarded to the Recording Secretary to be added to the file.
3. If there is still no resolution of the situation or apology, retraction, and/or restitution, then the situation will again be discussed among the P&MDLC Executive Committee. The Officers will review the situation and document. If three-fourths of the Officers are in agreement to proceed to the probation step in the process, then the offending member(s) will be put on probation for a period of six months or other appropriate time period set by the Executive Committee.



4. If after the probation period is served by the member(s) no improvement in attitude or actions is noted, and no apology, retraction, and/or restitution have been made, the Executive Committee may ask the member(s) to submit his/her resignation to the Committee, and arrange for replacement membership from his/her company.
5. If an offending member does not agree to resign, then the Executive Committee can refer the offending member to the IoPP Board of Directors for expulsion from IoPP in accordance with the IoPP member expulsion process.

## ATTACHMENT A

### MISSION STATEMENT/STRATEGIC PLAN

- Purpose:** The Pharmaceutical & Medical Device Labeling Committee of the Institute of Packaging Professionals is organized to communicate package label design and development and related issues of the pharmaceutical and medical device industries.
- Mission:** To openly review and discuss current and emerging non-proprietary information related to artwork development, materials, equipment, technologies, regulatory compliance, quality control and environmentally responsible packaging and to use it to foster improvements in package labeling which will achieve the highest quality standards.
- Strategic Plan:** The objectives of the Pharmaceutical & Medical Device Labeling Committee of the Institute of Packaging Professionals will be achieved through the following:
- Committee meetings with participation within the question and answer session, round table discussions, and technical and organizational presentations.
  - Presentation of educational seminars to industry and educational institutes.
  - Technical presentations and plant tours of the corresponding host and host companies.

## ATTACHMENT B

### CONDENSED STATEMENT OF ANTITRUST COMPLIANCE TO BE READ AT EVERY MEETING OF A TECHNICAL COMMITTEE

Approved by the Institute of Packaging Professionals, and posted on the IoPP website.

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“The Board of Directors of The Institute of Packaging Professionals has publicly stated its support for the policy of competition served by Federal antitrust laws and its intent to comply strictly with these laws. In support of the Statement, the officers of the Pharmaceutical & Medical Device Labeling Committee make the following requests at this meeting:

1. Every attendee should be familiar with the provisions of the IoPP Statement and General Rules of Antitrust Compliance, copies of which are available from the Chairperson or Corresponding Secretary of this Committee.
2. The agenda for this meeting shall be followed, and permission of the Chairperson must be obtained before any other matters of business are introduced.
3. During this meeting, there shall be no discussion of pricing methods, costs, volumes or conditions of production or sale, allocation of territories or customers, nor any discussion which might be construed as limiting any person or business from free access to any market, customer or source of supply.”

*In addition to this statement, the Officers of this Committee request that all Committee Members refrain from making derogatory or unfavorable comments regarding suppliers during open forum.*