RULES AND REGULATIONS

DRUG AND PHARMACEUTICAL PACKAGING COMMITTEE
OF THE INSTITUTE OF PACKAGING PROFESSIONALS

Article I  Purpose

The Drug and Pharmaceutical Packaging Committee of The Institute of Packaging Professionals is organized to study the overall packaging operations and related problems of the drug and pharmaceutical industry. Its object is to study the technical advances and problems in the packaging area of the pharmaceutical industry through its membership. The information solicited by this Committee at the meetings will be restricted to the scientific and technical aspect of packaging.

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 Operations Committee through its representative on the TOP Board and develop all written reports that the Committee deems beneficial to TOP. Participation in seminars will be at the discretion of the Committee.

Article III  Membership

Regular Membership:

The Committee is composed of individual members from companies in the pharmaceutical industry which are involved in the Research and Development of new chemical/biological entities and the manufacturing and marketing of human prescription drugs, which are primarily supported by a New Drug Application (NDA).

Each pharmaceutical company is allowed to have one member and one alternate on the committee. A corporation with more than one company/division with drug and pharmaceuticals as their primary business (whether or not they are independent operating companies) may assign an alternate from another company/division within the corporation.

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Corporations that have multiple independent operating companies are allowed one member per independent operating company providing the company and individual meet the membership requirements. An independent operating company within a corporation is defined as a company that has a separate Marketing, Manufacturing and Package Development/Engineering function from other companies within the corporation. (If a company within a corporation has independent groups for one or two of the listed functions but a combined third group, they are not considered to be an independent company.) It is the responsibility of the Committee to determine if multiple companies from one corporate entity applying for membership meet the requirements. In order to best make this determination the applying member must provide a company/corporate and department organization chart with their application.

When corporations merge and multiple individuals from the newly combined corporation are members of the Committee and these members are not covered by the rule for independent operating companies for corporations, as described above, it is the responsibility of the corporation to determine which member will remain on the committee. It is possible that one of the members will be primary and the other member will become the alternate. The new combined corporation, if not covered by the rule for independent operating companies for corporations, will be permitted to maintain only one membership (with one alternate).

Only the elected member or his/her alternate can vote on committee matters.

In general, a member must meet the following:

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

2. Be closely affiliated with the packaging operations for prescription pharmaceutical drugs and/or drugs which are supported by a New Drug Application (NDA) filing by the company. This suggests Packaging Development, Packaging Research, Package Engineering, Package Design or any group involved with the job of creating and/or evaluating new concepts to improve package techniques and package forms of the drug or pharmaceutical company the member represents. An organizational chart must be provided with application for membership that demonstrates the individual's job function and overall status within their company.

3. Be well informed about packages and the package operations of their company so that they are able to discuss subjects and contribute at Committee meetings.
4. Be recognized by their company as The Institute of Packaging Professionals member or alternate to the Committee. The individual applying for membership must obtain their immediate supervisors 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 prepared to establish a new membership for your company if retirement, resignation, promotion, a transfer in duties within the firm, company mergers or any happening which prevents the member (or alternate) from carrying out the responsibilities or meeting the requirements of a Committee member. The new member would be established according to the provisions of Article IV. Since membership is tied to companies and not individuals a member relinquishes his/her membership upon termination of their employment with a member company. If the individual is leaving the current member company to go to a non-member company that meets all of the qualifications for membership, the individual must apply for membership under their new company.

7. Be aware of the Committee's identification as a technical committee appointed as a support interest to The Institute of Packaging Professionals.

8. Be as generous in sharing ideas and creating projects as eliciting answers or solutions to problems.

9. The member is expected to attend all meetings. If it becomes impossible for a member to attend, the designated alternate should take his/her place. If a company is not represented by the bona fide Committee member at two consecutive meetings, the Committee secretary shall advise such member that failure to attend the next regular meeting and justify their absences will result in loss of membership on the Committee. If a company is not represented by a member or alternate at two consecutive meetings, the secretary shall notify both member and alternate that failure to attend the next regular meeting and justify their absences will result in loss of membership to them as well as their company. Only a member or an alternate can attend each meeting except by permission of the secretary.
Honorary Membership:

Retiring Committee members may be offered honorary membership if the following criteria has been met: The retiring member has served as chairman and has been an active and contributing committee member for ten years or more. Honorary membership includes an open invitation to attend committee meetings via Article VI. 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 not 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. Honorary members will receive committee mailings for a period of 2 years, renewable at the honorary members request.

Article IV  \textit{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.

The secretary will present the application to the membership at the next regular meeting of the committee.

The committee will vote on the application. A simple majority is required to approve a membership application. Once approved the member will attend the next meeting and subsequent meetings with full membership status.

Alternate members are not automatically elected to full membership upon the vacating of that membership by the regular member. When such a vacancy occurs, an alternate member may submit an application to become the regular member by meeting the requirements of Article III and IV of the Rules and Regulations of this Committee.
Article V  Alternates

Each company should establish in advance, an alternate who would attend meetings in place of the regular member when necessary. The alternate must submit an application as well as meet the qualifications of Article III. All alternates must be sponsored by the member from their company. The member must sign the alternates 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 VI  Guests

By invitation, a limited number of alternates, honorary members and guests may attend an official Drug and Pharmaceutical Packaging Committee Meeting provided the matter is cleared and the invitation is extended by Committee Secretary.

Article VII  Officers

The Committee has as its officers chairman, vice-chairman, and secretary who are elected by the committee.

Article VIII  Election of Officers

A three-person nominating subcommittee for the election of a new chairman, vice chairman, and secretary shall be appointed by the presiding chairman at the winter meeting. The nominating subcommittee shall present a slate of nominees to the assembled members at the summer meeting. The nominees shall be elected to office by a majority vote of the Committee members, and they shall take office immediately following election. The Institute of Packaging Professionals Technical Operations and Planning Board shall be notified by mail of the election of new officers by the outgoing chairman immediately following the summer meeting.
Article IX  Term of Office

The term for the officers will be one year beginning with the summer meeting. So as to permit greater opportunity for members to serve the Committee at the officer level, officers are limited to serving one (1) term in office. This rule may be revised at any time by a majority vote of the Committee members.

In the event that an incumbent must leave the committee and surrender the office, the following procedure applies:

- Incumbent Chairman Resigns - The Vice Chairman will assume the chair for the balance of the term year and would qualify to be elected to chairman for the following year.

- Incumbent Vice Chairman Resigns - The incumbent Chairman assumes and/or shares with the Secretary the duties normally performed by the Vice Chairman.

- Incumbent Secretary resigns prior to second meeting of term: The Chairman will appoint a nominating committee (either the last named committee or others by choice).

  * The nominating committee will select a candidate for Secretary and provide a motion and second for nomination of said candidate.

  * The Chairman or Vice Chairman will poll the members by phone or fax.

1. Announce the nominating committee candidate by name.
2. Ask for any other nominee.
3. Advise that a motion is made and seconded to approve nominating committee candidate.
4. Log and date the responses: yea or nay.
5. Upon completion of the vote, report in writing to all members.

Incumbent Secretary resigns after the second meeting. Vice Chairman assumes Secretary duties for final meeting of term year.
Article X  Duties of Officer

A. Executive Committee - Officers

1. Work together in planning meetings, arrangement, host, and communications with The Institute of Packaging Professionals and handling of the Drug and Pharmaceutical Packaging 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 Chairman

1. Preside at all Committee meetings. Assign members to subcommittees to outline and develop special projects

2. Handle outside inquiries regarding Drug and Pharmaceutical Packaging 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 DPPC's Mission Statement (Attachment A).

C. Duties of the Vice-Chairman

1. Serve on executive committee.

2. Preside at committee meetings during question and answer programs - presenting members' questions for discussion.

3. Assists secretary.

4. 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 request for members to indicate if they plan to attend and questions they want to submit for discussion at the meeting.

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D. Duties of Secretary

1. Prepare minutes of Committee meeting and distribute to members.

2. In cooperation with Chairman, Vice-Chairman and members, arrange for hosts, meeting places, and date for Committee meetings.

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

4. 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.

5. At the beginning of each official meeting of the Committee, read aloud for all present the antitrust compliance statement. (Attachment B).

6. 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.

Article XI  Meetings

The number of regularly scheduled meetings of the Committee will be as follows:
Winter Meeting - February or March
Summer Meeting - May or June
Fall Meeting - September or October

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

Article XII Amendment of the By-Laws

From time to time, these by-laws will require amendment to accommodate the changes which will occur to the committee's internal environment and the environment of the Pharmaceutical Industry which the committee serves.
The procedure will be as follows:

The Chairman shall appoint a standing subcommittee consisting of at least three (3) members to review and update the by-laws. The term of subcommittee members will be three years on a rotating basis. The purpose of this subcommittee is to present proposals as warranted by our changing environment to amend the by-laws of this committee. It is also recognized that from time to time individual members or the officers of the committee might present to the standing subcommittee proposed amendments to the existing by-laws. 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 regularly 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.

**Article XIII  Code of Conduct**

As a given, each individual elected to membership on this committee is expected to comport in an ethical and socially responsible manner.

Failure to behave in said manner shall be considered grounds to revoke an individual’s membership or deny member status to a candidate.

Behavior inimical to these standards, as a pattern, should be noted or brought to the attention of the officers of the committee.

The officers of the committee will counsel the errant member in a positive manner to eliminate any behavior that brings discredit or embarrassment to the committee, individually or collectively.

When a member has behaved in a manner contrary to the code of conduct and the officers determine that behavior to be damaging to the reputation of the Drug and Pharmaceutical Packaging Committee, individual members of the committee, to the packaging profession, or to a company hosting a committee
meeting, the Committee Chairperson shall submit a letter to the offending member/alternate, requesting the member/alternate to immediately cease the objectionable practice or make restitution, where property is involved. The letter should invite the member/alternate to offer a replacement company representative, if the situation cannot or will not be resolved.

In the event that counseling or the letter fails to eliminate the problem, the chairman will present the issue to the membership and request a motion, from the floor, to remove this individual from membership on this committee.
ATTACHMENT A

MISSION STATEMENT/STRATEGIC PLAN

Purpose: The Drug and Pharmaceutical Committee of the Institute of Packaging Professionals is organized to communicate package design and development and related issues of the pharmaceutical industry.

Mission: To openly review and discuss current and emerging non-proprietary information related to materials and equipment technologies, regulatory compliance and environmentally responsible packaging and to use it to foster improvements in package design and development which will achieve the highest quality standards.

Strategic Plan: The objectives of the Drug and Pharmaceutical Packaging Committee of the Institute of Packaging Professionals will be achieved through the following:

- through the committee meetings with participation within the question and answer session, round table discussions, and technical and organizational presentations.
- through the presentation of educational seminars to industry and educational institutes.
- through the 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, October 17, 1990

"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 Drug and Pharmaceutical Packaging 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 Chairman or Secretary of this committee.

2. The agenda for this meeting shall be followed, and permission of the Chairman 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."

Revision Date 9/9/96
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