

**Drug and Pharmaceutical Packaging Committee****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 challenges of the drug and pharmaceutical industry. Its objective is to study the technical advances and challenges in the packaging area of the pharmaceutical industry through its membership. The information solicited by the 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 TOC Board and develop all written reports that the Committee deems beneficial to TOC. Participation in seminars will be at the discretion of the Committee.

**Article III      Membership****Regular Membership:**

The DPPC is composed of individual members from companies in the pharmaceutical and biopharmaceutical industries and whose primary focus is in the Research and Development of new chemical/biological entities and the manufacturing and marketing of human prescription drugs, which are primarily supported by New Drug Applications such as NDAs and BLAs.

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.

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

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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 as described above, it is the responsibility of the sponsoring Company to determine which representatives will remain on the committee. Options are available to the sponsoring Company. Existing members and alternates of the Committee may be “grandfathered” with the consent of the sponsoring Company. In such circumstances, only one representative of the sponsoring Company will provide answers during the Q&A session. The “grandfather” provision will elapse once a committee member and alternate both leave the sponsoring Company or the committee, at which time the normal rules for representation, only one membership (with one alternate), will resume.

Alternatively, it is possible that one of the members will be the primary and the other member will become the alternate or any combination of existing members and alternates that constitute the normal rules for representation. Any changes to membership reorganization must be approved by the Drug and Pharmaceutical Packaging Committee.

In the event a non-member company merges with or acquires a member company, the existing member and alternate may maintain membership on the Committee under a “grandfather” provision provided their responsibilities in the newly formed company remain consistent with the membership requirements of the DPPC and are a member/alternate in good standing. The “grandfather” provision for the individual will elapse if the Committee member/alternate’s job responsibility is no longer consistent with the membership requirements of the DPPC, or if he/she leaves the Company or the Committee. The Executive Committee is responsible for overseeing adherence to the grandfather provision.

Only the 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.

In general, a member must meet the following:

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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 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 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. Attendance is defined as being in-person at the meeting venue(s) for all or a substantial portion of the multi-day agenda. If it becomes impossible for a member to attend, the designated alternate should take

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his/her place. The executive committee reserves the right to determine if a meeting will utilize an in person or virtual format. It is not expected that a face-to-face meeting will also be offered as a virtual meeting due to commitments made to host companies. In order for a member company to be considered as in attendance in the meeting they must participate according to the approved format for that meeting. Attendance for a virtual meeting is defined as being logged into the video conference for all or a substantial portion of the full meeting agenda. If a company is not represented by a member, alternate, or pre-approved company employee guest at two consecutive meetings, the secretary shall notify both member and alternate that failure to attend the next regular meeting and justify the absences will result in loss of membership to their company. Only a member or an alternate can attend each meeting except by permission of the secretary. A member company may appeal in the event of extenuating circumstances affecting their attendance at the discretion of the Executive Committee.

#### Honorary Membership:

Retiring Committee members may be offered honorary membership if the following criteria have been met. The retiring member has served as chairman and has been an active and contributing committee member and/or alternate 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 full time employment from an organization that does qualify for membership, the privilege is suspended for the duration of employment. If the organization does not qualify for membership on the Committee, the privilege of attending and receiving benefit from meetings will be at the discretion of the Executive Committee. For example, exceptions may be permitted for Honorary Members who work for or start consultancy businesses.

Honorary members must maintain membership in the Institute of Packaging Professionals. Honorary members must attend at least 1 meeting every two calendar years 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**    **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 secretary will receive any applications for membership (both regular member and alternate), and the application will be reviewed at the next scheduled Executive Committee meeting to ensure that the applicant meets the membership requirements as stated under Article III. Assuming that the applicant meets the membership requirements, then the application will be approved or denied by one of the two following procedures:

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For new members from companies that are NOT currently member companies (i.e. new companies to the committee) the election procedure will be as follows:

- 1 - The secretary will present the application to the membership at the next regular meeting of the committee.
- 2 - The committee will vote on the application. A simple majority is required to approve a membership application.
- 3 - Once approved, the member will attend the next meeting and subsequent meetings with full membership status.

If the application is for a replacement member or alternate from a company that already has a committee membership, then the approval process will be as follows:

- 1 - The secretary will send an e-mail to all members notifying them of the prospective new member or alternate, and including a copy of the application.
- 2 – Any concerns from a member regarding the qualifications of the individual or of the individual’s ability to adhere to the committee rules and/or code of conduct should be expressed to the Secretary in a confidential email.
- 3 – If no concerns are expressed within two weeks, the member will be notified by e-mail by the Secretary that they have been approved as a member and that they are eligible to attend all future committee meetings.
- 4 – If concerns are expressed, the matter will be discussed within the Executive Committee, and if not resolved, the applicant will be voted on at the next full committee meeting. In the case of a full committee vote, a simple majority is needed to approve the application.

Applicants may not attend a meeting until their application is approved, unless it is as a guest.

Alternate members are not automatically elected to full membership upon the vacating of the membership by the regular member. When such 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.

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#### **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 guests may attend an official Drug and Pharmaceutical Packaging Committee Meeting provided the guest is approved by the Committee Secretary. Guests who are not employees of a member company are also permitted to attend the meeting, but only if making a technical presentation or contributing to the meeting in some tangible way and are approved by the Committee Secretary.

At times it may be necessary to limit the meeting to only members because of space constraints by the Host.

Guest attendance at social events or host company tours outside of the official DPPC committee meeting should be approved by the meeting coordinator and the meeting host company.

#### **Article VII     Officers**

The Committee has as its officer's 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 will be comprised of the three most recent former chairman remaining as active members or alternates to the Committee. The former chairman furthest removed in time will lead the subcommittee. The nominating subcommittee shall present a slate of nominees (chairman, vice chairman, and secretary) 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

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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.

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#### **Article X     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 presiding over 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) and Rules and Regulations.
4. Serve on the Executive Committee

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

1. Serve on the Executive Committee.
2. At the beginning of each official meeting of the Committee, read aloud for all present the antitrust compliance statement. (Attachment B)
3. Assists Secretary.
4. Provides oversight and coordination with IOPP regarding the D&PPC website. Submits updates to IOPP relative to website content changes as required.



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#### **D. Duties of Secretary**

1. Prepare minutes of the DPPC meeting and distribute to members. Approval of the minutes shall be obtained for the DPPC at its next meeting. A copy of the minutes shall be sent to IoPP Headquarters, attn. IoPP Technical Council and Executive Director.
2. In cooperation with Chairman, Vice-Chairman., Meeting Host Subcommittee, and other members, arrange for hosts, meeting places, and date for Committee meetings.
3. In conjunction with the assigned DPPC meeting coordinator, and the host company, and no later than 45 days prior to a DPPC regular meeting, submit to members meeting details such as the host, meeting place, transportation and pertinent details 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. Preside during the benchmarking question and answer session at DPPC meetings – presiding over the questions (each question will be read out by the member or alternate who submitted the question(s) and logging answers given. Results of the benchmarking to be distributed to members along with the minutes of the meeting.
5. Maintain a membership attendance chart reflecting Company (member/alternate) attendance for a minimum of eight (8) of the previous meetings. This chart will be distributed to each member at the time of mailing of the meeting notice or incorporated into the meeting minutes.
6. Record retention – maintain a permanent record of membership lists, meeting hosts, locations, and dates. Maintain a record of meeting minutes for the current term year and 3 previous term years.
7. Serve on the Executive Committee

#### **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

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As needed, additional meetings may be called, or current meetings canceled, at the discretion of the chairman. Occasionally, organized roundtable discussions are held on relevant packaging topics, typically following the main Committee meeting, for those committee attendees able to participate. Such roundtables are voluntary, are subject to DPPC Bylaws, are announced as part of the overall meeting agenda, and are documented via brief summary notes supplied to membership. Host suppliers are not participants in roundtables. Non-DPPC participants (e.g. technology experts, consultants) may participate with prior approval of the Executive Committee.

#### **Article XII   Amendment of the By-Laws**

As required, these by-laws will be amended to accommodate the changes which will occur to the DPPC's internal environment and the environment of the Pharmaceutical Industry which the DPPC serves

The procedure for by-law amendment 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 purpose of this subcommittee is to present proposed amendments as warranted by our changing environment to the by-laws of the DPPC. It is also recognized that individual members and the officers of the DPPC may present to the standing subcommittee proposed amendments to the existing by-laws. It will be the responsibility of this subcommittee to present to the Executive Committee a written recommendation of any proposed by-law amendment. The officers of the DPPC will present the written recommendation to the DPPC membership during a regular scheduled DPPC meeting.

The DPPC membership shall discuss and revise, if necessary, the wording or intent of the proposed amendment. The revised proposed amendment will then be tabled until the next regularly scheduled meeting where it will be put to vote for approval by the DPPC membership. The discussions and final wording of the proposed amendment will be documented in the minutes of the meeting as a proposed change.

At the next regularly scheduled meeting, the proposed amendment as it was written and documented in the minutes of the previous meeting, shall be reviewed and put to vote for approval by the DPPC membership. 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 present at the meeting.

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#### **Article XIII   Code of Conduct**

Each individual elected to membership on the DPPC including Honorary Members 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 at the discretion of the Executive Committee.

Behavior contrary to these standards should be noted and brought to the attention of the officers of the DPPC.

The officers of the DPPC will counsel the errant member in a positive manner to modify behavior that brings discredit or embarrassment to the DPPC.

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, an individual member of the committee, to the packaging profession, or to a company hosting a DPPC meeting, the DPPC Chairperson shall submit a letter to the offending member/alternate, requesting the member/alternate to immediately cease the objectionable practice and make necessary restitution, where property is involved. If the offense warrants, a letter should invite the member/alternate to offer a replacement company representative.

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.

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#### **ATTACHMENT A**

##### **MISSION STATEMENT/STRATEGIC PLAN**

**Purpose:** The Drug and Pharmaceutical Packaging 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 expectations/trends (compliance) and environmentally responsible packaging and to use it to foster improvements in package 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 may (will) be achieved through the following:

- Through the DPPC meetings with participation in 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 member companies.

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#### **ATTACHMENT B**

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

**Approved by the Institute of Packaging Professionals, February 2007**

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“IoPP recognizes that the antitrust laws are designed to preserve free and open competition in the marketplace. IoPP is committed to compliance with all requirements of the antitrust laws. IoPP will not play any role in the competitive decisions of its members or in any way restrict competition in member-related industries. 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 matters of business are introduced. Minutes of the meeting shall be distributed to the committee membership.
3. During this meeting, there shall be no discussion of rates or pricing methods and policies, production quotas or other limitations on the timing, cost or volume of production or sale, or allocations of territories, markets, or customers. There shall be no discussion which might be construed as an attempt to orchestrate group boycotts, organize refusals to deal with third parties, or to prevent any person or business entity from gaining access to any market or customer for goods or services or to prevent any business entity from obtaining a supply of goods or otherwise purchasing good or services freely in the market.