

AAPS Scientific Opinions and Comments Policy

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Scientific, Regulatory, and Policy Opinions at AAPS

AAPS' mission is to *advance the capacity of pharmaceutical scientists to develop products and therapies that improve global health*. In fulfilling this mission, AAPS convenes conferences, workshops, and other meetings to advance scientific, regulatory, and policy topics. AAPS members also gather in the AAPS Communities for open scientific discussions for the same purpose. Work products that arise from these activities should represent the best-founded scientific data and agreed opinion of the scientific experts of the association. This policy provides a framework for the process by which such documents should be reviewed and approved by AAPS leadership. A separate AAPS Guide for Authors of Scientific, Regulatory, and Policy Opinions provides guidance to authors on the preparation and submission of such documents.

Content Categories and Publication Routes

The scope of this policy is centered on publication activities that are derived from groups within AAPS and activities that have been convened by AAPS, with the resulting documents representing information, an opinion, scientific findings, or viewpoints issued on behalf of the association. On occasion these documents may arise from a collaborative activity with a sister organization. In these cases, and as a general rule for publication management, **AAPS journals and communication outlets should be given priority consideration**. Table 1 summarizes the types of documents covered by this policy.

Type of Content	Publication Route	Considerations
White Papers that AAPS members have contributed to	AAPS Peer-Reviewed Journals	This includes the use of our journals in the evolution of new and developing scientific and regulatory opinions before AAPS has a single viewpoint.
General AAPS information or program-supporting scientific and industry information with no opinions or policy matters	<i>AAPS Newsmagazine</i>	Informing and educating our members and wider audience about topics AAPS is actively engaged in or is seeking wider discussion on within its membership.
Scientific white papers and opinions that AAPS members have contributed to, after AAPS journals have exercised right of first refusal or as bound by a collaborative agreement with another organization	Non-AAPS Journals	Need review and approval only if opinions expressed are meant to represent AAPS. If AAPS members participate/author but do not speak on behalf of AAPS, this is out of scope for approval by AAPS leadership.
Regulatory and compendial comments on behalf of AAPS	Direct Submission to Agency	Assuring that the comments represent AAPS as an organization requires preparation and a balanced review process.

Table 1: Types of documents covered by this policy

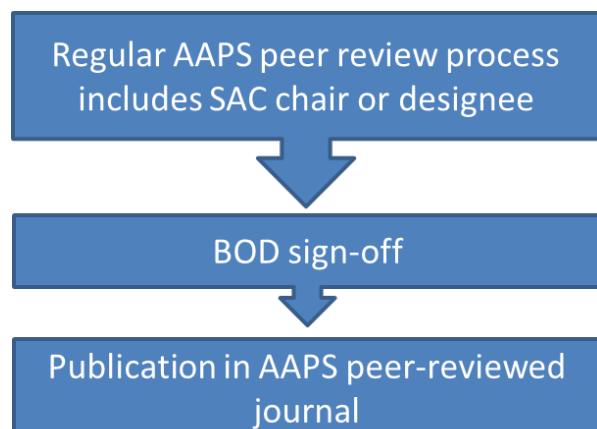
Publishing in an AAPS Peer-Reviewed Journal

Content Scope: White papers where authors present an opinion or opinions under their names that have arisen from deliberations that AAPS has convened (conference, workshop, or AAPS Community event), but that do not necessarily represent AAPS' organizational position. Commentaries and Meeting Reports are specifically defined in the INSTRUCTIONS FOR AUTHORS for AAPS Journals and do not require review and approval by the AAPS Scientific Advisory Committee (SAC) and the AAPS Board of Directors (BOD).

Approach:

The regular journal peer review process constitutes the main pillar of review. Once a paper has been identified to qualify as a white paper that has AAPS involvement, the responsible Editor-in-Chief will be responsible for including SAC representation in the review. The AAPS Board of Directors (BOD) can intervene and stop publication based on a substantiated concern but must then use SAC to resolve the concern with the appropriate journal editor-in-chief. The regular peer review process for publications of this type will include the SAC chair or a designee from SAC.

Review and Approval Process:



Publishing in the *AAPS Newsmagazine*

Content in the AAPS Newsmagazine is published under the oversight and with contributions from the magazine's Editorial Content Committee (ECC). As a general rule, the Newsmagazine is not considered an appropriate publishing venue for scientific opinions or White Papers, as its publishing scope and remit is to provide general news and updates to AAPS members. The newsmagazine could on occasion point to a White Paper or other contribution, especially if AAPS is seeking additional scientific input. Should content be submitted to the AAPS Newsmagazine that is deemed more appropriate for one of the other scientific publishing routes discussed in this policy, AAPS staff, under guidance from the ECC, will advance the contribution to the proper publication and review channel.

Publishing in a Non-AAPS Peer-Reviewed Journal

Content scope: Scientific white papers and opinions that AAPS members have contributed to, after AAPS journals have exercised their right of first refusal, or as bound by collaborative agreement with another organization. The primary consideration in this type of publication is how the expressed scientific or policy opinions are linked to AAPS. **If they are linked to an AAPS-convened deliberation and/or are deemed to represent AAPS, they are subject to review.**

Approach:

- Assure that AAPS journals always get right of first refusal for AAPS-initiated content.
- Assure that collaborations with other organizations proceed on pre-agreed terms that include publication clauses favoring AAPS Journals for publication and assure AAPS review if publication in a non-AAPS journal is part of the agreement. AAPS member volunteers must consult with AAPS staff to plan the execution of such a publication. AAPS members cannot enter into any type of agreement with another organization on AAPS' behalf.
- Assure that authors of publications that emanate from an AAPS-convened activity represent AAPS' involvement correctly and include a statement that clarifies AAPS's role.

If individual authors publish on a scientific matter that has emanated from an AAPS-convened activity and AAPS is mentioned in the paper, but the content does not represent an agreed-upon AAPS position, clarifying disclaimer language must be added to the paper, e.g., "opinions expressed in this publication are those of the authors and do not represent a consensus position of AAPS".

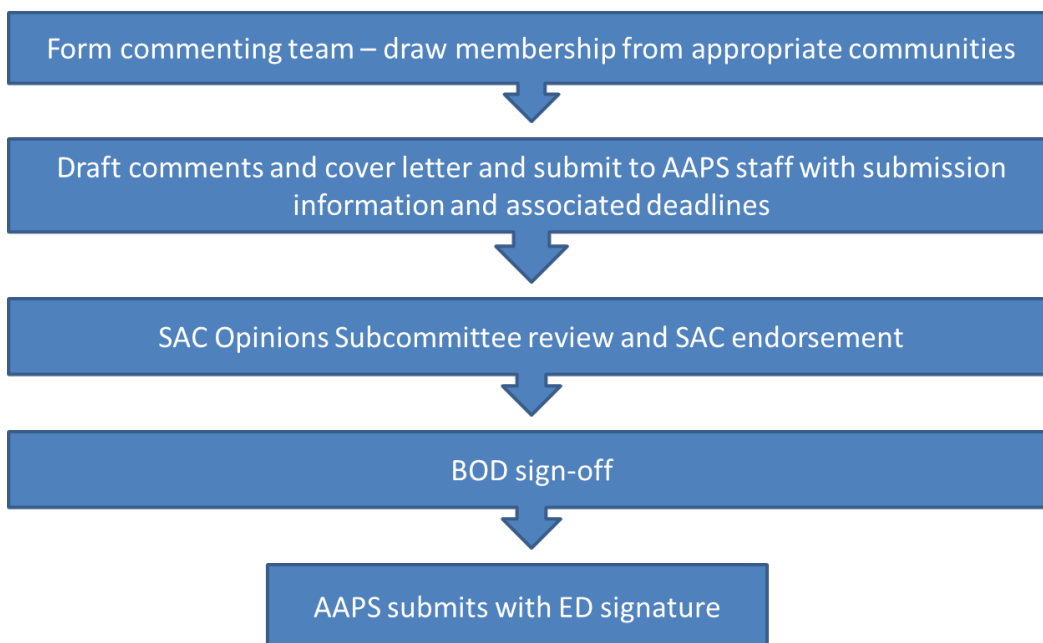
Regulatory, Compendial, and Policy Comments

Content scope: Comments on behalf of AAPS in response to regulatory, compendial, or policy documents published for public comments, e.g., FDA guidance documents, pharmacopeial monographs/chapters, ICH guidance, or WHO documents. The primary concern for this type of publication is to assure that opinions are developed that reflect AAPS' position and are in line with the organization's mission and scope, are free of advocacy, and have been developed with appropriate expert input from AAPS' membership.

Approach:

- Assure that comments are developed by an appropriate commenting team – drawing on the appropriate AAPS Communities for the right representation.
- Assure that comments developed are free of advocacy bias and not based on comments repurposed from another organization or source.
- Assure that comments are in the scope of AAPS' remit and within the expertise range of AAPS members.
- Assure that comments are assembled in a timely manner for submission by applicable deadlines. If a commenting process has multiple rounds of review or editing (e.g., in compendial and ICH settings), assuring that there is continuity in the AAPS commenting team to evaluate document progression.

Development, Review, and Approval Process:



Roles and Responsibilities

Scientific Advisory Committee (SAC)

1. Overall scientific oversight – provides recommendations to endorse, revise, or reject contributions and forwards endorsed papers to the Board of Directors for sign-off.
2. Assigns reviewers with appropriate expertise.

Board of Directors

1. Signs off on SAC endorsed contributions.
2. Has veto authority but must use SAC to resolve disputes.

AAPS Staff

1. Manages process and document flow.
2. Executive Director signs all policy, regulatory, and compendial opinions sent on behalf of the organization.