August 13, 2024

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

RE: Written Comments to Docket # FDA-2024-N-1809
FDA Listening Session: Optimizing the Use of, and Processes for, Advisory Committees

PharmApprove appreciates the Agency's efforts to optimize the use of and processes for Advisory Committees by soliciting input from stakeholders. We listened with great interest to the perspectives and voices that contributed to the FDA Listening Session on June 13, 2024.

All stakeholders can agree that the Agency's mission to promote and protect public health must be supported by sound, data-driven decisions regarding drug and biologic applications. An Advisory Committee meeting provides an opportunity for the Agency to receive outside, expert advice on scientific, technical, and/or policy matters by providing a forum for the presentation of pertinent information needed for fulsome consideration of the topic.

It is our view that Advisory Committee meetings are most productive and best serve public health when all parties have a level of shared understanding, there is transparency between FDA and the Applicant leading up to the Advisory Committee, and there are standardized best practices. Informed by our extensive work with global regulatory agencies and having supported Applicants in FDA Advisory Committees and EMA proceedings for over 20 years, we offer, herein, suggestions for changes to the current Advisory Committee processes in 3 areas: Committee Composition and Training, Pre-meeting Deliverables and Timelines, and Meeting Design.

Advisory Committee Composition and Training

We support efforts to 1) increase the number of Committee members with specific disease-state expertise and 2) enhance the Committee's understanding of the regulatory framework behind the discussion and voting questions posed by the Agency. Specific disease-state expertise allows a nuanced interpretation of the application-specific issues, a greater chance for robust meeting discussion and a fully informed outcome. Likewise, an understanding of the regulatory framework underpinning the Agency's questions reduces confusion during the meeting and enhances the Committee's ability to provide sound advice.

Pre-meeting Deliverables and Timelines

At the heart of a productive Advisory Committee meeting is a well-informed expert committee. To be well-informed, Committee members must receive clear written and oral presentations of

study results, analyses, and interpretations that are directly relevant to the questions posed by the Agency. The Advisory Committee process for deliverables and timelines could be modified to better inform the Advisory Committee. With the current process, Applicants do not receive timely guidance on the specific Agency questions, analyses, and interpretation to enable efficient preparation of clear, concise, and relevant Briefing Documents and Oral Presentations.

In the case of Briefing Documents, the Applicant's Final Briefing Document is due weeks before the Agency questions are provided to the Applicant. This scenario can lead to "everything but the kitchen sink" approaches to ensuring that enough information is included in the Applicant's Briefing Document to cover what *might* be needed to answer a broad range of potential Agency questions. As every drug or biologic application contains an enormous amount of detailed information, it is essential for the relevant information to be chosen carefully, summarized effectively, and presented concisely for the Committee to digest with ease. The current process places an undue burden on Applicants and Advisory Committee members.

In the case of Oral Presentations, the Applicant currently receives the Agency's presentation slides on the morning of the Advisory Committee Meeting. This scenario can lead to surprises, leaving the Applicant with little or no time to fully consider and prepare a response to the Agency's analysis and interpretation. Surprises run counter to a shared goal of transparent and productive discussion.

We support changes to the Advisory Committee processes to increase transparent communication between the Applicant and the Agency. Reference is made to our experiences with Oral Explanations and Ad Hoc Expert Group processes in Europe, in which major objections are documented and shared with the Applicant during the review, leading to a clear, shared understanding of the meeting's purpose. Adopting such a shared understanding would permit the Agency and the Applicant to understand the nuances of each other's analyses and interpretations, ultimately delivering more effective meeting materials.

Considering these challenges, we recommend adoption of a standardized process for improving Applicant-Agency communication in advance of an Advisory Committee Meeting that includes, at a minimum:

(1) At least one mandatory meeting between the Agency and Applicant to discuss specific Advisory Committee topics. While this is sometimes done during Mid and Late Cycle meetings for those applications that qualify, not all applications are eligible;
(2) Communication of the draft discussion and voting questions before the Applicant Briefing Document is due; and
(3) Delivery of the Agency's draft presentation slides to the Applicant at the same time as the Applicant's slides are due to the Agency, 7 days prior to the meeting, with final slides for both parties due the day before the meeting.

Meeting Design Considerations

We support the recommendation voiced by several stakeholders at the Listening Session for the inclusion of a professionally trained meeting facilitator as a non-voting committee chair. This would ensure consistency in meeting facilitation across committees and would also allow all expert voting members to focus on the meeting content and scientific discussion.

We also support modifications to the meeting agenda which allows opportunities for the Applicant to provide input during critical points of the meeting. Applicants have the deepest understanding of the application's dataset and allowing this to be shared contributes to a fair and open forum. Suggested meeting agenda enhancements include:

(1) allowing the Applicant to voice their perspective during Q&A sessions for questions that had been directed at the Agency;
(2) reserving formal time in the agenda prior to the Committee vote for the Applicant to provide a brief summary of their position on the discussion; and,
(3) defining a formal process for the Applicant to be recognized by the Chair for permission to speak during Committee discussion.

We support efforts to increase and clarify the public's participation in the Agency's decision-making process, as society benefits when the patient voice is heard and considered in making public health decisions. The Listening Session included several Open Public Hearing participants that felt disregarded by the Committees to which they testified. To address this, the Agency could clarify that the Agency will consider OPH voices in parallel to the Advisory Committee voice. Additionally, we support efforts for patient voices to be heard for all drug and biologic applications under consideration by the Agency, not just those for whom an Advisory Committee is being held.

We support retaining voting question(s), and can see advantages to the proposal raised in the Listening Session that suggested rephrasing yes/no voting questions to capture more nuance by the inclusion of a confidence scale, e.g., "On a scale of 1 to 5, how confident are you that …"

In conclusion, we appreciate the Agency's effort to enhance the Advisory Committee process. If you have any questions, we can be contacted at info@pharmapprove.com or support@ssistrategy.com.

Collectively,

The PharmApprove Team

www.ssistrategy.com