
Manual of Standard Operating Procedures and Policies

Regulatory - General Information

Procedures for Parallel Scientific Advice with European Medicines Agency (EMA); Pilot

SOPP 8001.6

Version #1

Date: November 27, 2006

1. Purpose

The purpose of this document is to describe the policies and procedures to be used by Center for Biologics Evaluation and Research (CBER) staff for participating in the pilot program between the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for providing "Parallel Scientific Advice" (PSA).

2. Definitions

Parallel Scientific Advice (PSA) refers to an exchange of views on scientific issues during the development phase of new medicinal products (i.e, new human drugs and biologics).

"Sponsor" refers to: (a) the "sponsor" of an Investigational New Drug Application (IND) in the US, (b) the "applicant" that submits a New Drug Application (NDA) or Biologics License Application (BLA) in the US, or (c) a potential marketing authorization applicant (MAA) under the centralized marketing authorization process in the European Union.

3. Background

On September 17, 2004, the EMA and the FDA agreed to undertake a pilot program to provide parallel scientific advice (PSA). The pilot began on January 1, 2005 and was extended per agreement of both parties on March 13, 2006. For the FDA, this program aligns most closely to pre-IND/end of Phase II meetings. During this pilot, PSA efforts should focus primarily on important breakthrough products. The expected advantages from such interactions are

- increased dialogue between the two agencies and sponsors from the beginning of the lifecycle of a new product,
- a deeper understanding of the bases of scientific advice, and
- the opportunity to optimize product development and avoid unnecessary testing replication or unnecessary diverse testing methodologies.

These meetings are conducted under the auspices of the confidentiality arrangement between the European Commission, the EMA, and FDA. The complete text of the agreed upon general principles for the pilot can

be found at <http://www.fda.gov/oia/pilotprogram0904.html>

4. Policy

PSA meetings are voluntary and usually occur at the request of the sponsor. A meeting may also be initiated by either the EMEA or FDA in cooperation with the sponsor. PSA meetings should focus primarily on specific questions or issues involving the development of a medicinal product on which the sponsor desires to have further scientific input from both EMEA and FDA. Usually, the sponsor should be included as part of the meeting. In addition, the two agencies will usually hold a pre-meeting tele- or videoconference and may hold a post-meeting tele- or videoconference without the sponsor in order to discuss further the issues posed by the sponsor.

The scope of products covered by this pilot should be limited in order to determine the usefulness of the program and what added value and costs, if any, it creates. Prime candidates for PSA under this pilot should be novel (e.g., products for orphan indications or pediatric populations) or breakthrough medicinal products, especially if the product is being developed for indications for which development guidelines do not exist or, if guidelines do exist, EMEA's and FDA's guidelines differ significantly. Such products generally should have been accorded "fast track" status in the US.

Each agency will provide, according to their usual procedures, their independent advice to the sponsor on the questions posed during the PSA. The advice of each agency may still differ after the joint discussion. Sponsors should not expect to always receive similar recommendations from the two agencies regarding drug development issues or marketing applications that have undergone PSA meetings. It is anticipated that following such parallel scientific meetings sponsors should have a clearer understanding what the respective requirements and perspectives of the two agencies are with regard to the development program discussed, and, if divergent, the reasons for the divergence.

Both agencies remain committed to meeting domestic process and review goals and timeframes. The PSA pilot should not be allowed to impact adversely on either agency's ability to meet its formal domestic performance expectations. Both agencies commit to be cognizant of the other's formal domestic performance expectations and to exhibit as much flexibility as possible in scheduling PSA meetings in order not to impact adversely either agency's ability to meet their formal domestic performance expectations.

These meetings will be in lieu of Prescription Drug User Fee Act (PDUFA) meetings (e.g., pre-IND, end of Phase II), and will not be subject to the performance goals for scheduling and holding PDUFA meetings.

Most PSA meetings conducted under this pilot should be a single occurrence focused on the specific development issue raised. This pilot should not be viewed as a continuing series of PSA meetings on the same specific product.

5. Responsibilities and Procedures

Request for a Meeting

The primary responsibility for coordinating all communications with the EMEA for PSA meeting requests is with the Associate Director for the EU (ADEU), Office of International Programs, Office of the Commissioner. Requests for PSAs and/or questions about how to submit a PSA meeting request from sponsors should be referred to the ADEU. The ADEU will forward those requests that pertain to CBER regulated products to CBER's International Affairs Advisor (IAA). The IAA is the primary responsible party for administering the PSA pilot within CBER.

For the EMEA, representatives from the Scientific Advice Working Party (SAWP) (an expert committee to the EMEA) are the assessors of who will participate in the pilot. The SAWP is comprised of representatives of the EU member countries and meets once a month for 2-3 days.

Requests can issue from a sponsor and be sent to EMEA, FDA, or both simultaneously. If a request is sent to

one agency, the other agency is notified by the respective point of contact. In addition, FDA and EMEA can request a meeting.

In the initial request for a PSA, the sponsor is to explicitly authorize the comprehensive exchange between the two agencies of all information relevant to the subject product, specifically including trade secret information (as defined by US statute). Pursuant to legally established authorities, both agencies will maintain the confidentiality of all such information.

The number of PSA meetings should be limited. Generally, no more than one PSA meeting per month should be scheduled. PSA meetings should generally occur via tele- or video-conference. On rare occasions staff from one agency may travel to the other agency for such meetings. Such travel should be at the expense of the agency for which the traveler is employed.

Responsibilities for evaluating, accepting/rejecting, and/or initiating a request

Upon receipt of a meeting request, the CBER IAA will contact the relevant review division to consider the merits of the request and to make a determination regarding the appropriateness of the request. Criteria for these meetings include:

- Meeting would otherwise serve as a pre-IND or end of phase II meeting
- Products are fast-track eligible and/or novel, or present issues where scientific advice differs between EMEA/FDA
- One meeting per month for CBER as a whole; one meeting per six months for a given review division.
- A preliminary assessment concludes scheduling the meeting is feasible

Requests for PSA meetings can be denied based upon timing and/or workload constraints or appropriateness of the product for the pilot program. A decision on whether to hold a PSA meeting or not should be made within 14 days of the request to CBER. The review Office Director must concur with the decision to accept or reject a PSA request. The CBER IAA will notify the ADEU of the Center's decision on a PSA meeting request. The ADEU will in turn notify the EMEA.

Similarly, if a review division is interested in initiating a meeting request, the review division RPM, with the concurrence of their Office Director, will communicate accordingly with the CBER IAA.

Responsibilities for managing the PSA meeting

Once a PSA meeting request has been agreed to by both EMEA and FDA, the meeting request will be sent to/received by the review division for meeting management and tracking in the appropriate CBER regulatory database.

The review Division RPM will be responsible for coordinating the scheduling of the meetings directly with the EMEA Point of Contact. Three meetings should be scheduled for each request:

- An internal meeting with FDA participants only.
- An one hour preparatory meeting with SAWP
- A 90 minute meeting with SAWP, FDA and the sponsor/applicant.

Meetings with the SAWP will need to be held on dates that conform to its schedule. The review Division RPM may request a copy of the SAWP calendar from the CBER IAA. In addition, due to time differences, meetings with the SAWP must start between 8:00 a.m. and 12:00 p.m. Eastern Time.

Minutes for the internal meetings should be entered in the appropriate CBER regulatory database and made a part of the administrative file.

If scheduling proves to be infeasible, the RPM should notify the CBER IAA.

The PSA meeting is intended to integrate into the regular SAWP meeting/review process, which is summarized below:

- Receipt of request for advice ("Day 1")
- Receipt of background package
- Assessment of package by two members
- Discussion of assessments (during regular SAWP meeting) - approximately "Day 30") this is the one hour preparatory meeting with FDA
- Preparation of questions, points of clarification and disagreement for company
- Meeting with company (during SAWP meeting - approximately "Day 60") - this is the actual PSA meeting. Meeting minutes are written in accordance with SOPP 8101.1 Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants
- Preparation of advice letter to company (Day 70-90)

The SAWP (via EMEA POC) will provide CBER (via the review division RPM) with courtesy copies of their assessments, and communications with the company (those both prior to and after the meeting). Note the company does not receive the assessments.

In certain circumstances, the SAWP or FDA may find it appropriate to NOT meet with the company at the same time. In those cases, separate meetings with the company may be held after consultation with the CBER IAA. If the SAWP believes that a joint meeting should not be held with the company, they will notify FDA after their "Day 30" meeting.

6. Appendices

[Appendix 1: Points of Contact for FDA/EMEA/PSA meetings](#)

7. Effective Date

November 27, 2006

8. References

[General Principles EMEA-FDA Parallel Scientific Advice Meetings Pilot Program](#)

[SOPP 8101.1 Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants](#)

9. History

| Written/Revised | Approved | Approval Date | Version Number | Comment |
|-----------------------------|---------------------------|-------------------|----------------|-----------------------------|
| Joan Wilmarth Blair, M.A | Robert A. Yetter, PhD. | November 13, 2006 | 1 | First issuance of this SOPP |

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