

July 2021

**GENERAL PRINCIPLES
EMA-FDA PARALLEL SCIENTIFIC ADVICE
(HUMAN MEDICINAL PRODUCTS)**

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services have a program to provide parallel scientific advice (PSA) to sponsors. The goal of the PSA program is to provide a mechanism for EMA assessors and FDA reviewers to concurrently exchange with sponsors their views on scientific issues during the development phase of new medicinal products (i.e., new human drugs and biologics). Such interactions are expected to increase dialogue between the two agencies and sponsors from the beginning of the lifecycle of a new product, provide a deeper understanding of the bases of regulatory decisions, optimize product development, and avoid unnecessary testing replication or unnecessary diverse testing methodologies. The agencies conduct PSA procedures under the auspices of the confidentiality arrangement between the European Commission, the EMA, and FDA.

EMA and FDA have agreed to the following principles regarding PSA procedures and meetings. Posting this “General Principles” statement on the websites of both agencies will make the PSA program procedures and goals more transparent and help answer many questions about the program. Each agency will post this statement on its website in accordance with its own procedures.

1. PSA procedures are voluntary and usually occur at the request of the sponsor; in special circumstances, EMA or FDA may also initiate the PSA process in full cooperation with the sponsor. “Sponsor” refers to: (a) the “sponsor” of an Investigational New Drug Application in the United States, (b) the “applicant” that submits a New Drug Application or Biologics License Application in the United States, or (c) a potential marketing authorisation applicant under the marketing authorisation process in the European Union.
2. PSA requests should focus primarily on specific questions or issues involving the development of a medicinal product for which the sponsor desires to have further scientific input from both EMA and FDA.
3. The PSA procedures should focus on sharing information and perspectives. Achieving harmonization and increased convergence is a potential beneficial outcome of the PSA process. Following PSA meetings, sponsors should have a clearer understanding of the

agencies' respective requirements and perspectives regarding the development program discussed, and if divergent, the reasons for the divergence.

4. The best candidates for PSA include important medicinal products, especially those being developed for indications lacking development guidelines, or if guidelines do exist, those for which EMA's and FDA's guidelines differ significantly. In addition, biosimilars, products with significant clinical safety, animal toxicology, or unique manufacturing concerns that could impede further product development are appropriate PSA candidates. Previous PSAs have involved medicinal products for oncology, anti-infectives, rare diseases, the pediatric population, and cardiovascular disease, as well as post-licensure commitment clinical trials.
5. The number of PSA procedures will be limited. A PSA procedure should be a single occurrence focused on the specific development issue raised. A PSA procedure accepted by both agencies should not be viewed to include a continuing series of PSA procedures on the same product.
6. The sponsor participates in a joint PSA meeting with EMA and FDA during the PSA procedure. In addition, the two agencies will conduct a pre-sponsor meeting tele- or videoconference to further discuss the sponsor's questions. The two agencies may conduct a post-sponsor tele- or videoconference if needed. On rare occasions staff from one agency may travel to the other agency for such PSA meetings. Such travel should be at the expense of the agency for which the traveler works.
7. The sponsor should usually focus on specific issues or questions in the PSA request. PSA issues or questions might occur in the margins of a FDA-designated "milestone" in the product development lifecycle, such as the end of phase 2 trials.
8. Sponsors wishing to nominate a product for PSA should address one single "Request for PSA" letter to both emainternational@ema.europa.eu at EMA and US-FDA-EUR@fda.hhs.gov at FDA. In this letter, the sponsor should provide the following information: (1) the product in development, (2) why a discussion with the assessors (reviewers) of EMA and FDA would be beneficial to the product's development, (3) specific questions requiring clarification, (4) the desired goals for the meeting, and (5) an explicit authorization for the agencies' comprehensive exchange of all information relevant to the product, including trade secret information (as defined by U.S. statute). Pursuant to legally established authorities, both agencies will maintain the confidentiality of all such information.
9. A PSA request does not guarantee the PSA procedure will be granted. For a variety of reasons, one or both agencies may decline to participate in such a procedure. If a sponsor's request for PSA is not granted, the sponsor is free to pursue a scientific advice procedure with each agency individually, following each agency's normal procedural rules. Alternatively, both agencies can engage in a "consultative

advice”.¹ In this case, a limited number of experts from either side will be invited to participate in the discussions of the other agency.

10. If both agencies grant the PSA request, the sponsor will receive an electronic mail message (email) from each agency acknowledging such agreement and indicating the primary contact person at each agency. The PSA process generally corresponds to the 70 day timeline of the EMA [Scientific Advice Working Party](#) (SAWP) and the timeline for a [Type B meeting at FDA](#). (The annual SAWP meeting schedule is also accessible via the SAWP web page.) As such, the presently established timelines for the two agencies to conduct scientific meetings are not greatly discordant. Given the nature of EMA work, the tele- or videoconference with the sponsor and both agencies will usually be scheduled around day 60, in the margins of the SAWP meeting. The designated primary contact for each agency will coordinate with the sponsor final meeting logistics, including timelines for submission of pre/meeting background information to both agencies. PSA meetings are not Prescription Drug User Fee Act (PDUFA) meetings and are not subject to the performance goals for scheduling and holding PDUFA meetings.
11. After a PSA procedure, each agency will retain its individual regulatory decision-making authority regarding drug development issues and marketing applications. The advice of each agency may still differ after the joint discussion. Each agency will provide the sponsor its independent advice on the questions posed during the PSA process, according to usual procedures and timelines. Sponsors should neither expect to receive similar recommendations from the two agencies regarding drug development issues nor expect to receive similar agency decisions regarding marketing applications that have undergone PSA. However, both agencies will strive to provide PSA responses that are convergent.
12. Both agencies remain committed to meeting domestic process and review goals and timeframes. The PSA procedure should not adversely impact 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

¹ The **Consultative Advice procedure** allows sponsors to request scientific advice from one regulatory agency and concurrently notify the other regulatory agency of the request. At the invitation of the first agency, the second will participate in the sponsor meetings or teleconferences as able. Unlike the parallel scientific advice process, the second agency will be expected to only engage on top level issues. The review and sponsor meeting will follow the timelines of the regulatory agency from whom the sponsor initially seeks scientific advice. Only the initially contacted regulatory agency will provide written scientific advice in accordance with standard agency meeting procedures.

and to exhibit as much flexibility as possible in scheduling PSA meetings to avoid adversely impacting either agency's ability to meet its formal domestic performance expectations.

13. Any fees applicable for scientific advice are unaffected by PSA status.