



June 2024

**GENERAL PRINCIPLES
EMA-FDA PARALLEL SCIENTIFIC ADVICE
(ANIMAL DRUG PRODUCTS)**

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) of the U.S. Department of Health and Human Services have a program to provide parallel scientific advice (PSA) to applicants/sponsors. The goal of the PSA program is to provide a mechanism for EMA assessors and FDA reviewers to concurrently exchange with applicants/sponsors their views on scientific issues during the development phase of new veterinary medicinal products. Such interactions are expected to increase dialogue between the two agencies and applicants/sponsors in the early lifecycle stages 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 CVM 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 applicant/sponsor. “Sponsor” refers to the sponsor of an Investigational New Animal Drug Application in the United States; “Applicant” refers to a potential marketing authorization applicant under the marketing authorization process in the European Union.
2. PSA requests should focus primarily on specific questions or issues involving the development of an investigational new animal product/veterinary medicinal product (VMP) for which the applicant/sponsor desires to have further scientific input from both EMA and CVM.
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, applicants/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. A PSA procedure should be a single occurrence focused on the specific development issue raised.
5. The applicant/sponsor will participate in a joint PSA meeting with EMA and CVM during the PSA procedure. In addition, the two agencies will conduct meeting(s) to further discuss the applicant's/sponsor's questions. The two agencies may conduct a post-sponsor videoconference if needed.
6. The applicant/sponsor should usually focus on specific issues or questions in relation to a specific (candidate) product in the PSA request. The PSA request may contain a high-level outline of the protocol with specific questions related to the study design.
7. Applicants/sponsors wishing to request a PSA should address one single "Request for PSA" request to both VetScientificAdvice@ema.europa.eu at EMA and cvmia@fda.hhs.gov at CVM. In this request, the applicant/sponsor should provide the following information: (1) the product in development, (2) specific questions requiring clarification (for EMA, in accordance with the requirements outlined in the [Guidance for Applicants](#)), and (3) 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 and relevant EU legislation). Pursuant to legally established authorities/applicable laws, both agencies will maintain the confidentiality of all such information.¹
8. If both agencies grant the PSA request, the applicant/sponsor will receive an email from each agency acknowledging such agreement and indicating the primary contact person at each agency. The PSA process generally corresponds to the 90-day timeline of the EMA's veterinary [Scientific Advice Working Party](#) (SAWP-V) and the timeline for a meeting at CVM. (The [annual SAWP-V meeting schedule](#) is also accessible via the EMA 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 trilateral meeting with the applicant/sponsor and both agencies will usually be scheduled in the 11th week of the procedure. The designated primary contact for each agency will coordinate with the applicant/sponsor final meeting logistics, including timelines for submission of pre/meeting background information to both agencies. The PSA meetings are not sentinel submissions under the Animal Drug User Fee Act (ADUFA) and are not subject to the performance goals for scheduling and holding ADUFA meetings.
9. 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

¹ A PSA request does not guarantee the PSA procedure will be granted. For a variety of reasons, one or both of the agencies may decline to participate in such a procedure. If a sponsor's/applicant's request for PSA is not granted, the sponsor/applicant is free to pursue a scientific advice procedure with each agency individually, following each agency's normal procedural rules.

provide the applicant/sponsor its independent advice on the questions posed during the PSA process, according to usual procedures and timelines. Applicants/sponsors should neither expect to receive similar recommendations from the two agencies regarding drug/VMP 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.

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 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.

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

Ideal timeframes:

- Day -30 (approximately) – Applicant submits a parallel scientific advice request to EMA
- Day 0 – Sponsor submits material to CVM once validated by EMA
- Day 0 - 70 – Internal pre-meeting at CVM; EMA coordinator prepares draft scientific advice report
- Day 70 – Exchange of draft comments between agencies
- Day 71 – 77 – Bilateral CVM/EMA meeting
 - Check alignment, highlight Q's for applicant/sponsor
- Day 74 - 80 – Send preliminary comments to applicant/sponsor
- Day 78 - 84 – Trilateral applicant/Sponsor, CVM, and EMA meeting – discussion of request/clarifications
 - Immediately after the trilateral meeting, a short bilateral CVM/EMA meeting to check alignment/alteration of advice
- Day 84 - 114 – CVM issues final meeting minutes to sponsor (30 days after trilateral); EMA sends final scientific advice report to applicant (following the CVMP meeting at which the report is adopted)