European Medicines Agency

U.S. Food and Drug Administration

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GENERAL PRINCIPLES

EMEA - FDA
PARALLEL SCIENTIFIC ADVICE

The European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) of the US Department of Health and Human Services have initiated a program to provide parallel scientific advice. The goal of this program is to provide a mechanism for EMEA and FDA assessors and sponsors to exchange their views on scientific issues during the development phase of new medicinal products (i.e., new human drugs and biologics). 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 regulatory decisions, and the opportunity to optimize product development and avoid unnecessary testing replication or unnecessary diverse testing methodologies. Parallel scientific advice should focus primarily on important breakthrough drugs or important safety issues in the following areas which have been identified as clusters of interest between the agencies: Oncology, Vaccines, Orphan Drugs, drugs in the Paediatric Population, Nanotechnologies, Advanced Therapies, Pharmacogenomics and Blood products. Parallel Scientific Advice procedures are conducted under the auspices of the confidentiality arrangement between the European Commission, the EMEA, and FDA.

The EMEA and the FDA have agreed to the following principles regarding these meetings. Both EMEA and FDA agree that making this "General Principles" statement public on the websites of both agencies will make the program procedures and goals more transparent and will help answer many questions about the program that may exist in the general public. Each agency will post this statement on its website in accord with its own procedures for posting such documents.

1. These parallel scientific advice procedures usually occur at the request of the sponsor, but, in special circumstances, may also be initiated by either EMEA or FDA in full cooperation with the sponsor. Parallel scientific advice procedures 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 a meeting during the course of the procedure. In addition, the two agencies may decide to have pre-meeting tele- or videoconferences or post-meeting tele- or videoconferences just with each other in order to discuss further the issues posed by the sponsor. "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 authorisation applicant (MAA) under the marketing authorisation process in the European Union.

2. The scope of products covered by this program needs to be limited due to limited resources. The following areas have been identified as clusters of interest between the agencies: Oncology, Vaccines, Orphan Drugs, drugs in the Paediatric Population, Nanotechnologies, Advanced Therapies, Pharmacogenomics and Blood products. Prime candidates for parallel scientific advice should be important 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. In addition, products with significant clinical safety, animal toxicology, or unique manufacturing concerns that could impede the further development of the product should be considered prime candidates for parallel scientific advice.

3. The number of parallel scientific advice meetings will be limited.

4. The goals for Parallel Scientific Advice procedures should focus on sharing information and perspectives, rather than specific harmonization of study or regulatory requirements, although if harmonization is achieved, that could be a beneficial outcome. It is anticipated that following parallel scientific meetings it should be clearer to sponsors 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. Parallel scientific advice procedures should be a single occurrence focused on the specific development issue raised. A procedure which has been accepted by both agencies should not be viewed as a possibility of a continuing series of parallel scientific advice meetings on the same specific product.

5. Parallel scientific advice procedures are voluntary and should normally be initiated at the request of a sponsor. The sponsor should usually focus on "milestone" meetings, such as the "end of phase 2 meeting" or specific issues or questions. Requests for participation should be sent by the requesting sponsor through designated central points of contact at EMEA and FDA so that the evaluation of the request can be most efficiently performed by both agencies and needed documentation can be obtained. Sponsors that wish to nominate a product for parallel scientific advice should address one single "Request for Parallel Scientific Advice" letter to both Emer Cooke at EMEA and Janice Soreth at FDA. In this letter, a sponsor should explain why it believes a discussion with the assessors of the two agencies would be beneficial to its product development. The sponsor should identify the product and the anticipated topic(s) to be addressed in as much detail as possible, including specific questions it would like clarified and its desired goal(s) for the meeting. In addition, in the request for parallel scientific advice, the sponsor should 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. A request for a parallel scientific advice procedure is no guarantee that such a procedure will be granted. For a variety of reasons, including scheduling conflicts and resources at a specific time, one or both of the agencies may decline to participate in such a procedure. If a sponsor's request for parallel scientific advice is not granted, the sponsor is free to pursue a scientific advice procedure with each agency individually, following each agency's normal procedural rules, on the issue(s) nominated for parallel scientific advice.

6. If both agencies agree to conduct the parallel scientific advice procedure, the sponsor should receive an electronic mail message (Email) acknowledging such agreement. The acknowledgement Email should state the primary contact person at each agency. The presently established timelines for the two agencies to have scientific advice meetings are not greatly discordant: A type B meeting in the US should be scheduled in 60 days from the request to the FDA; for the EMEA, the advice is issued in most cases 70 days from the start of the EMEA procedure. Given the nature of the EMEA work, the tele- or videoconference should usually be scheduled around day 60, in the margins of the Scientific Advice Working Party meeting. The calendar of these meetings will be sent in advance each year to the FDA. Those primary contact persons should work with the sponsor on final logistics of the meeting, including timelines for submission of pre/meeting background information to both agencies. 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.

7. Meetings during a Parallel scientific advice procedure should generally occur via tele- or videoconference. 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 works.

8. After parallel scientific advice procedure, the two agencies will retain their individual regulatory decision-making authority regarding drug development issues and marketing applications. Each agency will provide their independent advice to the sponsor on the questions posed during the parallel scientific advice, according to their usual procedures and timelines. The advice of each agency may still differ after the joint discussion. Sponsors should neither expect always to receive similar recommendations from the two agencies regarding drug development issues nor expect always to receive similar decisions by the two agencies regarding marketing applications that have undergone parallel scientific advice.

9. Both agencies remain committed to meeting domestic process and review goals and timeframes. Nothing in the parallel scientific advice procedure should 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 parallel scientific advice meetings in order not to impact adversely either agency's ability to meet their formal domestic performance expectations.

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