GENERAL PRINCIPLES

EMEA - FDA
PARALLEL SCIENTIFIC ADVICE
MEETINGS

PILOT PROGRAM

September 17, 2004

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 pilot program to provide parallel scientific advice. The goal of this pilot 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 scientific advice, and the opportunity to optimize product development and avoid unnecessary testing replication or unnecessary diverse testing methodologies. During this pilot, parallel scientific advice efforts should focus primarily on important breakthrough drugs as explained further in this document. These meetings are conducted under the auspices of the confidentiality arrangement between the European Commission, the EMEA, and FDA. This pilot will last one year, and will commence with the first meeting being held no sooner than January 2005. At the end of one year, EMEA and FDA will assess the experience and value, if any, and determine a future course.

The first of such formal parallel scientific advice discussions took place in September 2003 for an orphan medicinal product. As sponsor and agency interest in such meetings has increased, 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 pilot program procedures and goals more transparent and will help answer many questions about the pilot 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 meetings usually occur at the request of the sponsor, but, in special circumstances, may also be initiated by either EMEA or FDA in cooperation with the sponsor. Parallel scientific advice 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 videoconferences and may hold a 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 centralized marketing authorisation process in the European Union.

2. 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 parallel scientific advice under this pilot should be important (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. Based on experience during this pilot, it is likely that changes to this initial scope procedure will be introduced once more experience is gained.

3. During this pilot, the number of parallel scientific advice meetings should be limited. Generally, no more than one parallel scientific advice meeting per month should be conducted. Based on experience during this pilot, it is likely that changes to this initial “number of meetings” procedure will be introduced once more experience is gained.

4. Given the limited time frame for this pilot, most parallel scientific advice 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 possibility of a continuing series of parallel scientific advice meetings on the same specific product.

5. Parallel scientific advice meetings 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 in the pilot 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 Arielle North at EMEA and Michelle Limoli 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 meeting is no guarantee that such a meeting will be granted. This is a pilot program with a limited scope of products, issues, and numbers of meetings that will be considered. 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 meeting. If a sponsor’s request for parallel scientific advice under this pilot is not granted, the sponsor is free to pursue a scientific advice meeting with each agency individually, following each agency’s normal procedures for such meetings, on the issue(s) nominated for parallel scientific advice.

6. If both agencies agree to conduct the parallel scientific advice meeting, the sponsor should receive an electronic mail message (Email)r 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 type 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 margin of the Scientific Advice Working Party meeting (two days each month). The calendar of these meeting 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. Parallel scientific advice meetings 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. Each agency will provide their independent advice to the sponsor on the questions posed during the parallel scientific advice, according to their usual procedures. 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 meetings. It is anticipated that following such 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.

9. Both agencies remain committed to meeting domestic process and review goals and timeframes. Nothing in the parallel scientific advice pilot 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 meetings are unaffected by the meeting being a parallel scientific advice meeting.

11. The agencies will assure that records are maintained to facilitate an assessment of the benefits and detriments of the pilot.