



U.S. Food and Drug
Administration



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-
GENERAL



European Medicines Agency

GENERAL PRINCIPLES

EMEA/VETERINARY MEDICINES AND INSPECTIONS UNIT – FDA/CENTER FOR VETERINARY MEDICINE PARALLEL SCIENTIFIC ADVICE MEETINGS

22nd May , 2008

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services initiated a pilot programme to provide parallel scientific advice in 2004-5. The goal of this pilot was to provide a mechanism for EMA and FDA assessors and sponsors to exchange their views on scientific issues during the development phase of new veterinary medicinal products (i.e. new veterinary drugs, maximum residue limits). This programme of co-operation in the field of scientific advice will now continue from 2008, subject to annual review. 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 basis of scientific advice, and the opportunity to optimise product development and avoid unnecessary testing replication or unnecessary diverse testing methodologies. Parallel scientific advice efforts should focus primarily on requests received from applicants at their initiative. These exchanges are conducted under the auspices of the confidentiality arrangement between the European Commission, the EMA, and FDA. This programme forms part of the Implementation Procedures for Veterinary Medicinal Products Cluster agreed between the EMA Veterinary Medicines and Inspections Unit and the FDA's Center for Veterinary Medicine. At the end of each year, EMA and FDA will assess the experience and value of the experience to date and determine a future course.

In response to sponsor and agency interest in parallel scientific advice meetings , the EMA and the FDA have agreed to the following principles regarding these meetings. Both EMA and FDA agree that making this "General Principles" statement public on the websites of both agencies will make the parallel programme procedures and goals more transparent and will help answer many questions that may originate from the general public. Each agency will post this statement on its website in accordance with its own procedures for posting such documents.

1. Parallel scientific advice exchanges usually occur at the request of the sponsor, but, in special circumstances, may also be initiated by either EMA or FDA in cooperation with the sponsor. Parallel scientific advice exchanges 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 EMA and FDA. The two agencies will usually hold a tele- or videoconference in order to discuss the issues posed by the sponsor. Usually, the sponsor will not be included as part of this meeting. "Sponsor" refers to: (a) the "sponsor" of an Investigational New Animal Drug application (INAD) in the US, (b) the "applicant" that submits a New Animal Drug Application (NADA) or (c) a potential marketing authorisation applicant (MAA) under the

centralised marketing authorisation processes in the European Union. In the latter case it is the European Community which issues a decision based on an opinion of the Committee for Medicinal Products for Veterinary Use (CVMP). In reaching this opinion the Committee will take into account the scientific advice to the applicant drawn up by its Scientific Advice Working Party (SAWP-V) which it will have previously endorsed. In the case of requests concerning products to be authorised through the European Mutual Recognition/Decentralised Procedure, it is recognised that the competent authority granting the market authorisation will be based in a Member State.

2. The scope of products covered is limited in order to determine the usefulness of the programme and what added value and costs, if any, it creates. Prime candidates for parallel scientific advice should be important (e.g., products for minor use or minor species) 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. It is likely that changes to this initial scope of the procedure will be introduced once sufficient experience has been gained. Requests for parallel scientific advice may also be made in relation to establishment of maximum residue limits (MRLs) for veterinary medicinal products.
3. Parallel scientific advice exchanges are voluntary and should normally be initiated at the request of a sponsor. The sponsor should usually focus on specific issues or questions. FDA/EMEA may ask a sponsor to further narrow the scope of the topic or further refine the specific issue or question before accepting the request as appropriate for parallel scientific advice. Requests for parallel scientific advice 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 the necessary documentation can be obtained. Sponsors that wish to nominate a product for parallel scientific advice should therefore address one single "Request for Parallel Scientific Advice" letter to both vetscientificadvice@emea.europa.eu at EMEA and to Michelle Limoli in the Office of International Programs 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 exchange. The sponsor should provide all relevant data and information in its possession for review by the FDA no less than 60 days prior to the scheduling of the meeting. The timing of submission to EMEA should be agreed with the project manager to ensure business timelines can be met. FDA or EMEA may extend this review period based on the quantity of information or available resources in line with their respective procedures. In addition, in the request for parallel scientific advice, the sponsor should explicitly authorise 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. 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.
4. If both agencies agree to conduct the parallel scientific advice exchange, the sponsor should receive an electronic mail message (Email) acknowledging such agreement. The acknowledgement Email will state the primary contact person at each agency. At this time a timetable will be agreed between the two authorities for the various activities involved. If it is not possible for any reason to agree a timetable that is mutually acceptable, the applicant will be

informed that parallel scientific advice is not possible in this case and that they should submit requests to each authority separately. Given the nature of the EMEA work, the tele- or videoconference should usually be scheduled around day 30, in the margin of the Scientific Advice Working Party meeting (one half-day each month). Other dates may be considered for teleconferences dependent on the availability of the individuals involved. The calendar of these meetings will be exchanged in advance each year between the FDA/EMEA. The primary contact persons will work with the sponsor on final logistics of the meeting, including timelines for submission of pre-meeting background information to both agencies. No part of this procedure is intended to replace or substitute presubmission conference procedures provided for in regulations or guidances.

5. Parallel scientific advice exchanges 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.
6. Each agency will maintain its own records of any meetings held and will provide their separate independent advice to the sponsor on the questions posed during the parallel scientific advice, according to their usual procedures. However, where possible, there will be an exchange of draft reports prior to the tele- or videoconference between the EMEA/FDA or an exchange of final reports when this is not possible. 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 programme discussed, and, if divergent, the reasons for the divergence.
7. Both agencies remain committed to meeting domestic process and review goals and timeframes. Nothing in the parallel scientific advice exchange 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.
8. Any fees applicable for scientific advice meetings are unaffected by the meeting being a parallel scientific advice meeting.
9. The agencies will assure that records are maintained to facilitate an assessment of the benefits and detriments of the programme.