



Confidentiality Arrangements Concluded between the European Union (EC and EMEA) and the US Food and Drug Administration/DHHS

Implementation Procedures for Veterinary Medicinal Products Cluster

22nd May, 2008

I. INTRODUCTION

Reference is made to the Confidentiality Arrangements concluded on 12 September 2003 between European Commission and EMEA (EU) and the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services in the context of regulatory co-operation and transparency between the U.S. Government and the European Commission.

FDA and the EU established an implementation plan describing the processes for exchange of information with respect to human medicines. This procedure describes the specific processes for exchange of information with respect to veterinary medicines.

This document sets out the practical arrangements for the exchange of the various types of information with respect to Veterinary Medicines. The exchanges will occur between the EMEA and its Veterinary Medicines and Inspections Unit and the Committee for Medicinal Products for Veterinary Use (CVMP) and the FDA and its Center for Veterinary Medicine (CVM). FDA and the EU intend that these arrangements will follow the programme as set out below.

It is recognised that in the veterinary sector such arrangements may currently apply only to the product categories and programs that both FDA/CVM and EMEA/Veterinary Medicines and Inspections Unit have legislative authority to regulate and administer.

II. IMPLEMENTATION PROCEDURE

II.1. CVM and EMEA's Veterinary Medicines and Inspections Unit will closely monitor the implementation of the Confidentiality Arrangement with respect to veterinary medicines and will take corrective action if considered necessary. Experts from both parties may hold quarterly meetings (via video or teleconference) based upon mutually agreed upon agendas.

II.2. Ad hoc Working Groups may be established based upon work to be undertaken. Managerial staff will participate in Working Group meetings with other technical staff as necessary. Generally, these Working Groups will disband once their work is completed.

- II.3. Meetings of the Working Groups will be timed to enable CVMP members and any other managers, technical staff and experts deemed appropriate, to attend.
- II.4. The agenda for meetings will be drafted jointly by each party and agreed by all participants at least 5 days beforehand. The agenda may include, but is not limited to, information exchanges in the following areas:
- Review of applications
 - Provision of scientific advice
 - Post-authorisation activities, include line extensions/supplemental use applications
 - Pharmacovigilance activities
 - Regulatory activities
 - Establishing Maximum Residue Limits
- II.5. In advance of each meeting, and to the extent required for meaningful discussion, both parties will exchange written updates to comprise summaries of the items identified and only issues of significant concern arising out the exchange of written information would be placed on the agenda.
- II.6. In addition to scheduled meetings, this procedure provides for *ad hoc* exchanges of documents such as guidelines and position papers, as well as information on applications or issues of mutual concern as appropriate.
- II.7. When providing input into the development of regulatory guidelines, the commenting party shall make clear whether the comments provided should form part of the formal consultation on the guideline or whether they are provided in accordance with the confidentiality arrangement, whilst remaining in compliance with FDA Good Guidance Practices and the Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework (EMEA/P/24143/04).
- II.8. Participants of both FDA/CVM and EMEA/CVMP may participate by invitation at each other's technical committees as and when the need arises.
- II.9. Both parties will cooperate with a view to improving coordination of inspections of manufacturers of veterinary medicinal products.
- II.10. All exchanges of non-public information will be coordinated through the Head of Unit, Veterinary Medicines and Inspections for EMEA, and Michelle Limoli, Office of International Programs, FDA to ensure appropriate coordination and tracking of activities and interactions

III. MONITORING OF THE IMPLEMENTATION

EMEA's Veterinary Medicines and Inspections Unit and FDA's Center for Veterinary Medicine will produce a joint report reviewing progress under this implementation plan twelve months after its initiation with a view to assessing its success and any need for change. This and subsequent reports will be presented at the yearly bilateral (FDA/EU) meetings held under the auspices of the Confidentiality Arrangement.