



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 February 2010  
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## Performance of the Agency's scientific procedures; veterinary products <sup>1</sup>

Management Board meeting 18 March 2010

### Background note

This note updates the Management Board on surveys of the level of satisfaction with the procedures for authorisation of veterinary medicinal products through the centralised procedure and plans for an analysis of referrals and arbitrations to the Committee for Medicinal Products for Veterinary Use (CVMP).

### Matters for consideration

A joint survey between the Agency and IFAH-Europe (previously with FEDESA) of the centralised procedure for veterinary medicinal products was carried out since 1998 to obtain feedback on the satisfaction with the centralised procedure from industry as well as rapporteurs and advise on any improvement measures. Reports of the surveys were presented and discussed at several EMA/IFAH-Europe (FEDESA) Infodays over the years. The last report of the Joint EMA/IFAH-Europe survey of the centralised procedure for veterinary medicinal products 2005-2007 was presented at the EMA/IFAH-Europe Infoday in 2009. The results demonstrated again a high degree of satisfaction with the procedure and identified a small number of actions for the European Medicines Agency that have largely been completed. Due to the high level of satisfaction expressed and the large workload involved in completing the survey, IFAH-Europe requested that the survey be discontinued to allow the resources of its members to be devoted to other priority areas. In line with quality management principles of continuous improvement, the Agency wishes to reinstate an assessment of the level of satisfaction with the services it provides. Planning has therefore started to develop proposals for survey of the centralised procedure during 2010 that, subject to agreement with IFAH-Europe, will reduce the workload expected of applicants and rapporteurs whilst still generating useful information.

As has been brought to the attention of Management Board on previous occasions, considerable resources within CVMP and the secretariat have been focussed in the last three years on referrals and arbitrations by CVMP. In March 2009, IFAH-Europe published the results of the joint IFAH-Europe/CMDv/EMA survey of Article 33 referrals during the period 2006-2007 which highlighted the different perspectives of applicants, CMDv and CVMP on the reasons for, and resolution of, arbitrations

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<sup>1</sup> This document presented for information will not be discussed at the meeting unless specifically requested by a member.



by CVMP. A follow-up survey is underway and consideration is being given to extending its scope to cover also referrals under Articles 34 and 35.

The Agency will present to the June Management Board meeting an analysis of referrals and arbitrations carried out over the last three years. This will serve as background information to proposals currently being developed by the joint CVMP/CMDv Task Force on Referrals which will be presented to both the Management Board and to Heads of Veterinary Medicines Agencies when the group has completed the first phase of its work.