

**Public consultation on the HMAv report on possible improvement of the  
legislation related to  
veterinary medicinal products**

The European legislation for Veterinary Medicinal Products, last updated in 2004, has proven to be a useful tool in recent years. However, it has become progressively complex and some practical problems are being encountered with its implementation. This was noted by the Heads of Veterinary Medicines Agencies (HMAv) during internal discussions and also during stakeholders meetings.

In order to address this issue and to contribute to possible improvements, HMAv decided to establish a Task Force Working Group (TFWG) in April 2008, with the mandate to identify the main hindrances and to propose possible improvements for the short, medium and long term.

In order to implement this mandate, a group composed of representatives from National Competent Authorities (NCAs), the European Commission and the EMEA was set up.

The TFWG presented to HMAv a report during their meeting in Marienbad on 19 May 2009 under the Czech Presidency and HMAv agreed to launch an external consultation on the issue as recommended by the TFWG.

This report presents an overall vision, specifies strategic objectives and addresses different aspects of outstanding importance such as the availability of veterinary medicinal products, generics, authorisation procedures and pharmacovigilance.

It must be underlined that the report has been prepared as a discussion document to stimulate debate on important issues and that some of them touch areas that may not be in the mandate of all NCAs which make up the HMA network. Proposals are ideas to be further discussed.

The European Commission is responsible for proposing changes to the legislation and has announced that they will present “in 2010 an assessment of the problems in the application of the veterinary medicinal products directive with a view to making, where appropriate, legal proposals”. HMAv is willing to contribute to a provision of innovative ideas. This consultation will help HMAv to develop proposals to offer to the Commission for consideration as part of their review.

The documentation attached is submitted for consultation up to the 1<sup>st</sup> September 2009.

Any comment should be sent to: [hma-ps@imb.ie](mailto:hma-ps@imb.ie)