



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2014
EMA/299310/2014 Noted
Management Board meeting of 12 June 2014

Proposal for the establishment of an AD hoc expert group on VEterinary Novel Therapies (ADVENT)

Issues for consideration

In a series of 'Horizon Scanning' meetings held with the leading pioneer companies in the animal health sector, they identified a need for the Agency to provide an increased level scientific and regulatory guidance on novel veterinary therapies.

EMA and CVMP have already recognised the need for more guidance and, in response, the Agency is improving the procedure for scientific advice and has opened up the Innovations Task Force for veterinary products. In addition to the measures already taken, the need for public guidance at the class level, rather than confidential advice at the individual product level, was confirmed by CVMP. In this way companies can receive guidance on what is expected in the veterinary domain with respect to classes of products new to veterinary medicine, even if they are well known in human medicine, such as cell therapy, monoclonal antibodies and bacteriophages.

Following a request from CVMP at their February 2014 meeting, the secretariat prepared a proposal for an Ad Hoc Working Group on Veterinary Novel Therapies (ADVENT). A draft mandate and terms of reference for the group were endorsed by CVMP at their March meeting (EMA/139331/2014). This mandate and terms of reference formed the basis for seeking formal approval to create such a group which was given by the EMA Strategy Board on the 29 March 2014.

A novel approach is proposed for this group in view of the need rapidly to produce guidance on a range of topics using the minimal possible resource in recognition of the scarcity of experts within the network with knowledge of novel veterinary therapies. A small 'core group' will be created containing experienced regulators and this will be supplemented with other 'specialist groups' of experts related to each of the technologies on which guidance is being produced. Physical meetings will be kept to a minimum and, once established, most of the work will be done remotely. This approach also has the advantage that it makes the most effective use of the specialised expertise made available by NCAs by using a variable pool of experts and limiting their involvement to only as long as is required to produce guidance in particular areas.

The cost of ADVENT to the EMA has been estimated in 207,978.36 EUR yearly, based on a 'worst case' scenario. This cost includes the costs of delegates and the cost of a dedicated secretariat consisting of 1 Scientific Officer and 1 Assistant. In practice these posts will most likely be filled with temporary staff unless appropriate redeployments within the existing Establishment Plan can be identified.

