

MANDATE

WORKING GROUP ON AUTOGENOUS VACCINES

Background:

In the past, two surveys have been completed to investigate the topic. Already in 2004, the need for harmonised requirements was highlighted by the majority of Member States. The autogenous vaccines market is growing and it is alarming that they are excluded from Community legislation. Consequently a more general survey was circulated in 2013. The result shows that the majority of Member States identified the need for a harmonised set of requirements (definition, restrictions, quality and control, labelling, usage, etc...).

During the HMA meeting in Vilnius (Lithuania) in September 2013, the need for clarification of the definition of autogenous vaccines was identified, as well consideration of the need to develop a harmonised approach within the European Union. The HMA TFIL (Task Force on Improvement of Vet Legislation) was therefore asked to prepare a paper for HMA consideration on these topics.

HMA endorsed the proposals prepared by the TFIL at their meeting in Athens in February 2014. An additional survey should be prepared for circulation in order to have a better vision of the practices in Member States. HMA supported the creation of a working group held by CMDv to work on autogenous vaccines.

Mandate:

The mandate of the CMDv's working group on autogenous vaccine is:

- To analyse the results of the survey initiated at the CMDv meeting in April 2014 in order to have a better vision of the practices in Member States;
- To discuss the consequences of deletion of article 4(1) of Directive 2001/82/EC, which allows Member States the possibility not to apply the marketing authorisation process, as described in the Directive, to live autogenous vaccines;
- To clarify the words "same locality" and to explain the concept of epidemiological links between farms, and
- To define good practices regarding manufacture, control and distribution of autogenous vaccines (to elaborate on minimal requirements) and to make proposals regarding pharmacovigilance of autogenous vaccines.