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Veterinary Medicines Division

Report on the operation of the Steering Group for the Joint EMA/HMA action plan on availability of veterinary vaccines

Background

The Heads of Medicines Agencies (HMA) and European Medicines Agency (EMA) have developed a joint high level strategy for the network until 2020 inclusive, the 'EU Medicines Agencies Network Strategy', and a multiannual work plan (MAWP) for its implementation. The strategy identifies increasing the availability of veterinary medicines as a priority area for action by the European medicines regulatory network and a specific action (n°17) is dedicated to this strategic priority in the MAWP.

On 25 March 2015, a joint EMA/HMA workshop was held at the EMA bringing together experts from national competent authorities and industry to exchange views on requirements for the authorisation of veterinary vaccines in the EU. The aim was to explore how to improve the availability of veterinary vaccines. In particular, the objective of the workshop was to consider if the current level of requirements and the way in which they are interpreted remains proportionate to the risks and benefits of these products. The workshop concluded with a number of key recommendations aimed at developing proposals to enhance availability of veterinary vaccines whilst maintaining the current high level of protection of animal and public health and the environment.

Arising from this workshop, EMA and the HMA drew up a joint action plan to bring together several ongoing regulatory activities concerning availability into a single, overall plan to facilitate:

- best use of resources in the European medicines regulatory network;
- efficient cooperation between all actors involved, including marketing authorisation holders, regulatory authorities and the European Commission (EC).

In February 2016, HMA and EMA established a joint steering group (SG) to strategically oversee the plan's implementation.

In March 2016, EMA's Committee for Veterinary Medicinal Products (CVMP) established an ad-hoc expert group on veterinary vaccine availability (CADVVA) to support CVMP and the steering group in implementing the actions under CVMP responsibility: that is to identify, prioritise and make public CVMP activities in the area of veterinary vaccine availability included within the plan.

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Along with the above groups, the HMA, CVMP and its Immunologicals Working Party (IWP), the veterinary Coordination Group for Mutual Recognition and Decentralised procedures (CMDv) and the pharmaceutical industry are expected to be actively involved in implementing the action plan.

Progress against action plan

The original Action Plan has been maintained as a 'living document' by being updated as the work of the Steering Group has progressed to indicate the status of each action (complete; in progress; no longer relevant).

The great majority of actions in the original plan have been initiated, with a number completed. Highlights included:

- Carrying out an in depth review of the proposals presented by the animal health industry for promoting the availability of veterinary vaccines. Proposals considered appropriate for regulatory follow up were evaluated for their feasibility and anticipated added value. Those considered likely to be both feasible and to bring added value were added to the Action Plan. The analysis of industry recommendations was published on the EMA website.
- Holding a Joint HMA/EMA Focus Group Meeting (FGM) with invited stakeholders in June 2017 on the challenges faced by industry in carrying out field efficacy trials for veterinary vaccines that led to a series of recommendations to EMA and CVMP with particular emphasis on improving predictability to industry as to when field efficacy trials will and will not be required for the purposes of obtaining a marketing authorisation. A report on the FGM, together with recommendations from the SG to CVMP based on the outcome of the FGM, have been published on the EMA website.
- In response to a letter from IFAH-Europe (now AnimalhealthEurope), recommending to CVMP and EMA to explore the feasibility of introducing the Vaccine Antigen Master File (VAMF) for veterinary vaccines, CADVVA considered the request and provided initial reflections. The EMA has further proposed a "preliminary business case" on the VAMF concept which is currently under discussion at the CVMP.
- The EMA established a website on veterinary vaccine availability that, in addition to the dedicated meetings of the Steering Group with stakeholders, helps to promote communication and raise the profile of the issue of veterinary vaccine availability.

Actions initiated and/or completed by other actors include the following:

- The CMDv published a recommendation for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA in March 2017.
- The EMA published the revised guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS) and limited markets on 20 April 2017. The guidance provided is in effect since 1 November 2017.
- The EMA/CVMP/IWP has delivered training for immunologicals assessors in October 2016, focusing on efficacy assessment, and again in October 2017, focusing on quality assessment.
- The CMDv conducted a survey of MS in Q3 2017 to ascertain 1) the extent to which vaccines are authorised exceptionally at a national level (authorised based on limited data in accordance with Articles 7, 8 or 26(3) of the Directive) and 2) a list of diseases for which there is currently no authorised vaccine. A report on the findings of the survey is currently being drafted by the CMDv.

Only one significant action in the original action plan has not been pursued. The possibility of exploring a public private partnership in the area of veterinary vaccines was included in the action plan but has not been taken up by either the Network or industry and is therefore no longer being followed up.

The following actions were added to the original action plan:

- As a result of the analysis of the proposals from AnimalhealthEurope arising from the 2015 workshop, a number of topics have been proposed for follow up by regulators (e.g. use of serology as a correlate of protection). At the present time, the SG is awaiting industry's prioritisation of potential future topics before considering how to approach them. Prioritisation is essential as only very limited resources will be available within the Network to pursue any new activities during 2018/2019.
- During 2017 the need was identified to develop a harmonised approach within the EU to application of the new risk assessment based approach to detection of extraneous agents in veterinary vaccines following the introduction of revised CVMP guidance on this topic and in light of the ongoing review of relevant monographs of the European Pharmacopoeia. Strategic discussions between EMA/CVMP and the EDQM will take place during 2018 to ensure alignment. This work is of high relevance to the SG due to its potential impact on availability of veterinary vaccines, particularly in the case of re-use of existing master seeds.

Ongoing actions and proposals for the future

The CVMP and its IWP have already included within their work programme a considerable volume of work directly or indirectly related to the Action Plan on Availability of Veterinary Vaccines, namely:

- Developing a reflection paper on measures to promote availability of veterinary vaccines in emergency situations.
- Reflecting on the feasibility and impact of introducing the VAMF concept for veterinary vaccines.
- Reflecting on the most appropriate approach to providing greater clarity to applicants as to when field trials will or will not be required (e.g. criteria to apply, the possibility of establishing lists, revision of existing guidance etc.). This reflection will also take account of the EMA analysis of field efficacy data submitted in support of marketing authorisation applications for veterinary vaccines in the EU centralised procedure.
- Work relating to application of the risk based approach to extraneous agent detection in veterinary vaccines.
- Reflecting on the most appropriate approach to providing additional guidance on factors to be consider in assessing the benefit risk balance for particular types of veterinary vaccines (e.g. inactivated, live, companion, farm animal etc.).

In addition to the activities relating to vaccine availability ongoing at the CVMP/IWP, the SG will have to consider proposals for future activity arising from or relating to:

- Industry's prioritisation of potential future topics (based on proposals presented by AnimalhealthEurope for promoting the availability of veterinary vaccines arising from the 2015 workshop);

- The CMDv survey of MS to ascertain 1) the extent to which vaccines are authorised exceptionally at a national level (authorised based on limited data in accordance with Articles 7, 8 or 26(3) of the Directive) and 2) a list of diseases for which there is currently no authorised vaccine; and,
- The ongoing revision of the legal framework for veterinary medicinal products, in particular, the elaboration of technical guidance on data requirements for immunological veterinary medicinal products.

However, recognising the range of topics currently under consideration by the CVMP/IWP, and the existing workload of the IWP, work on any additional topics that may be identified by the SG could only start in 2019 or 2020 once substantial progress has been made on the already agreed topics.

In addition to considering proposals for future activity, the SG has an important role communicating progress on the Action Plan to Industry and other stakeholders. An important stakeholder in the area of vaccine availability is the European Directorate for the Quality of Medicines (EDQM). The SG plans to communicate with the EDQM on progress with the Action Plan and the conclusions of the FGM on field efficacy trials.

Recommendation

The Steering Group recommend the continuation of their work for a further period of two years.

The majority of the actions included in the original action plan have been initiated, with a number completed. To date, the SG has been of value in coordinating, monitoring and communicating to relevant stakeholders the activities and progress of the various partners and stakeholders from whom concerted action is required to address the complex and challenging issues that limit availability of veterinary vaccines. However, many of the actions that have the potential to impact on vaccines availability are on-going. In addition, there is a need to consider proposals for future work and prioritise activities. Therefore, continuation of the work of the SG is needed to coordinate activities, to consider and prioritise future activities and to oversee and communicate on progress on the Action Plan.

In addition, the SG recommends that the CVMP consider extending the mandate of the CADVVA group for a further period of two years in order that it can continue to support the CVMP and the SG in implementing the actions under CVMP responsibility. To date, the CADVVA group has been of value in identifying, prioritising and refining (clarifying/determining scope of) CVMP activities. Meetings of the CADVVA group would be convened on an as-needed basis to consider any proposals for future CVMP/IWP activity from the SG.

For 2018, the intention would be to complete the work already included within the action plan but not to add any substantial new activities. Should the need for new activities be identified, these would need to be programmed for 2019 onwards according to priority and available resource, particularly with respect to the IWP of CVMP. On this assumption, the EMA would propose to continue to provide the secretariat to the SG.