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From: [redacted]
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To: EO-PresubmissionConsultation
Subject: Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: Ombudsman public enquiry EMA presubmission activities FVE_final.pdf

Follow Up Flag: ema5
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Dear Mrs. Emily O'Reilly,
Please find enclosed the response from the Federation of Veterinarians of Europe on the inquiry OI/7/2017/KR.
Friendly greetings,
Nancy De Briyne
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How the European Medicines Agency engages with medicine producers before they apply for authorisations to market their medicines in the EU

- Invitation to comment within the European Ombudsman's inquiry OI/7/2017/KR

Public consultation

Response by FVE – the Federation of Veterinarians of Europe

FVE is the European umbrella organisation of national veterinary associations from 39 European Countries. In total, we represent about 250 000 veterinarians in Europe. For more information: www.fve.org.

Questions

1. It may happen that EMA staff members and experts who participate in pre-submission activities will be involved in the subsequent *scientific evaluation and/or marketing authorisation* procedure for the same medicine.

To what extent is this a matter of concern, if at all?

FVE, who follows closely all activities of the EMA, does not have a concern about this, on the contrary we welcome it. We are convinced that EMA has sufficient robust and rigorous procedures in place to separate the advice function from the one on final decision.

In the veterinary field, where the market is very small, it is particularly beneficial to have early engagement between EMA and the MAH. This way it is possible to ensure the requirements are well understood, critical issues are identified and a proper benefit/risk assessment is ensured.

It also ensures consistency between the delivered Scientific Advice and the scientific evaluation of the final product dossier during the marketing authorisation process.

All these things are extremely important in the veterinary field, in which we have a lack of availability of veterinary products including vaccines for many species and many conditions. In addition, the number of experts in specific fields e.g. biotechnology is extremely small, which makes total separation impossible and detrimental.

Are there specific pre-submission activities of particular concern in this regard?

As emphasised above, we do not think that any pre-submission activities are of concern. **EMA has robust and rigorous procedures in place with ensure impartiality of decision making**.

Specifically the opportunity to ask scientific advice is very beneficial. Through the scientific advice procedure, EMA can advise on the appropriate tests and studies in the development of a medicine. This is designed to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients. The advice EMA prepares is based upon the expertise of a scientific assessment team nominated by EMA.

This is especially important for novel technologies and could boost innovation. These products require novel assessment techniques to ensure they are safe and effective.

How should EMA manage such situations?

We believe EMA has established rigorous procedures in place to ensure it works in an independent, open and transparent way and impartiality of decision making. EMA asks all involved experts to sign a declaration of interests and has a very robust system for disclosure and management of potential conflicts of interest for experts.

2. Should EMA allow experts from national authorities, who have previously provided scientific advice at national level on a particular medicine, to be involved in EMA's scientific evaluation of the same medicine?

Yes. EMA should allow experts (assessors) from national authorities, who have previously provided scientific advice at national level on a particular medicine, to be involved in the scientific evaluation of the same medicine.

This for the following reasons: 1/ it is beneficial to have as expert somebody who has already knowledge and experience with the type and the specificities of the product. This is beneficial for all products but especially for novel products. 2/ the number of experts with expertise in certain fields, especially in novel technologies, is very limited. It is more important to have somebody with strong expertise than to just pick any expert, who might be totally unfamiliar with the type of product.

In addition, EMA relies on the European Regulatory Network. Over the years a strong collaboration has been developed by the Heads of Medicines Agencies and EMA, which has led to a strong and robust regulatory environment working together to ensure safe and effective medicines for human and animal patients. It would be detrimental for the whole assessment procedure to no longer allow to use the expertise of well-qualified national experts.

EMA has procedures in place to ensure the independence of its scientific assessments. The Agency takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests that could affect their impartiality.

3. What precautionary measures should EMA take to ensure that information and views provided by its staff members and experts in the context of pre-submission activities are not, in practice, considered as a "binding" pre-evaluation of data used to support a subsequent application for authorisation?

It is very clear to all medicine developers that all information and views provided in pre-submission phase is non-binding. It is stated in all possible ways (e.g. on EMA website, on the guidance documents, etc.), and medicine developers are very well aware of it.

4. Is the way in which EMA engages with medicine developers in pre-submission activities sufficiently transparent?
If you believe that greater transparency in pre-submission activities is necessary, how might greater transparency affect:

   - EMA's operations (for example the efficiency of its procedures, or its ability to engage with medicine developers)
   - and medicine developers?

We believe the pre-submission activities are sufficient transparent and never had anybody from our membership putting this into question.

Is there a need, in particular, to enhance the transparency of scientific advice EMA provides to medicine developers?

We do not see a need for this.

Would it, in your opinion, be useful or harmful, for example, if EMA:
- disclosed the names of the officials and experts involved in the procedures;
- disclosed the questions posed in scientific advice procedures; and/or
- made public comprehensive information on the advice given.

It is difficult for us to foresee how much this would influence negatively the potential authorisation and innovation of new products. While transparency can only be applauded, it should be done in a way that does not hinder the incentive of companies to bring forward new products. As said earlier, the first priority in the veterinary field is to increase the availability of safe and effective veterinary medicines across Europe.

It is noted that EMA follows the EU access-to-documents procedure.

If you have other suggestions, for example regarding the timing of the publishing of information on scientific advice, please give details and the reasons for your suggestions.

No

5. What would the advantages and disadvantages be of making scientific advice, given to one medicine developer, available to all medicine developers?

This is a question for industry to answer. See answer to question 4.

6. Should EMA be limited to providing scientific advice only on questions not already addressed in its clinical efficacy and safety guidelines[4]?

No. The problem is that guidelines cannot cover everything and every possible situation. Therefore, scientific advice helps to ensure that the right studies are done. This increases the quality of the submissions. If no advice is given, the company may have to repeat studies, which would create additional administrative burden, require more laboratory animals to complete the necessary studies, impose additional costs and take longer before a product comes on the market.

7. Any other suggestions on how EMA can improve its pre-submission activities? If so, please be as specific as possible.

No

Additional information

Compared to human medicines, veterinary medicine is a very small sector with a lot smaller turn-over. Over the last decades, we have seen that the number of companies investing in animal health products decline. This leads to lack the number of products available on the market to treat animals, which is especially problematic for minor species (e.g. rabbits, turkeys, fish, goats, etc.) and minor indications (less frequently seen diseases). Diseases can spread from animals to humans and vice-versa, this is what we call zoonotic diseases. Therefore, if we cannot keep our animals healthy, this can endanger human health and food safety.

In the last decade, the animal sector has done great efforts to move from treatment to prevention ("prevention is better than cure"). Great efforts have been and continue to be done to reduce the amount of antibiotics used for animals, with positive results (-20% overall use in the EU up to over -50% in certain EU countries). However, prevention is not easy without the use of products such as vaccines to prevent certain viral or bacterial diseases. Therefore, there is a great need for new products and more innovative products, a segment that definitely needs pre-submission advice given.