5 May 2014
EMA/776691/2013 –Rev.1[1]
Veterinary Medicines Division

Public consultation regarding the request to the European Medicines Agency from the European Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

Consultation procedure

1. Background:

The European Medicines Agency (EMA) has received a request from the European Commission (EC) for scientific advice on the impact on public health and animal health of the use of antibiotics in animals[2]. An ad hoc AntiMicrobial Expert Group (AMEG) has been created to prepare the response to this request. Membership of the group is made up of experts from both the Committee for Medicinal Products for Human Use (CHMP), the Committee for Medicinal Products for Veterinary Use (CVMP), the CVMP Antimicrobials Working Party and the CHMP Infectious Diseases Working Party, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA).

In the interest of transparency, and in order to provide stakeholders with the opportunity to input information, data or views, the EMA is proposing to conduct a consultation exercise as part of the preparation of the advice.

The EMA is organising a one day meeting with stakeholders on the 28th February 2014 that will take the form of an orientation meeting and provide an opportunity for stakeholders to ask questions for clarification before they are invited to provide written comments as part of the consultation. However, for comments to Question 2, and because of time constrains, initial comments can also be provided before the mentioned meeting. For Questions 3 and 4 comments in writing should only be provided after the meeting.

2. Target groups(s)

Input is sought from all stakeholders; international organisations, veterinary regulatory bodies, animal health industry, human and animal practitioners and any official organisation that may be interested in providing comments.

[1] The timetable for the publication of draft answer to question 2 has been revised.
[2] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142070.pdf

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

In order to obtain input in a way that allows efficient and practical management of responses, priority will be given to comments received from associations rather than from individuals.

3. Purpose and scope

The European Medicines Agency would like to consult stakeholders on questions 2, 3 and 4 of the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals from the EC. The detailed questions can be found here.

The answer to the first request from the EC was successfully provided before the end of July 2013 and is now available from the EMA[3], and EC web pages. Due to the short time available to answer this part of the request, no input could be sought from stakeholders, and for this reason the first request from the EC is not within the scope of this consultation.

4. Comments and their consideration

The request from the EC is published on the EMA web page and there will be targeted communication depending on the request for each of the questions.

The deadline for response depends on the date for delivery of the response to the EC, see below details on the deadline for the response to each of the questions.

The comments received will be published on the EMA web page and will be taken into account when preparing the answers to the EC. Due to the short deadline it may not be possible to publish the response to individual comments before the deadline for reply to the EC but, subject to the volume of comments received, responses should be published in due course.

5. Question 2:

Advice on classes or groups of antibiotics ranked according to their relative importance for their use in human medicine, in particular considering whether these antibiotics are essential to treat multi-resistant infections in humans in the European Union (EU). The European Medicines Agency should take into account the existing work of the World Health Organisation (WHO) on critical antimicrobials and consider the need, advantages, disadvantages and feasibility of categorising antibiotics as for example first line, second line or last resort antibiotics.

Rankings of antimicrobials already exist from international (WHO, OIE) and national organisations and these will be taken into account for the preparation of a draft response. Input from these organisations will therefore be of special relevance.

Several countries either already operate, or plan to operate, systems for classifying antimicrobials, and information on such systems will be of high interest. Examples of risk management measures for critically important antimicrobials (CIA) from these countries will be especially welcomed.

[3] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/07/WC500146812.pdf, http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146813.pdf and http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146814.pdf

Consultation

The AMEG is working on a categorisation based on the WHO and OIE lists of critically important antimicrobials in man and animals, respectively. One of the objectives of the stakeholders meeting on 28 February 2014 will be to provide an opportunity to exchange views and answer questions in relation to the intended list. The preliminary comments, the discussions during the meeting, and the written comments received subsequently (after publication of the draft answer), will be taken into account in the preparation of the final answer to the EC request.

Please provide preliminary comments in preparation of the answer to the second request from the EC, especially taking into account the terms of reference as included in the EC request.

Potential sources of information

Input is sought from those stakeholders most involved in, and affected by, any classification scheme that could be proposed (international organisations, human and veterinary regulatory bodies, health industry, professional bodies representing human and veterinary clinical experts and practitioners).

Timetable

- EMA to publish initial request for input from stakeholders: by end December 2013.
- End of initial consultation: 17 February 2014.
- Consultation meeting with stakeholders: 28 February 2014.
- First draft answer published for consultation: June/July 2014.
- End of written consultation: September 2014.
- Finalisation of response to the EC: December 2014.

6. Question 3:

Advice what the possible impact could be on the treatment of resistant bacteria in humans of granting marketing authorisations for new classes of veterinary antibiotics, and whether there is a need to restrict or ban the use in animals of certain new classes of antimicrobials or antibiotic substances (especially those that are important in human medicine) that are currently not authorised. It is stressed that the advice could discuss a positive impact (for example, better management of resistance in animals) or a negative impact (for example, increased risk of development of resistance in humans).

Input is sought from those stakeholders most knowledgeable in the development of new antimicrobials including, but not limited to, the animal health industry and clinical experts in animal health.

To assist AMEG in preparing the first draft of the response to the request an information gathering exercise will take place with stakeholders. The specific questions on which the EMA is seeking information are provided on the template for comments.

During the stakeholders meeting on 28 February 2014 there will be an opportunity to exchange views in relation to the proposed questions on which input is sought.

The discussions during the meeting, and the written submissions received in response to the specific questions posed, will be taken into account by AMEG as part of drafting the proposed response to the EC request.

The draft will then be published for consultation before preparing the final response to be provided to the EC.

Potential sources of information

Veterinary practitioners, with their input preferably channelled through their associations. Information on off label use of antimicrobials, especially on the use in animals of antibiotics authorised in human medicine would be of special importance.

Pharmaceutical industry, public health experts.

Draft timetable

- EMA to publish targeted list of questions for consultation: by end December 2013.
- Consultation meeting with stakeholders: 28 February 2014.
- Deadline for responses to specific questions for information gathering: 1 April 2014.
- First draft answer published for consultation: June/July 2014.
- End of written consultation: September 2014.
- Adoption and publication: December 2014.

7. Question 4

Advice on the risk mitigation options [alternatives], including an assessment of costs and benefits, related with the use of certain classes of antibiotics or antibiotic substances that are of critical importance in human medicine and are currently authorised as veterinary medicinal products.

Input is sought from those stakeholders most affected by any proposals to control the use of antibiotics in veterinary medicine, namely veterinary regulatory and professional bodies, the animal health industry, clinical experts, the farming community and others.

In preparation of the answer to the request an information gathering exercise will take place. The specific questions on which the EMA is seeking information are listed below.

During the stakeholders meeting on 28 February 2014 there will be an opportunity to exchange views and provide clarification in relation to the proposed questions.

The discussions during the meeting, and the written answers to the questions subsequently provided, will be taken into account in the drafting of the proposed response to the EC request.

The draft will then be published for consultation before preparing the final response to be provided to the EC.

Draft timetable

- EMA to publish targeted list of questions for consultation: by the end of December 2013.
- Consultation meeting with stakeholders: 28 February 2014.
- Deadline for responses to specific questions for information gathering: 1 April 2014.
- First draft answer published for consultation: June/July 2014.

- End of written consultation: September 2014.
- Adoption and publication: December 2014

8. How to submit your contribution

Comments on this public consultation should be submitted using the document provided (see links below) and should be submitted to vet-guidelines@ema.europa.eu by the deadline established for each question. Stakeholders are recommended to use the template provided to ensure timely consideration of their comments.

- Submission of comments to Question 2.
- Submission of comments to Questions 3 and 4.