Date:

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| EMA/CVMP/SAWP/11888/2020Veterinary Medicines Division |   |

Request for Scientific Advice (SA)

PART A – Scientific questions

Delete all text in GREEN

Table of contents (if applicable)

Applicant’s background information 1

<This section should be in style of an executive summary and maximum of 5 pages. Describe only relevant issues related to current scientific advice; do not copy all information in references.>

Insert text

**1. Question 1**

<The questions should be prospective and concern the future development of a medicinal product. Each question should be comprehensible when read in isolation. The applicant should indicate their intended path, along with the justification for this, taking into account guidance where available. In their response, SAWP-V will provide statement whether in agreement or not with the applicant’s position, and justification for their position. **Questions should not ask for general advice, for example how to design a study, but should show how the applicant intends to design the study and their justification for the choices made.**>

Insert text

* 1. Applicant’s position 2

<Relevant concise justification should be provided. Do not copy excessive amount of text from references here.>

Insert text

1. Question 2

Insert text

* 1. Applicant’s position

Insert text

<Continue depending on the number of questions.>

**Annexes**

Reference list (if applicable)

<Provide copies of relevant references as **separate documents**.

Other annexes (also to be included as separate documents) can include for example:

* additional background information (e.g. product profile)
* information relating to the questions (e.g. relevant study protocol(s) and/or study report(s) – as detailed as possible)
* details of previous scientific advice received from other parties (e.g. from any EEA national competent authorities, other relevant international competent authorities)
* relevant guidelines (other than CVMP guidance documents).>

***Notes***

1 The focus should be on relevant background information related to the subject of the scientific request.

2 Each question should be followed by the applicant’s position.

The completed Request for Scientific Advice in MS Word format (please **do not convert it to PDF**) should be uploaded in the *Documents from Applicant* section of the electronic submission form in IRIS. More information on the use of IRIS can be found on the IRIS homepage, <https://iris.ema.europa.eu/>.

PART B – Preliminary risk profile for an antimicrobial substance or veterinary medicinal product - Assessment request

Table of contents (if applicable)

Applicant’s background information 3

<This section should be in style of an executive summary and maximum of 3 pages. Describe only relevant issues related to current Preliminary Risk Profiling (PRP) request; do not copy all information in references.>

**Applicant’s PRP assessment request**

<The applicant should provide information relevant to the PRP in line with the *technical requirements and scientific approach provided in Tables 1 and 2 in section 3.3 of the* *Answer to the request from the European Commission for updating scientific advice on the impact on animal health of the use of antibiotics in animals – Preliminary risk profiling for new antimicrobial veterinary medicinal products* (EMA/CVMP/CHMP/682199/2017). Taking account of this guidance, the applicant should indicate for the antimicrobial substance/medicine in question their estimate of the potential consequences or risk to human health due to AMR, along with the justification for this. A consideration should also be provided on potential consequences to animal health and farming/aquaculture if use of the future antimicrobial/medicine is restricted in animals.

The SAWP-V will make an evaluation of the data presented and, on this basis, provide a justification of its position regarding the potential consequences or risks to human and animal health, options for high-level risk management measures and identified data gaps relevant for a Marketing Authorisation application (Table 3 of the PRP guidance).>

**Hazard identification**

<*Resistance to the AM and/or resistance determinants to the AM in zoonotic pathogens and/or commensal organisms that may be transferred to humans or to organisms potentially pathogenic to humans.*>

Insert text

**Release assessment**

Insert text

**Exposure assessment**

Insert text

**Consequence assessment**

Insert text

**‘Risk-risk’ scenario**

<*i.e. consequence of restricting use in animals*>

Insert text

**Applicant’s Questions 4**

<This section can include any questions on specific aspects of the PRP from the applicant.>

**1. Question 1**

<The questions should be prospective and concern the future development of an antimicrobial medicinal product. Each question should be comprehensible when read in isolation.>

Insert text

1.1 Applicant’s position

<Relevant concise justification should be provided. Do not copy extensive amount of text from references here.>

Insert text

2. Question 2

Insert text

2.1 Applicant’s position

Insert text

<Continue depending on the number of questions.>

**4. Annexes**

Reference list (if applicable)

<Provide copies of relevant references as **separate documents**.

Other annexes (also to be included as separate documents) can include for example:

* additional background information (proposed product profile)
* Information on antimicrobials from the same or similar (sub)classes; use in human medicine; use in veterinary medicine in 3rd countries; preclinical studies; relevant surveillance data on AMR and antimicrobial consumption.
* details of previous scientific advice received from other parties (e.g. from any EEA national competent authorities, other relevant international competent authorities; unless provided in Part B)
* relevant guidelines and considerations from national/international bodies (other than CVMP guidance documents; unless provided in Part B).>

***Notes***

3 The focus should be on relevant background information related to the subject of the PRP assessment request.

4 Follow the instructions for the structure of a request for scientific advice described in European Medicines Agency *Guidance for applicants requesting scientific advice* (EMEA/CVMP/SAWP/172329/2004-Rev.6). Each question should be followed by the applicant’s position and justification.

Follow the guidance on technical requirements and scientific approach to the PRP provided in section 3.3 of the *Answer to the request from the European Commission for updating scientific advice on the impact on animal health of the use of antibiotics in animals – Preliminary risk profiling for new antimicrobial veterinary medicinal products* ([EMA/CVMP/CHMP/682199/2017](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/answer-request-european-commission-updating-scientific-advice-impact-public-health-animal-health-use_en-0.pdf)).

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