EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AMEG's proposal for an Early Hazard Characterisation to encourage the development of novel antimicrobial VMPs

EMA veterinary medicines innovation day

Presented by Helen Jukes on 19 April 2018
AWP chair

Questionnaire for Stakeholders: Early Hazard Characterisation/ Preliminary Risk Profile for new antimicrobial VMPs

- Sent on 21 March 2018
- To all CVMP interested parties
- Aimed at those interested in development of **novel antimicrobial VMPs**

13 March 2018
EMA/123258/2018

Questionnaire for Industry: Early Hazard Characterisation / Preliminary Risk Profile (PRP)

1. Background

1.1. AMEG opinion requested in 2013

In 2014, following a request from the European Commission, the EMA published advice on the impact on public health and animal health of the use of antibiotics in animals. Part of this advice was to consider the impact on AMR of the authorisation of new classes of veterinary antimicrobials, and if

Background

In 2014, EMA's Antimicrobial Advice ad hoc Expert Group (**AMEG**) was requested to provide advice to the European Commission on:

- **Authorisation of new classes of veterinary antimicrobials**
- **impact** on **AMR**, and
- the need to **restrict their use** in animals

Conclusion

- A **specific risk assessment** would be needed for **each new substance**, **tailored to the conditions of its use** (e.g. target species)

Recommendation

- To introduce an **early 'hazard characterisation' prior to MA application** for new antimicrobials

2017, new request for AMEG opinion

Term of reference 1: Update on the AMEG categorisation

Term of reference 2: **Advice on the Early Hazard Characterisation (EHC) concept**

- *Detailed analysis of the benefits and risks of the EHC; if the analysis would merit continuing with the proposal:*
  - *Further details on the procedure*
  - *Technical requirements*

Concept

EHC re-named: 'Preliminary Risk Profile' (PRP)

Aim

To **encourage development** by industry of **new antimicrobial VMPs**, by providing advice

- at **early stage of product development**, before clinical trials
- on potential **AMR public health risks** in relation to the **substance / product**
- the need for **risk management measures** (at high level) including potential refusal to authorise

Questionnaire

Q.1: Please comment on the scope of substances / circumstances to be considered for the PRP

Possible scenarios

- New classes/substances not authorised in human or veterinary medicine
- Human authorised classes/substances, not yet authorised in veterinary medicine
- Extension from companion animal to food animal use, or new food animal species
- New combinations
- Substances presently authorised for individual animal use → group oral treatment

Q.2 a) At what stage of product development would the PRP be of help?
b) At each stage, what information would be available?

Stage	Potential information available
Substance only	Antimicrobial class, spectrum of activity, known resistance mechanisms Importance of the substance to human medicine Potential for AMR transfer from animals to humans
Substance + target animal spp. e.g. Food-producing spp., Companion animal spp., Minor/Major spp.	Specific hazards associated with spp. e.g. resistant Salmonella spp. Extent of use (major/minor spp.) Routes of AMR transfer e.g. food, contact
Substance + target spp. + pharmaceutical form	Exposure of zoonotic and commensal bacteria e.g. gastrointestinal microflora Extent of use e.g. group or individual animal treatment

Q.3. Please comment on the benefits and risks of the PRP, e.g.

Benefits	Risks
Increased regulatory predictability at early stage may encourage development of new antimicrobial VMPs	Assessments may require regular review due to unpredictable emergence of new AMR mechanisms

Q.4. Please provide suggestions for improving the concept, or advise if the concept does not merit further development

Please submit your responses to the questionnaire to Zoltan.Kunsagi@ema.europa.eu

by **26th April**, 2018

Thank you for your attention

EUROPEAN MEDICINES AGENCY

Any questions?

Further information

Zoltan.Kunsagi@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**