Annex

Examples of issues which would normally not be considered as grounds for a potential serious risk to human or animal health or for the environment and should therefore not trigger a referral- or arbitration procedure[1].

Efficacy:

- The absence of an active comparator study versus a specific veterinary medicinal product
- Performance of field trials for vaccines with historical controls instead of with unvaccinated contemporary controls, if non-vaccination is unacceptable
- Lack of a comparative clinical trial with a reference product registered in a particular concerned Member State, when efficacy has been demonstrated with the reference product authorised elsewhere in the EU
- For pharmaceutical drugs, the absence of clinical studies performed in the concerned Member State when new Minimal Inhibitory Concentration (MIC) data from this concerned Member State are available and show equivalent susceptibility to the target micro-organisms in the Member State where the clinical trials were carried out

Safety:

- Missing toxicological data of the individual active substances, if safety has been established for the fixed combination product(s)
- Demanding additional safety warnings on the summary of product characteristics for one or several non-target animal species without supportive data

Quality:

- A requirement to use alternative analytical methods if the methods proposed in the documentation have demonstrated their suitability
- A requirement to use complementary analytical tests if these tests do not provide any additional results in terms of product safety
- A lack of testing for physico-chemical parameters which are not relevant to the pharmaceutical form of the product during in-use stability studies
- A request to tighten the limits of the active ingredient for the shelf-life specification of the finished product
- Lack of technical information on equipment used for physico-chemical analysis during the development studies, where a specific description of the equipment has been provided

Overall risk-benefit:

- Issues not related to the scientific requirements to demonstrate efficacy, safety and/or quality
- For products with well-established veterinary medicinal use authorised according to Article 13a of Directive 2001/82/EC as amended, the absence of data from new pre-clinical tests or clinical studies if posology is based on “systematic and documented use” and the safety is based on pharmacovigilance data

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[1] This current list is not exhaustive and will be reviewed and updated as examples are identified. This list should be used as guidance only. The examples do not necessarily apply to every application. They have to be considered carefully in the context of every particular application made to the competent authorities.

- Reference to a Note for Guidance that is still a draft version when the studies concerned were initiated or non-compliance with a current guideline where this has been justified

Information:

- The claimed indication cannot be granted because this would trigger the need of harmonising the summary of product characteristics of the other products approved at a national level
- The absence of contra-indications which appear on the summary of product characteristics of other veterinary medicinal products of the same class, when the scientific data provided in the documentation for the new product shows that that the same contra-indications do not apply