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EMA/CVMP/IWP/618299/2021
Immunologicals Working Party (IWP)

# Overview of comments received on the draft guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances (EMA/CVMP/IWP/251947/2021)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

| Stakeholder no. | Name of organisation or individual |
|---|---|
| 1 | AnimalhealthEurope |

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# 1. General comments – overview

| Stakeholder no. *(See cover page)* | General comment (if any) | Outcome (if applicable) |
|---|---|---|
| 1 | AnimalhealthEurope welcomes the opportunity to comment on this draft guideline. Market authorisation under exceptional circumstances is based on article 25 (and article 26) of Regulation EU 2019/6. The exact wording for the scope in this article is *"circumstances related to animal or public health"* and *"for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided"*. There is no time component in this article. The "immediate availability" can be addressed "in case of" an outbreak. In past experiences, those MAs in exceptional circumstances were granted for an "existing" threat, *i.e.*, facing an actual outbreak in the EU. There was no discussion yet on outbreak readiness, *i.e.*, the immediate availability on the market when the disease will occur. Absence of vaccine against a listed disease (articles 5 and 6 of Regulation EU 2016/429) is by itself a significant risk. The referenced articles state: *"The [disease-specific] rules for the prevention and control of diseases"*.<br>Prevention does not mean waiting for the disease to be present to cure it, but "be ready".<br>With this in mind, we propose to include in this guideline scope not just to (line 62) *"in the face of an outbreak of new or re – emerging infectious diseases"* but to *"in the face of an outbreak **or recognition threat of an outbreak***". The readiness should not obviously replace classical development and we acknowledge that | **Accepted.**<br>The additional text proposed has been added to the sentence: 'This 'exceptional use' provision has been introduced into the legislation to address potential availability concerns in the face of an outbreak or recognition of the threat of an outbreak of new or re – emerging infectious diseases in Europe with the potential for severe impact on animal or public health.'<br><br>Nevertheless, whether a particular marketing authorisation application is eligible for submission under Article 25 of Regulation (EU) 2019/6 (Applications in exceptional circumstances) will need to be considered on a case-by-case basis. |

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| | "*its use may be restricted only on authorities' request*" when an outbreak is present in the EU (stated in the annex of the product information). | |
| 1 | It is stated that "*this guideline replaces the CVMP related guidelines ("Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue" (EMEA/CVMP/IWP/37267/2008) and the "Guideline on requirements for an authorisation under exceptional circumstances for vaccines for use in birds against avian influenza (EMEA/CVMP/IWP/222624/2006))*.<br>In addition, in the current revision of the guideline for multi-strains dossiers (EMA/CVMP/IWP/105506/2007 Rev. 1) "*It is envisaged that submission of a multi-strain dossier would not be appropriate in response to an emergency situation. The minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use are therefore not considered within the scope of this guideline.*"<br>To summarise, how do we consider the multi-strain concept within the present guideline for authorisation under exceptional circumstances? In conjunction with the number of circulating strains/serotypes of BTV, FMD or avian influenza and in combination with the absence of cross-protection among them, an outbreak requiring vaccination with approved strain/serotype and new emerging one is likely to occur.<br>Furthermore, past experiences have shown (BTV 8 and 1) that epidemiological situations constantly evolve, meaning that outbreak of a new strain/serotype can occur together with, or subsequent to, a previous one. | **Not Accepted**<br><br>Exceptional circumstances conditions are applied to MAAs, but not to variations. The outcome of an application under Art. 25 is a MA, not the approval of a change to a MA. So, independently of whether the Art. 8 MA is supported by a multi-strain dossier or not, it is not possible to then apply Art. 25 to variations.<br><br>In Annex II of Reg. 2019/6, it is stated in section V.3.2 that "A multi-strain dossier means a single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains […]" The scope of the existing multi-strain GL states that multi-strain dossier applications (and variations) are not intended for exceptional circumstances. |

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| | We suggest including in the scope "*a (variation) application to add a strain/serotype in an existing approved multistrains dossier can be urgently introduced in response to an emergency/exceptional situation*". | |
| 1 | It is stated that "*The requirements of the guideline on vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/283631/2021), including possible data reductions/omissions foreseen, are applicable in case an already certified vPTMF is used for an application under exceptional circumstances.*"<br>Similarly, the application for multi-strain dossiers and related Guideline (EMA/CVMP/IWP/105506/2007 Rev. 1) should be added, such as: "The requirements of the guideline on vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/283631/2021), **and the guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (EMA/CVMP/IWP/105506/2007 Rev. 1),** including possible data reductions/omissions foreseen, are applicable in case an already certified vPTMF **or multistrains dossier** ~~is~~ **are** used for an application under exceptional circumstances." | **Not Accepted**<br>See comment above |
| 1 | The proposed guideline clearly indicates that procedural aspects including the approach to re-examination of MAs are out of the scope. However, it is emphasised that this aspect should follow harmonised procedure at EU level, avoiding several national procedures/timelines conducted in parallel.<br>Furthermore, it should be kept in mind that post-authorisation requirements to generate data in accordance with the requirements of Annex II of Regulation (EU) 2019/6 should not be unrealistic and | No update proposed. |

| Stakeholder no.<br>*(See cover page)* | General comment (if any) | Outcome (if applicable) |
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| | too demanding in timelines to ensure MA under exceptional circumstances will not be withdrawn by applicant instead of being transformed into a full MA, considering the risk of re-emerging diseases. | |

## 2. Specific comments on text

| Line no. | Stakeholder no. | Comment and rationale; proposed changes | Outcome |
|---|---|---|---|
| 103-108 | 1 | **Comment:** For the sake of clarity, both sentences related to re-examination of MAs can be reduced to a single sentence, moving the sentence "Veterinary medicinal products other than IVMPs are out of the scope of this guideline" to line 95.<br>**Proposed change:** "Such requirements for individual IVMPs will be set on a case-by-case basis ~~and are not in the scope of the present guideline~~. ~~Veterinary medicinal products other than IVMPs are out of the scope of this guideline~~. It is emphasised that procedural aspects including establishing criteria for re-examination and validity of a marketing authorisation in exceptional circumstances are not in the scope of the proposed guideline." | **Accepted** |
| 171 | 1 | **Comment:** Requirements linked with GMP implementation (as required by the inspectorate) should also be adapted to allow companies moving forward internally, not only to register a product, but also to produce it. Inspection bodies should also allow for less GMP data (e.g., with regard to requiring 3 validation batches before production of a new product, or full validation studies for some less critical tests/parameters), considering the possible reductions in data requirements as defined in the present guideline.<br>**Proposed change:** "The ~~IVMP must be manufactured under GMP conditions~~ **reductions in requirements** | **Not Accepted**<br>As stated in Annex II of Regulation 2019/6, fulfilment of GMP requirements, as requested in Part I, is mandatory. |

| Line no. | Stakeholder no. | Comment and rationale; proposed changes | Outcome |
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| | | **are also applicable to allow the start of in GMP-approved facilities. Specific adapted validation plan shall be available for inspection**.*"* | |
| 185 | 1 | *"A vaccine must only contain active substances (one or more) epidemiologically relevant for the emerging disease situation concerned*."<br>**Comment:** Ideally this means relevant once the vaccine is available on the market. So, by extension at application, the relevance should not be only epidemiological, but include a potential threat (preparedness).<br>**Proposed change:** "A vaccine must only contain active substances (one or more) epidemiologically relevant **due to outbreak or threat** for the emerging disease situation concerned". | **Accepted** |
| 370 | 1 | *"Marketing authorisation granted in exceptional circumstances and therefore assessment based on customised requirements for documentation".*<br>**Comment:** With regards to multistrain dossiers.<br>**Proposed change:** "Marketing authorisation **or strain/serotype addition (name of strain/serotype)** granted in exceptional circumstances and therefore assessment based on customised requirements for documentation*".* | **Not Accepted** – see comments above |