Availability of Veterinary Vaccines

Industry Perspectives

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Introduction

- Joint EMA/HMA Workshop on requirements for the authorisation of veterinary vaccines in the EU (March 2015)
  - Are regulatory requirements proportionate ? In EU versus in US ?
  - Vaccine development programs are often global, in order to improve availability, the authorities need to take this into account
  - **Not (only) about unmet need, emerging diseases or MUMS**
  - Focus includes vaccines against “classical diseases”
- IFAH-Europe did provide a list of recommendations/priorities before the workshop

Introduction

- EMA/HMA analysis of Industry's recommendations (Dec 2016)
  - 5 different categories : efficacy/safety; regulatory; benefit/risk methodology; quality/manufacturing; EP requirements
  - Proposed actions / Expected contributors / Priorities and general timelines ("short term, "medium term", "long term")
- Industry perspectives in next slides :
  - In general
  - Specific to key priorities

Industry perspectives

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In general:

- Welcomes the progress (analysis of Industry's recommendations) made recently, and the increased visibility of the overall project
- Multiple parties (EMA/HMA/CVMP/IWP/CADVVA/EDQM/Industry/…) are involved…Good dialog and coordination will be key for success.
- Agree with EMA/HMA on the need to prioritize the actions
- Agree on the priorities listed as « high » (i.e., field trials and serology)

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In general:

- Agree in general with the proposed contributors for the different actions
- Clarification on the time-span for the actions (versus « short term », « medium term », « long term ») would be beneficial
- Occasionally, some misunderstanding on Industry's proposals and recommendations
- Need for actions : timely and sequentially

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Field trials:

- **1st priority for Industry** : clarify the requirements and re-consider the approach
- Field efficacy trials for veterinary vaccines:
  - Complex, demanding, long, costly …and unpredictable by nature
  - No guarantee of challenge exposure
  - Trends for increased requirements
  - Failure to (re-)demonstrate efficacy (all claims !) under field conditions may result in negative and counter-productive SPC statements
  - Should not be a « tick-box exercise »
  - Impact on availability

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Field trials:

- Field efficacy trials add limited value (for licensing purposes)…
  - …if all claims are demonstrated under lab-controlled conditions
    - Unique situation of veterinary vaccines
    - Statistically significant differences are important
  - Limited value supported by several recent MA outcomes
- Industry welcomes a joint focus group of industry and regulators in 2Q2017
  - Scope should not be limited to assess whether the Guideline on field trials should be revised – It should also envisage the next steps
  - IFAH-Europe's Position paper (Feb 2017)

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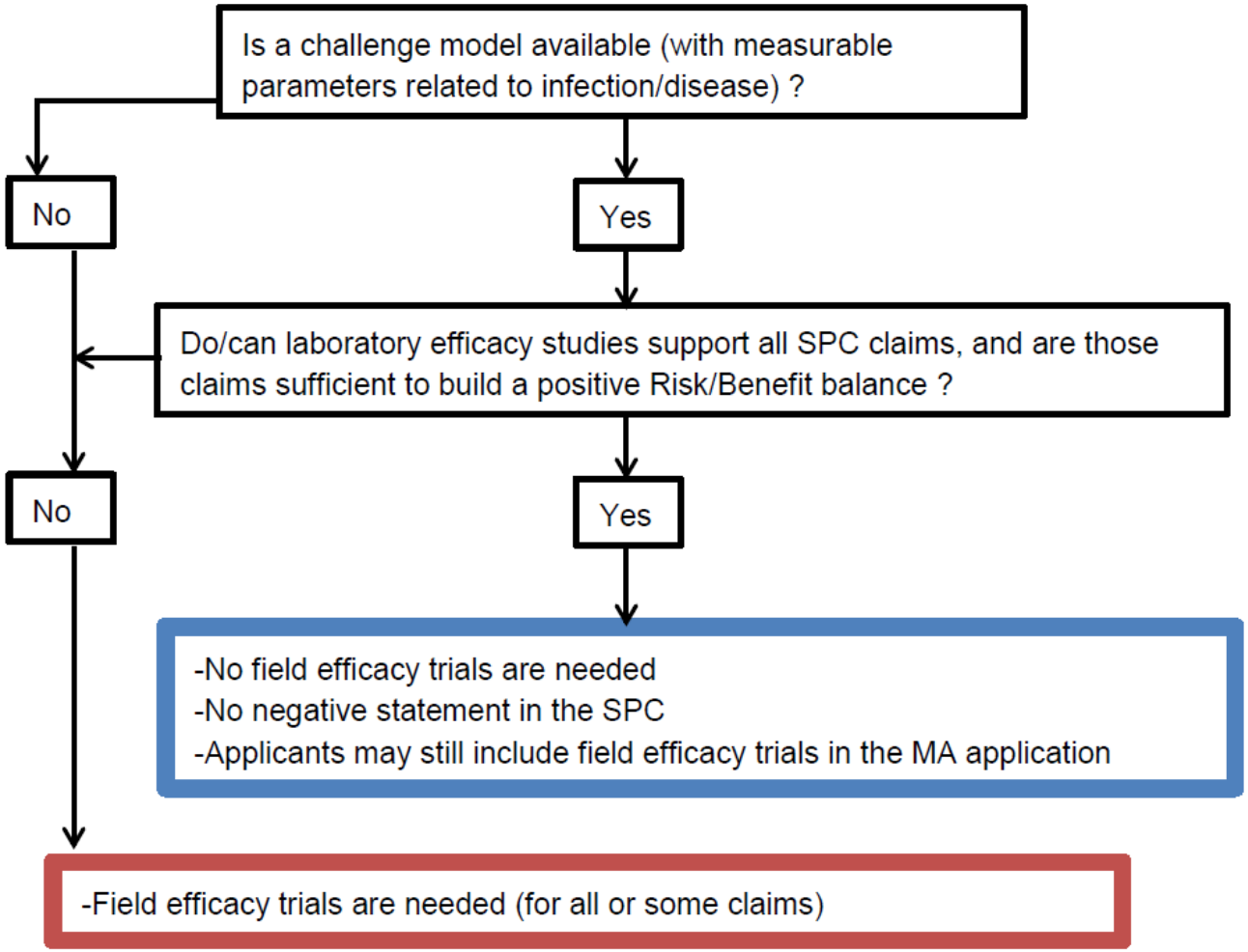
Field trials: Proposed decision tree (1)



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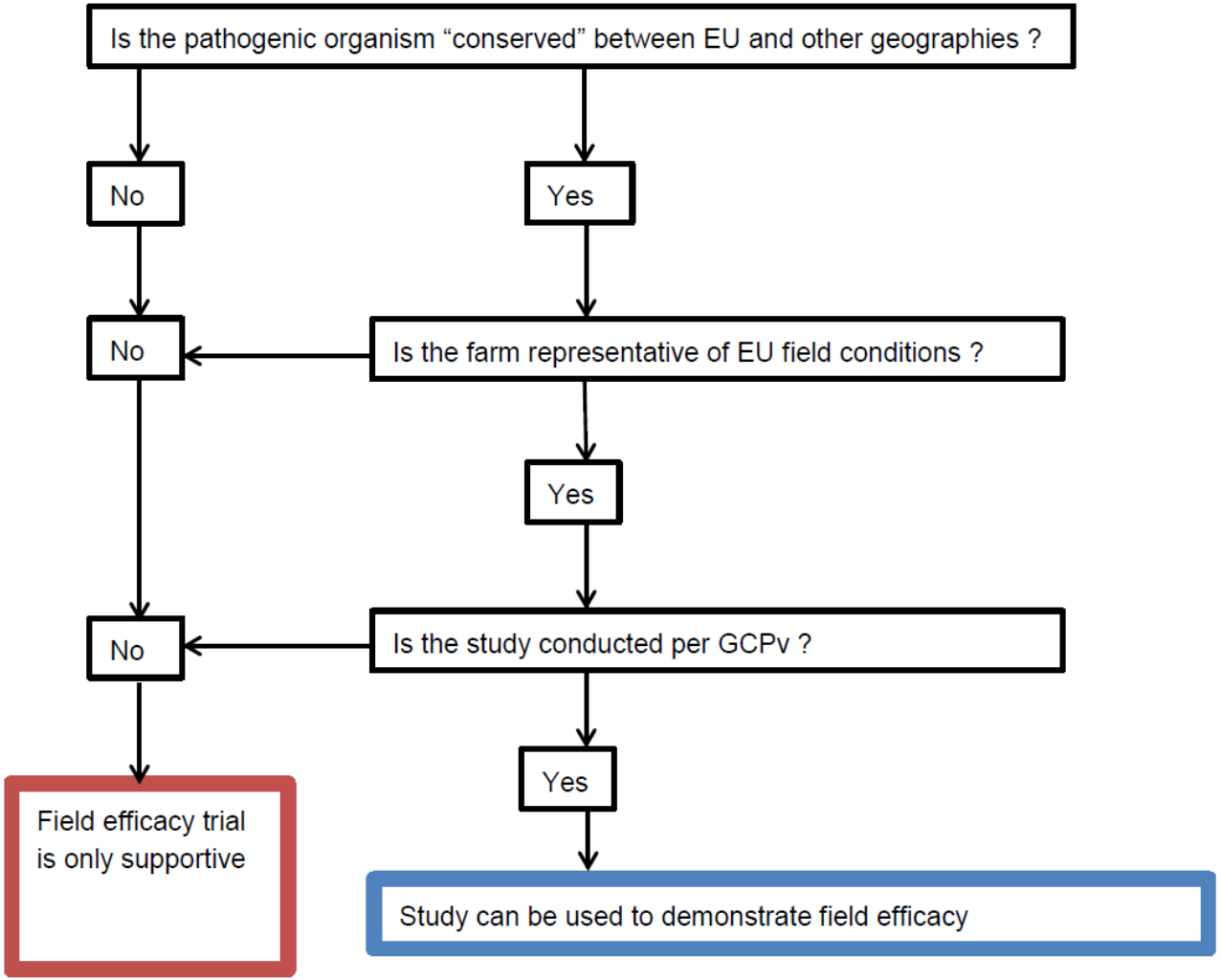
Field trials: Proposed decision tree (2)



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Serology:

- **2nd priority for Industry** : re-investigate the requirements on the use of serology (and possibly other immune parameters)
  - as surrogate of protection (marker of immunology) :
    - Association of vaccines
    - Duration of immunity, response to booster, alternative vaccination schemes,…
  - as correlate of protection (marker of efficacy) :
    - Possibility to use commonly-defined thresholds
- More in line with 3Rs
- Industry welcomes the possibility for a focus group meeting, and will follow-up with proposals

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MUMS Requirements

- Recent revisions of the requirements have been disappointing
- Further discussions are required to achieve optimal guidance in this area

Stepwise Submission

- A two-step (with and without the field safety trial(s) may improve vaccine time to market (better/quicker availability in EU and more competitiveness for export)

MRP and Repeat MRPs

- CMDv analysis is welcome and Industry looks forward to contribute
- Relevant for Veterinary Vaccines, but not only

Conclusion

- Industry welcomes the progress made, and is keen to move forward. It is now two years since the workshop
- Industry is prepared (and willing) to contribute, where relevant
  - Good progress on concrete proposals for field trials
- Clarification on the timespan of “short, medium and long term” in the EMA/HMA analysis would be beneficial
- Good dialog and coordination will be key for success

Conclusion

- Regular and timely updates from the steering group would be beneficial
- The earlier involvement of industry who can share the experience and data would result in better guidance
- We need to look at the issue with fresh eyes and develop smarter ways to move forward
- Industry and Regulators share the same goal: the availability of safe and efficacious vaccines to protect animal health !

Thank you

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THANK YOU