EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# EMA Veterinary Portfolio Reviews "Horizon scanning"

General feedback from the 2015-2016 review

EMA Veterinary Info Day 2017

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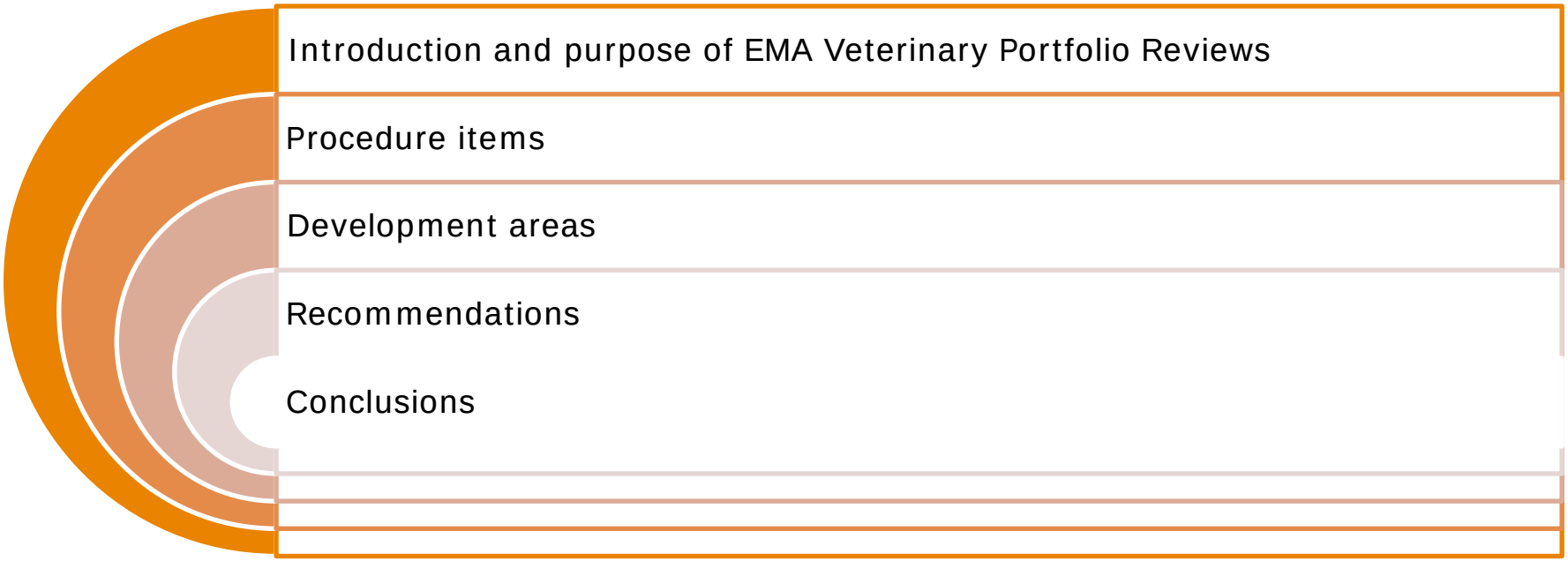
# Overview


Introduction and purpose of EMA Veterinary Portfolio Reviews
Procedure items
Development areas
Recommendations
Conclusions

# EMA Veterinary Portfolio Reviews - introduction and purpose

## History and background

- First time in 2011-2012; overview presented at EMA/IFAH–Europe Info Day in 2014
- An activity held on a regular base in the Human Division (Business Pipeline)

## Participants and timing

- Inclusion by invitation, bilateral discussions in confidence
- Meetings held 2015-2016

# Objective of EMA Veterinary Portfolio Reviews

- To anticipate challenges the EMA and its Veterinary Medicines Division might face in forthcoming years
- To facilitate the planning of the workload
- To have a dialogue on development trends
- To allow companies to share experience on the EMA/CVMP procedures
- To identify areas in possible need for improvement of work practices

# Main topics raised on *procedures* and *regulatory items*

| | |
|---|---|
| Support - continuous dialogue | • *throughout development and assessment* |
| ITF initiative | • *scope, possibility of parallel ITF with FDA/CVM* |
| SA procedure | • *wider advice, dialogue, parallel SA with FDA* |
| MRL requirements | • *excipients, "Art 6(3)" (MRL exemption for horses)* |
| MUMS requirements | • *"too demanding"* |
| Assessment | • *quality of assessment, advance dossier presentation* |
| Submission | • *one submission platform* |
| Global cooperation | • *regulatory authorities in other regions, VICH* |

# Main topics discussed on development trends

Example areas

- Alternatives to antimicrobials
- Therapies for chronic diseases
- Novel therapies
- Novel vaccines
- Other areas of interest

# Operational recommendations for consideration

| | |
|---|---|
| Dialogue | More open and continuous dialogue with applicants throughout development and regulatory phase<br>Including dialogue in the scientific advice procedure |
| Feedback | Exchange feedback after procedures between an applicant and EMA/CVMP<br>Use surveys |
| Communication | Informing more about the EMA support initiatives (e.g. ITF)<br>E.g. newsletter |
| Submission | Implementation of the Common Repository throughout the network |

# Recommendations for consideration

**More guidance?**

- Association (vaccines)
- Antimicrobials (specific substance types)
- MUMS/limited market (3 revised guidelines published, one in finalisation)
- Combinations (pharmaceuticals, vaccines)

**Need for expertise?**

- Novel vaccines (specific biotechnological types)
- Nanotechnologies & nano-devices
- Antimicrobials (specific substance types)
- Novel therapies (monoclonal antibodies, stem cells, other)

# Conclusions

Useful initiative:

- Facilitates prediction of expertise necessary in future
- Message given and received on need for more open and continuous cooperation between the Agency and applicants
- Regulatory and scientific challenges identified and development trends discussed
- Resource consumptive; sensitive

Next step: Further reflections on most useful timings, frequency, structure

# Thank you for your attention

## Further information

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