Europe IFAH
Representing the European Animal Health Industry

Pharmacovigilance:

Vision and needs for the future

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Pharmacovigilance

- World Health Organization: the science and activities relating to the **detection, assessment**, **understanding** and **prevention** of adverse effects or any other medicine-related problem.

- VICH: **detection** and **investigation** of the effects of the use of products, mainly aimed at **safety** and efficacy in animals and **safety** in people exposed.

- **Situation:**
- Veterinary pharmacovigilance has expanded rapidly.
- The perception is of increasing administrative burden with no added value to safety
  - Companies have seen a dramatic increase in resources (staff, facilities) required for this area.
  - There is an urgent need to reverse the current drift towards disharmony.

Vision: 0-5 years

- **Overall aims**
  - to increase harmonisation/common approach
  - Decrease administrative burden & increase focus on safety

- **3 key areas**
  - Detailed Description of the Pharmacovigilance System (**DDPS**)
  - Periodic Safety Update Reports (**PSUR**)
  - **GENERAL**

DDPS

- Currently required to be submitted with **every** MA application;
- Any change triggers **variations and fees**
  - Including change in Qualified Person for PharmacoVigilance (QPPV)
  - Where DDPS previously accepted, minor national agency comments in subsequent procedure can trigger new version
- i.e **Major administrative burden and cost**
- *Recent CMDv "WG on improvement of MRP/DCP" pilot:*
  - *DDPS Declaration as used on the human side;*
  - *the applicant can complete the declaration to state that the DDPS has already been previously assessed.*
  - *This should avoid repeat re-assessments and reduce the number of questions (avoid questions on the DDPS).*
  - *The CMDv will run a voluntary pilot for 12 months for new DCPs.*

DDPS VISION

- **DDPS replaced by:**
  - **Certification of MAH**
    - Based on inspection
- or
  - **Masterfile**

- **Change of system (DDPS): Variations**
  - per **MAH**, not MA;

- **Change of QPPV**
  - QPPV not part of DDPS
  - List of QPPVs held in register
  - Change not triggering variations

PSUR

Current situation

- **Frequency**
  - All products have mandatory PSUR cycle regardless of risk profile
  - New PSUR cycle sometimes requested for ‘copycat’ licences
  - Change of DLP to join harmonised cycle requires variation - cost
  - Renewals – clinical & safety expert statements

- **Contents**
  - Complex with multiple tables & calculations
    - ‘recommended’ in Volume 9b can be interpreted as ‘required’
  - Assessment comments received requesting ‘updating’ PSURs with no cases
  - Administrative content
    - SPCs ‘to be included’
    - List of MAs ‘to be included’

PSUR VISION

- **Frequency**
  - Flexible calendar with reduction of PSUR frequency based on product risk profile
  - All NCAs to follow synchronised cycle
    - vaccines to be included
    - No variations required to join synchronised cycle
  - Eliminate renewals

- **Contents**
  - Simplified content
    - If non serious cases are required to be submitted electronically to Eudravigilance, option to remove line listings & simplify tables/calculations
  - Administrative content to be minimised
    - SPCs not required to be included
    - List of MAs not required to be included

GENERAL

Current situation:

- National interpretations/legislative requirements cause added complexity
- Fees vary widely & can be complex to administer
- No EU product database
- No global database/exchange of data
  - MAHs submit same data multiple times
- VICH guidelines not implemented
  - Regional differences/additions generate different requirements to be met
  - Countries setting up new systems have no ‘standard’ & generate additional/different requirements

GENERAL VISION

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Harmonisation:

- No national interpretations/legislative requirements
- One yearly fee per MS/agency (based on number of licences held) to cover all pharmacovigilance activities
- EU product database
- Global database/exchange of data
    - MAHs submit a case **once**

- VICH guidelines implemented with no regional differences/additions so requirements uniform
    - Countries setting up new systems also use the same uniform requirements or global database

SUMMARY

- IFAH Europe welcomes the opportunity to identify needs for the future to improve veterinary pharmacovigilance

- With the time needed for new legislation to be put in place, IFAH Europe urges everyone to identify & pursue opportunities within the existing framework to maximise the effectiveness of veterinary pharmacovigilance in the next 5 years

- IFAH Europe welcomes some recent initiatives & hopes to have future opportunities to participate in developing the way forward for the next decade

Thank you for your attention