Pharmacovigilance:

Latest developments - Industry perspective

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PV: Latest developments – Industry perspective

- Directive 2001/82 as amended: what has evolved?
- Directive 2001/82 as amended: in practice?
- Veterinary legislative review: how to optimise the system?

Directive 2001/82 as amended: What has evolved?

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2004 legislation introduced significant changes :

- Detailed Description of the PhV System (DDPS)
- Electronic reporting
- Increased frequency of Periodic Safety Update Reports
- PhV inspections
- More channels for the collection of PhV data, e.g.:
  - Animal owners/breeders via healthcare professionals
  - Reporting of suspected transmission of infectious agents via VMPs

Directive 2001/82 as amended: In practice?

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Detailed Description of the PhV System (DDPS)

- Part of the dossier for each MA
  (but PhV system is applicable for all products of the MAH)

- Minimal changes result in major impact on administrative tasks and costs
  (without benefit for the re-assessment of safety of products)

Directive 2001/82 as amended: In practice?

Electronic Reporting and PSUR

- Same requirements for all products irrespective of associated risk
- PSUR preparation requirements significantly increased for all products
  - after implementation of Volume 9B regardless of product risk profile
  - e.g. need to present data by using various tables
- More frequent PSURs may result in more frequent SPC changes (cost and resource intensive)

Directive 2001/82 as amended: In practice?

Pharmacovigilance Inspections

- No real harmonization of inspections
  - duplicating efforts between MSs
- Costs
  - e.g. central inspection: 17 400€

Directive 2001/82 as amended: Impact of changes?

- Significant increase in costs
- Significant impact on workload:
  - new requirements with associated new processes, training, software (requires time & effort to implement)
- No real benefit to the PhV system
  - Are changes necessary and proportionate to the needs of the veterinary PhV system?
- Implementation of changes in a consistent & harmonized way?

Directive 2001/82 as amended: Impact of changes?

- High level agreement (e.g. HMA) that veterinary pharmacovigilance must be:
  - simplified
  - proportionate to the risks and resources of the sector

- But not reflected at operational level

  = continued increase and discrepancies in requirements and bureaucracy

Vet. legislative review: Purpose?

- Rationalise the system / reduce unnecessary administrative burden
- Have a simplified PhV system that is:
  - Proportionate (to safety requirements)
  - Workable in an EU with 27 MSs (and more) and can be operated by all MAHs (of all sizes)
  - Increased efficiency of agencies network
    - leading to reduced national requirements
    - and improved decision making

Vet. legislative review: Purpose?

- REMINDER: to focus on the specificities of veterinary PhV in comparison to human PhV:
  - Dual purpose: to support animal and public health
  - Wider scope of vet PhV
  - Reporter: patient vs. vet
  - Type of exposure e.g.
    - mass treatment
    - short duration (production animals)
  - Type of signal (visual observations of gross pathology)
  - Many fewer cases reported in veterinary PhV

Vet. legislative review: Chance to improve

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- DDPS:
  - Apply the master file concept (with only product specific aspects/dossier)
- Electronic reporting:
  - Extend to non-serious cases in an appropriate way (e.g. reduce amount of PSURs needed)
- PSURs:
  - Frequency and requirements based on risk evaluation
  - All MSs to join the EU work-sharing initiative
  - Avoid national requirements/preferences
  - Accept Eudralink submissions

Vet. legislative review: Chance to improve

- Inspections:

  Increase harmonization/ communication between MSs
  - No duplicating efforts between MSs

- Signalling/ Trending:
  - Ensure expectations are appropriate to vet. med. and harmonized between MSs
  - Provide flexibility for company
    - e.g. use of database, analyzing tool

Vet. legislative review: Industry wishes

- New legislation appropriate to vet. med.
  - Significant reduction in administrative burden
- Increased communication between regulators and industry
  - e.g. workshop on signalling/trending
- Proportionate and harmonized requirements/ fees
  - e.g. current fees for PSURs: 0€ to ~2,200€
- Provide sufficient time to industry for implementation
  - e.g. changing internal processes, software, training

Harmonized, simplified and strong PV system