Future Legislation: Pharmacovigilance – Industry Vision

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on behalf of IFAH-Europe – Infoday March 2017

Note: this review is based on original Commission Proposal for a new Veterinary Medicines Regulation (VMR) and subsequent European Parliament Amendments

Industry (including Pharmacovigilance) strongly supports the Commission's original stated objectives for this proposed new regulation

- Increase the availability of veterinary medicinal products
- ✓ **Reduce administrative burdens**
- ✓ **Stimulate competitiveness and innovation**
- ✓ **Improve the functioning of the internal market**
- Address the public health risk of antimicrobial resistance (AMR)

Industry's PhV aims are closely aligned with the Commission's original objectives

Reduce administrative burden

- Eliminate un-value added activities: >>95% PSURs have no actioned signals
- Move away from PSURs: worked for national/EU only situation (≤ few 100s of cases), but not for >10k global cases
- Improve NCA harmonisation – avoid minor differences in interpretation

Focus on value added activities

- 'Risk-based' rather than 'one size fits all'
- Take advantage of modern technology
  - ✓ Data handling (XML exchange)
  - ✓ Single entry point / methodology
  - ✓ Analytical tools (statistical signal detection)
  - ✓ All data (submit all cases)

Future proof Vet PhV approach

- New VMR likely to be in place to 2030+…

In addition, the European Parliament contributed some constructive suggestions

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PhV Database

- Including all interested parties in the functional design of the PhV database
- PhV database must be a partnership between all Agencies / MAHs and work for all

EU QPPV

- Reflects supervisory role rather than need to actually perform all tasks

Responsibilities for Signal detection

- Clarifies responsibilities of both Agencies and MAH and necessity for communication during processes

Signal Management

- Encouraging Agencies to consult with MAH during Agencies' own Signal Management processes

However, Industry also has some concerns on the developing text…

Increasing complication of reporting timelines

- NCA record ≤15 days / MAH serious cases ≤15 days / non-serious ≤42 days
- Original Commission proposal of 30 days is more appropriate (including data transfers MAH↔NCA)

Antimicrobial Resistance

- Industry fully understands the importance of Antibiotic Resistance, and
- Lack of efficacy is clearly within scope of PhV (and, if found to be due to resistance, this would be included in report), but
- The more general '*Signs of antimicrobial resistance after use*' is not clear, practical or in most cases even product related / product specific

Environmental Risk Assessments / Monographs

- Should be addressed elsewhere in the VMR as not part of PhV (covered previously during this meeting)

And, in addition (…concerns on developing text…)

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Incidence rates

- Clearly important but will require provision of sales data: this must be as un-burdensome as possible

MAH should take all possible steps to encourage Reporting'

- MAH external responsibilities are to facilitate reporting
- NCA have a number of other levers to encourage reporting..

Transparency of PhV data held by Agencies

- Industry fully understands the drive to greater transparency, but has real concerns about misunderstanding and misleading use of such information

'Post marketing surveillance studies'

- Minor point: surely what is meant is 'post marketing **safety** studies'?

While the overall Commission objectives are still valid, need to ensure …

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Improved understanding of Signal Detection / Management

- Not 'one size fits all' for all products / MAHs (/ NCAs?)
  - ➢ No or few AEs – may be manual / paper based
  - ➢ Products with 100+ AEs – spreadsheet / statistical
  - ➢ Products with multiple 100s/1000s AEs – should be statistical

Avoidance of an INCREASE in administrative burden

- Developing Signal Detection and keeping PSURs, as is, will increase administrative burden, without value add
- Take a risk-based approach to PhV activities
  - ✓ Risk-based signal detection timelines
  - ✓ ? Additional specific measures early in product lifecycle ?

Resistance to change is overcome (?)

- Current revenue models should not drive 2020s PhV strategies
- Due to 'ownership' or investment in current PSUR processes?

In addition Industry sees benefit in early discussion (before VMR finalisation)…

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To prepare full implementation of Signal Management

- Understand Agency needs for confirmation of MAH Signal Management activities: must allow electronic exchange
  NB: this is a prerequisite for database development

- Need agreement on approaches to signal validation, assessment, communication (requires discussion on data elements and structure)

- Agency Signal Assessment will likely require additional data from MAHs
  - E.g. sales data for incidence assessment: need for early discussion regarding approach (as multiple ‘on-demand’ requests of MAH will be very burdensome)

In addition Industry sees benefit in early discussion (before VMR finalisation)…

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To enable rapid IT system development and deployment

- Neither many Agencies / MAHs have a particularly good track record in timely deployment (variety of reasons)
- Anticipated transitional timelines will be very tight

Impact of case volumes on EMA / NCA

- e-reporting all cases will substantially increase non-serious EEA / Third Country individual case reports (currently only reported in PSUR line list) – not clear that this is fully understood by Agencies


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