Electronic exchange of Pharmacovigilance data: the industry journey so far and the look ahead to the future

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- EudraVigilance Vet, the journey
  - Current obligations and challenges
  - Next steps: Access policy, Surveillance and Reporting schema
- Electronic reporting, hand in hand with PSUR requirements
- Opportunities for changes
International Federation for Animal Health-Europe:
- The federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe

- 15 corporate and 16 national associations members (2 associate members – 2009 annual report)

- Membership covers 95% of the European market for veterinary products

More information at: http://www.ifaheurope.org/
EudraVigilance vet

- Central EU database set up by EMA:
  - Contains adverse reaction reports to all veterinary medicines authorised in the EU
  - Reports received from EU regulatory agencies and pharmaceutical companies

- Role of EudraVigilance Vet:
  - To collect safety information on medicinal products => To allow Competent Authorities to carry out scientific assessment
  - To support animal and public health
The journey

- September 2003: 1st EV Vet Joint Implementation Group (JIG) meeting

- Where are we today?
  - All parties report electronically
    - *Some refinements still needed (ACK, duplicates...*)
  - Useful references developed, including the Reporting schema (v. 1.02, Feb. 2009)
Current reporting obligations (1)

- Schema (version 1.02, Feb. 2009): focus on expedited reports (15 days), *i.e.* animal serious and human cases

- **MSs obligations**: to the EU central DB and concerned MAH(s)

- **Industry obligations**
  - Same reporting route, regardless of the product’s authorisation procedure
Differentiation is with the origin of the case, i.e. EU vs 3rd country

- EU cases: to MS where the case occurred within 15 days
  - The MS sends it to the EU database, when the case becomes accessible to all other MSs
Current reporting obligations (3)

- 3rd country cases: to EU database only within 15 days
  - National reporting requirements still apply:
    - Challenge for industry: having to comply with several databases (national and EU)
  - Requirements necessary for an efficient PhV system, i.e. to support animal and public health?
Industry current challenges

- Need to identify duplicates when reporters send cases to the MAH and CA

- National CAs specificities:
  - Cases re-sent to MAHs with minor changes or own assessment (creates duplicates)
  - National databases: discrepancies in trade names; breed names that do not import properly...

  All generate significant additional workload, especially on MAHs with large portfolio and high number of cases (manual check)
Solutions at hand and next steps

- **Today’s solutions**
  - Remove national requirements
  - MSs to follow the EMA XML to guarantee successful importing of cases

- **Considerations for next steps**
  - Access policy
  - Surveillance / signal detection
  - EU reporting schema
    - Non-expedited reports
    - 3rd country cases
    - *Expedited EU cases: status quo*
Final draft (October 2010), 3 levels of access:

- Competent Authorities: all the information
- Public:
  - Summary data of all cases (w/o narrative, Data Protection)
  - Search function by active ingredient or product (aggregated information)
– Marketing Authorisation Holders:
  ▪ Same as public, i.e. no products data ownership

  ▪ EMA vision for the future: provide MAHs with access to a tool for surveillance purposes

  ▪ EMA proposed gradual implementation with focus on CAPs to start with (complete products dictionary only available for CAPs)
- CAPs: <5% total EU market (3 MAHs hold 62% of CAPs)
- Information on very few products to be delivered to the veterinary profession and general public
  - How valuable is such information?
  
  - *IFAH-Europe proposal: implement the Access Policy only once it can provide information on all products on EU market*
Surveillance: IFAH-Europe proposal

- **CAs responsibilities - Europe**
  - From EU database with central coordination and oversight
    - *Central EU database to contain all EU pharmacovigilance reports*
  - VICH regions: promote exchange of analysis

- **MAHs responsibilities**
  - From their own database
  - Best use of the available worldwide data
Reporting schema: IFAH-Europe proposal

- **Non-expedited cases**
  - Marketing Authorisation Holder
    - To the EU database by the next PSUR Data Lock Point or within 90 days
  - Competent Authority
    - To the MAH and EU database by the next PSUR Data Lock Point or within 90 days
• **3rd country cases**
  - Necessary in the EU database?
  - VICH considerations
    - Most 3rd country cases occur in VICH regions
    - Promote exchange of information between the regions to also prevent duplication of information in each regional DB
    - Develop a global database?
  - Non-VICH regions cases are available from MAHs’ databases (will be part of the MAH assessment)
E-reporting evolution goes hand in hand with PSURs

- EV Vet signal detection will allow for:
  - A reduction in the number of PSURs
  - A more flexible approach with focus on benefit/risk
  - *Pending available complete products’ dictionary*
Ifah-Europe proposal

- PSUR calendar set according to time product on the EU market and benefit/risk profile:
  
  < 10 years: submit a PSUR once a year for 4 years, then every 3 years (i.e. in years 7 and 10)
  
  > 10 years: no PSURs, unless CVMP justifies otherwise on safety ground
Meanwhile...

- Pending completion of a products’ dictionary, other alternatives to be put in place to achieve **simplification** with PSURs

- HMA initiative for “PSUR synchronisation and work-sharing”
  - Welcomed by industry
  - Ambitious, where 1 assessment per active substance (multiple products and formulations covered)
  - Assessment remains complex and duplicated
  - Work-sharing? Decrease in workload?
Simplified handling of PSURs: IFAH-Europe proposal

1 product (several MAs across Europe),
1 PSUR per product,
1 assessment per product

= work-sharing

- All parties to benefit from 1-1-1 approach
- Synchronise the assessment further per active substance as a next step
- Established submission calendars per active remains applicable
Opportunities for changes

- Next version of EV Vet
- EU legislative Review: Commission Better Regulation on VMPs (April 2010)
  - CVMP analysis (July 2010)
- Other important references
  - Heads of Medicines Agency
    - HMA\textit{v} Reflection Paper (draft, June 2009)
  - European Medicines Agency Road Map to 2015 (draft, 26/01/2010)
Common theme

Common messages
- Efficient European regulatory system
- Better use of resources
- Benefit/risk approach
- Work-sharing
- Simplification
- No systematic alignment with human framework

Common goals
- Simplified PhV system
- Better use of electronic reporting
- Proportionate to safety requirements system
- Increased efficiency of agencies network
The journey continues...

Take advantage of these opportunities to ensure we achieve these common goals

Today’s views may evolve as the system matures
Thank you for your attention

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List of acronyms (1)

- AE  Adverse Event
- CA  Competent Authority
- CAPs  Centrally Authorised Products
- CVMP Committee for Veterinary Medicinal Products
- DB  Database
- EC  European Commission
  http://ec.europa.eu/
- EMA  European Medicines Agency
  http://www.ema.europa.eu
- EV Vet  EudraVigilance Vet
  http://eudravigilance.emea.europa.eu/veterinary/
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<thead>
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<th>Acronym</th>
<th>Description</th>
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<td>HMA</td>
<td>Heads of Medicines Agencies</td>
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