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Health Canada:
Use of big data in regulatory medicine
Lessons learned and opportunities for the future

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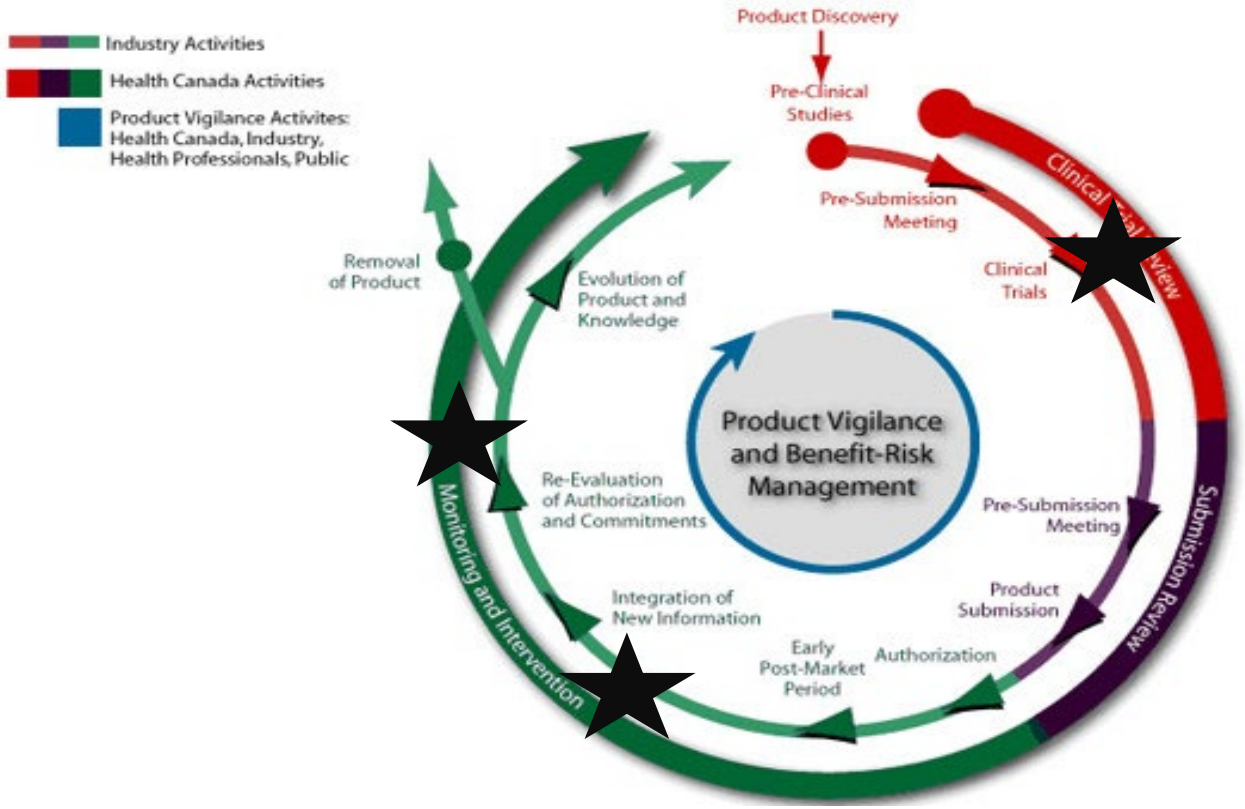
Veterinary Big Data Stakeholder Forum, June 1, 2021

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Areas of Interest

1. Real-World Evidence in Effectiveness Evaluation
2. Pharmacovigilance
3. Antimicrobial Sales, Use and Resistance



Real-World Evidence in Effectiveness Evaluation

- Spring 2019, Health Canada (human-side) promoted the acceptance of Real-Word Data & Real-Word Evidence (RWD/RWE) in support of regulatory submissions
- Published simultaneously with the companion document **Elements of Real World Data/Evidence Quality throughout the Drug Life Cycle**
- This initiative was implemented in collaboration with industry partners
- Began tracking submissions using RWD/RWE
- Began a RWE Working Group, including representation from the Veterinary Drugs Directorate (VDD)

Lessons Learned from our Colleagues

- RWD/RWE can be a useful tool, but cannot replace RCT as the pivotal evidence in new entities
- RWD/RWE submissions vary widely in quality
- Sophisticated data processing and analytical techniques are helpful, but do not reduce the need for human evaluation
- The study protocol is vital to project success
- There are many challenges to keep in mind:
  - Addressing biases
  - Suitability of data to answer clinical question
  - Availability/ownership of data

RWD/RWE in Canadian Veterinary Drug Approvals

- Canada already takes a weight of evidence approach in evaluating drug submissions
- Potential areas for focus for RWE/RWD:
  - Minor Use/Minor Species
  - Reduce need for extra-label drug use through an increased number of product approvals (ie. human-approved drugs, compounding)
- Issue with a lack of data volume even greater with Canadian veterinary data
- There's a lack of Canadian-specific databases – may need an international approach
- When assessing biases, will need to consider the source of data based on location
- Requires industry support and collaboration to drive need for training and resource allocation

Pharmacovigilance

- The Veterinary Drugs Directorate, along with the Canadian Centre for Veterinary Biologics, Canadian Food Inspection Agency invested in an electronic pharmacovigilance database
  - Continue to explore functionalities and on-board additional companies
- Identifying safety concerns from databases and literature implemented through an algorithm-based system with the HC library to search the EMBASE database of 8,500 journals
- Supplement with a 'google-alert' system to monitor web-based information
- Active participation in international working groups to improve harmonization and standardization
  - VICH, including Signal Detection WG
  - Trilateral discussions with the EMA, CVM-FDA
  - VeDDRA terms

Pharmacovigilance

- Current system is adequate for the size and nature of adverse event data collected in Canada – serious Canadian cases and unexpected serious adverse events internationally
  - Limited by sales volume, numbers of reported AEs, comparative data
- Continue to assess the benefit of implementing additional signal detection tools
- Use of artificial intelligence or neural networks does not remove need for evaluation of causality
- To have sufficient numbers to support additional tools likely need an international approach
- Collaboration between industry and regulators is needed
- International adverse events databases would provide all regulators with more information to inform potential post-market decisions

Antimicrobial Sales, Use and Resistance

- Following international best practices, we collect reports on the sale of veterinary antimicrobials in order to:
  - Support surveillance and interpretation of patterns and trends of antimicrobial resistance (AMR),
  - Provide relevant information that could help assess the impact on human health from the use of specific antimicrobials in animals
- An electronic data collection tool, the Veterinary Antimicrobial Sales Reporting (VASR) system, has been developed in collaboration with the Public Health Agency of Canada (PHAC)
- Uses ATC Vet Codes, HC/PHAC have assigned **temporary** ATCvet codes for products without official codes
- Species data is estimated
- Antimicrobial Use and resistance data is collected from sentinel farms

Sales data challenges & successes

- Sales ≠ Use – and how to communicate
- Protecting business information with provincial & animal species stratification
- Provincial reporting improvements by animal species (i.e., numerator and denominator information)
- Important insights on sales in 11 animal species & compliments existing farm use data
- Providing support tools to enhance reporting experience
- Applying DDDvet
- More detailed comparison/integration between sales and AMU

Take Home Messages

1. Highly trained personnel may be a more limiting resource than IT infrastructure
2. RWD/RWE can be a useful tool, but does not replace traditional studies
3. For Canada to progress in the area of Big Data we need a standardized and harmonized approach with other jurisdictions
4. Early collaboration with industry is needed and welcomed