Implication of Potency Specifications

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"Sometimes the first duty of intelligent men is the restatement of the obvious." - George Orwell
Goal

• To ensure that Safe and Effective products are available to the end-users
Implication of Potency Specifications

• What impact does potency specifications have on efficacy and safety of veterinary biologics?

• At the core of our goal.
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Expectations: Safety and Efficacy

- Veterinary biologics are not 100% safe and effective.
User Expectations

- Users expect products to be safe and effective.
Industry Expectations

- The expectation of the veterinary biologics industry is to market products with predictable performance profiles.
User Feedback

• How well are our current potency standards performing?
• Reports of potential lack of efficacy are infrequent.
• Majority of cases received by CVB are AERs associated with safety issues.
Difference in User Expectations

- User
- Products used
- Application; expectations may vary depending on product application. e.g., inoculation vs course spray.
- Species (e.g., Companion vs livestock vs poultry & aquaculture)
- Multiple products administered
- Off-label use (expectations?)
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Challenges to Expectations
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Expectations in High Risk Animals
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Potency Considerations

• We are currently considering how data could be used to replace potency standards while ensuring product efficacy and safety.
Implication of Potency Specifications

• Potency is a balance between efficacy and safety

• Minimal potency requirements to ensure efficacy

• Should there be maximum potency requirements regarding safety?
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Potency

• Does changing potency specifications impact efficacy and safety of veterinary biologics?

• What users expect?

• Is there an opportunity to improve safety of products by implementing new potency specifications?
Role of Pharmacovigilance

- "However beautiful the strategy, you should occasionally look at the results." - Winston Churchill

- No potency assay correlates perfectly with efficacy in the field. Thus, pharmacovigilance plays a significant part of understanding how potency specifications impact observed product performance.
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Goals regarding PV & User Expectations

• Narrow the gap between product performance and user’s expectations.
• Aligning user’s expectations with product performance profile.
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What Pharmacovigilance cannot do

• Make end users report all events
  – Lack of reporting = lack of detection
• Eliminate reporting bias:
  – Selection based on seriouness, animal, media
• Determine causality
  – Accuracy of information reported
  – No control group
  – Other factors
    • Handling, storage, administration, health status, concomitant product
Summary

• The impact of product safety and efficacy must be considered when proposing changes to potency specs.
• The expectations of users.
• PV as a tool to assess impact
• An opportunity to improve product safety?