



United States Department of Agriculture

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Implication of Potency Specifications

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



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Goal

- **To ensure that Safe and Effective products are available to the end-users**

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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.**



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User Expectations

- **Users expect products to be safe and effective.**

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Industry Expectations

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

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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.**

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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.**

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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?**

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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 seriousness, animal, media
- **Determine causality**
 - Accuracy of information reported
 - No control group
 - Other factors
 - Handling, storage, administration, health status, concomitant product

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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?**