Applying VICH Guidelines: OVERVIEW
Focus on stability

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6th cycle regional seminar for OIE focal points for veterinary products
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4 CATEGORIES

- ANALYTICAL VALIDATION
- IMPURITIES
- STABILITY
- SPECIFICATIONS
1. Analytical validation

> Validation of analytical procedures: Definition and Terminology
  - VICH GL1 - Implemented in October 1999

> Validation of analytical procedures: Methodology
  - VICH GL2 - Implemented in October 1999
2. Impurities

- **Impurities in New Veterinary Drug Substances**
  - VICH GL10(R) – January 2008

- **Impurities in New Veterinary Medicinal Products**
  - VICH GL11(R) – January 2008

- **Impurities: Residual Solvents in new veterinary medicinal products, active substances and excipients**
  - VICH GL18(R) – July 2011
3. Stability

> **Stability Testing of New Veterinary Drug Substances and Medicinal Products** VICH GL3(R) – January 2008

> **Stability Testing: Requirements for New Dosage Forms**
  * VICH GL4 Annex to the VICH GL3 Implemented in May 2000

> **Photostability Testing of New Drug Substances and Products**
  * VICH GL5 (Quality - Stability) - Implemented in May 2000

> **Stability Testing for Medicated Premixes**
  * VICH GL8 - November 1999

> **Bracketing and matrixing designs for stability testing**
  * VICH GL45 - April 2011

> **Statistical evaluation of stability data**
  * VICH GL51 February 2014

> **Stability testing of new biotechnological/biological veterinary medicinal products**
  * VICH GL17 June 2000
4. Specifications

> Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances + Decision Trees
  • VICH GL39 - November 2006

> Decision Trees
  • VICH GL39
Stability Guidelines
What is the objective of VICH stability guidelines?

- Provide guidance for conducting the stability studies of new drug substances or medicinal products that will support a re-test period (drug substance), a shelf life (drug substance/medicinal product) and recommended storage conditions.

- Define the stability data package for a new drug substance or medicinal product that is sufficient for a registration application.

- Provide recommendations for the evaluation of stability data.
What are the stability guidelines applicable to new drug substances and new medicinal products according to their type?

**PARENT GUIDELINE: VICH GL3**
«Stability Testing of New Veterinary Drug Substances and Medicinal Products”

Annex: guideline GL 4
«Requirements for New Dosage Forms “

Further guidance for medicated premixes:
VICH guideline GL 8

Further guidance for biotechnological/biological products:
VICH guideline GL 17
DEFINITIONS (1/2)

➢ **New dosage form**: a new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as the existing approved product.

➢ **Different pharmaceutical product types include**

   ➢ different administration route (e.g., oral to parenteral),
   ➢ new functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and
   ➢ different dosage forms (e.g. capsule to tablet, solution to suspension).
DEFINITIONS (2/2)

- **Medicated premix** (Type A Medicated Article): a medicated premix is a veterinary medicinal product consisting of a mixture of one or more drug substances, generally with a carrier, that is prepared to facilitate oral administration of the drug to animals when mixed with feed.

- **Biotechnological/biological product** (scope of VICH GL17): well-characterized proteins and polypeptides, and their derivatives which are isolated from issues, body fluids, cell cultures, or produced using recombinant deoxyribonucleic acid (r-DNA) technology. The guideline does not cover antibiotics, heparins, vitamins, cell metabolites, DNA products, allergenic extracts, conventional vaccines, cells, whole blood, and cellular blood components.
Structure of VICH Stability guidance: General methodology for protocols and data analysis

Where to find general recommendations for designing the protocol of stability studies and evaluating data?

**VICH GL3** *(Parent guideline)*
«Stability Testing of New Veterinary Drug Substances and Medicinal Products”

- Stress testing
- Selection of batches
- Design of stability studies
- Stability commitments
- Evaluation of data
- Statements/Labeling

**VICH guideline GL 5**: «Photostability Testing of New Drug Substances and Products”
- Testing equipment and protocol
- Stepwise procedure for photostability testing from the API to the packaged drug product

**VICH guideline GL 45**: «Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products”
- Bracketing: methodology and interpretation of data
- Matrixing: methodology and interpretation of data

**VICH guideline GL 51**: «Statistical evaluation of stability data”
- Recommendations for use of statistical analysis
- Interpretation of stability data in accelerated and intermediate conditions for extrapolation of data at the long-term condition
**Link to the presentations of VICH stability guidelines**

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<td>Stability Testing of New Veterinary Drug Substances and Medicinal Products and Requirements for New Dosage Forms (Annex to VICH GL 3)</td>
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Access to the guidelines and training material

> VICH website
GUIDELINES

QUALITY
ANALYTICAL VALIDATION | IMPURITIES | STABILITY | SPECIFICATIONS

SAFETY
ENVIRONMENTAL SAFETY | METABOLISM AND RESIDUE KINETICS | TOXICOLOGY |
TARGET ANIMAL SAFETY | ANTIMICROBIAL SAFETY

EFFICACY
GOOD CLINICAL PRACTICE | ANTHELMINTICS | BIOEQUIVALENCE

Analytical validation

- Validation of analytical procedures: Methodology
  VICH GL2 (Validation methods) – Implemented in October 1999
- Validation of analytical procedures: Definition and Terminology
  VICH GL1 (Validation definitions) – Implemented in October 1999
Module 2 - Quality

- VICH Guidelines on Stability: Overview
- VICH GL3 (R) & 4 - Stability testing of new veterinary drug substances and medicinal products + Annex GL4 - Requirements for new dosage forms
- VICH GL5 - Photostability testing of new veterinary drug substances and medicinal products
- VICH GL8 (R) - Stability testing for medicated premixes
- VICH GL10: Impurities - GL on impurities in new veterinary drug substances
- VICH GL11: Impurities: GL on impurities in new veterinary medicinal products
- VICH GL18 (R): Impurities: Residual solvents in new veterinary medicinal products, active substance and excipients
- VICH GL45 (R) - Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
- VICH GL51 - Statistical evaluation of stability data