

Towards a Global Regulatory Dossier Framework for Veterinary Medicinal Products...

Training Seminar for
Focal Points on Veterinary
Products for the Africa region

(English-speaking Africa)
7th cycle

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 **WORLD ORGANISATION FOR ANIMAL HEALTH**
Protecting animals, preserving our future

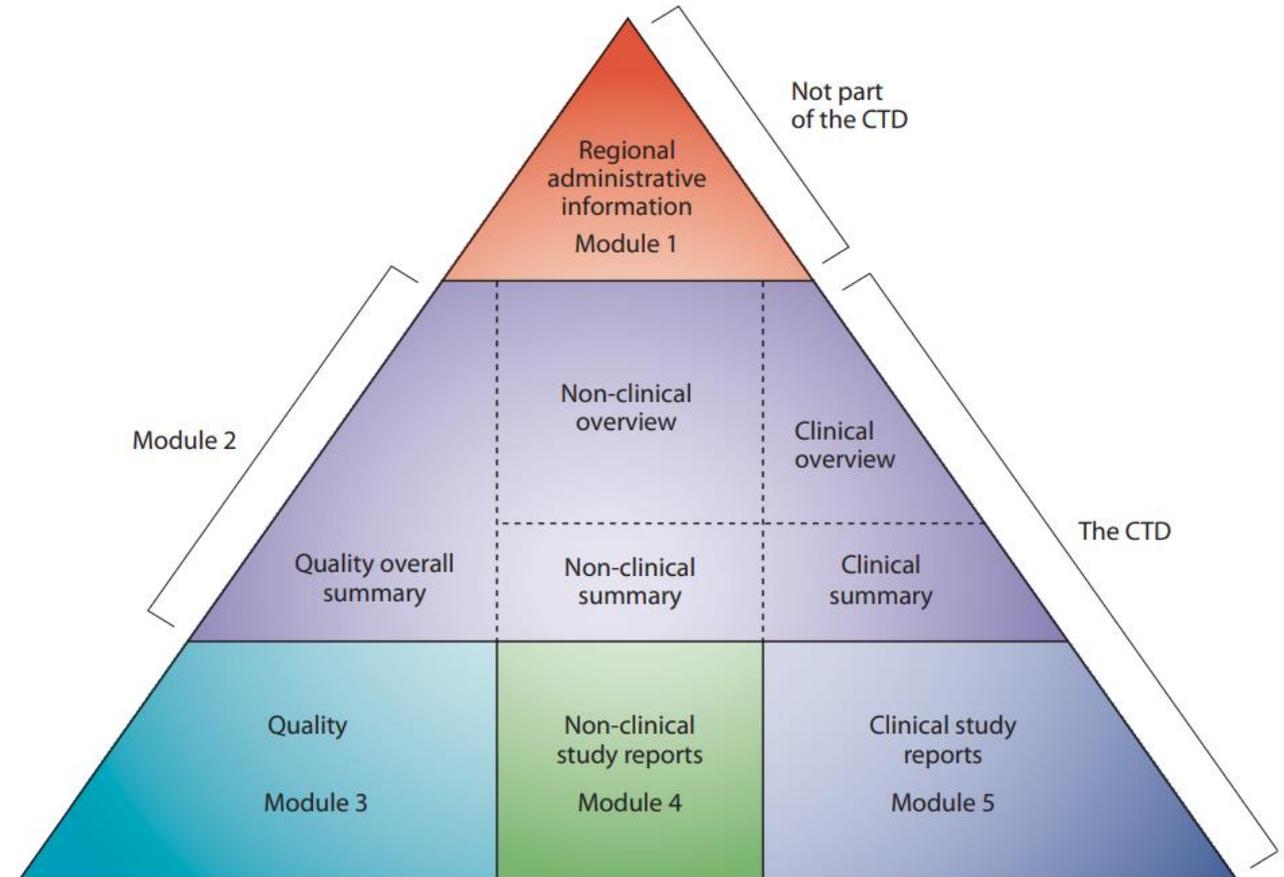
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Starting Point: some history

- Evolution:
 - ICH agreed in 2003 to a CTD or Common Technical Document; later e-CTD
 - Vet agencies in several geographies can accept parts of dossier in “human” CTD format
 - others do not accept this
 - Vet industry and vet agencies reluctant to adopt CTD, also because e-CTD would be beyond capabilities in the veterinary world

The CTD triangle of ICH (July 2003)

1. *Regional admin info*
2. Summaries & Overviews
3. Quality
4. Non-clinical studies
5. Clinical studies



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

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 - Vet industry and vet agencies reluctant to adopt CTD, also because e-CTD would be beyond capabilities in the veterinary world
- “Hypothesis” for vet products: several different dossier structures exist globally

Starting point: Analyzing current veterinary dossier structures

- HealthforAnimals compared dossier structures for pharmaceutical VMP in 8 geographies:
 - Camevet, China, EAEU, EU, Japan, South Africa, UEMOA, USA

Analyzing 8 national or regional dossier structures for VMPs... a high-level overview

Comparative table of Marketing Authorization Dossier

European Pharmaceutical Dossier: Common African Dossier: MDRH	Latin American Pharmaceutical Dossier: MDRH	ECER (European Economic Area) Dossier	Japanese Pharmaceutical Dossier	United States Dossier for CVM Regulated products (pharmaceuticals)	South African Dossier Requirements for Stock dossier	China Pharmaceutical Dossier: (China Animal Health Administration) (CAHA)
<p>Part I Summary of the Dossier</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>Part II Quality</p> <p>2.1. Description of the quality control system 2.2. Description of the quality control procedures 2.3. Description of the quality control records 2.4. Description of the quality control results</p> <p>Part III Safety & Efficacy</p> <p>3.1. Description of the safety and efficacy studies 3.2. Description of the safety and efficacy results 3.3. Description of the safety and efficacy conclusions</p>	<p>Part I Summary of the Dossier</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>Part II Quality</p> <p>2.1. Description of the quality control system 2.2. Description of the quality control procedures 2.3. Description of the quality control records 2.4. Description of the quality control results</p> <p>Part III Safety & Efficacy</p> <p>3.1. Description of the safety and efficacy studies 3.2. Description of the safety and efficacy results 3.3. Description of the safety and efficacy conclusions</p>	<p>1. General Information</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>2. Pharmacokinetic, Pharmacodynamic and Biopharmaceutical Data</p> <p>2.1. Absorption and disposition 2.2. Pharmacokinetics 2.3. Pharmacodynamics 2.4. Biopharmaceutics</p> <p>3. Safety and Efficacy</p> <p>3.1. Safety 3.2. Efficacy 3.3. Conclusions</p>	<p>General Summary (A comprehensive summary of the dossier)</p> <p>1. Product description, including the name, strength, dosage form, and route of administration. 2. Pharmacokinetic, pharmacodynamic and biopharmaceutical data. 3. Safety and efficacy data. 4. Conclusions.</p> <p>1. General Information</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>2. Pharmacokinetic, Pharmacodynamic and Biopharmaceutical Data</p> <p>2.1. Absorption and disposition 2.2. Pharmacokinetics 2.3. Pharmacodynamics 2.4. Biopharmaceutics</p> <p>3. Safety and Efficacy</p> <p>3.1. Safety 3.2. Efficacy 3.3. Conclusions</p>	<p>Part 1. Data of Pharmaceutical Product</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>Part 2. Safety and Efficacy</p> <p>2.1. Safety 2.2. Efficacy 2.3. Conclusions</p> <p>Part 3. Environmental Data</p> <p>3.1. Environmental data 3.2. Environmental data 3.3. Environmental data</p>	<p>1. General Information</p> <p>1.1. Identification data 1.2. Description of the product 1.3. Description of the manufacturing process 1.4. Description of the packaging 1.5. Description of the distribution</p> <p>2. Pharmacokinetic, Pharmacodynamic and Biopharmaceutical Data</p> <p>2.1. Absorption and disposition 2.2. Pharmacokinetics 2.3. Pharmacodynamics 2.4. Biopharmaceutics</p> <p>3. Safety and Efficacy</p> <p>3.1. Safety 3.2. Efficacy 3.3. Conclusions</p>	<p>1.1. Application form for submission (Registration Form)</p> <p>1.2. Product name 1.3. Description of the product 1.4. Description of the manufacturing process 1.5. Description of the packaging 1.6. Description of the distribution</p> <p>2.1. Safety and Efficacy</p> <p>2.1.1. Safety 2.1.2. Efficacy 2.1.3. Conclusions</p> <p>3.1. Environmental Data</p> <p>3.1.1. Environmental data 3.1.2. Environmental data 3.1.3. Environmental data</p>
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Starting point: Analyzing current veterinary dossier structures

- HealthforAnimals compared dossier structures for pharmaceutical VMP in **8 geographies**:
 - Camevet, China, EAEU, EU, Japan, South Africa, UEMOA, USA
- **Conclusion**
 - No more “international summary dossiers”
 - Content mostly the same
 - Order and naming conventions differ
 - Level of detail sometimes different
 - Confusing for many “third country” authorities

Vision, in a nutshell...

- **Guideline at VICH level**
 - Products in scope as defined in local legislation
- **Global Dossier Framework:**
 - A modular skeleton
 - Standard location for data sections
 - Authorities decide locally/regionally on granularity and level of detail

Potential issues, working towards a vet GRDF

- **Creep** of requirements
- Requirements **above legal** requirements
- **Resources** (VICH EWG) to be invested by all stakeholders to create a VICH GRDF
- Geographies will need to **adapt legislation** to the new structure
- Authorities “**grabbing**” **opportunity**
 - to reopen approved dossiers asking standard reformatting of whole dossier
 - to ask reformatting of all dossier for (minor) variation(s) in one part
- Upgrade will also be needed for API manufacturers (**closed ASMF**)
- Scope limited to **VICH regulated** products : regional exceptions!
- In transition period, need for **correlation tables** between old and new format

Benefits/opportunities of a vet GRDF...

- In line with **trend** not to accept international summary dossiers
- Get **rid of current confusion** @ reg agencies globally, created by different structures from Japan, US and EU
 - While content is essentially the same, order and granularity can differ
- **Skeleton approach**
 - allows regions/countries to ask for the granularity required by law
 - allows not requiring some sections (if not in legal requirements)

More benefits/opportunities of a vet GRDF...

- **Global standard**

- Stimulus for global **convergence** and harmonisation
- Increased **probability of entry in more markets**
 - GRDF enables truly global development plans
 - parallel or joint assessments are empowered by GRDF
 - mutual recognition is strongly facilitated by GRDF
- These last two points result in less resources and time required to bring vet products faster and to more places where they are needed
- Common global framework **simplifies building** of **electronic** pdf files, and therefore **paperless** submissions

In conclusion: the vision, short-mid-term

- **Short- to mid-term** a VICH modular skeleton for dossier content
 - Chapters on admin info, chemistry-manufacturing, pharmacology and safety, efficacy info and an “additional info” section for “local data”
 - High-level modules, with a level of granularity as required by local law
 - Some modules, like chemistry-manufacturing, can be close to human CTD to allow re-use of human dossier or active substance master file
 - Allowing easier development of e-submission platforms

In conclusion: our vision, long-term

- **Long-term:** a single veterinary dossier, acceptable everywhere
 - VICH facilitates further future convergence of dossier content
 - More need for same or similar dossiers, responding to increased recognitions and joint/parallel reviews
 - Long-term, a single submission of a dossier in a common filing system, allowing countries and regions to recognize approved dossiers easily