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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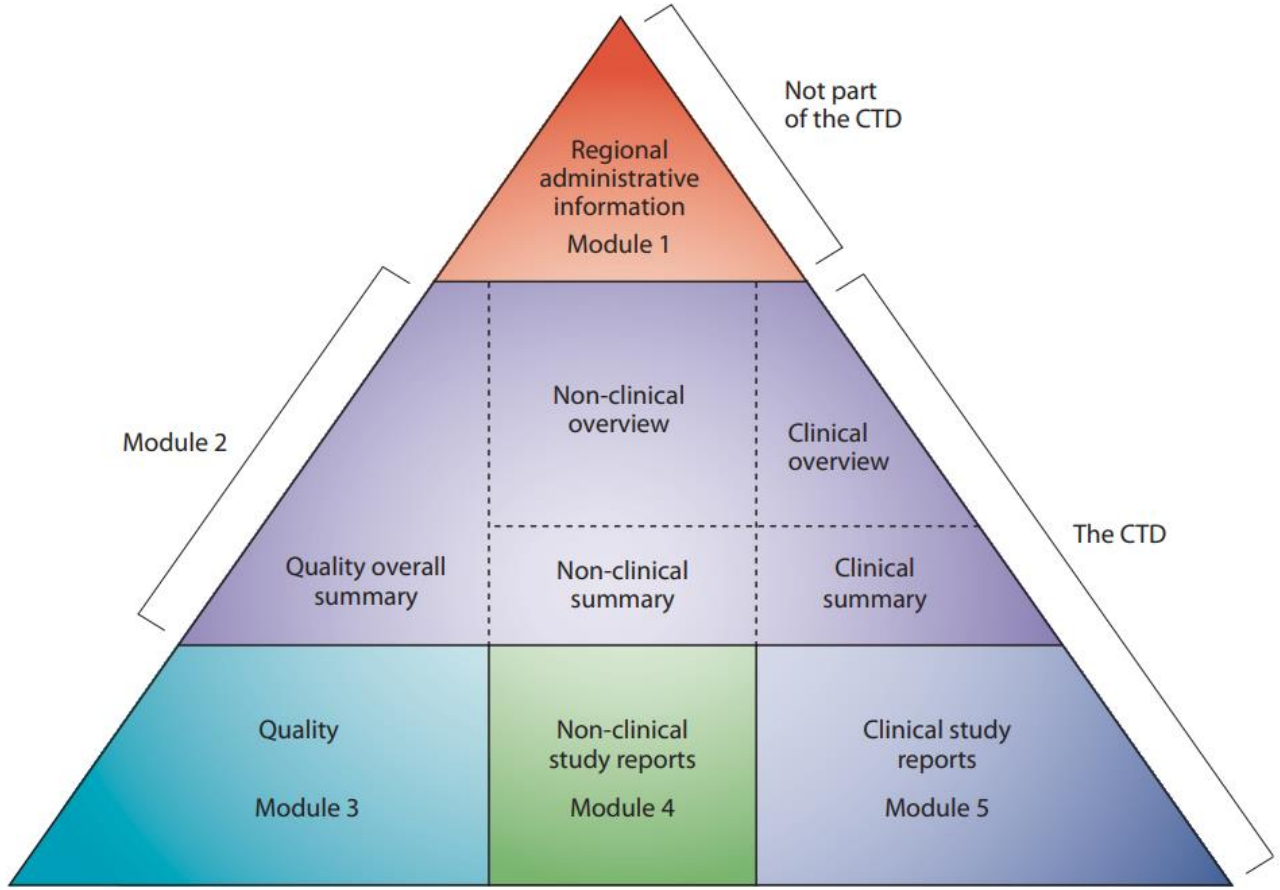
Starting Point: some history

- 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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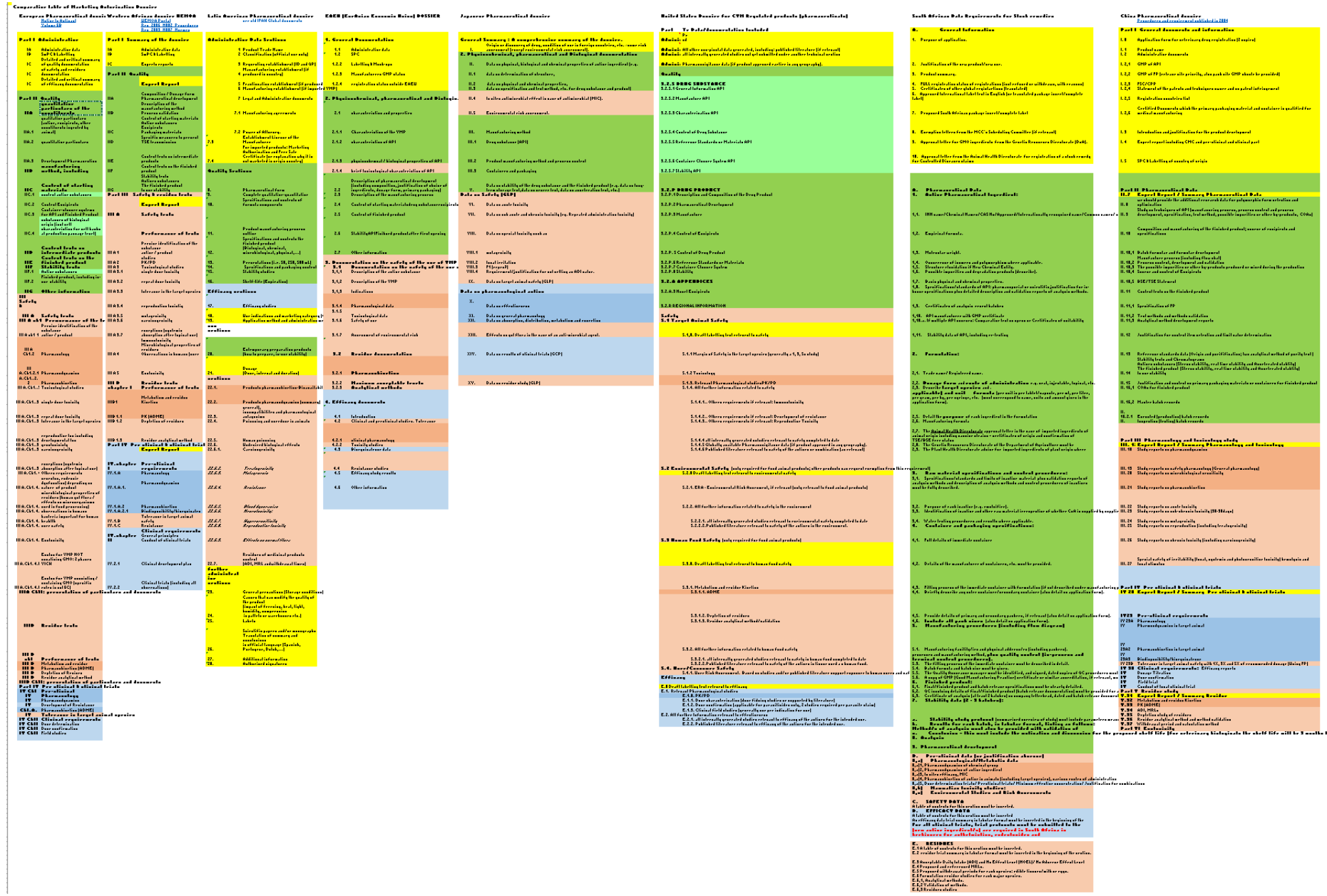
- “Hypothesis” for vet products: several different dossier structures exist globally

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



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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

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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

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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

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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