



Health  for Animals
global animal medicines association

6th VICH Conference

UNLOCKING AFRICA'S POTENTIAL

26 - 28 February 2019, Capetown

Animal Health Product availability and accessibility

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Enabling the Business of Agriculture 2017

- “The level of **Transparency, Predictability** and **Efficiency** of relevant regulatory systems is critical to private sectors decisions to supply a market with VMP, and thus can affect the availability of effective and safe VMPs in the market. “

- **Format of the dossier**
 - **EU : Notice to Applicants**
 - **CTD, Other format, Application form**

- **Type of studies**
 - **Specific studies for AM**
 - **Specific studies for Antiparasitics**

- **GL acceptances**
 - **VICH studies**
 - **Non VICH Studies**
 - **GCP/non GCP studies**

➤ **GL Acceptances : Stability**

VICH GL3

Stability Testing of New Veterinary Drug Substances and Medicinal Products

VICH GL4

Requirements for New Dosage Forms

VICH45

Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products

VICH GL4

Requirements for New Dosage Forms

Difficulties for multiple API suppliers

VICH45

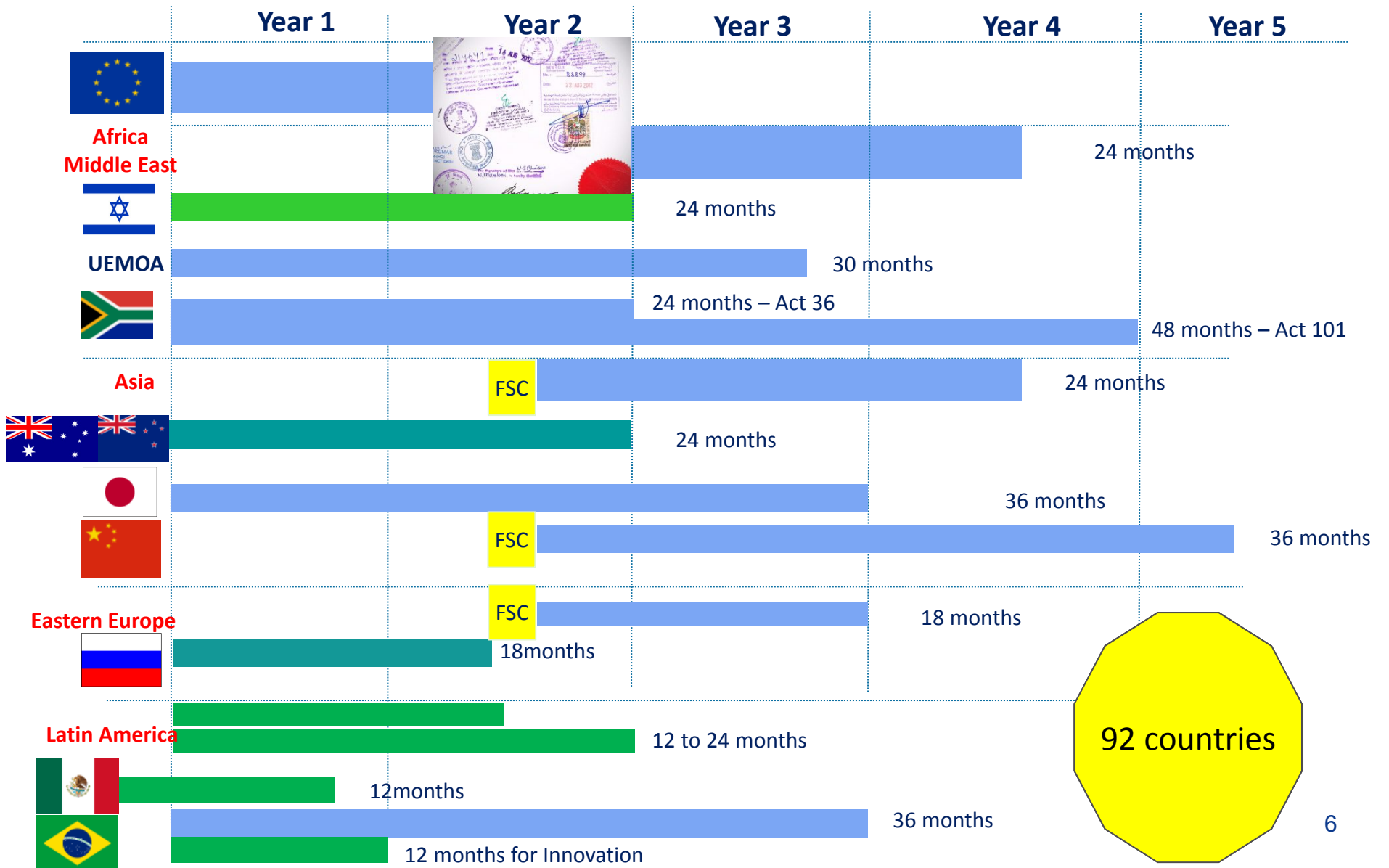
Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products

Difficulties for specific packaging for specific market

Predictability

Timeline of registration

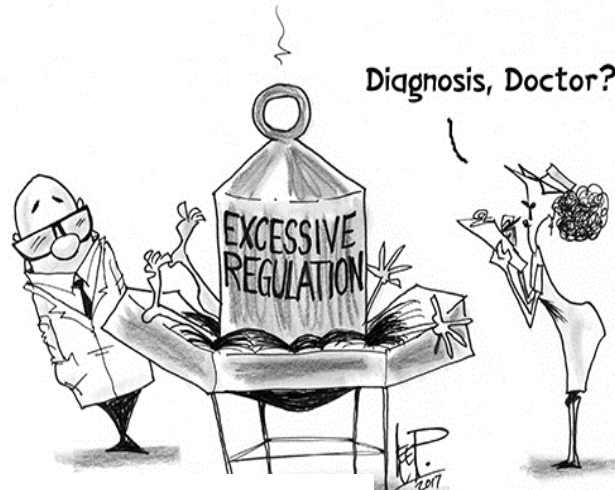
Predictability



92 countries

Predictability

M



Multiple Projects



New Competitors

Predictability



Africa
Middle East



UEMOA



Asia



Eastern Europe



Latin America



5 to 10 years



Time for registration = Time to market

- Fast track system in BR for innovation
- Fixed Time line in EU - Centralised Procedure, MRP/DCP
 - Support Innovation

Access to larger market in one registration process

- UEMOA – 8 Unified countries
- EAC – Tanzania, Kenia, Uganda, Burundi, Rwanda
- EU – 28 member states
- CAMEVET : Tomorrow ?
 - Better ROI, save resources

Market protection

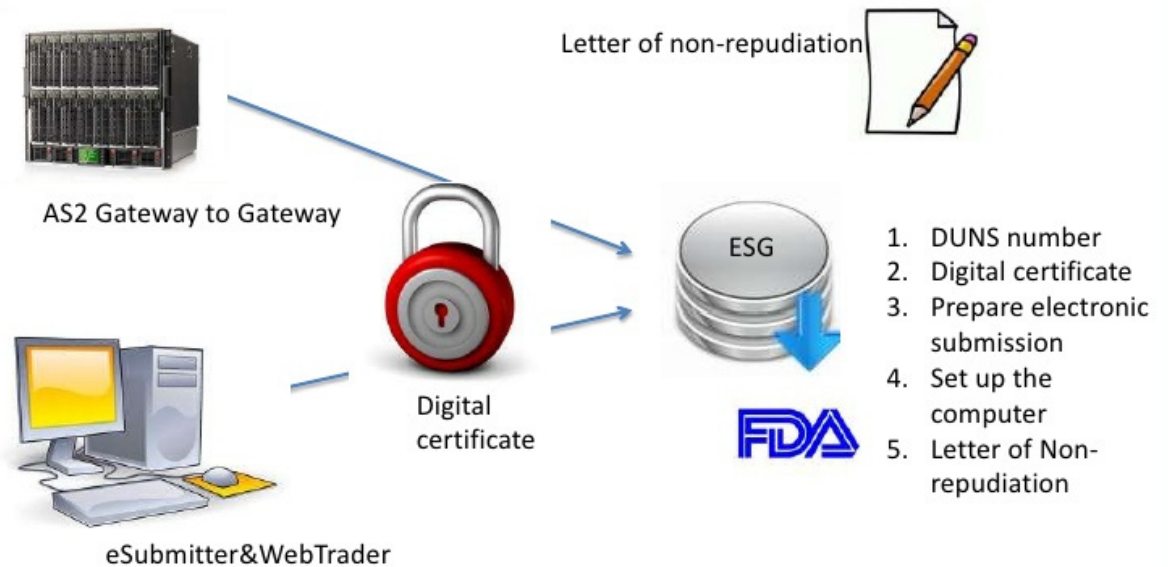
- Only legally authorized or imported products
- Avoid black market, counterfeit
- Non controlled quality products,
 - Animal Health & Welfare

Submission process

From Paper time



To electronic submission



Submission process

Tomorrow a full ?

VDR
Virtual Data Room



Web Hosted
Efficiency & flexibility for National Competent Authorities and applicants

Key drivers for availability and accessibility to new markets

*It is important that **regulations are** streamlined and **efficient** in order **not to discourage** suppliers from entering and operating in markets*

Transparency

- **Better knowledge of regulatory environment**
 - **Convergence and harmonization**

Predictability

- **Remove some barriers** (Geographic or administrative)
- **More mutual recognition**
 - **Association network**

Efficiency

- **Time to market, secure the market**
- **Innovate with new technologies**
 - **Reduce the cost**

Better value to Society

Thank you for your attention

