Regulatory Affairs
South Africa (Act 36/Act 101)
/SADC Experience

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SADC Regulatory involvement

- **Ceva South Africa provide products/ maintain registrations in 10 SADC affiliate countries**
- **Regulatory environment structure**
  - Developed – policies and guidelines established (e.g. SA)
  - Recently established (+/- 5y) – policies and guidelines not well defined, first round of abbreviated registrations for established products in market (e.g. Zambia)
  - Newly established (+/- 1y) – policies and guidelines not well defined, struggling to start regulatory process. (e.g. Mozambique)
  - No regulatory process - accept registrations from developed Regulatory systems (e.g. Swaziland)
General challenges experienced

- Harmonization within country regulatory systems
  - SA – Act 36, Act 101
- Guidelines
  - SA – Act 36, recently and newly established organisations (e.g. Zambia, Mozambique)
  - Interpretations of guidelines (e.g. Residue studies)
  - Regional differences (e.g. Stability requirements, post importation testing)
- Registration Timelines
  - Staff capacity (Act 36 – Public Private Partnership)
  - Traceability through the process
  - Expert evaluation capacity (e.g. GMO)
• **Submission Format**  
  ❖ Forms and requirements not standardized  
  ❖ Requirements mostly the same (Regulatory staff spend a lot of time restructuring documents for submission)  
  ❖ Sample Submission  
  ❖ Artwork submission  

• **Submission Language**  
  ❖ Preferred main language spoken in the country (e.g. Portuguese - Mozambique)  

• **Country Presence**  
  ❖ Determined according to market development and size  
  ❖ Registered office (e.g. SA, Mozambique)  
  ❖ Distribution agent, Representative agent (e.g. Namibia, Zimbabwe)  
  ❖ Requirements not the same for all countries
• **Communication**
  - Difficult, with mostly lack of response
  - Accessibility – difficult to obtain meetings
  - Mistakes on registration documentation (particularly in recently established authorities – leads to delays)

• **Duplication of API’s**
  - Refusal of permission to import (e.g. Doramectin/Ivermectin vs Eprinomectin)

• **Fees**
  - Exorbitant increase in registration and retention fees (tripled in 3 years in one instance)
  - Some companies have opted for cancellation of some registrations
• Registration Cycles
  ❖ Retention and/or renewal cycles
  ❖ Range 1/3/5 years

• New Legislation
  ❖ Complementary Medicine (SA)
  ❖ General vs. Veterinary Medical Devices - SA implemented, only mentioned on some other regulatory websites (e.g Botswana, Zimbabwe)

Thank you