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)

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- **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

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- **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

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- **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