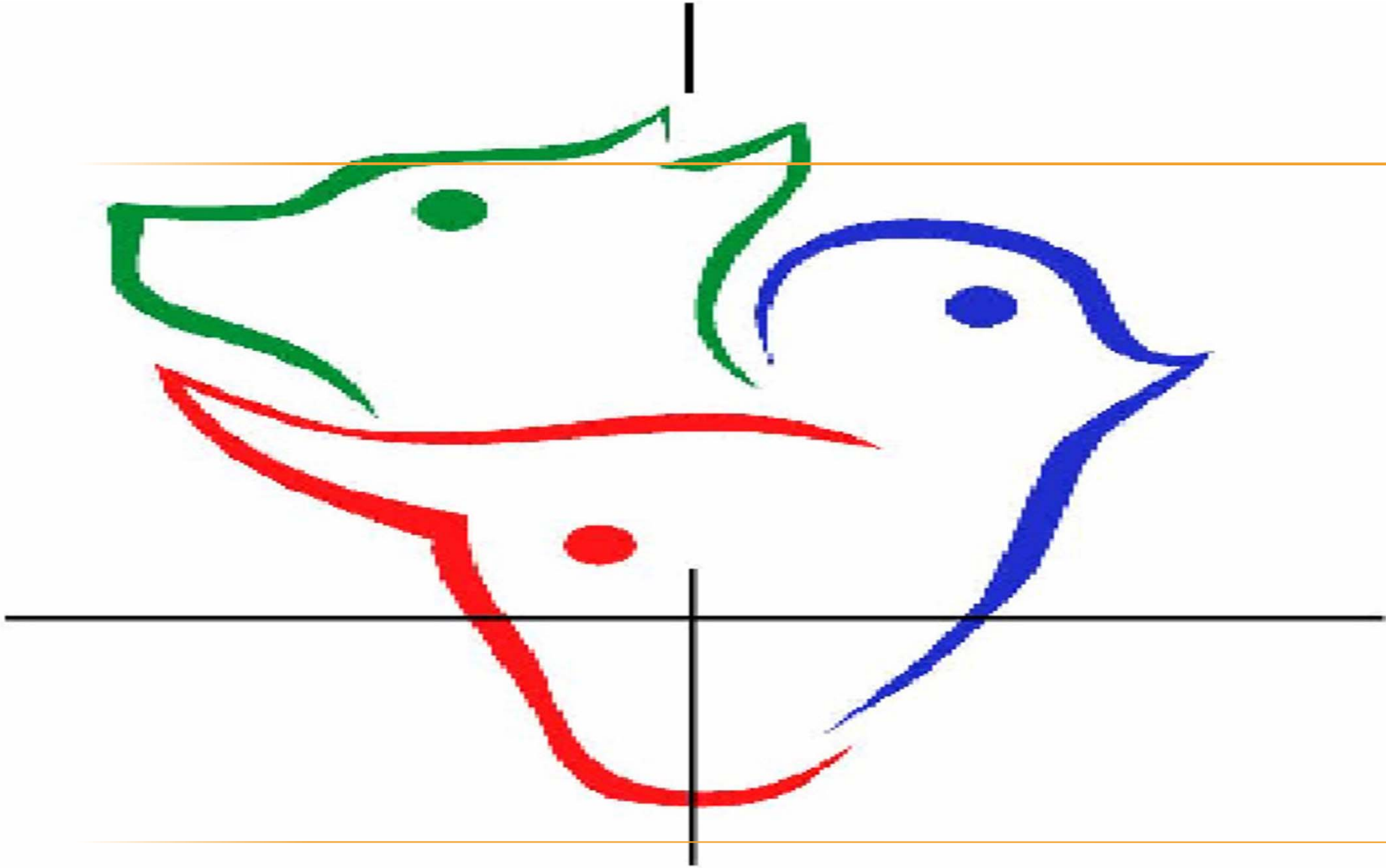

SAAHA

INTRODUCTION

SAAHA

- SAAHA represents majority of product importers, manufacturers /suppliers.
- When compared to Human Pharmaceutical and Crop Protection, the Animal Health market is relatively small.
- Antimicrobials, Anthelmintic/Endectocides, Ectoparasiticides and Vaccines are by far represent about 85 % of the market.
- Registration of Animal Health Products follows similar procedures and principles to those for Human Medicines, with a number of differences.
- Veterinary medicinal products are frequently used under conditions not encountered with Human Medicines.
- Veterinary products treat a large number of very different species.
- Animal farming conditions may range from “harsh environment” to “controlled”/ intensive production facilities.
- Most animal products are administered according to animal weight and treatment weights may range from a few grams to tons.
- Veterinary medicinal products ae frequently used under conditions not encountered with human medicines.

LEGISLATION

- Acts directly applicable to the registration of veterinary products are the **Medicines and Related Substances Act (101 of 1965)** and the **Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act** (Act 36 of 1947).
  - Act 101/1965 is administered by DoH and is responsible for registration of all Human Medicinal Products and certain Veterinary Products.
  - Act 36/1947 is administered by DAFF, responsible for regulation of stock remedies amongst other things.
  - Generally, products for use by vets registered under Act 101 and products to be used by farmers or consumers are registered under Act 36.
- Other Acts:
  - **Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)** - controls drug residues.
  - **Animal Diseases and Parasites Act (Act 35 of 1984)** – controls importation and use of vaccines, plus treatment of specific controlled diseases.
  - **Veterinary and Paraveterinary Professions Act (Act 19 of 1982)** – controls professional conduct of vets and other professionals (incl. vet nurses, vet technicians & vet reps)
  - **Pharmacy Act** – as with Human Medicines, manufacture and registration of vet products controlled by Act 101/1965 require supervision of a pharmacist for various functions.
  - **Abbatoir Hygiene Act** (Act 121 of 1992).

STATUS OF REGISTRATION APPROVALS

- Act 101
  - Vet dossiers are separated and processed separate to human dossiers. Vet dossiers are reportedly moving as fast as fast-track dossiers, but that responses from the Vet Clinical Committee are slower. Some responses taking as long as 5 months, although the official requirement is 2 weeks.
  - Once dossier evaluations are up to date, vet unit will address the backlog and look then look at old medicines.
  - Current registration times reported by members:
    - Updates: 18 months
    - New applications: 36 months
    - New chemical entities: 5 yrs
    - Package inserts: 2-3 yrs
    - Pre-screening: 12 months
- Act 36
  - Stats given not representative of members 'submission.
  - Adverts approval taking aprrox 60 days for approval.
  - Act 101/1965 is administered by DoH and is responsible for registration of all Human Medicinal Products and certain Veterinary Products.
- Both Acts101 and 36 expressed concern at the poor standard of vet dossiers and stock remedies dossiers, respectively.

CHALLENGES

SAAHA

- ✓ Backlogs
- ✓ Not predictable
- ✓ Inconsistencies
- ✓ Harmonisation of Acts 101 & 36?