



HARMONIZATION OF VETERINARY REMEDY REGULATIONS IN SUBSAHARAN AFRICA


AN INDUSTRY PERSPECTIVE-

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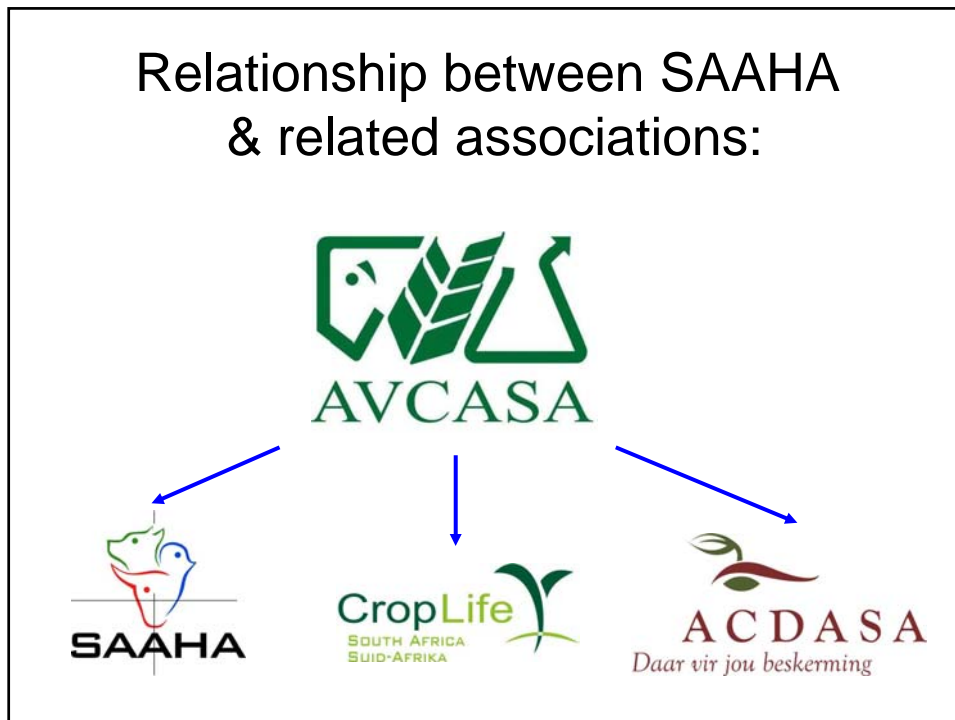


PRESENTATION CONTENTS

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- 3. Current legislative environment
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Relationship between SAAHA & related associations:



INTRODUCTION TO SAAHA

- ❑ The South African Animal Health Association:
 - ❑ Is the only Industry body
 - ❑ Represents in excess of 90% of the establishments involved in the importation, manufacture, marketing and distribution of Veterinary Pharmaceuticals.
 - ❑ Currently represents 17 member organisations (both multinational and local)



ECONOMIC IMPORTANCE OF VETERINARY PHARMACEUTICALS

- Veterinary Pharmaceuticals are an important component in the safe and efficient supply of quality meat based protein, and are thus an significant contributor to national animal product production.
- 2003/4 preliminary gross value of animal production is reported as being R30.7 billion (US\$ 4.4 billion), which represents 42.8% of the Gross Value of Agricultural Production.
- 2003/4 estimates of expenditure on meat, milk & eggs is R56.9 billion (US\$ 8.1 billion)
- 2003 SACU exports of animal based products is reported as being R1.4 billion
- 2009 imports of meat into SA is R4.0 billion
- It is estimated that our meat production will need to increase by 25% within the next 5 years.



ECONOMIC IMPORTANCE OF VETERINARY PHARMACEUTICALS

- Veterinary Pharmaceuticals market:
 - SA: (90%)
 - Total reported to SAAHA R1,634 billion (US\$ 233m)
 - 35% Parasiticides
 - 27% vaccines
 - 23% Antimicrobial
 - 15% Other
 - Sub-Saharan Africa: (10%)
 - Few associations
 - Little accurate sales statistics
 - Export survey of top 5 AH Companies in SA
 - US\$ 25.6m (10%)
 - Similar segmentation with ectoparasiticides playing an even bigger role.



CURRENT LEGISLATIVE ENVIRONMENT SUB-SAHARAN AFRICA

- ☐ Varied:
 - ☐ Zimbabwe, Kenya, South Africa
 - ☐ Sophisticated & relatively expensive
 - ☐ Cost of registering an ectoparasiticide in:
 - ☐ SA is approximately US\$150 000 – access sales of >US\$70m
 - ☐ In Zimbabwe is US\$ - US\$250 plus trial work
 - ☐ In Kenya is US\$750 plus US\$20,000 for clinical trials and all others (including factory inspections of US\$3000 for Uganda)
 - ☐ together access sales of less than US\$7m
 - ☐ Botswana, Namibia
 - ☐ Accept SA approvals
 - ☐ Part of SA sales figures
 - ☐ Zambia
 - ☐ Require only SDS



CURRENT LEGISLATIVE ENVIRONMENT IN SOUTH AFRICA

- ☐ There are two Acts under which Veterinary Pharmaceuticals may be registered:
 - ☐ The Medicines & Related Substances Control Act 101 of 1965
 - ☐ Falls under the Department of Health
 - ☐ Veterinary Pharmaceuticals defined as Veterinary Medicines
 - ☐ The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947
 - ☐ Falls under the Department of Agriculture, Forestry & Fisheries.
 - ☐ Veterinary Pharmaceuticals defined as Stock Remedies



EFFECTS OF FRAGMENTED REGULATORY ENVIRONMENT

□ IN GENERAL

- Duplicated and disjointed requirements
 - Dossiers
 - Trial protocols
 - Differing levels of scrutiny
 - Differing quality standards
- Confusion, duplicated trials
- Increased, and unnecessary costs
- Fewer registrations, e.g. Zimbabwe
- Less competition
 - Less choice
 - Higher prices
- Poorer quality products
- Loopholes



NEED FOR HARMONIZATION

□ IN SOUTH AFRICA

- Act 36/1947 (DAFF)
- Act 101/1965 (NDH)

□ Complementary medicines

- e.g. Mosquito/fly, tick repellent
 - USA - GRAS
 - EU – no registration required
 - Listed as complementary medicine for use on humans including babies
 - Must be registered by Act 36 for use on animals – requirements unknown
- e.g. Herbal tick and flea collars/bands
 - Must be registered by Act 36 – requirements unknown while used on humans with impunity

□ Compounding

- Act 10/65 purpose: to provide for when there is no registered product available
- Being misused by the container full.



THE WAY FORWARD ? SAAHA PROPOSAL




SAAHA PROPOSAL

- IN SOUTH AFRICA
 - One legislative act be promulgated, to be administered by a SINGLE National Department, which will be dedicated solely to the registration and control of Veterinary Pharmaceuticals, which are currently registered as either Veterinary Medicines or Stock Remedies. Without this internal harmonization how do we harmonize internationally?
 - Not a new idea: *May 1994 ANC Agricultural Policy section 9.5 – Veterinary Pharmaceuticals*. This document states: "The ANC supports the control of veterinary pharmaceuticals by a single body, namely the Department of Agriculture."
 - Already a huge amount of work done (VPPC) aimed to facilitate the harmonized registration & control of veterinary remedies. But set aside - Resuscitate!!



SAAHA PROPOSAL

IN SUB-SAHARAN AFRICA

- Africa to request observership of VICH (USA, EU, Japan) with Canada, Australia, NZ.
- SEAVDRAC to be resuscitated and expanded to include all of sub-Saharan Africa
- Stepwise implementation of harmonization to cater for National and personal imperatives, including National Pride and personal security.
 - Don't wait!
 - Set each objective with timelines!
 - How does one eat an elephant? Bite by bite!



SAAHA PROPOSAL

IN SUB-SAHARAN AFRICA (continued)

- Begin with issues where success is most likely and threats to National identity and individual concerns are less serious:
 - Stage 1: Harmonized Labeling (1 year)
 - Stage 2: (2 years)
 - QA and QC standards
 - Efficacy and safety of compounds/Als is already established in US, EU etc.
 - It is the varying levels of implementation of Quality Assurance that determines the safety and efficacy of the products sold in our countries.
 - Submission including protocol rationalization
 - Stage 3: (2 years)
 - Centers of excellence for different remedy categories e.g. ectoparasiticides for cattle (Kenya); Sheep anthelmintics (South Africa) etc.....



BENEFITS ACHIEVED THROUGH HARMONIZATION

- Quicker approvals
- Less costly approvals
 - For Authorities and
 - For Industry
- Remedies more readily available in poorer countries – improved production
- Remedies cheaper – cheaper food/protein
- Remedies of better quality
- Meet Governments' food security goals.



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- Also to Prof Gerry Swan and Dr Bonaventure Mtei for their useful inputs and advice on the history of this subject and their considered routes to success.
- To Bayer, Virbac & ISPAH for sharing their confidential sales figure split with me for the greater good
- To Ernest Schay of Bayer who provided the slide template and some registration cost statistics
- I trust that we will all now put our heads together to consider all we have heard during this seminar and commit ourselves to making the resolutions taken later, here, work for the benefit of all the citizens of the continent.



BITE BY BITE – a reminder

