SEAVDRAC

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Introduction

Ghana; Kenya; Mauritius; Mozambique; Namibia; Nigeria; South Africa; Tanzania; Uganda; Zimbabwe

- Southern and Eastern African Veterinary Drug Regulatory Affairs conference inaugural meeting occurred in 1997 with support of OIE
- Follows SEAMRAC and Search regional harmonisation initiatives
- Attended by 26 delegates from 11 countries in Africa

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Program of 1st meeting of SEAVDRAC

- Theme 1: Legislation and Regulatory Aspects
- Theme 2: Veterinary drug and Biological Regulatory Procedures
- Theme 3: Registration process – Technical Requirements
- Theme 4: Manufacture, Importation and Risk Assessment
- Theme 5: Distribution and Use
- Theme 6: Pharmacovigilance and Monitoring
- Theme 7: Liaison and Co-Operation with industry
- Theme 8: Harmonisation

Resolutions of 1st meeting of SEAVDRAC

1. Undertakes to be recognized as the representative body of the drug regulatory authorities concerned with veterinary products within the region
2. Requests to be included in the consultative process of VICH
3. Investigates the feasibility of establishing uniform or alternatively centralized regulatory procedures – to this purpose the congress proposes that a working committee be established to prepare recommendations for these procedures for consideration at the next conference

Resolutions of 1st meeting of SEAVDRAC

4. Crafts a standard application form and a standard format for application dossier within the participating countries
5. Encourages training of officials from drug registration authorities in the fields of e.g. quality assurance, inspections, evaluation of application dossiers – this training should be sought from regional and international bodies
6. Encourages member countries to establish an inventory of available expertise, human and facility or laboratory resources, and data bases or networking that which may be shared among countries

Resolutions of 1st meeting of SEAVDRAC

7. Encourages the drug regulatory authorities of member countries to exchange information on technical aspects, systems and data from pharmacovigilance of registered products;
8. Encourages the establishment and/or harmonisation of existing conflicting national legislation
9. Encourages the formation of representative industry associations in this region
10. Encourages industry to undertake local research and development bearing in mind the unique disease conditions and wildlife resources in Africa

Resolutions of 1st meeting of SEAVDRAC

11. Undertakes liaison with SEAMRAC
12. Encourages other regions within Africa to take similar initiatives and promotes cooperation in the various regions
13. That a follow-up meeting will take place in one year of this meeting

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

1. Recognising the increasing extent of counterfeit medicines, repacking and use of homebrew formulations and accepting that there are dangers to the practices to human and animal health, to recommend to government to bring these practices to the attention of the relevant law enforcement authorities with the recommendation that adequate resources be used to combat these practices
2. Taking cognisance that the numbers and diversity of regulatory systems leads to unnecessary duplication in the evaluation and approval of veterinary medicinal products recommends that governments embark on a course of harmonising licensing and registration systems.

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

3. To develop procedure(s) (e.g. training) assuring greater awareness of international standards regarding Maximum Residue Limits for food animals and their products for application at the national and international level
4. Provide, as appropriate, training modules on risk analysis regarding veterinary medicines to facilitate compliance with Codex alimentarius standards for food animals and their products
5. Assist African nations by making provision for relevant documents at the international level on the quality management systems for laboratories to control residues of veterinary drugs in food and risk assessment procedures

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

6. Improve awareness for producers and consumers to potential public health issues with regard to residues of veterinary drugs in field
7. To harmonise and apply measures consistent with international standards (e.g. Codex) with regard to residues of veterinary drugs in food
8. To investigate the possibility of creating and maintaining a Web-Site for SEAVDRAC for exchange of information, reporting of adverse reactions and for the listing of standardized procedures and guidelines.
9. To develop standard technical guidelines within the southern and eastern African region for the prudent use of antimicrobials in animals.

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

10. To implement appropriate monitoring of antimicrobial usage within the southern and eastern African region in accordance with the guidelines developed by the O.I.E.
11. To develop a harmonised programme for the monitoring and surveillance of antimicrobial resistance in southern and eastern African region in accordance with the guidelines developed by the O.I.E..
12. Acceptance of a single, internationally acceptable standard (e.g. VICH guidelines) for stability, clinical studies, GMP etc..
13. Standardise on number of drug samples required by regulatory authorities.

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

14. Taking into account that the responsibility that is vested in the Department of Health to control medicines and the responsibility of the Department of Agriculture to ensure the safety and security and the availability of veterinary products to the community to encourage governments to include both the Minister of Agriculture and the Minister of Health to act jointly in the regulation and control of veterinary medicinal products
15. To develop regional guidelines for technical requirements for the market authorisation of new pharmaceutical entities, generic compounds and biologicals
16. Accepting the need for the production and sale of quality veterinary medicinal products and the national accreditation of manufacturing and laboratory facilities to recommend that governments institute internationally accredited quality inspection systems

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

18. To follow up on the proposal of His Excellency The Minister of Medical Services Dr Anangwe, to facilitate at interministerial level, possibly through a conference, a recommendation to advance communication by electronic means on regulation of human and veterinary medicines between the countries party to the SEAVDRAC conference. Such communication aims to facilitate the harmonisation of authorisation procedures by advancing a mutual understanding and recognition between the countries concerned to ensure the provision of adequate, safe, high quality medicines in southern and eastern Africa
19. This SEAVDRAC conference recognising the need for post registration pharmacovigilance reporting methodology encouraging member countries to cooperate in the transfer of data between authorities recognising the need for safe Veterinary Medicinal Products

Resolutions 2nd SEAVDRAC Conference, Nairobi, Kenya, 23 – 26 July 2000

20. This SEAVDRAC conference proposes that three working groups, viz. Registration, Legislation and Drug Control, be formed to develop harmonized Guidelines and Procedures on the topical areas as identified
21. Training in biological evaluation and standards for development should be encouraged. For example individual countries regulatory authorities should consider the utilization of biologics training programmes such as IICAB

Conclusion

- Need and importance of harmonization
- SEAVDRAC had very good start but could not be sustained due to lack of political support
- Resolutions taken remain very relevant today
- SEAVDRAC served as an excellent opportunity for technical and operational staff involved in drug regulatory matters for communication and exchange of ideas
- Harmonization is a step-wise process whereby operational procedures are more easily achieved than technical agreements