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SAAHA Position on the sale of unregistered products

Overview

SAAHA investigated the activities, legalities and opinions of major role players in the industry on the sale of unregistered medicines in the animal health industry. Issues including prescribing for extra-label use of medicines, compounded products (including compounding an unregistered parallel product to an already registered product) or the selling of unregistered raw active ingredients for medicinal purposes were all investigated. The SAAHA Executive Committee agreed that the following position be adopted on these points:

1. Sale of raw material

The uncontrolled importation and sale of raw active ingredients by veterinarians and/or companies without the control of a pharmacist and the necessary validation of the quality of the active should not be allowed. SAAHA condemns and does not support this practise.

2. Compounding

SAAHA recognises that there is a need in the animal health industry for compounding under certain conditions. SAAHA supports the recommendations of Prof Swan on the basis on which compounding may take place:

- it must be to the benefit of the patient (animal)
- it addresses a specific need
- there is no registered alternative available
- compounding needs to be patient driven, for exceptional cases where no alternative is available and as examples in game, small volume or where different routes of application are the only practical solution

SAAHA agrees that the intent of the compounding must be to the benefit of the patient and not for the commercial benefit of the owners.

SAAHA agree that in the case of compounding, the facilities and standards should be regulated and regulations enforced, and adopts the principle that compounding should take place under GMP conditions.

SAAHA interprets that compounding falls under the jurisdiction of both Act 101 of 1965 and the Pharmacy Act of 1954. SAAHA understands that compounding appears to fall outside of the jurisdiction of Act 36 of 1947 as this Act does not make provision for prescriptions and/or compounding and therefore SAAHA adopts the principle that actives listed ONLY under Act 36 may not be compounded by pharmacists.

SAAHA is concerned that the lack of data on withdrawal times on compounded medicines may place the consumer and thus the intensive protein production industry at risk. SAAHA agrees that there are certain circumstances where compounding for food producing animals may be required. Consideration of the risk-benefit for the patient and user in terms of efficacy, safety and residues are the responsibility of veterinarians (Prof Swan). SAAHA supports the right of the veterinarian to exercise his or her clinical judgment in prescribing an unregistered product for a specific animal health problem where a registered suitable alternative is not available in the South African market and the risk of product residue entering the human food chain is adequately addressed in line with regulatory guidelines.

SAAHA agrees that the "copying" of registered products through compounding should not be allowed.

SAAHA agrees that the extra-label use of registered medicines is part of the practice of the veterinary profession and should remain. SAAHA recognises the similarity in the requirements for control of residue in food producing animals when medicines are used extra-label or as compounded medicines. Consideration of risk-benefit based on efficacy, safety and residues are also the responsibility of veterinarians as in the case of compounded medicines. SAAHA therefore adopts the same position on extra-label use of medicines in food producing animals as detailed above for compounded products.

SAAHA recognises the problems that the lack of registered products brings to the growing wild life industry. The meat from the wildlife industry will be for human consumption and extra label use is part of this industry. SAAHA supports a broad-based approach including all stakeholders to address these concerns.

Signed: _____
President of SAAHA