NOTICE 1397 OF *2006*

DEPARTMENT OF AGRICULTURE

POLICY ON STOCK REMEDIES IN SOUTH AFRICA

The Minister of Agriculture hereby publish the policy on stock remedies in South Africa for comments by the general public. Comments must be submitted in writing within 30 days of publication of this notice to:

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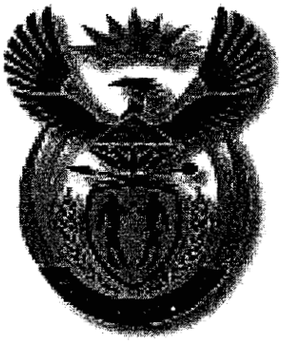

DEPARTMENT OF AGRICULTURE

POLICY ON STOCK REMEDIES IN SOUTH AFRICA

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POLICY ON STOCK REMEDIES IN SOUTH AFRICA

1. INTRODUCTION

Stock remedies are used to treat or prevent disease or enhance production in animals. The misuse of stock remedies has negative implications for export of produce, consumer and public health as well as animal health and welfare. Their appropriate use has positive implications for agricultural development and socio-economic upliftment. It therefore follows that a national policy on stock remedies is necessary to support the appropriate regulation and use of stock remedies.

The Government's intention (as set out in the Agricultural Policy) is to ensure that agriculture is able to contribute to achieving national economic and social objectives. In view of the three strategic aims identified ('making the sector more efficient, internationally competitive', 'supporting production, stimulating an increase in the number of new small, small scale and medium-scale farmers', and 'conserving agricultural natural resources'), a sector plan was developed for agriculture. In the Sector plan various core strategies are identified, including those for 'Equitable access and participation' and 'Global competitiveness and profitability'. It is from this sector plan that the strategic plans arise. Of importance when considering stock remedy policy is ensuring access to sufficient, safe and nutritious food as well as eliminating skewed participation and inequity in the sector.

As background to the development of a policy on stock remedies, it should be noted that the regulation of animal medicines is the responsibility of two departments (Department of Health and Department of Agriculture) in South Africa. The Department of Agriculture regulates "Stock Remedies" (animal medicines that are generally available over the counter to the public, including farmers). Stock Remedies registered under Act No. 36 of 1947 to enable the farmers to access medicines to treat the most common diseases of economic importance in livestock such as heart water, redwater, internal parasites and external parasites. The Department of Health regulates scheduled "Veterinary Medicines". These are highly ethical animal medicines that have specified distribution channels through veterinarians or persons registered in terms of Veterinary and Para-veterinary Professions Act, Act 19 of 1982. Several terminologies are used to refer to medicines intended for use on animals. These terminologies are Stock Remedies, Veterinary Medicines and recently alternative/ complimentary veterinary medicines. The International Cooperation on Harmonisation of Technical Requirements for the registration of Veterinary Medicinal Products (VICH) refers to medicines intended for use on animals as Veterinary Medicinal Products. In this document the term "animal medicine" will include all the medicines intended for use on animals' i.e Stock Remedies, Veterinary Medicines, Veterinary Medicinal Products and alternative/complimentary veterinary medicines.

In terms of legislation, Stock Remedies are registered under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, Act No. 36 of 1947 while Veterinary Medicines, are registered under the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).

Each of the Acts refers to the other in their definitions of Stock Remedies and Veterinary Medicines respectively. To quote the Agricultural Policy: "The limitations of this system are that conflicts can arise over the appropriate regulatory mechanism to be used" (although this is in part addressed by the schedules of Act 101). Inadequate attention may be given to the specific issues relating to agriculture in considering the registration of new veterinary medicines and the regulations concerning their use; and that insufficient attention is given to the need to establish a properly regulated distribution network which serves livestock owners in poorer areas." If an Animal Medicine is listed on the schedules of Act 101, and an applicant wishes to register a stock remedy containing the active through Act No. 36 of 1947, application must be made to the Scheduling Committee of the Medicines Control Council for exemption of the active from scheduling in which case it can be registered through Act No. 36 of 1947.

An attempt to rationalise the Animal Medicine regulation process was made with legislation that was proposed in 2000 (the South African Medicines and Medical Devices Regulatory Authority (SAMMDRA) Act). This Act was intended to address the situation by regulating all animal medicines under the same body. The Act made provision for the establishment of a South African Medicines and Medical Devices Regulatory Authority, which in turn would have established a Veterinary Medicines Standing Committee. This committee would have been responsible for making recommendations on registration and regulations which would have required the approval of both the Minister of Health and the Minister of Agriculture. The latter would also have made an appointment to the Board of the Authority. As part of the Act to establish the Authority, stock remedies was to be removed from Act No. 36 of 1947 thereby consolidating responsibility for veterinary medicines and providing scientific expertise and an effective inspectorate through the Authority.

The Standing Committee recommendations would have been expected to facilitate the accessibility of veterinary medicines (though regulations on the licensing of dealers and re-packing of smaller quantities, for example), but the task of developing veterinary medicine services was to remain the responsibility of the National Department of Agriculture, Provincial Departments and the industry itself. Particular attention was to be paid by the Government *to* the training of veterinary assistants so that more diagnostic services would be made available and more treatments undertaken in rural areas, with refrigeration and other facilities made more widely available by commercial suppliers. The SAMDRA Act, however, was never implemented.

In 2003 the Agricultural Production Enhancement Agents (APEA) bill was developed to replace the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, **1947** (Act No. 36 of 1947) but there were no policies or problem statement (for example on stock remedies) to support drafting the bill. A decision was made by the Department of Agriculture to develop policy documents to support review of Act no. 36 of 1947 or drafting a new Act to replace Act no. 36 of 1947.

"The International Cooperation on Harmonisation of Technical Requirements for the registration of Veterinary Medicinal Products" (VICH) is a haramonisation project that brings together the

regulatory authorities of the European Union, Japan and the United States and experts from the animal health industry to discuss scientific and technical aspects of new product registration. Regulatory authorities and industry experts from Australia, New Zealand and Canada participate as observers and OIE as an associate member. Any standards generated by this body can be used by other regulatory bodies.

2. PROBLEM STATEMENT

The current legislation for the regulation of stock remedies (the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) is too broad to fully address the regulatory requirements for stock remedies.

2.1 Legislative nature of the problem

Act No. 36 of 1947 is essentially outdated and does not address many of the requirements for a modern regulatory system:

The scope of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) is broad, covering regulation of Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies under one Act, while the scope of the Medicines and Related substances Control Act, 1965 (Act No 101 of 1965, as amended by Act 90 of 1997) covers orthodox human and veterinary medicines (as listed in the schedules of the Act).

Registration of stock remedies should and may require inputs from other Departments. This is sometimes difficult as formal structures for the evaluation of stack remedies (according to the various departmental mandates) are currently not in place. A number of other Acts influence the registration of stock remedies:

- The Animal Disease Act, 1984 (Act No. 35 of 1984) provides for the control of animal diseases and parasites, for measures to promote animal health, and for matters connected therewith. This Act will be replaced by Animal Health Act, 2002 (Act 7 of 2002). Permission to register some stock remedies is required from the directorate Animal Health (DoA) which regulates the Animal diseases Act (e.g. controlled animal diseases)

- National Environmental Management Act, 1998 (Act No. 107 of 1998) provides for cooperative environmental governance by establishing principles for decision making on matters affecting the environment. Stock remedies, when used in production animals, may have an impact on the environment through excretion onto natural grazing or through fertilization of lands. Ectoparasiticidals may have an impact on e.g. oxpeckers, waterways, and anthelmintics may impact on dung beetles.

- Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) provides for the health and safety of persons at work (e.g. in the manufacturing or use of stock remedies).

- Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act No 54 of 1972) sets Maximum Residue Limits for veterinary drug residues in food in its regulations

- Hazardous Substance Act, 1973 (Act No. 15 of 1973), classifies hazardous substances. The implementation of the Globally Harmonised System of Chemical Classification and Labelling (GHS) must be in place by 2008. The GHS comprises the following main elements: Hazard Classification, Classification Criteria, Test Methods and Hazard Communication. This has implications for the labelling of stock remedies.

- Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) provides measures for managing activities involving GMO's. Vaccines for the immunization of animals, for example, may contain components that are genetically modified.

Act No. 36 of 1947 does not adequately address Constitutional requirements in relation to Bill of Rights, Access to Information, openness and transparency in decision making and also just administration action. Act No. 36 of 1947 does not adequately incorporate international obligations and agreements which South Africa is Party to or may be party to.

Act No. 36 of 1947 does not address the issue of expired products and container management

2.2 Capacity and research

Although there is current capacity in South Africa to deal with Animal Medicine registration, regulation and research, attention will need to be paid to the succession of existing experts.

There is suboptimal use of expertise under the current Animal Medicine regulatory systems.

The ARC (Onderstepoort) does some research relating to Stock Remedies, but more targeted research would be appropriate in the future to make use of the available resources. In addition, research could be focussed on alternative technologies to find more appropriate stock remedies, or technologies which counter the negative effect of current stock remedies.

2.3 Current problems associated with Stock Remedies

The name stock remedy may be considered confusing, as pet/ companion animal products are included in the grouping.

Stock remedies include: anthelmintics, ectoparasiticides, dermatological shampoos, vitamin and injectable minerals, production enhancers, some intramammary medicines and antimicrobials. There is no formal classification system for the various stock remedies, although appropriate categorisation according to pharmacological norms is used (eg. Pyrethroid ectoparasiticide).

Due to the definition of a stock remedy (see background section) with the industry taking advantage of the situation, a lot of products that were supposed to be registered as veterinary medicines under Act No. 101 of 1965 were registered under Act No. 36 of 1947. This situation can lead to some highly ethical products landing in the hands of lay people resulting in their incorrect use which can lead to the product being ineffective, the development of resistance or toxicity.

There are a number of farm feeds that are registered for use in animals as supplements and supportive therapy (in for example paste, solution or tablet form) and they are not feeds/ food. Examples are electrolyte solutions for rehydration and colostrum-based products as anti-diarrhoeals. A "grey area" has thus been created in the South African Animal Medicine regulatory environment, allowing for medicinal claims to be made by "nutritional products".

Currently autogenous vaccines are not registered, nor are there minimum standards of quality, safety and efficacy, although they are widely used in animal production. Complimentarylalternative medicines are currently used in animals of which the quality, safety and efficacy of many remains questionable.

Some stock remedies are used for the treatment or prevention (e.g. vaccines) of controlled diseases. Access by farmers to such stock remedies may encourage treatment of controlled animal diseases without involvement of Veterinary Services, which may be a problem that can lead to the spread of some of the diseases.

2.4 Problems associated with Production Enhancement Products

2.4.1 Antimicrobials

In-feed antimicrobial stock remedies can be either therapeutic (treatment of diseases) or sub-therapeutic (prevention of diseases) and growth promoting. Prescription-only therapeutic in-feeds are registered through the MCC. Antimicrobial growth promotants can contribute to antimicrobial resistance, and therefore have implications for both human and animal health.

Antimicrobial growth promoters are still widely used in South Africa to increase production. Some countries have banned a number of antimicrobial growth promotants. In the future should South Africa export more of its livestock products to other countries, there will be increased pressure to ban and or adapt its policies with those of importing countries and also limit the use of these stock remedies for local consumption. There are a number of registered antimicrobial growth promotants in South Africa, but this will be reviewed.

Bodies such as Codex Alimentarius and the OIE have codes of conduct regarding the minimisation of antimicrobial resistance. These focus on various areas including regulation of antimicrobials monitoring of antimicrobial resistance.

2.4.2 Growth promoting hormones

Growth-promoting hormones are generally registered through Act No. 36 of 1947. They increase feed efficiency and are predominantly used in intensive beef production (feedlots). However, there are some public concerns about environmental contamination and the EU has banned the use of growth-promoting hormones. A number of hormonal growth promotants and BST are registered as stock remedies in South Africa.

Due to increased consumer awareness there has been a lot of debates worldwide on the safety of the food after use of growth promoting agents in animals. This led to some countries banning the use of growth promoting hormones. Some of these products can also be classified as endocrine disrupting agents that enter the food chain via direct consumption of products of treated animals, plants from land fertilised with contaminated manure and/or drinking of contaminated water.

There are a number of registered growth promoting hormones in South Africa, but these will be reviewed.

2.5 Registration of Stock Remedies

The evaluation process that determines whether a stock remedy may be registered is based on scientific proof of quality, efficacy and safety. An applicant provides a dossier of evidence to substantiate the quality, efficacy and safety of the product. The applicant declares that the data presented is authentic and therefore truly reflects the quality, manufacturing, safety and efficacy of the stock remedy. Technical advisors to the Registrar evaluate the presented material based on science, accepted norms and standards and make recommendations on registration of the proposed stock remedy.

It should be noted that registration and not marketing authorization is approved, this subtle difference means that applicants are independently responsible for commercial issues (e.g. ensuring that patents etc. are respected).

Attention to the following must be paid during the registration process:

Consumer Safetv and Chemical Residues

Stock remedies are sometimes used in food producing animals and chemical residues may remain in the meat, milk and eggs. It is necessary to ensure that consumers are not dangerously exposed to chemical residues by assigning correct withdrawal periods. This is being addressed, but not optimally (see antimicrobial resistance).

Antimicrobial Resistance

The potential for an antimicrobial stock remedy to select for resistance in human and animals should be assessed by both the Departments of Health and Agriculture respectively. This is currently not the case.

Environmental Safetv

Stock remedies must be evaluated for environmental safety according to accepted norms such as The International Cooperation on Harmonisation of Technical Requirements for the registration of Veterinary Medicinal Product (VICH) guidelines. Some of the animal medicines are classified as Persistent Organic Pollutants (POP's) (e.g DDT) while others are classified as endocrine disruptor substances (EDS) (e.g some antimicrobials and hormones). Both the EDS and the POPs result in contamination of the environment. The endocrine disrupting substances enter the food chain via direct consumption of products of treated animals, plants from land fertilised with contaminated manure and/or drinking of contaminated water with EDS. Endocrine disruptor substances result in disturbances in the hormonal system of animals and humans resulting in variety of hormonal abnormalities including fertility.

There is a global move to focus on ecotoxicity, with international standards for testing methods (e.g. OECD standards). Government monitoring of environmental impact is of critical importance.

User Safety

Some stock remedies can be dangerous for the user (e.g. dips) thus appropriate precautions and **warnings** are placed on the label. In certain instances (e.g. injectable stock remedies) specific skills are required for the administration/ application of a stock remedy and inadequate skill may place the safety of the user and the target animal in jeopardy. Currently assessment of the user precautions and warnings (to ensure Occupational Health and Safety) are done by Act No. 36 of 1947 and not by the Department of Labour. Stock remedies are classified through the **SANS** 10304 but their marking and labelling is determined by Act No. 36 of 1947.

Scientific Reasoning

By requiring scientific proof of efficacy and safety, the burden of responsibility is placed on the applicant to support safety and efficacy of their product. The Department of Agriculture relies only on the documents submitted by the applicant to register the products. This information may not always be correct. Good Clinical Practice therefore needs to be followed during a study/ trial. GCP is not monitored by the Act No. 36 of 1947 inspectorate and there is also lack of capacity in this area.

Peer Review

During the process of evaluation through Act No. 36 of 1947 there is no formal peer review mechanism. Ideally, a registration dossier should be extensively/ fully evaluated by more than one evaluator.

Review

There is currently no mechanism for the review of stock remedy registrations.

2.6 Regulation of Stock Remedies

Access to stock remedies

Stock remedies may be used to treat animal parasites, diseases and to prevent diseases. For treatment to be successful the parasite or disease needs to be identified or appropriately diagnosed, and this requires that the individual (e.g. farmer) treating the animal would have the ability to correctly identify the problem. Often, this may not be the case.

According to Act No. 36 of 1947 anyone can sell Stock Remedies. The reality is that sellers may not have the appropriate skills to correctly advise farmers on the use of stock remedies, or the skills or facilities to appropriately store stock remedies. In addition registers need not be kept, making the traceability of food products e.g. for veterinary residues difficult. Also, one may not repack stock remedies into smaller packs for resale which is common practice with distributors.

Anyone can buy Stock Remedies. The reality is that buyers may not have the appropriate skills to correctly and safely apply some stock remedies.

Importation and trade aspects

Importation of an unregistered stock remedy or veterinary medicine is prohibited through Act No. 36 of 1947 and Act No. 101 of 1965 respectively. Cancelled registrations would be considered to be unregistered and the importation would therefore not be allowed. Only registered stock remedies may be imported and sold in South Africa. The Stock Remedy regulator does not prescribe procedures for "importation for exportation" (products in transit through SA to another country) and for exportation as this falls outside the current scope of Act No. 36 of 1947. Other institutions/bodies involved in importation of animal medicine in terms of commerce are the South African Revenue Services, Department of Trade and Industry and Custom Services; in terms of importation of veterinary medicines, the Department of Health; and in terms of protecting national herds/ flocks from sanitary and phytosanitary threats, the Directorate of Animal Health. There is lack of coordination on the activities of these bodies on import/export issues relating to animal medicines.

Inspection. Compliance and Enforcement

For effective regulation of animal medicine and to ensure compliance, legislation should be accompanied by a strong inspection service and enforcement measures. Currently the inspection service is not effective, penalties are not deterrent and the public and industry do not play any role in law enforcement activities. All these have led to high level of non-compliance in the animal medicine industry in South Africa. GMP accreditation is often a requirement for international trade by stock remedy manufacturing companies. GCP is a registration requirement of many regulatory bodies globally. The inspectorate of Act No. 36 of 1947 does not perform GMP inspections on the manufacturing companies, nor do they perform GCP inspections on clinical trials.

Food Safetv Aspects

The monitoring of veterinary drug residues in food and of antimicrobial resistance in the general human and animal population are not performed at a level that allows for the development of risk management programmes, including the review of stock remedies.

Standards setting

Act No. 36 of 1947 is involved in Standards setting by means of SABS Standards committees on an ad hoc basis

2.7 Socio-economic issues

There are a number of socio economic issues which are not being affectively addressed:

Participation in the Stock Remedv Manufacturing Industry

The stock remedy industry faces various challenges many of which affect the country's economy or are affected by the country's economy. The industry operates in a highly competitive environment that must continuously respond to the new challenges with regard to safety, efficacy, quality and suitability of the products.

The industry is diverse: manufacturers either manufacture locally, or import, and are either subsidiaries of bigger multinationals or are purely South African companies, and access by new stakeholders is difficult.

The Farming Community/ The Users

The availability and utilisation of stock remedies is skewed. The majority of Stock remedies are used in the commercial sector under extensive and intensive conditions. Access is through cooperatives or the manufacturer/ distributor, while there is little to no availability in outlying rural areas. Here communal husbandry plays a role in how parasites and diseases are treated and prevented, access to advice on stock remedies is limited and the appropriate storage of stock remedies is suboptimal.

Public Awareness

The majority of people in SA are not aware of the potential threats, danger and impact of the misuse and mishandling of stock remedies (e.g. adverse reactions).

Within this context the general public and consumers who are the most vulnerable victims of poisoning and /or contamination and residual effects are not being properly or adequately advised.

There is no formal mechanism to educate the public and raise awareness on the safety issues associated with animal medicines.

3. POLICY OBJECTIVES

The following broad objectives have been identified with regards to stock remedies:

- Provision of one focussed, effective and efficient regulatory system that ensures
  - Appropriate and effective access by farmers to stock remedies
  - The consistent safety of stock remedies, and thus the safety of animals, consumers and users
  - The consistent efficacy of stock remedies and thus efficient livestock production
  - Consistent, acceptable quality of stock remedies to ensure consistent efficacy and safety
- Ensuring that decisions are based on scientific principles and in the public interest taking into account the South African situation.
- Creation of a framework for rationalisation and harmonisation. of registration requirements and procedures (internationally, regionally and locally)
- To provide regulatory enforcement programs:
  - To safeguard human, animal and environmental health;
  - that provide effective and uniform administration of laws and rules which will assist in facilitating national and international trade;
  - to increase consumer confidence through strong and effective enforcement.

4. POLICY TO ADDRESS THE PROBLEMS

4.1 Legislation

Legislature that allows effective, responsible registration and regulation of stock remedies is required. The use of an appropriate term for stock remedies should be encouraged. Formal structures and mechanisms that allow other Departments to exercise their mandates during the registration and regulation of stock remedies must be put in place. The legislation on regulation of stock remedies must be brought in line with the constitution of the republic of South Africa.

4.2 Registration of stock remedies

The registration requirements for stock remedies need to be harmonized. Access to appropriate expertise is necessary for registration evaluations of acceptable standards. Appropriate and acceptable peer review mechanisms should be established.

All aspects of the evaluation (including consumer, user, environmental and animal safety) need to be given due and appropriate consideration.

A mechanism for the registration of autogenous vaccines should be introduced.

4.3 Labelling

The labelling of stock remedies should facilitate the understanding as well as the correct use of stock remedies.

Warnings must be standardized (within stock remedies and between stock remedies and veterinary medicines) to ensure compliance with for example withdrawal periods. Precautions must be practical to protect the users of stock remedies.

4.4 Review

The review of stock remedy registrations is a necessity. A system should be put in place to continuously review registered stock remedies. An urgent example is growth promotants **(both** antimicrobial and hormonal). Farm feeds that have medicinal claims need to be reviewed and possibly be re-registered as stock remedies.
A mechanism for the registration of complementary veterinary medicined stock remedies needs to be developed and implemented.

4.5 Classification

Stock remedies should be formally classified according *to* South African requirements, and designated groups should be restricted to certain categories of sellers (including veterinarian-only) and buyers, a good example is antimicrobials (e.g. intramammaries and injectables).

The implementation of the GHS must be in place by 2008. **A** programme therefore needs to be developed and implemented.

4.6 Access to Animal Medicines

To ensure that appropriate and reliable advice is given to farmers/ public using specified stock remedies, licensing of sellers will be required. Licensing of sellers will also be required to ensure

the reliable repackaging of stock remedies into smaller packs for resale. Strict requirements for the storage of stock remedies needs to be formalized.

There should be selective access to certain stock remedies by farmers/ public with acceptable skills and training (e.g. Organophosphate dips)

4.7 Inspection, Compliance and Enforcement

The inspectorate needs to be developed to be able to inspect and accredit GMP and GCP. Formal principles, requirements and guidelines for the "importation for exportation" of stock remedies must be established. Special attention should be paid to increasing capacity within the inspectorate in order to ensure compliance.

4.8 Pharmacovigilence and the Awareness of the General public

Information on stock remedies (e.g. labels) as well as a formal pharmacovigilence (post registration) programme needs to be put in place and be accessible to the public.

4.9 Participation in the Stock Remedy Manufacturing/ Distributor industry

Methods to increase participation in the stock remedy manufacturing and distributor industry should be explored, and implemented.

4.10 The Farming community

The farming community requires better information transfer with regards to stock remedies. The licensing of sellers will go a long way to providing a framework for the support that is required.

4.11 SADC

Control systems in the SADC region should be standardized in order to regulate importation, distribution and use of veterinary drugs. The harmonisation of VMP registration procedures should be facilitated.

4.12 Other Countries

Co-operation with other countries should be developed.

5. Organisation and Administration

The recommended policy option for stock remedies is government-led regulation with the regulator of stock remedies housed at the Department of Agriculture. The Department of Agriculture in consultation with other government departments will be responsible for Stock Remedy legislation and its regulation, conducting human health, safety and efficacy assessment, surveillance monitoring, as well as compliance.

This policy advocates the formation of Advisory Committee(s) in order that views of all sectors on Stock Remedy are taken into account. The functions of this Advisory Committee(s) will range from policy-making to review the technical aspects of applications for registration. Membership will comprise of government and non-governmental organizations, which include experts from various fields such as agricultural researchers, toxicologist, chemists and environmentalist.

This policy considers the possibility of giving local and provincial Governments the legislative mandate to investigate the use, sale and importation of products; perform on-site inspection of the usage and storage of products, and educate individuals, local officials and users.

6. REFERENCES

1. Agricultural Policy: National Department of Agriculture, 1998
2. Department of Agriculture, the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).
3. Department of Agriculture, Animal Health Act, 2002 (Act 7 of 2002).
4. Department of Health, Medicine and Related Substance Control Act, 1965 (Act 101 of 1965).

7. POLICY OWNER

Directorate of Food Safety and Quality Assurance, Department of Agriculture.

ANNEXURE A

DEFINITIONS/GLOSSARY OF TERMS

Act 36 refers to the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

Act 101 refers to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965)

Animal medicine refers to medicine intended for use on animals and include both the stock remedies and veterinary medicine

anthelmintics means Animal Medicine that destroys or causes the expulsion of parasitic intestinalworms

antimicrobial means Animal Medicine used *to* destroy microbes, prevent their development, or inhibit their pathogenic action

autogenous vaccines are specific vaccines intended for emergency and restricted use (time/and/or locality) and are safe non-spreading products derived from specific pathogens isolated from a specific animal/bird or herd/flock of animals/birds

complimentary medicines means herbal or alternative medicine.

Ecotoxicity refers to the potential environmental toxicity of residues

ectoparasiticide means Animal Medicine used to control ecto/ external parasites

endocrine disruptor substance means an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism or its progeny or (sub) populations.

growth promotant means Animal Medicine that improves growth and/ or feed efficiency i.e. improves production

harmonisation means the act or state of agreeing or conforming.

Maximum Residue Limit as defined by the Foodstuffs, Cosmetics and Disinfectant Act of 1972 means the maximum concentration of the residues of a veterinary medicine or a stock remedy, (including specified metabolites, reaction or conversion products or impurities) that remain in a foodstuff referred to in these regulations, resulting from the use of any such veterinary medicine or stock remedy, expressed in milligrams of the veterinary medicine or stock remedy per kilogram of the foodstuff.

orthodox medicine means conventional medicine as prescribed by medical doctors and their allied health professionals.

Persistent organic pollutants (POPs) are chemical substances that persist in the environment, bioaccumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. This group of priority pollutants consists of pesticides (such as DDT), industrial chemicals (such as polychlorinated biphenyls, PCBs) and unintentional by-products of industrial processes (such as dioxins and furans).

Pharmacovigilence refers to post registration surveillance

Production enhancement products means products that improve or increase outputs (e.g. feed conversion)

Pyrethroid a class of insecticide

Rationalisation means systematic organisation; the act of organising something according to a system or a rationale

registration means The legal process by which stock remedies are recognised as being safe and effective, and securities brokers or dealers become legally entitled to sell securities

regulation means the state of being controlled or governed

stock remedies are defined in Act *36* as "a substance intended or offered to be used in connection with domestic animals, livestock, poultry, fish or wild animals (including wild birds), for the diagnosis, prevention, treatment or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, but excluding any substance in so far as it is controlled under the Medicines and Related Substances Control Act, **1965** (Act **101** of **1965)"**.

target species means the intended species

traceability means the ability to trace and follow a feed product or any substance intended to be, or expected to be incorporated into a feed product through all stages of production, packing, processing, handling and distribution.

veterinary medicine means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, **1947** (Act 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour. This is the definition according to Act **101** of **1965**
Veterinary Medicinal Products

withdrawal period means period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use and the production of foodstuffs from such animals, in order to ensure that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits.

ANNEXURE B

ACRONYMS/ABBREVIATIONS

BST	Bovine Somatotropin
EDS	Endocrine disruptor substance
EU	European Union
DDT	Dichloro-diphenyl-trichloroethane
DEAT	Department of Environmental Affairs and Tourism
DoA	Department of Agriculture
DoH	Department of Health
GCP	Good Clinical Practice
GHS	Globally Harmonised System of Chemical Classification and Labelling
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
OECD	Organisation for Economic Co-operation and Development
POP	Persistent organic pollutants
SA	South Africa
SABS	South African Bureau of Standards
SADC	Southern African Development Community
VICH	The International Cooperation on Harmonisation of Technical Requirements for the registration of Veterinary Medicinal Product