



Improved management of drugs, hormones and pesticides in Africa

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ABSTRACT

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Drugs, hormones and pesticides are chemical compounds used for alleviation of various diseases in animals. There are many classes of drugs which have been used and in the case of natural steroid hormones these have been used to increase mass gain by stimulating protein anabolism. Pesticides have been used for many years in the control of ectoparasites which transmit important human and livestock diseases. The purpose of the present article is to review procedures for management of veterinary products to facilitate national and international trade.

These compounds and/or their metabolites have the potential to cause undesirable health effects to either target animals or consumers. Most African countries do not have competent authorities to conduct risk analysis for veterinary drug and pesticide residues in edible tissues. Because of the possible undesirable health effects from residues of veterinary compounds, the FAO/WHO established expert groups to establish acceptable daily intake and maximum residue levels (MRLs) for each drug or pesticide. In the case of natural steroids like oestradiol, progesterone and testosterone implants, no withdrawal period is required since there is no risk to the consumer. Bulls can have levels of testosterone ranging from 535–10 950 pg/g, heifers 92–250 and treated steers 100 pg/g, respectively. Data to enable approval of drugs and pesticides is to a large extent similar and include toxicity studies, reproductive studies, stability studies, safety, efficacy, tissue residue depletion studies and environmental impact.

Good practice in the use of acaricides as indicated on the label is inevitable so that residue levels of these compounds remain below the specified MRL.

Enactment and enforcement of legislations by various countries for the control of registration, sale, distribution and usage of ethical products should be enforced including use of prescriptions by veterinarians.

Good practice in the use of veterinary drugs is the recommended or authorized usage of drugs. It should be enforced to ensure safe animal products for human consumption and to facilitate regional or international trade. In conclusion, for efficient production of animal protein from food producing animals all veterinary products should be approved prior to use, residue monitoring programs should be implemented; veterinarians and producers must use these compounds prudently using recommended good practices.

INTRODUCTION

Drugs, hormones and pesticides are chemical compounds used for alleviation of various diseases in animals. They can be used either for curative, spe-

cific disease control or prophylaxis. These compounds can also be used as production aids in food producing animals to enhance mass gain for early market (Mitema 2004). Hormones, in particular the steroids, have been used as production aid com-

pounds for increased mass gain by stimulating protein anabolism to attain early market maturity. Pesticides have been used for many years as either sprays, pour-ons, in dips or in baths to control ectoparasites like ticks, flees, mite, lice, etc. Examples of acaricides which have been used include inorganic arsenicals, organochlorine compounds (BHC, lindane and toxaphene), organophosphates (dichlorvos and chlorphentyphos), carbamates (sevin), natural pyrethrins, formamidines (amitraz) synthetic pyrethrins (cypermethrin, alpha cypermethrin, deltamethrin, permethrin, etc). Tick resistance to acaricides is quite rampant and hence prudent use and monitoring of acaricides to minimize resistance is important. Ticks transmit important livestock diseases like anaplasmosis, babesiosis and theileriosis. Theileriosis (East Coast fever) is a very fatal disease to exotic cattle in eastern Africa and unless proper tick control is practiced, there can be serious economic losses.

The purpose of this presentation is to review procedures for the management of veterinary products to facilitate national and international trade.

DRUGS

Drugs are pharmacotherapeutic armaments used regularly for therapy and disease control in animals. There are many classes of drugs used which include, among others, antimicrobial agents, antihelminics, antiprotozoal agents, hormones and anti-inflammatory compounds.

Chemical compounds are xenobiotic in the mammalian body and have to be metabolized to safe and water soluble metabolites. Drug compounds and/or their metabolites have the potential to cause undesirable health effects to either target animals or consumers. Undesirable health effects may include among others acute or chronic toxic effects and long term effects like carcinogenic, teratogenic, genotoxic, reproductive or developmental disorders. In the case of antimicrobial agents, antimicrobial resistance development can occur due to non-prudent use of these compounds.

International trade implications

Most African countries do not have competent authorities to conduct risk analysis for veterinary drug and pesticide residues in edible tissues. Risk analysis is a science-based decision to protect consumers from possible hazards from residues. Risk analysis comprises risk assessment, risk communication

and risk management. Because of the possible undesirable health effects from residues of veterinary compounds, the FAO/WHO established expert groups to establish maximum residue levels (MRLs) for each drug or pesticide. The role of the Expert Committee on Food Additives and the Joint Meeting on Pesticide Residues is to establish health-based guidance values for residues of veterinary drugs and pesticides, respectively, by establishing an acceptable daily intake (ADI). ADI refers to the total amount of drug residues and metabolites in edible tissues which human beings can consume throughout life without causing undesirable effects and is expressed as mg/person/day. An ADI is an output of a risk assessment of the compound, following application of the first two steps of risk assessment paradigm: hazard identification and hazard characterization. An ADI is derived from the NOEL or lowest observed level (LOEL) from either appropriate toxicological, pharmacological, microbiological or epidemiological end point applying appropriate safety factor. Once an ADI has been established, maximum residue limit (MRL) can be derived taking cognisance of other factors. An ADI derived from toxicological end point utilizes appropriate laboratory animals. Established MRL is apportioned to various edible tissues like fat, kidney, liver, meat, eggs, milk and eggs according to dietary patterns. MRL refers to the maximum amount of chemical residue legally permitted to be in edible tissues or recognized as safe and is expressed as mg/kg.

HORMONES

Steroid hormones are produced mainly in the gonads and major compounds used for anabolic purposes are oestradiol, progesterone and testosterone.

Endogenous steroid tissue hormone levels are high in most of normal untreated bulls, pregnant heifers and cows and thus proper use of natural steroids as implants do not significantly increase tissue levels above those found in animals' physiological state (WHO 1982). Bulls can have testosterone levels ranging from 535–10,950 pg/g, heifers 92–250 and a treated steer 100 pg/g, respectively (Roche 1991).

In the case of natural steroids like oestradiol, progesterone and testosterone implants, no withdrawal period is required. Anabolic steroids (nandrolone, norethandrolone, ethylestrenol) are derivatives of testosterone that enhances anabolic effects with reduced androgenic effects when synthetic non-steroidal oestrogens include stilbene or zeranol. Anabolic steroids stimulate haematopoiesis, appetite

and mass gain. Adverse effects of anabolic steroids include hepatotoxicity, masculinization and early closure of bone epiphyses in young animals. Because of their undesirable health effects, their use by producers as implants should follow strict label instructions. In most countries, especially the European Union, their use as growth promoters has been banned. The proper use of steroids is defined as implantation of steroids in a site of the body that does not enter the human food chain for instance ear implantation and proper adherence to designated withholding period prior to slaughter.

ACARICIDES

Ectoparasiticides should be regulated for use in most African countries to facilitate use of quality products. In Kenya, acaricides are regulated by Pest Control Products Board (CAP 355), which is a different agency from the one controlling drugs and hormones. Data to enable approval of pesticides to a large extent is similar to those for drugs and include toxicity studies, reproductive studies, stability studies, safety, efficacy, tissue residue depletion studies and environmental impact among others (Blagburn & Lindsay 2001). Good practice in the use of acaricides as indicated on the label is inevitable so that residue levels of these compounds are below the specified MRL for each compound. The FAO/WHO's Joint Meeting on Pesticide Residue is the expert committee that establishes the MRLs of the acaricides for use in food producing animals. African countries should adopt the Codex standards of the FAO/WHO on pesticide residues to facilitate improved national and international trade.

INTERVENTIONS IN PROPER MANAGEMENT OF VETERINARY COMPOUNDS

Adoption of the Codex standard

In order to promote regional and international trade among member states in Africa, prudent procedures in the management of veterinary products is inevitable. Edible tissues of animal origin should contain residue levels of veterinary drugs and pesticides below the recommended MRL to facilitate trade. One of the World Trade Organization treaties for instance Sanitary and Phytosanitary Measures requires that all edible animal products should use the Codex standard. The Codex standard is the basis for international trade for edible animal products. MRLs of the various drugs and pesticides established become adopted as the Codex standard for the re-

spective compound. African governments through their respective veterinary regulatory authorities should adopt the Codex standards to facilitate trade. The risk management for chemical residues is through adherence to the withdrawal period for each particular veterinary compound administered to food animals.

Legislative framework

Enactment and enforcement of legislations by various countries for the control of registration, importation/sale, distribution and usage of ethical products should be encouraged. Although most African countries have regulatory legislation, these are, however, not properly enforced. Lack of enforcement may be due to either political interference, lack of awareness on risks associated with these compounds, lack of trained personnel or lack of financial resources. In the case of veterinary products' regulation, it is important that all drugs should be registered before market authorization in respective countries. Prescriptions by veterinarians for ethical products is important before products are used.

Registration of all products

Registration of veterinary products ensures that these compounds are safe, efficacious and of good quality to target animals. One of the registration requirements is that the residues of these products are safe to consumers in case of food producing animals. Environmental safety of metabolites of veterinary compounds is gaining importance especially for products eliminated via faeces and would otherwise contaminate the environment and alter biodiversity. Review of veterinary compounds before market authorization is a tedious process that requires the presence of legally established competent authority. The review process requires that drug companies/sponsors supply relevant data to support pharmaceutical quality, residue study, toxicological study, environmental impact assessment, safety to target animals and consumer or clinical efficacy. Most African countries do not have well trained scientists to conduct and review processes before drug approval and use of experts from other countries with competent regulatory authorities may be necessary. Review and approval of pesticides for the control of ectoparasites in most countries in Africa is governed by different legislation. The mission of regulation of pesticides is basically to ensure safe, efficacious and quality products. Environmental safety of pesticides is given a lot of consideration since these compounds find their way in the envi-

ronment. Tissue residue depletion data for specific pesticides is also assessed to ensure that MRL levels are observed to facilitate international trade. Establishment of surveillance programmes for residue monitoring of various drugs, hormones and acaricides should be implemented by all countries.

GOOD AGRICULTURAL PRACTICES

Drugs

The use of veterinary products, especially in food producing animals, should be closely regulated by the concerned regulatory authority, the professionals, producers and the industry. Good Practice in the use of Veterinary Drugs is the recommended or authorized usage of drugs. It envisages that veterinarians take control of the usage of drugs and advise on pesticide application. The veterinarians should give adequate information to producers concerning withdrawal periods as recommended by the manufacturers before animal products are sold or slaughtered for human consumption. In order to achieve proper usage of drugs to ensure safe animal products for human consumption and facilitation of regional or international trade, the following guidelines should be observed and where possible enforced by the concerned parties:

- Accurate diagnosis should be obtained where possible before treatment, which should be guided by principles of maximum effectiveness combined with minimum risk. Specific treatments should employ few products and avoid combination therapy.
- Veterinarians and producers should avoid overuse or misuse of drugs to minimize development of resistance, for instance in the use of antibacterial agents or anthelmintics. Antimicrobial or anthelmintic resistance tends to cause delays in clinical recovery and escalates treatment costs.
- The use of prescriptions for ethical drugs should be enforced to ensure correct dosage, site and route of administration.
- Whenever products are used off-label or extra-label, due to lack of authorized product or certain disease conditions, veterinarians in using these products in food producing animals should exercise a lot of considerations and ensure that extended withdrawal period time is assigned for the drug prior to marketing of either milk, meat or eggs. Extra-label use should only be used by a qualified veterinarian or somebody under his/her supervision.

- Records of all veterinary products administered to food animals should be kept including quantities, date of administration and the identity of animal. Records should be kept for at least 2 years and be available when required by competent authority.
- All medicinal products should be stored properly according to the label instructions and in compliance with national laws. All expired drugs medicines/products should be disposed of safely according to the label instruction.
- All antimicrobial treatments should follow recommended guidelines on prudent use to minimize antimicrobial resistance among food borne pathogens like *Salmonella* spp., *Campylobacter* spp., *Escherichia coli* and *Enterococcus faecium* (WHO 2000). Veterinarians should use antibiotics judiciously following a clear clinical indication and after antimicrobial susceptibility test has been conducted.

Pesticides

Good agricultural practice in the management of acaricides is quite important to minimize environmental contamination and development of tick resistances.

- The right formulation (dip, spray, collars and pour-on) should be applied to food animals. A spray formulation product should not be used in the dip or as pour-on.
- Pesticides must be stored in a dry place and protected from extremes of temperature. Most pesticides can retain their activity for at least two years. They must be kept out of reach of children.
- Pesticides containers should be thoroughly washed and washings including either the spray or dip material properly disposed. The washed containers must not be used to contain food materials.
- Regular acaricide efficacy surveillance on ticks should be conducted by regulatory authorities to protect the animals from tick infestation.

In conclusion, for efficient production of animal protein from food producing animals, it is almost a must to use drugs, acaricides and to some extent natural steroids. Organic production of edible animal products in Africa is still possible in some parts of the continent especially among pastoralists, but this is becoming less common since most local people use

dewormers. Good clinical veterinary practices and good agricultural practices in the use of veterinary products on food producing animals are crucial to enable producers to market their products without trade hindrances. All veterinary products should be approved prior to use and veterinarians and producers must use these compounds prudently.

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