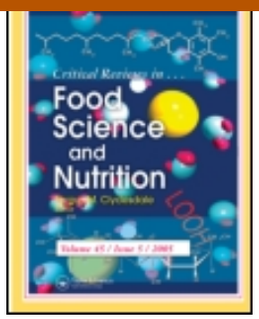

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Review of the Regulation of Veterinary Drugs and Residues in South Africa

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The food safety risk analysis framework of the FAO/WHO is used in the review of veterinary drug and residue regulation in South Africa to determine possible inefficiencies within this system. Results indicate that a variety of challenges relating to the processes of risk assessment, management, and communication do exist, although these occur within a fragmented system of legislation, functions, and structures. Addressing these challenges therefore requires a change to a more collaborative and integrated system. It is indicated that for such a change, the underlying challenges of inadequate horizontal communication, poor conceptualization, and awareness of functions of the system are required to be dealt with.

Keywords Veterinary drug residues, risk analysis, food

INTRODUCTION

The use of veterinary drugs in food-producing animals has yielded many benefits from increased quality of life of animals and, therefore, production of quality food as well as economic gains related to fewer losses in livestock rearing (National Research Council, 1999; Morley et. al., 2005). Veterinary drugs used in food producing animals have, therefore, been useful to sustain animal food production. However, with the benefits related to use of veterinary drugs in animals, their use may also be cause for concern due to effects that the residues of these drugs could have on consumers.

Concerns regarding veterinary drug residues in foods differ based on the type or category of drug used in the animal. The Codex Alimentarius Commission (CAC) lists on their website 11 functional classes of veterinary drugs. However, these can be combined into the five categories of veterinary drugs, as described by the National Research Council of the United States of America (USA). These include: topical antiseptics, ionophores, hormone and hormone-like drugs, antiparasitic drugs, and antibiotics or antimicrobials (National Research Council, 1999). The first category refers to all drugs used on the surface on the animal to prevent or combat infection like iodine in solution, while the second category refers to drugs that alter stomach microorganisms for enhanced nutrient uptake efficiency like monensin (also considered an antimicrobial). Antiparasitic drugs like abamectin are used for treatment of parasites in animals while hormone/hormone-like drugs are generally used for faster growth of animals through efficient feed conversion, of which examples include recombinant bovine somatotrophin (rBST) and ractopamine. Antibiotics are perhaps the most well known and are used for treatment against microorganisms that create or exacerbate infection. Examples include tetracycline or gentamycin.

However, of these categories indicated by either the National Research Council or the CAC, the two most widely debated for their use in food animals is antimicrobials and hormone/hormone-like drugs. Use of antimicrobials in food producing animals has sparked the concern of the possible build-up of resistance of bacteria found in humans because of exposure to antimicrobials in animal-source foods. This could mean that treatment methods with similar if not the same antimicrobials in humans for illness could be rendered less effective. Antimicrobial resistance is of concern because antimicrobials are not only used for therapeutic purposes via dose-controlled administration to protect animals against pathogenic bacteria, but are

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also used subtherapeutically (when administered through feed) to increase efficiency in food uptake and utilization in animals (National Research Council, 1999; Doyle, 2006). Off-label use, where a specific veterinary drug has not been tested for and used on different animals and/or changes in dose, has also increased the concern of build-up of resistance by bacteria in humans (National Research Council, 1999; Catry et al., 2003; Doyle, 2006). A further concern of the use and misuse of antimicrobials as well as other types of veterinary drugs is exposing susceptible human populations to increased concentrations of these drugs thus exacerbating allergic and/or toxic responses (National Research Council, 1999). Antimicrobials can also interfere with the intestinal microbial balance (Cerniglia and Kotarski, 2005), which can allow for the overgrowth of exogenous pathogens (Jeong et. al., 2009) allowing for increased illness related to the digestive system.

Other veterinary drugs, particularly growth promoting chemicals that have corresponding hormones in humans, have also received much attention as it has been postulated that it could have effects on humans. The rBST case between the USA and the European Union (EU) indicates the controversy in the use of this hormone (Brinckman, 2000; Collier, 2000) whether it is for effects on humans or animal welfare reasons. Other hormones like oestrogens are also in the spotlight because studies indicate that even minute amounts of exogenous oestrogens could potentially alter reproductive ability and development particularly in young children (Andersson and Skakkebaek, 1999; Partsch and Sippell, 2001; Aksglaede et. al., 2006). Beyond the risks to human health, veterinary drug residues in excreta of livestock may affect ecosystems and have toxicity concerns for specific organisms in the environment (Yoshimura and Endoh, 2005).

The understanding that residues of veterinary drugs could be a likely food safety and public health concern prompted the need for various countries to control the administration of veterinary drugs to food producing animals. Countries developed a regulatory system of legislation, structures, and function for controlling veterinary drugs and their residues. In South Africa, the regulatory system was initiated as far back as 1947 when veterinary drugs were registered as stock remedies under the Department of Agriculture (Act 36 of 1947). After this initial regulation, the control of veterinary drugs and veterinary drug residues has evolved considerably. The current regulatory system is the focus of this paper.

The review of the regulation of veterinary drug residues is conducted under the framework of food safety risk analysis as described by FAO/WHO, (2006) although the existing system was never modeled on this framework. The application of this framework is for insight into the possible inefficiencies and/or challenges of the veterinary drug residue regulatory system as it is a recommended model by the global authorities on food control systems, the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) (FAO/WHO, 2006). This review categorizes the legislation, structures, and functions relevant to the regulation of veterinary drug residues as it occurs in South Africa based on risk assessment (RA), risk management (RM), and risk communication (RC) (FAO/WHO, 2006). The regulatory system is also discussed to define the challenges that are present and to determine whether and how they can be addressed.

RISK ANALYSIS AND THE REGULATION OF VETERINARY DRUG RESIDUES

South Africa's registration of veterinary drugs is conducted under two different Acts, the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). These two Acts separate drugs for animal use into veterinary drugs (Act 101 of 1965) and stock remedies (Act 36 of 1947). Because of these two pieces of legislation, risk analysis functions are conducted for both Acts. Table 1 provides a summary of the structures, legislation, and functions of the regulatory system of veterinary drug residues under the categories of risk assessment, risk management, and risk communication. The following sections are based on the information provided in Table 1.

Risk Assessment

Act 101 of 1965 is administered by the Department of Health (DoH) where risk assessments are conducted by technical subcommittees of a specialist Council called the Medicines Control Council (MCC). Specific to veterinary drugs, the Veterinary Clinical Committee (VCC) of the MCC conducts the risk assessment of all veterinary drugs requesting registration under Act 101 of 1965. In addition, the Biologicals Committee (BC) conducts risk assessment on biological-based veterinary medicines like vaccines. The VCC, BC, and MCC are composed of academics as well as government representatives. The Registrar: Act 101 of 1965 is a senior manager in the DoH, in the section of Pharmaceutical and Related Product Regulation and Management. The registrar holds the register of drugs (including veterinary drugs) and heads the secretariat support to the MCC. Amendments to Act 101 of 1965 in 2008 have made provision for the South African Health Products Regulatory Authority (SAHPRA) which will replace the MCC (The Medicines and Related Substances Amendment Act, Act 72 of 2008; Chanda et al., 2010). This change was legislated after a task team compiled recommendations to improve the efficiency of the registration of medicines under Act 101 of 1965 (DoH, 2008).

The four parts of risk assessment, as described in by FAO/WHO, (2006), can be identified in existing functions under Act 101 of 1965. This includes hazard identification where risk managers do not commission a risk assessment as the current process allows for the compulsory assessment of all veterinary drugs (includes food safety assessment). Hazard

characterization is conducted by the VCC (and BC where applicable) where safety, efficacy, and toxicology are assessed. Food safety toxicology and exposure assessment is also conducted at this level as the Directorate: Food Control (representing the mandate for food safety) is represented at the VCC meetings. Exposure assessments require a food basket for the various tissues of food producing animals that are consumed as foods. Since South Africa does not have its own food basket, the international values based on those utilized by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are used in the exposure assessment by the VCC. The resultant maximum residue limit (MRL), which is recommended for publication under the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is also determined at this time although there has been lack of capacity for the calculation and extrapolation for MRLs. Risk characterization, the last of the four components of risk assessment, is encapsulated in the recommendations that the VCC (and/or BC) puts forward to the MCC for final decision on a veterinary drug. The MCC, after final decision (risk management stage), will route these conclusions back to the Office of the Registrar: Act 101 of 1965 for communication to the applicant. The risk assessment system under Act 101 of 1965 makes use of a peer-review system for evaluation of veterinary drugs and its risk assessments are separated both structurally and functionally from those of risk management (Chanda et. al., 2010), a favored separation to distinguish between science and policy issues (FAO/WHO, 2006, 49).

The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) regulates veterinary drugs as stock remedies and was created to provide easy over-the-counter access to veterinary drugs by farmers. Under this Act, an applicant needs to register their stock remedy by submitting an application to the Registrar: Act 36 of 1947 of the Department of Agriculture, Forestry and Fisheries (DAFF). Risk assessment is conducted in-house by officials of the office of the Registrar as well as the DoH, Directorate: Food Control, either in-house or through expert consultants. In comparison to processes under Act 101 of 1965, risk assessment and risk management functions are not separated and assessments under Act 36 of 1947 do not make use of a defined peer-review system (Chanda et. al, 2010). Therefore, although risk assessments are conducted by both registration Acts, the process of assessment under these two Acts is inconsistent.

Similar to risk assessment under Act 101 of 1965, hazard identification is encapsulated in the process of registration where all stock remedies applying for registration need to undergo a risk assessment. Hazard characterization is conducted by officials of both DAFF and DoH (Directorate: Food Control) where efficacy, safety, and toxicology assessment are conducted. Exposure assessment is a function of the DoH, Directorate: Food Control, where food basket values of JECFA are also used to determine approximate exposure but because of the lack of capacity to calculate and extrapolate MRLs, this function does not occur routinely. This is, therefore, also the reason why the risk management strategy of publication of MRLs has a poor record of being updated. Risk characterization is conducted by both the DoH and DAFF, although the process is not distinct as the risk assessment and risk management processes are not separated.

Risk Management

A variety of risk-management strategies have been identified, although they may not have been specifically intended for management of veterinary drug residues. They do, however, contribute or have the potential to contribute to the control of veterinary drug residues and are categorized in Table 1. The two registration Acts as well as Act 54 of 1972 legislate the majority of risk-management strategies, although specific structures for risk management strategies are really only evident under Act 101 of 1965 with the MCC as the risk-management body. In addition, the office of the Registrar: Act 101 of 1965 supports this risk management body due to its secretariat responsibilities. For both Act 54 of 1972 and Act 36 of 1947, risk-management decisions are conducted together with risk assessments. Some risk-management strategies like extension services and residue monitoring are not specifically legislated but are conducted by respective Departments under their overall mandate.

Registration of Veterinary Drugs and Control of Access

The registration of veterinary drugs is probably the first aspect of regulation of veterinary drugs and thus regulation of residues of these drugs. Registration of drugs is also the initial regulation for the control of animal health, animal production, and public health concerns (Fingleton, 2004) and is therefore wider than the public health concern of exposure to veterinary drug residues via foods. Many countries employ registration of drugs, including veterinary drugs as a risk-management strategy. These include Zimbabwe under the Medicines and Allied Substance Control Act, 1969; New Zealand under the Agricultural Compounds and Veterinary Medicines Act, 1997; Taiwan under the Veterinary Drugs Control Act, 1971; and the United States of America under the Federal Food, Drugs and Cosmetics Act, to name a few.

In South Africa, as was indicated previously, both Acts 101 of 1965 and 36 of 1947 are registration authorities with designated Registrars who administer these Acts. However, for control of access of veterinary drugs, only Act 101 of 1965 has a scheduling requirement where drugs are scheduled according to their safety profile and their access is controlled either over-the-counter or through prescription from a qualified veterinarian. Act 36 of 1947 allows over-the-counter access for all registered stock remedies, which includes antimicrobials. This is problematic because misuse of antimicrobials in animals elevates the risk of development of resistance.

Commissioning a Risk Assessment

Since this task is conducted by risk managers (FAO/WHO, 2006, 37), it is considered a risk-management function.

However, it has been discussed earlier under risk assessment for both pieces of legislation that require registration of veterinary drugs/stock remedies.

Publication of MRLs

One of the most prominent RM strategies, specifically for veterinary drug residues in food, is the publication of MRLs of veterinary drug residues in foods of animal origin. This includes MRLs for meat and organs of animals as well as secondary products like eggs of fish and poultry, and milk from cattle and goats. In addition, for veterinary drugs that accumulate in fatty tissue (fat soluble), an MRL specific to fatty portions of the animal is also provided. This RM strategy is heavily dependent on the risk assessment of the veterinary drug for toxicity as well as the withdrawal period (withholding period) in specific animals.

Many countries employ this RM strategy, Australia under standard 1.4.2 of the Food Standards Code; the USA where MRLs are known as tolerances under the Food, Drug and Cosmetic Act, 1938; the European Union under the Council Regulations EEC 2377/90; Japan under the Food Sanitation Law, 1947, and the Positive List of Maximum Residue Limits for Agricultural and Veterinary Chemicals (brought into effect on the 29 May 2006); and the Philippines under the Philippine National Standard /BAFPS 48:2007 ICS 11.220: Veterinary Drug Residues in Food: Maximum Residue Limits. Even countries that don't specifically publish MRLs of their own, and use Codex Alimentarius Commission (CAC) standards as references (CAC/MRL 02/2008) inadvertently utilize this RM strategy as the CAC standards set MRLs for veterinary drug residues in foodstuffs. In South Africa, MRLs should be extrapolated from data after the risk assessment has been conducted under both registration Acts but MRLs included in Regulations No. R. 1089 of 1992 were also based on limits of the Codex Alimentarius Commission (CAC). However, Regulation No. R. 1089 of 1992 has only been amended once in 1999 to include new MRLs and the poor updating of this publication can be attributed to a lack of capacity in calculating withdrawal periods and extrapolating for MRLs. The enforcement of published MRLs is delegated to the provinces and local municipalities of the country and is addressed in the following section.

Compliance Monitoring

Compliance monitoring involves the requirement to determine and react to exceeding limits of published MRLs. The function of compliance monitoring requires specific activities that are resource-intensive. For example, inspectors are required for sampling of meat and animal-source foodstuffs, while laboratories are required for the analysis of residues in these foodstuffs. For sampling, sampling methods, and number of samples play an important role in sampling validity while, for analysis, highly qualified personnel and expensive laboratory equipment and test material are required. In addition, methods of analysis need to be accredited internationally to have integrity as a reliable method (Serratosa et. al., 2006). Other specific activities like fines for concompliance, destroying noncompliant foods, and/or prosecuting of the responsible person(s) is also required for compliance monitoring. Therefore, although the publication of MRLs does exist in certain countries, the compliance to the published MRLs is often not policed because of resource constraints, constraints in the knowledge and skill of inspectors, and analysts and poor credibility of state laboratories, if these laboratories exist.

In South Africa, compliance monitoring related to the publication of MRLs is inferred because Environmental Health Practitioners (EHPs) of the provinces and districts are authorized to enforce regulations of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, including that of Regulations No. R. 1089 of 1992. In addition, the National Health Act, 2003 (Act 61 of 2003) indicates under its definitions that food control enforcement is a responsibility of local municipalities. EHPs of provinces and local municipalities collect samples and submit to forensic chemistry laboratories managed by the National Department of Health. In addition, provinces and local authorities must budget for collecting and courier of samples to laboratories, which adds extra burden on the budget of the particular Department of the provincial or local authorities.

However, compliance monitoring of veterinary drug MRLs by the Department of Health (as conducted by Provinces or local municipalities) is not routinely conducted except for testing of antimicrobials in honey, a recent requirement (Campbell, 2009, personal communication), and this could be attributed to, among other reasons, the lack of analytical testing capability by the Department of Health laboratories (Campbell, 2009, personal communication; Tholo, 2009, personal communication).

Other specific activities within this risk management strategy like issuing of fines, ban, seizure, and destruction of foodstuffs and/or refusal to allow entry of the foodstuff into the country, if it is not compliant, are addressed in the Foodstuffs, Cosmetics and Disinfectants Act, 1972. The Act allows for fining manufacturers (with no stipulation of maximum fine) for noncompliant foodstuffs as well as destruction of the condemned foodstuffs. Foodstuffs not compliant and presenting at ports of entry are also refused entry if not compliant or of poor quality. However, even though these stipulations do exist, since sampling and analyses are rarely conducted, these are not currently applicable for veterinary drug residues.

Residue Monitoring

Residue monitoring involves the sampling of foodstuffs to determine trends in use of veterinary drugs and to identify areas for further and directed monitoring (WHO/FAO, 2009). Residue monitoring also provides information on whether veterinary drugs have been used according to the label or whether off-label use is prevalent in the country. Usually only one, or a few veterinary drugs are chosen and tested for in meat and meat products. No enforcement or follow-up actions are typically

carried out in residue monitoring. The WHO/FAO, (2009) indicates further that monitoring and sampling relating to residues like directed sampling, special or pilot surveys, and targeted sampling. These are either for determining trends of residues in foodstuffs or to investigate in detail the accumulated levels of residue in a combination of foods after preparation. Sometimes there is little distinction between residue monitoring and compliance monitoring and the two can be combined. Countries that have indicated programs include mainly developed countries like the EC under Directive EC 90/23; Canada through the National Chemical Residue Monitoring Programme, or NCRMP; the USA through the National Residue Program of the Food Safety and Inspection Service; and New Zealand under the Food Residues Surveillance Program, where it is less common in developing countries.

The Department of Agriculture, Forestry and Fisheries (DAFF) has a National Residue Export Control Programme which tests for residues of chemicals (including veterinary drugs) in carcasses intended for export as well as a small, very limited, residue monitoring program for animal products consumed in South Africa due to financial constraints of analyzing large samples. However, residue monitoring is conducted by private retail and manufacturing companies, particularly for substances like antibiotics in milk since antibiotics may hamper production of cheese and yoghurts that require start up cultures (Cogan, 1972).

Extension or Outreach Services

Extension or outreach services within the context of veterinary drug and residue regulation is discussed here as an RM strategy largely because the FAO/WHO, (2003) text indicates that Information, Education, Communication and Training (IECT) functions should be a part of a food control system where various stakeholders are informed, educated, and trained on food-control issues. IECT functions of government, particularly to rural and small-holder farmers of developing countries, allows for encouragement and/or specific training for the establishment of animal health-management strategies which are fundamental for controlled use of veterinary drugs.

Due to the existence of parallel subsistence and commercial farming in South Africa, the former of which usually exists as small-holder or rural-based farmers (Gehring et. al., 2002), awareness is much more important. Subsistence farmers are typically poor, live in rural areas away from resource centers, have high levels of illiteracy, and have generally limited access to resources for the rearing of their livestock (Gehring et. al., 2002; Keyyu et. al., 2003; Jones, 2009, personal communication). Bearing in mind the existence of subsistence farming together with the understanding of government's requirements for enhancing rural or small-holder farmers in South Africa, outreach, communication, and education is an important RM strategy for enhancing these farmers' awareness on animal food production techniques, use of veterinary drugs, and impact of residues on human health.

In South Africa, DAFF conducts extension services through extension officers who typically provide information on animal production while animal health technicians together with regional veterinary practitioners provide information and assistance on animal health including use of veterinary drugs. However, because these outreach services are provided by DAFF, they are limited to information of agricultural legislation and techniques and the impact of veterinary drug residues to human health is not extended to farmers. Outreach activities are also conducted by the Farm Unit of the National Council of Societies for the prevention of Cruelty to Animals (NSPCA) (Jones, 2009, personal communication) with some manufacturing companies also having outreach programs. Although the Directorate: Food Control has a designated official for IECT functions, little has been done on communication and education regarding veterinary drug regulation and residues as compared to IECT material for general food hygiene and food preparation.

Risk Communication

Risk communication is not specifically legislated under any one of the three Acts, but aspects of compulsory communication, for example, between the Medicines Control Council (MCC) and the applicant, are legislated in Act 101 of 1965. The Section that administers the Act, called the pharmaceutical and related product regulation and management, is actually a communication structure although largely for communication between applicants and the MCC. Similarly, Act 36 of 1947 legislates communication between applicant and Registrar as well as other individuals or bodies constituted in terms of the Act like appeal boards. Communication for other stakeholders, particularly the public, is however not legislated nor a constant function under either of these Acts. However, the Department of Agriculture, Forestry and Fisheries (DAFF) has extension services which are a part of risk communication although this is limited to communication to farmers and to communication of only agriculture-based knowledge and techniques.

Act 54 of 1972 also has no legislated communication requirements and existing communication is limited to provinces and local authorities who enforce regulations of the Foodstuffs, Cosmetics and Disinfectants Act, 1972. However, information on the function and services provided by both registration authorities and Act 54 of 1972 are available on their respective Departmental websites.

DISCUSSION

The application of the risk analysis framework to the overall structural-functional relationship of the veterinary drug and residue system provides insight into the various challenges of the system. These include inconsistent risk assessment processes between the two registration Acts, lack of, or poor compliance monitoring (due to inability of laboratories to analyze samples),

limited residue monitoring under the national residue program, limited extension services, poor updating of MRLs due to human capacity constraints and non-defined risk communication strategies, particularly to the public. Although challenges like the updating of MRLs and analyses capability of the DoH laboratories can be attributed to lack of technical, financial or human capacity which can be addressed through training and adequate budget allocations, the majority of challenges can still be addressed through collaboration and communication to structure resources for better functioning. The inability to communicate and collaborate on common issues highlights the results of the review of the system under the risk-analysis framework which show the presence of fragmented structures (between DAFF and DoH), functions (duplicated or similar functions of the DAFF, DoH and local authorities) and legislation (Acts 36 of 1947, 54 of 1972 and 101 of 1965), a characteristic previously described for the entire food control system (Chanda et. al., 2010).

Considering the fragmented structure, function, and legislation through which risk assessment, management, and communication occur, collaborative integration will form the basis for suggestions to address challenges not limited to capacity constraints.

Risk Assessment

Risk assessments between the VCC, Directorate: Food Control and Department of Agriculture, Forestry and Fisheries (DAFF) are rarely collaborative which sometimes results in registration of the same products under two different registration Acts. Regarding structures, only the Department of Health has a defined risk assessment body, the VCC (or BC), to conduct risk assessment. In both DAFF and the Directorate: Food Control, there are no defined risk assessment structures, which is expected, as they are not legislated under Acts 36 of 1947 and 54 of 1972. For risk assessment structures and functions to be carried out efficiently as per guidelines of the FAO/WHO, (2003), the first step needs to be the legislating or documenting of collaborative risk assessment, if they are not combined altogether. It is suggested that this could be initially legitimized through signing of memoranda of understanding (MoU), which are currently utilized agreements in government for specific shared functions. This would also address the inconsistency in risk assessments conducted by both DAFF and DoH in terms of peer reviews, control of access of drugs by scheduling, and separation of both risk assessment and risk management. For registration and control of access of veterinary drugs, these too can be made more collaborative across the two registration Acts so as to streamline resource-intense functions.

Risk Management

The processes of risk management in terms of both structures and functions are also fragmented between the two registration Acts and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 that mandates each Department or section to conduct their own risk management (RM) functions. These RM strategies are, like the risk assessments, not collaborative, which means that where resources could be pooled they are distributed so that they are not efficiently utilized. For example, inadequate compliance monitoring of veterinary drug MRLs by the Department of Health (as conducted by Provinces or local municipalities) and the limited residue monitoring for the country conducted by DAFF could be addressed by pooling sampling and analyses resources (use of the parastatal laboratory at the Onderstepoort Veterinary Institute (OVI) and utilization of EHPs and agricultural inspectors for sampling). It is suggested that this too could be done through memoranda of understanding. In addition, the DoH and DAFF should obtain information from the many food retailers and manufacturers of the country that routinely conduct monitoring on foods, sold or produced. This will provide valuable data required to determine usage of veterinary drugs and compliance to published MRLs of foodstuffs.

Pooling of resources, where fragmentation in both structures and functions exist, can also be conducted in the RM strategy of extension or outreach services. Since extension services do exist through DAFF, the Directorate: Food Control should request that information on the risks of animal production and animal health techniques to human health also be included in information material. Therefore, information to farmers would be holistic with impact of improper use and/or misuse of veterinary drugs being understood.

Lack of collaboration is also a limiting factor for risk-management strategies that need to be implemented but are not. Monitoring for antimicrobial resistance is one of the biggest concerns regarding use of not only veterinary antimicrobials but also antimicrobials used in human medicine. Internationally, this issue has been addressed by the World Health Organisation (WHO), World Organisation for Animal Health (OIE), and the Codex Alimentarius Commission (CAC) under the WHO Global Principles for Containment of Antimicrobial Resistance in Animals Intended for Food, the OIE International Standards on Antimicrobial Resistance, and the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005). In South Africa, it has only been considered at the academic level (Nel et. al., 2004). However, antimicrobial resistance monitoring occurs at medical facilities and through private facilities largely for human medicines. Based on this situation, a streamlined program between the Departments of Health and Agriculture, Forestry and Fisheries, together with private sector units that are already conducting resistance monitoring, should be initiated to address this RM function.

Risk Communication

As indicated in Table 1, the communication of risk relating to veterinary drug residues does not occur through formal channels except from registration authority to the Directorate: Food Control and vice versa (for record purposes and eventual

publication of the residue limit in regulations) as well through publication of MRLs as regulations in the Government Gazette. However, regulations are scientific and it is not known what reach the Government Gazette has on the public. In an effort to pool resources, the Departments of Agriculture, Forestry and Fisheries and Health as well as other stakeholders like retailers and food manufacturers should collaborate on the development and financing of a holistic communication package to the public and farmers. This consolidates communication material and reinforces the message of risks related to veterinary drug residues to the public. To some extent, although not directly involving the public, collaborative risk communication does occur between food associations, retailers, the Directorate: Food Control, and the Department of Agriculture, Forestry and Fisheries through meetings of the Food Legislation Advisory Group (FLAG) hosted by the Department of Health.

CONCLUSION

The variety of challenges in the system of veterinary drug and residue regulation is linked to the fragmentation of structures, functions, and legislation, which are prohibitive to communication and collaboration, essential aspects for a functioning system. The presence of inadequate horizontal communication is indicative of poor awareness and conceptualization of how the various legislation, structures, and functions for veterinary drug and residue control function as a system. This is limiting as without the understanding of shared functions, departments and sections tend to isolate their functions, which is apparent within the veterinary drug and residue regulatory system. This in turn deepens fragmentation and poor communication, which results in a cycle of poor communication, poor collaboration, and fragmentation. Thus, as identified challenges are being considered, the recommendation is that collaboration should be the basis for change within the system and this requires that communication, awareness, and conceptualization of the system are addressed first.

Therefore, the risk analysis framework has proved an applicable instrument in defining the challenges related to the South African regulation of veterinary drug residues. It has also assisted in exposing underlying challenges of poor horizontal communication between structures and functions of the system and poor conceptualization and awareness of the system—highly relevant issues that may sometimes be too subtle to identify as fundamental challenges.

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