

LEGISLATION FOR VETERINARY DRUGS CONTROL

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Introduction

Quality, safety and efficacy (or effectiveness) – these are the three main concerns of veterinary drugs control. Among the risks for a country of the ineffective regulation of its drug supply are :

- introduction of drugs of unknown quality – in some cases counterfeit, unlabelled or expired drugs, drugs withdrawn from sale in other countries and being dumped or drugs produced cheaply without the necessary regard for quality;
- inadequate labelling of drugs (a particular problem where many people are illiterate), so that users are not properly informed on dosage, expiry date, dangers and precautions;
- breach of special requirements (e.g., refrigeration) for storage of certain drugs;
- failure to observe withholding periods, that is, the period after an animal has been treated with a drug, during which its products (meat, milk, eggs) must be withheld from the market;
- use of drugs after their expiry (or “use by”) date;
- drug residue build-ups in livestock products – a threat to local consumers and to export markets.

Frequently these problems have a cascading effect – a drug which is inadequately labelled is inappropriately used, so the animal is ineffectively treated, but resistance is developed in the animal and in humans consuming the animal’s products.

While veterinary drugs control is not a new subject for legislation, increasing attention has been given in recent years to the subject, and indeed to veterinary legislation in general. Outbreaks of foot and mouth disease (FMD) and mad cow disease (bovine spongiform encephalopathy - BSE) in Europe show that biosecurity¹ concerns affect not only developing countries, but have major social and financial impacts on developed countries as well. The broad topic of veterinary legislation covers animal disease control, control of veterinary drugs, regulation of the veterinary profession and the control of animal feeds.

A recent study by the FAO Legal Office (FAO 2002) observes a number of trends which have affected the incidence and control of animal diseases world-wide over the last decade, the main ones being increases in the movement of animals as a result of improved transport systems, structural adjustment programmes in many countries (e.g., privatisation) which have reduced official animal health services, political instability and climate change (ibid., 53-56). Apart from these “empirical changes”, the study notes that new international agreements (e.g., under the WTO), and new programmes and organisations also address veterinary issues (ibid., 57-65). As a result of all these developments, many countries have sought FAO assistance in revising their veterinary legislation.

This paper stems from the author’s experience since 2000 as an FAO consultant advising governments in three developing countries (Mozambique, Rwanda and Nepal) on their veterinary legislation, in particular that controlling the supply of veterinary drugs.² Because of the international dimension of drug manufacture and supply, this technical assistance involved examining not only the existing legislation in the countries concerned, but also the corresponding laws of neighbouring countries either where the drugs originated or through which they travelled in transit. The paper draws on that experience, but veterinary

¹ In FAO terminology, “biosecurity” involves the strategic management of biological risks in food and agriculture – in its broadest sense – in order to achieve food safety and protection of the life and health of animals and plants, as well as the environment.

² The Final Reports on each consultancy are FAO 2001 (for Mozambique), FAO 2003 (for Rwanda) and FAO 2003a (for Nepal).

drugs laws from other countries will also be included in the study, with a view to getting a more representative range of experience both geographically and in level of development.

The aim of the paper is to provide helpful background to governments contemplating a review of their veterinary drugs legislation, on the main issues involved and the options available for dealing with those issues. It should, perhaps, be stressed that the paper is not intended to present a "model" for drafting a veterinary drugs law. While certain conclusions are drawn in the paper on how (in the author's view) the various matters should be addressed, in the end it is a matter of tailoring a law to suit the particular needs and circumstances of the country concerned. There is no substitute for careful consideration of these matters in each case.

The paper begins with a discussion of the goals of veterinary drugs control, looking at where the subject lies within the general topic of animal health, and how drugs control relates to other topics such as human health. When drafting veterinary drugs legislation, lawyers (like the author) need to get the technical advice of veterinary surgeons, pharmacists and drug administrators, but they also need to understand the domestic and international legal framework within which the proposed law must operate. Drugs are one chemical input in animal production; insecticides, animal feeds and fertilizers are others. How does veterinary drugs control relate to the regulation of these chemicals? Drugs control covers not only drugs for use on animals but also drugs for human use. How does the veterinary drugs regime relate to the regime for controlling human drugs? A further aspect is that the proposed legislation must be appropriate to the particular needs and circumstances of the country concerned. These matters will be examined in the paper. The relevant international agreements and organisations relating to animal health, veterinary drugs and trade will also be considered.

The paper will then identify the main legal and institutional issues involved in veterinary drugs control, in particular in regulating the manufacture and import of veterinary drugs, their distribution around the country, and their provision to the buying public. How various countries have addressed these issues will be shown during the treatment, and for this purpose the following countries have been chosen:

- Africa: Botswana, Malawi, Mozambique, Rwanda, South Africa, Zambia and Zimbabwe;
- Asia : Nepal and Sri Lanka;
- Pacific : New Zealand;
- North America: the Province of Alberta, in Canada.

This selection covers a number of regions and different levels of development. Although the attempt was made to select a representative sample, the above list includes three countries where the author has drafted veterinary drugs laws, while other countries were selected because their legislation was readily available. The laws included in the study are listed in the Annex.

The final part of the paper mentions some operational aspects (e.g., staffing, facilities, and public awareness-raising) which will need to be considered in planning and implementing veterinary drugs laws.

The goals of veterinary drugs control

The broad goals of controlling drugs used on animals are to preserve the health of the animals, improve animal production and protect public health. Veterinary drugs control is, however, only one aspect of these broad subjects of public policy and legislation, and the real goals of veterinary drugs control are much narrower. The scope of a veterinary drugs law is determined by its goals, so it is important to distinguish the goals of veterinary drugs control from the broader goals of promoting and protecting animal health, animal production and public health. A few words will now be said on the place of veterinary drugs within these broader topics.

Animal health and veterinary drugs. Animal health relies heavily on veterinary drugs for controlling pests and diseases, but an animal health law extends much further. Its main concern is the movement of animals and animal products, which can be the vectors for transmission of pests and diseases within and between countries. Such laws typically provide the veterinary authorities with strong powers to control animal movements, inspect animals and place them in quarantine, and even to destroy infected animals, animal products and equipment. A country's status as free - or relatively free - of major pests and diseases can have enormous trade benefits, so the laws are usually enforced rigorously by the national authorities, and scrutinised carefully by international bodies to ensure that they are not used as unfair restraints on trade. Some countries (e.g., Australia and Malawi) are developing more extensive stock registration systems, so that individual animals and their products can be traced from abattoirs, etc., back to the farms where they originated. These measures have obvious advantages for disease control, but also for improving the country's reputation for disease-free products.

Animal production and veterinary drugs. Just as veterinary drugs contribute to animal health they also contribute to increased animal production, but clearly there are many other contributing factors. The drugs are administered to the animals by veterinary surgeons, government officers or private operators with some technical training, and often by the owners of the animals themselves. Requirements for their safe and effective administration will depend on the particular drug, but the question of who can carry out various veterinary procedures also arises, so the subject of veterinary practice regulation is also involved in animal production – as, indeed, it is in animal health. Another subject which overlaps both animal health and animal production is animal feeds. Laws on this subject regulate the manufacture and supply of animal feeds, and the raw materials used in their production. Certain additives are prohibited, or restricted for use on particular species only. Another overlap is involved here, with the next topic of human or public health.

Public health and veterinary drugs. By eating animals and animal products (meat, milk, eggs, etc.), humans are liable to consume whatever chemicals the animal has consumed or been exposed to – veterinary drugs, but also insecticides used on the animal, herbicides and fertilizers used on pastures and chemical additives used in its feed. Some of these substances are toxic (in particular, pesticides and herbicides), and some are undesirable in other ways for use on animals whose products are consumed by humans. The human health consequences of chemical residues in animals is a subject which is hotly debated, between farmers, chains of food suppliers, pharmaceutical companies, drug regulators, public health administrators and consumer groups. Not only is there disagreement among interest-groups within countries, but between countries the impact of a drug ban on trade in animal products ensures that a country's motives for banning certain drugs will be questioned. The European Union, for example, in 1999 banned all antibiotics used on humans from being used on animals as growth promotants (AGPs), and similarly the EU has banned the use of hormonal growth promotants (HGP) on cattle. The USA, Canada

and Australia allow such hormone use (subject to maximum residue levels), and the EU is in a World Trade Organisation dispute with the USA over its ban.

The two main substances of concern in this debate are hormones and antibiotics. As a general rule, hormone use on animals (mainly cattle, pigs and poultry) is confined to intensive-management farming (feed-lots, etc.), where oestrogen-like hormones are used purely to grow the animal out more quickly and economically. While it has been argued that some hormones are carcinogenic, or can lead to the early onset of puberty, their supporters maintain that, when used according to good veterinary practice, they present no risk to the public. It is said that people already eat naturally-occurring hormones at a higher concentration than those found in cattle given HGP.

The concern over antibiotics is more serious, and the risk of over-use of antibiotics is not so open to doubt. Use of antibiotics such as penicillin on animals increases the potential for penicillin-resistant bacteria to develop in the animal products, which in turn could make humans consuming those products less responsive to future penicillin treatment. Use of cautious terms like "potential" and "could" shows that there is still disagreement over the health risks, however, and it is argued by some that the risks have been exaggerated. For example, the body Food Standards Australia New Zealand, which sets the maximum levels at which antibiotics can be present in food in those two countries, claims it is highly unlikely that the consumption of antibiotic residues in food would lead to the development of resistance, because antibiotic residue levels in the food are already very low, and are likely to be further reduced by cooking and other food processing and also by metabolism in the gut. The EU is not convinced, and as mentioned in 1999 it banned the use of antibiotics in animal feeds – but only those which were also used on humans, and only where they were used purely for growth promotion.

The guarded approach taken by national and regional bodies to restrictions on the use of veterinary drugs, particularly in the face of potential serious and long-term risks to human health, is evidence that major economic considerations and powerful interest-groups are involved. International organisations have long been interested in animal health issues, including the use of veterinary drugs. The Office International des Epizooties (OIE, now called the World Animal Health Association), created in 1924, is an intergovernmental organisation which collects and distributes information on animal diseases to its 158 member states, and assists them with their disease control activities. It also sets the internationally-recognised standards for animal health and trade. The Codex Alimentarius Commission (Codex), a subsidiary organ of FAO and WHO, develops the internationally-recognised standards for food safety, including for veterinary drug and pesticide residues in food.

Most recently the international emphasis has been on trade liberalisation, and barriers to trade have, therefore, been under scrutiny. Controls on the movement of animals and animal products, and on such products when they have been treated with certain chemicals, are clearly barriers to free trade. In accordance with World Trade Organisation requirements, however, - in particular the Agreements on Agriculture, on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), and on Technical Barriers to Trade - such controls are acceptable provided that they are based on international standards (as set by the OIE and Codex), or can be justified on scientific grounds. At the international level, these are the main requirements which a veterinary drugs law must now meet.

So the goals of veterinary drugs control are to be met within a wider framework of international obligations, and a national framework of a country's domestic laws on animal health, animal production and human health. With respect to the drugs themselves, it is widely recognised that the goals of regulating the supply of veterinary drugs are to guarantee

their quality, safety and efficacy at the time of their administration to the animal. In a 1993 FAO publication, these terms were defined as follows:

- Quality means that medicines must be manufactured with appropriate quality control procedures, in premises that are inspected and licensed; the ingredients must be of appropriate purity, in the correct proportions and correctly processed; the containers must be robust with secure closures; and the labelling must be accurate and informative.
- Safety is interpreted widely, to include the animal being treated and in-contact animals; the user, including the veterinarian, farmer or pet owner administering the medicine; the consumer of livestock products from treated animals; and the environment.
- Efficacy means that the medicines must be effective against the diseases, in the species of animals, at the dose rate, frequency and duration of treatment, and by the route of administration claimed by the manufacturer. (FAO 1993:349-50)

These, then, are the goals which must be met by a veterinary drugs law, and the lawyer's role in drafting such a law is to design a legal instrument which enables the technically-qualified experts to make all the decisions necessary to achieve those goals.

The legal and institutional issues

The main legal and institutional issues involved in the regulation of veterinary drugs arise with respect to the following :

- i) scope of the law;
- ii) definition of the key concepts;
- iii) drug administration;
- iv) drug registration;
- v) classification of veterinary drugs;
- vi) manufacture, import, distribution and sale;
- vii) enforcement.

This part of the paper will examine how the veterinary drugs laws from a range of countries have dealt with the key issues in the above list, and draw some conclusions.

i) Scope of the law

In the preceding part, the point was made that the scope of a veterinary drugs law is determined by its goals – that is, to guarantee the quality, safety and efficacy of the drugs. It was also seen that veterinary drugs control is part of a number of wider topics (in particular, animal health, animal production and public health), and that veterinary drugs are only one of a number of chemical substances taken in by animals, others being insecticides, herbicides and feed additives. In some countries, the legal provisions which apply to veterinary drugs are incorporated in a law covering these wider topics, or these other substances. A number of countries in southern Africa, for example, handle the control of animal drugs within their law covering the control of drugs generally, for both animal and human use. South Africa, Zimbabwe, Malawi, Tanzania and Zambia all have one main law - and a single agency - dealing with all medicines and other drugs, whether for use on animals or humans, and other countries in the region (Botswana, Mozambique and Swaziland) are moving in that direction. The New Zealand law applies to all agricultural compounds and veterinary medicines, terms which are given wide meanings and include pesticides, fertilizers and stock feeds. A related development (possibly inspired by the US Food and Drug Administration) is the trend to include animal health, plant health and food safety under the control of a single agency.

This paper is a study of laws for veterinary drugs control, and the fact that particular laws have gone beyond that subject into related fields is not a critical consideration for the purposes of that study. For example, there may be strong practical reasons to combine the control of veterinary drugs with the control of human drugs - because such an approach can allow a more rational use of technical facilities and skilled staff. From a legal viewpoint, however, whether a single agency controls all drugs, or veterinary and human drugs are handled by separate agencies, is a relatively minor issue. In the following treatment, differences in the scope of different laws will be noted, but the concentration will be on how the laws deal with veterinary drugs, and the fact that the laws might also deal with other matters is mainly incidental. The matters usually covered with regard to veterinary drugs are the introduction of drugs into the country (by manufacture there or by importation from outside the country), their circulation in the country, and their supply to the end-user. Each of these main activities can be divided into separate aspects, as will be seen below.

Also incidental to a veterinary drugs law is the matter of veterinary practice. Of course, how the drugs are administered to animals is a relevant question, and the law's provisions regulating the availability of veterinary drugs will have some bearing on that question. But it would take the law beyond its main concerns (drug quality, safety and efficacy) if aspects of veterinary practice were also included.

Other things usually excluded from a veterinary drugs law are hazardous drugs and dangerous substances. While some of these (e.g., anaesthetics) are commonly used on animals, because of their dangerous nature and the fact that they are covered by international treaties they are usually given special treatment in laws of their own, so it is preferable to leave them outside the veterinary drugs law. At the same time, it is usual to include insecticides which are manufactured for use on animals within the scope of a veterinary drugs law. The same substances may also have industrial or horticultural uses, but matters like their strength will vary considerably depending on their use, and different information is needed on how they should be used. For different reasons, the provisions of a veterinary drugs law are usually not applied to ayurvedic (herbal) medicines and other traditional animal remedies. Sometimes (as in Nepal) these are covered by their own legislation, but it is generally not desirable for a law regulating modern drugs to apply to traditional remedies administered in accordance with customary usage.

In conclusion, the scope of a veterinary drugs law should –

- include all drugs (including insecticides) manufactured for administration to animals;
- not include hazardous drugs and dangerous substances, where these are already covered by their own legislation;
- not include traditional animal remedies administered in accordance with customary usage;
- not include aspects of veterinary practice, beyond what is involved in limiting the availability of certain drugs.

For the avoidance of doubt, it is useful for the law to state specifically what it includes and what it does not.

ii) Definition of the key concepts

When drafting a law on a particular subject certain concepts are always central, and they may be used in the legislation with specific meanings. By defining these key concepts at

the beginning, the precise meaning they will have through the rest of the law is made clear. In the case of veterinary drugs legislation, the key concepts are “animal” and “veterinary drug”.

“Animal”: If the scope of the proposed law is confined to veterinary drugs, then it should be clear that it applies only to drugs intended to be used on animals.³ Some countries prefer to list those species covered by the definition. For example, the definition in the Sri Lankan law reads –

“animal” means cattle, buffalo, sheep, goat, pig, fish, horse, mule, ass, dog, cat, bird, bee and includes any other animal domesticated or wild whether kept in captivity or wild or under control or otherwise.

The definition has a number of elements – it lists the common domesticated animals, including pets (sometimes referred to as “companion animals”), and the definition adds bees, which are insects, but ones with economic importance as producers of honey. Then the definition adds a clause to include other animals, whether domesticated or wild – a sort of “catch all” provision. If the intention is to embrace all animals other than humans, a better approach may be to follow the New Zealand example, which reads –

“animal” means any living stage of any member of the animal kingdom except human beings.

“Veterinary drug”: The term used varies; sometimes “veterinary medicine” is used, and in some countries (e.g., Sri Lanka) a division is made between “veterinary drugs” and “veterinary biological products”. Some definitions are lengthy, but the Zimbabwean definition is concise, clear and comprehensive –

“veterinary medicine” means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in –

- (a) the diagnosis, treatment, mitigation or prevention of disease or abnormal physical or mental state or the symptoms thereof in an animal; or*
- (b) restoring, correcting or modifying any physical, mental or organic function in an animal.*

The definition used in the Canadian Province of Alberta is even more concise (although it is confined to production animals) –

“medicine” means drugs, vaccines and biological supplies for the prevention, treatment, control or eradication of disease in production animals.

Some countries specify in their definition that the term does not include animal feeds or instruments, etc., used on animals.

Whether the definition should include pesticides used on animals is something for each country to decide. Pesticides are used on animals for the control of insects (e.g., biting flies), arachnids (e.g., ticks) or other pests in or on their bodies (e.g., worms), so substances used for dipping, drenching or pouring on the skins of animals could be treated as veterinary

³ There may not be any need for a separate definition of “animal” if the proposed law will apply to all drugs, for use on both animals and humans.

drugs. Where the same substances also have other uses (e.g., industrial), it may be necessary to regulate the substances under both the veterinary drugs law and the general pesticides law. A similar situation exists with many drugs (e.g., antibiotics) which are used on both animals and humans. The drug will be packaged differently for its different uses, and the dosage, instructions and so on will be different for its use on humans and on animals, so it makes sense to regulate the drug under both the animal and human drug systems. Much depends on the scope of the proposed law, and whether it is part of a broader law covering drugs and chemicals for uses in addition to treating animals.

Other terms may also be defined, for clarity or convenience. For example :

“Manufacture”: Because the character of the drug, and the accompanying instructions on its use, can be affected by certain changes in its original form, it is usual to provide along the lines of Botswana’s proposed law –

“manufacture” includes all operations involved in the production, compounding, formulation, filling, packaging, re-packing and labelling of a veterinary drug”.

The point of this extended definition is that any such processing of the drug is also covered by the requirements which apply to its manufacture. The goals of quality, safety and efficacy can thereby be safeguarded.

In conclusion –

- “animal” should be widely defined, to include all commercial, domestic and wild animals, fish and insects which are likely to be treated with veterinary drugs;
- “veterinary drug” should also be widely defined, to include :
 - drugs, insecticides, vaccines and biological products,
 - used or presented as suitable for use,
 - to prevent, treat, control or eradicate animal pests or diseases, or
 - to be given to animals to establish a veterinary diagnosis, or
 - to restore, correct or modify organic functions.
- “manufacture” should be widely defined, to include formulation, filling, packaging, re-packing and labelling of veterinary drugs.

iii) Drug administration

In some countries the veterinary drugs law is part of a system for the regulation of all drugs, while in others the law concerned deals only with veterinary drugs. In the former case, it is usual to put the administration of the law under the authority of the local Ministry of Health, but it is also usual to provide that the decisions on veterinary drugs are made by a specialist body. If the law deals only with veterinary drugs, then it usually comes under the authority of the local Ministry of Agriculture. Examples of each approach will now be considered, but it should first be stated that there is no consensus on which approach is

preferable. In southern Africa, for example, a review conducted by the author of eight SADC countries in 2000-01 showed that seven of them (South Africa, Botswana, Zimbabwe, Malawi, Tanzania, Zambia and Swaziland) had a single agency for both animal and human drug administration, while Mozambique was planning to move in that direction. The likely explanation is that Mozambique is the only one of the eight without an historical British connection. The long-standing UK practice is to combine the regulatory systems for human and animal drugs (while making special provision for the latter). On the other hand, the practice in a wide range of countries – Argentina, Chile, Peru, Belize, Mexico, Estonia, Algeria, Jordan, Republic of Korea, New Zealand and Sri Lanka – is to place the regulation of veterinary drugs under their Ministries of Agriculture.⁴

South Africa is an example of the “single agency” approach. The South African Medicines and Medical Devices Authority is made responsible for the control of all medicines, including medicines for veterinary use. The Act is administered by the Minister of Health, but it is provided that, in relation to a matter concerning veterinary medicines, the Minister must act in consultation with the Minister of Agriculture. The affairs of the Authority are managed by a Board, one of whose members represents the Minister of Agriculture. The Board is advised by Standing Committees, one of which deals with veterinary medicines.

Sri Lanka is an example of the “separate agency” approach. The Veterinary Drug Control Authority controls the manufacture, import, export, sale and use of veterinary drugs, issues licences for their manufacture or importation, carries out tests, advises the Minister of Agriculture, promotes research and disseminates information. The Authority is chaired by the Director of Animal Production and Health (required to be a veterinarian), and other members include a representative of local veterinary drug manufacturers and specialists in pharmacology, parasitology and clinical practice.

As mentioned, it is an open question whether the “single agency” or “separate agency” approach is preferable. The following reasons are given in support of the “single agency” approach:

- the great overlap between human and animal medicines, with the same concerns over quality, safety and efficacy applying to both;
- correspondingly, the same (or very similar) criteria are involved in deciding on their manufacture, import, sale, labelling, advertising and so on;
- a single body can share information, personnel, facilities;
- interdisciplinary issues (e.g., whether a particular drug should be reserved for treating humans only) can be resolved better by a single body, taking account of all the relevant considerations;
- having separate systems opens the way for abuse, with drug registrations being sought under the less demanding system;
- in general, a desire to avoid unnecessary duplication (in personnel, facilities, etc.), with the corresponding extra costs involved being passed on to the consumer in higher prices for drugs.

Against this, it is argued that veterinary drugs always receive the lower priority if they are administered together with human drugs under the control of human health authorities, and this causes delays in the processing of veterinary drug matters.

⁴ Information supplied by FAO's Animal Health Service.

It is true that many of the above reasons for a single agency can be met within a system with separate agencies for animal and human drug administration, provided there is good co-operation between the two agencies. This can be facilitated by cross-membership – with each agency having someone from the other agency among its membership – and sharing of facilities. There is no doubt, however, about the necessity for veterinary drugs to be given special treatment, either by having their own special agency, or by having the decisions on veterinary drugs within a single agency made by a special body. This is because of the special considerations which apply to veterinary drugs as distinct from human drugs. Thus –

- a) Animals and animal products are eaten by humans, and any chemicals in the animals can be passed on to humans. For some drugs, it is important to specify the withholding period (WHP), during which the animal or its products should not be consumed.
- b) Some drugs are only used on animals, for treating pests and diseases which do not occur with humans.
- c) The priorities may be different where the drug is to be used for veterinary use.
- d) Drugs can have different effects on different animal species. They may affect animals differently from humans, and some animals differently from others.
- e) It is important to monitor drug use on animals, and rotate drugs to reduce the chance of resistance to a particular product building up.
- f) Dispensing arrangements for veterinary drugs are usually different. Unlike doctors, veterinarians commonly prescribe the drug, supply it and administer it to the animal.
- g) Veterinary drugs are often administered by the farmer. This means that particular attention must be given to labelling, so that the farmer is clearly informed on dosage and the necessary course of treatment, the expiry date of the drug, and any special handling requirements (e.g., refrigeration) to maintain the drug's efficacy or to safeguard the person administering the drug.

In conclusion, on drug administration –

- international practice varies, between having a single agency to administer all drugs and having separate agencies for animal drugs and human drugs;
- having a single agency for both offers greater opportunity for rationalising drug administration, avoiding duplication and gaining practical benefits (e.g., sharing facilities); at the same time, these advantages can largely be achieved under separate agencies, provided that there is good co-operation between them;
- whether a country adopts a single or a separate agency approach is, therefore, mainly a matter of what fits in best with the existing laws, local institutions and informed choice;
- if a single agency approach is adopted, it is essential that the decisions on veterinary drugs be made by a specialist body, to take into account the special considerations which apply to veterinary drugs.

iv) Drug registration

The general international practice is for drugs to be registered, before they can be introduced to a country for any manufacture, importation, distribution and sale there. Many countries operate a system for registering the drugs, while others issue product licences. Some countries give priority for registration to products contained in an "Essential List of Veterinary Drugs", that is, a list of the drugs considered to be essential for the country concerned, based on its livestock needs and circumstances. The main steps involved are application for registration; evaluation of the application and decision whether to register the drug; and registration of approved drugs. Before discussing each of those steps, however, it should be emphasised that registration is the critical step in a country's drug administration system, and, with a few exceptions to deal with emergencies or special circumstances, everything important (manufacture, importation, distribution and sale) depends on whether a drug has been registered under the process prescribed by the law or not.

(a) Application for registration

There is a fairly standard set of details which a person must provide, when applying to register a drug. Apart from details of the applicant (name, address, contact details, etc.), detailed information is commonly required in order to compile a dossier on the drug, in particular –

- its name, ingredients, manufacture, pharmacology, toxicology;
- its registration details elsewhere;
- its purpose, route of administration, dosage, side effects, contra-indications;
- its container, packaging and labelling.

Further information may also be required on the country of its origin, what trials and tests have been conducted, its claimed shelf life, directions for its use, particular hazards, package inserts, proposed advertising and promotional material. Some countries require that the applicant have a registered office in the country.

As for further provisions, Zimbabwe's law provides that products must be registered in their country of origin before they can be registered in Zimbabwe. Malawi provides a simpler ("fast track") form for registration of products already in widespread use in other countries with a recognised, reliable drug registration system. In Mozambique, products already registered in EU countries and the USA get such preferential treatment, allowing speedier registration of the drugs with less demand on officials.

(b) Evaluation of the application and decision

Applications for registration are considered by the drug administration agency or its specialist committee on veterinary drugs, and a decision is made on whether trials or testing must be conducted in the country concerned. Because the membership of this body represents the technical and other interest-groups qualified to make decisions on drug registration, it is not necessary for the law to spell out in detail the matters they must address. Some simple statement of the objectives of drug registration might be included, however, along the lines of this provision in a proposed law for Nepal –

The registration of veterinary drugs has the objectives of ensuring that the veterinary drugs authorised to circulate in Nepal are safe, effective, of good quality and in a form appropriate to the real needs of the people.

New Zealand's law does specify the matters which must be addressed in deciding on an application to register a "trade name product" (the term used by the NZ law, which includes veterinary drugs). The decision is made after considering "the risks and benefits" likely to result from use of the product, and the law provides -

The only risks and benefits relevant to [that decision] are –

- (a) risks to trade and market access for primary produce containing any substance, mixture of substances, or biological compound that forms a part of the trade name product;*
- (b) risks to agricultural security;*
- (c) risks to the welfare of animals which result from treatment with or exposure to any substance, mixture of substances, or biological compound that forms a part of the trade name product;*
- (d) risks to domestic food residue standards;*
- (e) the benefits of the trade name product and the likely consequences of the public not having access, or having restricted access, to the trade name product, including consideration of whether alternative means of achieving the stated purpose of the trade name product are available.*

A tool found useful in some countries is the "Essential List of Veterinary Drugs". The nature and purpose of Essential Lists are apparent from the proposed Rwandan provision –

The Ministry [of Agriculture] shall compile an essential list of veterinary drugs, which shall contain the veterinary drugs considered as essential for the nation, selected with regard to the most common pathologies, veterinary concerns and economic criteria.

The essential list shall be compiled according to a recognised form of pharmacological classification.

The essential list shall be reviewed and updated by the Ministry from time to time, so as to remain relevant to the current needs for veterinary drugs in the nation.

Veterinary drugs comprising substances on the essential list shall be given first priority for registration.

As can be seen, the main purpose of an Essential List is to assist in prioritising drugs for registration. Drugs not on the Essential List can still be registered, but they will not be given any priority.

Two other relevant issues are what it is that is being registered, and what is the difference between a registration and a product licence. The first question relates to the scope of the law (see above), and in particular the definition of "veterinary drug". Some countries define the term as referring to substances (e.g., the Zimbabwean definition, above),

some define it as referring to products (e.g., the term “trade name product” used in New Zealand – see above), and some laws cover both substances and products. The term “substance” is more general than “product”, which implies some manufacturing process under which substances (active ingredients, excipients, etc.) are combined to produce the veterinary drug in a form which is ready to be administered to the animal. A substance does not result from a manufacturing process. Raw materials, for example, are substances, and they are not usually administered as such to animals. However, anything which is administered to an animal for therapeutic (healing) purposes - whether a substance or a product - should go through the veterinary drug registration process, so it is important that the definition of “veterinary drug” encompasses both.

As for the second question, there does not seem to be any important difference in legal effect between registering a drug by giving it a number in a register, and issuing a licence for the drug. The latter may have some practical value to the licensee, but this raises the matter of what consequences flow from registration – whether by one method or the other. The general position is that registration (or issue of a product licence) gives no special rights to the registrant (licensee), as is made clear in the New Zealand law –

The provisions of this Act do not give the registrant of a trade name product ... the sole right to import, manufacture, sell, or use that trade name product.

So, once a new drug has been registered for introduction and circulation in a country, anyone suitable can be authorised to manufacture, import, distribute and sell that drug. The registration is, in a sense, a “public good”, for the general benefit of the public. In a similar way, it is usual to make a registration of indefinite duration, unless it is cancelled for some reason. Against this, however, it might be felt desirable to provide that a drug registration expires after a fixed period (say, 5 years), to allow regular review of the drug and risk assessment based on new information.

At the time of registration, decisions should be taken on the drug’s classification, its packaging and its labelling – matters which will be dealt with below.

(c) Registration

The final step after evaluation is the registration of approved drugs. This is a simple legal step, and some provision may be made for veterinary drugs to be given the prefix “V” (to distinguish them from the same drugs registered for use on humans), and a unique number for each registered drug. Some countries provide an appeal procedure, for applicants whose registration has been refused. It is also usual to make some provision to protect confidential information (trade secrets, etc.) supplied in support of an application to register a drug.

In many countries, all registered drugs are included in a “National Formulary of Veterinary Drugs”. The contents of a National Formulary are apparent from Nepal’s proposed provision –

In compiling the National Formulary, the Veterinary Drugs Advisory Committee shall -

- (a) include all veterinary drugs which are registered at the time of its compilation;*
- (b) designate the veterinary drugs by their generic name or international common denomination;*
- (c) adopt a recognised form of pharmacological classification;*

(d) show, for each veterinary drug, such information on its use, including its classification, active ingredients, route of administration, indications, dosage, counter-indications, side effects and other matters, which the Committee considers are important for users to know.

The National Formulary is a valuable tool for all those involved in livestock production. But it can also have important legal consequences. Thus, the authority to manufacture or import veterinary drugs, and to distribute and sell them in the country, is often confined to those drugs which have been entered in the National Formulary. The main reason is that, without the information about the drug's use that the National Formulary provides, it would not be safe for the drug to be circulating in the country. For flexibility, however, it is desirable to allow exceptions to this rule, as illustrated by Rwanda's proposed provision –

Authorisation to manufacture, import, distribute or sell veterinary drugs in Rwanda may only be granted for registered veterinary drugs which are included in the National Formulary of Veterinary Drugs.

For special reasons and after receiving the opinion of the National Commission for Veterinary Drugs, the Minister may authorise the distribution of a registered veterinary drug not yet included in the National Formulary.

In an animal health emergency, the Minister may authorise the distribution of an unregistered veterinary drug. Such authorisation shall be given for such a period, and upon such terms and conditions, as the Minister regards as appropriate for dealing with the animal health emergency.

In conclusion, on drug registration –

- registration (or issue of a product licence) is the critical step in veterinary drug administration;
- an Essential List of Veterinary Drugs is a handy tool for prioritising drug registration;
- decisions on applications for drug registration are made by the statutory body of technical experts, based on a dossier providing the necessary information on the drug and its uses;
- registration is a “public good”, and does not by itself confer sole rights over the drug on the person registered;
- it is helpful for good drug administration for all registered veterinary drugs to be included in a National Formulary of Veterinary Drugs, together with the basic information on their use;
- in general, only drugs included in the National Formulary should be authorised for manufacture, importation, distribution and sale in a country.

v) Classification of veterinary drugs

As mentioned above, when the decision is made by the technical body to approve the registration of a veterinary drug, it is desirable for a number of other matters also to be decided. These mainly relate to the availability of the drug, and its packaging and labelling requirements. Based on a review he conducted of drugs legislation (human and veterinary medicines) in southern Africa in 2000-01, the present author wrote :

“Apart from the characteristics of the medicine, the other key matter in a regulatory system is access to the registered medicines. The pattern of southern African legislation is to control access pretty tightly. Common features are to require persons to be licensed to sell medicines, and only to allow pharmacists to sell medicines to the general public. Usually there is some relaxation of this latter restriction, in some cases to allow veterinarians to treat animals in their care (as in Malawi), and also to allow the general sale of over-the-counter (OTC) medicines. Mozambique has a provision in its *Medicine Law* restricting the distribution of medicines to only those listed in the *National Formulary*, and other countries use a scheduling system to control drugs supply – most notably Zimbabwe, which has no less than eight schedules specifying the outlets, and special terms and conditions of sale, for all drugs registered in the country.” (FAO 2001:28)

In an earlier part of this paper, the special considerations which apply to veterinary drugs are listed, among them being the different arrangements made for dispensing veterinary drugs, and the fact that veterinary drugs are often administered by the farmer. The tight requirements for selling medicines to the public should be relaxed in the case of veterinary drugs, to take account of these special considerations. The general goals of quality, safety and efficacy apply just as much to veterinary drugs as to human drugs, but a balance must be struck which permits reasonable availability to veterinary drugs in rural areas. The body best qualified to strike this balance is the statutory body of technical experts, and the lawyer's job is to give them a range of options in the legislation which is sufficient to cover the different classes of veterinary drugs. The “classes” referred to here are not pharmacological classes, but rather categories of availability.

In the case of veterinary drugs, it may be possible to cover the basic availability options with four categories. Drawing on the southern African legislation, and on discussions with technical experts,⁵ the present author has prepared draft legislation for Mozambique, Rwanda and Nepal, which provides for veterinary drugs to be classified into four categories – prescription only, pharmacy, authorised dealer and general sale. The Rwandan provision, for example, says –

At the time of registration, veterinary drugs shall be classified as one of the following:

- a) *prescription only;*
- b) *pharmacy*
- c) *authorised dealer;*
- d) *general sale.*

The criteria for each class of veterinary drug and the restrictions that apply to each class are as follows :

⁵ In particular, Dr R. D. Sykes, South African National Department of Agriculture, and Prof. G. Swan, Department of Pharmacology, Onderstepoort Faculty of Veterinary Science, University of Witwatersrand.

a) *Prescription only*

Criteria: *veterinary drugs subject to restrictions on supply and use based on international conventions, or on special precautions to avoid unnecessary risks or on the necessity for precise diagnosis.*

Restrictions: *such veterinary drugs may only be sold to the public by a veterinarian or a pharmacist, and only in accordance with a written prescription of a veterinarian.*

b) *Pharmacy*

Criteria: *veterinary drugs which require advice to be given regarding potential risks, undesirable interactions, method of use or conditions of storage or safe disposal.*

Restrictions: *such veterinary drugs may only be sold to the public by a veterinarian, a pharmacist or a licensed dealer.*

c) *Authorised dealer*

Criteria: *veterinary drugs not suitable for general sale.*

Restrictions: *such veterinary drugs may only be sold to the public by a veterinarian, a pharmacist, a licensed dealer or an authorised dealer, and only in unbroken packages as prepared by the manufacturer.*

d) *General sale*

Criteria: *any other veterinary drug.*

Restrictions: *such veterinary drugs may be sold by any person or establishment, in unbroken packages as prepared by the manufacturer.*

There are various aspects to this provision, in particular –

- Each drug category is a combination of criteria and restrictions, which basically relate to drug availability. No attempt is made to allocate particular drugs, or classes of drugs, into one or another category. This is the job of the technical body, when each veterinary drug is registered.
- Drug availability relates to who can sell the drug to the public, and under what circumstances. Veterinarians can sell any veterinary drug to the public. Pharmacists can sell any drug, but “Prescription only” drugs require a prescription from a veterinarian. The terms “veterinarian” and “pharmacist” are usually defined in the legislation dealing with veterinary and pharmacy practice. Two new terms which require definition are “licensed dealer” and “authorised dealer”. A “licensed dealer” is licensed under the veterinary drugs law to manufacture and/or import veterinary drugs, while an “authorised dealer” is authorised to deal in specified drugs, under certain terms and conditions. They will be examined in the next section of this paper, but again it should be remembered that the technical body will know what drugs each type of dealer can dispense, and can allocate each veterinary drug to a category accordingly.

- It is worth repeating that the aim is to balance the goals of guaranteeing a drug's quality, safety and efficacy with the goal of making the drug reasonably available in the country concerned. Veterinarians may argue for a more restrictive regime, confining drug supply mainly to themselves and pharmacists, but what use is that in countries where veterinarians and pharmacists only practise in the major cities? It is certainly appropriate to confine some drugs to veterinarians and pharmacists, but there are many other veterinary drugs which can be stocked at town and village level and sold to farmers, provided that certain conditions of storage and dispensing are met. It may not be ideal, but the aim is to strike a practical balance. Each country must decide on the balance which suits its own needs and circumstances.

To follow up this last point, it should not be thought that the need to relax veterinary drug availability is only a developing country need, for remoteness from urban services is a problem for most farmer communities around the world. The Canadian Province of Alberta makes liberal provision for persons other than veterinarians or pharmacists to sell livestock medicines. Such persons must be licensed, and they must have completed a training course on the proper handling of drugs, but they can then sell any of a long list of drugs, including certain injectable vaccines, certain antibiotics, preparations for the control of internal and external parasites and insect pests, treatments for surface wounds and skin diseases, and even "growth promotants and hormone preparations in the form of implants and feed additives labelled by the manufacturer for use in production animals". The Albertan law requires records to be kept by licensees, there are restrictions on the manner of sale (only over-the-counter, at the licensee's place of business) and certain storage requirements. There are also duties imposed on the licensee, but these will be examined under the next section.

In conclusion, on classification –

- veterinary drugs should be classified at the time of their registration, so as to indicate the restrictions which apply to their prescription and dispensing;
- the different categories provided by the law should reflect the main options for drug availability, having regard to the nature of the drugs and the outlets through which they can be made available;
- veterinary drug classification requires a balance to be struck between the goals of guaranteeing the quality, safety and efficacy of the drugs, and the goal of making the drug available in the country concerned;
- the most suitable body to strike that balance in registering any drug is the technical body, which should make its decisions taking account of the country's particular needs and circumstances.

vi) Manufacture, import, distribution and sale

These are the main activities which a veterinary drugs control law aims to regulate. The law must ensure that the drugs are of good quality, are safe and efficacious at the time of their manufacture or their importation to the country, while they are being distributed around the country to the drug retailers, and when they are sold to the eventual consumers. If the country concerned has a drug export industry, the law must also concern itself with exportation of veterinary drugs. As discussed above, none of these stages in manufacturing, importing or exporting, distributing or selling a veterinary drug can take

place legally unless the drug has already been registered. In other words, the decision has already been made that the drug is suitable for the country, and persons are now being licensed to manufacture, import, distribute and sell that registered drug. The licensing system must also be suitable to the country concerned, and in particular take into account social conditions in rural areas and limitations on administrative capacity. A system which is too restrictive will block farmer access to important veterinary drugs, and will invite infringement of the law. Each stage in the supply of veterinary drugs will now be considered.

(a) Manufacture

Most countries have a drug manufacturing industry, no matter how small. Often its main purpose is the production of priority drugs for treatment of common human illnesses, so the industry is usually regulated under human drugs legislation. In many cases, drug manufacturers will be producing drugs for both human and animal use – frequently, in fact, the same drugs. As discussed above, there are some special considerations which apply to veterinary drugs. Their packaging and labelling will reflect those differences, but not their manufacture; in each case, whether drugs are for use on animals or on humans, the manufacture concerns are the same – the quality, safety and efficacy of the drug. So, the common practice is to “piggy back” the veterinary drug manufacture requirements onto those for human drugs. For example, the provision in the law proposed for Nepal is –

The total or partial manufacture of veterinary drugs in Nepal is only allowed in drug industries which have been established under the Drugs Act and which have been licensed under this section.

Nepal has an elaborate system for drug administration (although its emphasis is on drugs for human use), with detailed requirements for the licensing of manufacturers. In particular, the factories must meet certain standards of construction, and be under the supervision of a suitably-qualified technician. Standards also apply for drug manufacture, based on the WHO’s Good Manufacturing Practices (GMP). Instead of duplicating these requirements, the proposed law simply adds the further need for a licence where the factory is producing drugs for veterinary use. Whereas the factory itself is licensed under the *Drugs Act*, it is further authorised to produce veterinary drugs under the veterinary drugs law. The licence should specify which veterinary drugs will be manufactured, allowing the livestock authorities to monitor veterinary drug production in the country.

(b) Import

For many countries, the main sources of their veterinary drugs lie outside the country. Drug importers will normally require an import licence under the country’s Customs legislation, but they should also hold a licence under the veterinary drugs law to import the drugs concerned. The same requirement should also apply to the export of veterinary drugs, in countries which have a drug exporting industry. Again, to take an example from Nepal –

(1) The import/export of veterinary drugs is only allowed by establishments which have a technical director with skills recognised by the Department [of Livestock Services] and which have been licensed under this section.

(2) Upon an application in writing and payment of the prescribed fee, the Department may grant a licence to an appropriate establishment to import, export or import and export the veterinary drugs specified in the licence.

(3) *The period, terms and conditions of an import/export licence under this section shall be specified in the licence.*

(4) *The form to be used for the application and grant of an import/export licence may be prescribed.*

(5) *A person travelling with a registered veterinary drug for use on his or her own animal is exempted from the requirement for an import licence under this section.*

(6) *His Majesty's Government may, by special licence, authorise the import of an unregistered veterinary drug for a special purpose.*

The last two provisions provide exceptions to the general requirements. Subsection (5) relaxes the requirement for an import licence, where persons are bringing in veterinary drugs for use on their own animals. For convenience, licences under the veterinary drugs law are not usually required in such cases (although an import licence under the Customs law may still be required). Note, however, that the drug must be a veterinary drug which has been registered for use in the country. The second exception – Subsection (6) - is intended to allow the Government to make special provision for special cases, where it would not be practicable, or necessary, to require someone to go through the drug registration process. Such a special case might be where a stud bull is being brought into the country, and a certain drug has to accompany it. Another case might be grant of a special licence to import a drug for the purposes of scientific research.

With regard to export of veterinary drugs, in one sense the quality, safety and efficacy of exported drugs is of more concern to the importing country than the exporting country, although these matters will have obvious trade repercussions if the exporting country has a significant drug production industry. There may also be international obligations involved, and the need for reciprocity in quality assurance. Sri Lanka, for example, treats veterinary drugs in the same way as animals and animal products in this regard, providing –

(1) *No person shall export any animal, animal product, veterinary drug, veterinary biological product, semen or embryo except under the authority of a permit issued by the Controller of Imports and Exports on the recommendation of the Director [of Animal Production and Health].*

(2) *No recommendation shall be made by the Director for the issue of a permit to export any animal, animal product, veterinary drug, veterinary biological product, semen or embryo unless the exporter produces to the Director a certificate from an Authorised Officer, before exportation.*

(3) *For the purpose of this section "Authorised Officer" means a veterinary surgeon authorised by the Director in that behalf.*

A similar requirement applies to the importation of veterinary drugs, etc., into Sri Lanka, with the necessary certification to be provided by the Chief Veterinary Surgeon in the country of origin, or a veterinary surgeon authorised by that official. While these requirements are quite appropriate for animals and animal products, it might be doubted whether they are required for all veterinary drugs.

(c) Distribution

Distribution is the stage between a drug's introduction to the country (by manufacture or importation), and its sale to the general public. Distributors buy the drugs from manufacturers or importers, and sell them to the retailers. Some countries require such distributors to be specially licensed, but others feel that the need to regulate such "middle men" can be met by the general requirements for storage and transport of veterinary drugs,

and by controls on packaging, labelling and advertising. Malawi, for example, makes special provision for a “wholesale dealer’s licence”, and minimum requirements are laid down for a wholesaler’s premises, including for storage, cleanliness and security. At the time of a veterinary drug’s registration (see above), the requirements for its packaging and labelling are specified, and these usually include requirements for storage. It can then be provided in the veterinary law’s enforcement provisions (see below) that it is an offence to store drugs contrary to the storage requirements specified on their labels. It is also usual to provide that any tampering with the drugs is an offence. Other controls are imposed on distributors by general offences, such as the sale of “expired” drugs (see below, under “Enforcement”).

(d) Sale

Assuming that the quality, safety and efficacy of the drugs have been protected so far by the foregoing controls on manufacture, import and distribution, the final stage of the marketing process at which quality control must be guaranteed is when the drugs are actually sold to the buying public. At this stage, the decisions taken on drug classification (see above) become crucial, because each drug’s classification determines how it can lawfully be made available to the public. The main categories proposed above are –

- Prescription only;
- Pharmacy;
- Authorised dealer;
- General sale.

The terms Prescription only, Pharmacy and General sale (sometimes called “over the counter”, or “OTC”) are understood by the drugs trade, but the veterinary drugs law should specify how a person can qualify as an “Authorised dealer” for the purposes of the law. What is required is a simple procedure for persons to be authorised in writing by the appropriate official (e.g., the Minister of Agriculture, or Director of Livestock Services) to deal in veterinary drugs which are classified as “Authorised dealer” drugs, on conditions relating to the storage of the drugs, and the giving of necessary advice on their use to the buying public.

In the Canadian Province of Alberta, the duties of a person (other than a veterinarian or a pharmacist) licensed to sell veterinary drugs to the public are listed, as follows –

- (1) *A licensee shall –*
- (a) *only sell medicine in containers labelled by the manufacturer,*
- (b) *draw to the attention of a purchaser of medicine any precautions to be taken with respect to the minimum amount of time that must elapse –*
- (i) *between the administration of the medicine to a production animal and the slaughter of the animal, and*
- (ii) *between the administration of the medicine to a production animal and the time at which the products from the animal may be used for human consumption,*
- (c) *draw to the attention of a purchaser of medicine any toxicity warnings or other precautions on the label,*

(d) *display a sign, in a form determined by the Director [of the Animal Industry Division], in a prominent location within the licensee's premises that -*

(i) *emphasises the importance of proper use of medicine, and*

(ii) *refers customers to a staff person who holds a qualification certificate for clarification of any questions regarding the safe and proper use of medicine, and*

(e) *immediately after the expiration date of any medicine, remove the medicine and keep it separate from other stock until it is destroyed or returned to the manufacturer.*

(2) *No licensee shall -*

(a) *repackage or alter the contents of any medicine,*

(b) *give away, barter or sell any medicine as an inducement to purchase other merchandise,*

(c) *sell medicine after the expiry date of the medicine,*

(d) *refuse a request to provide a receipt to any person who purchases medicine from the licensee, or*

(e) *diagnose, prescribe or otherwise contravene the Veterinary Profession Act.*

These duties indicate the matters which could be included in an authorisation to a dealer, but it must be remembered that the requirements will vary from country to country depending on the facilities available, and it is in the public interest that veterinary drugs are made available to meet the country's livestock needs.

Breach of a dealer's conditions should lead to action for suspension or cancellation of the authorisation to deal in veterinary drugs, in the normal way. Otherwise, it might be acceptable not to fix a period for the authorisation but leave it indefinite – unless it is cancelled. The alternative is to make the authorisation into an annual licence, but this means that the licensee must make annual applications for renewal. For persons operating at town or village level, this might be an unnecessary inconvenience.

In conclusion, on drug manufacture, import, distribution and sale –

- a country's system for regulating the supply of veterinary drugs must take account of its social conditions and administrative limitations, especially in the rural areas;
- the aim is to ensure that the drugs are of good quality, safe and efficacious, through the chain from manufacture or import of the drugs, to their distribution to retail outlets and eventual sale to the end user;
- the requirements for drug manufacture are much the same for human and animal drugs; there is no need, therefore, to duplicate these requirements, but in the case of veterinary drugs it is appropriate that manufacturers and

importers receive a separate licence from the livestock authorities, so that (for example) they can monitor drug supply and use;

- separate licensing requirements may not be needed for veterinary drug distributors; they will already be covered by the general requirements for storage and transport of the drugs, and controls on packaging, etc.;
- the main controls on sale of veterinary drugs are covered by the drug classification system, which sets out the restrictions which apply to the availability of the different categories of drugs – e.g., Prescription only, Pharmacy, Authorised dealer, and General sale;
- the regulatory system should not be too restrictive or administratively demanding; duplication of requirements and unnecessary bureaucratic steps should be avoided.

vii) Enforcement

A law which is not enforced is a bad law. At the same time, it is also bad practice to introduce laws which do not reflect a country's real needs and circumstances – and are, to that extent, unenforceable. A common problem in many countries is their limited capacity to enforce legal requirements, and administrative capacity should always be a prime consideration, when drafting a regulatory system. Where laws impose unrealistic burdens on the public, they create unnecessary illegal behaviour, they undermine respect for the law in general, they invite selective application and – inevitably – the risk of corruption. The underlying reasons for the regulatory system must always be kept in mind, and only such interference caused to people's lives and businesses as can be justified by those reasons.

Having made these preliminary points, it should be acknowledged that a regulatory law needs "teeth" if it is to be taken seriously. The usual legal measures for enforcing the requirements of a law are penalties for offending those requirements, and the withdrawal of legal authority to carry out certain activities covered by the law. A simple illustration of the kind of offences which are appropriate for a veterinary drugs law is provided by the Offences section in Nepal's draft law –

- (1) *The following activities are prohibited, and shall be punished by a fine -*
 - (a) *the manufacture of veterinary drugs without a manufacturer's licence under this Act;*
 - (b) *the import or export of veterinary drugs without an import/export licence under this Act;*
 - (c) *the publication or advertisement of false or misleading information relating to the use, usefulness or effectiveness of a veterinary drug;*
 - (d) *the sale or release for sale of a veterinary drug contrary to the requirements of Section 20 [see below];*
 - (e) *the unauthorised disclosure of confidential business information gained in the course of carrying out a function or power under this Act.*
- (2) *The following activities are prohibited, and shall be punished by a fine -*
 - (a) *the storage or transport of veterinary drugs in a manner contrary to the requirements of their labels or containers;*

(b) *the administration of an unregistered veterinary drug to an animal.*

Section 20 of the draft law reads –

- (1) *Veterinary drugs may only be sold to the public in accordance with the restrictions laid down under [the classification section] of this Act;*
- (2) *A person shall not sell veterinary drugs whose manufacture or import is contrary to this Act.*
- (3) *A person shall not sell veterinary drugs whose validity date has expired.*
- (4) *A person shall not release a veterinary drug for sale without the packaging and labelling required according to its registration.*

The fines or other punishments for offences should be set in accordance with the penalty policies of the country concerned. It is usual to add a further provision, as in Nepal –

In addition to the fines referred to in this section, any veterinary drug involved in the offence may be seized, and a competent court may order compensation to be paid to a person who has suffered loss or injury as a result of the offence.

Powers of inspection are also important, along these lines (again from Nepal) –

The Department [of Livestock Services] has the power to carry out inspections in order to ensure that the requirements of this Act are being fulfilled, and for this purpose may–

- (a) inspect establishments which engage in the manufacture, import, export, distribution or sale of veterinary drugs;*
- (b) inspect and copy records relating to the manufacture, import, export, distribution or sale of veterinary drugs;*
- (c) inspect storage premises or transport facilities used for veterinary drugs;*
- (d) collect samples of veterinary drugs for purposes of analysis.*

Officers may be authorised to carry out the powers of inspection in the Act, and to initiate the prosecution of offences.

The other main method of enforcement of the law's requirements mentioned above is withdrawal of legal authority to carry out certain activities covered by the law. The main ones in the case of veterinary drugs are licences to manufacture, import, export, distribute or sell the drugs to the public. The risk of losing such a licence is a powerful commercial incentive to observe the law's requirements. The terms and conditions of such licences can be drawn up so as to include the main requirements for maintenance of drug quality, safety and efficacy, and can also require the keeping of records (on sales of veterinary drugs, etc.) and reporting on relevant matters (e.g., any adverse reactions to a drug). They can also include provision for the suspension or even cancellation of the licence, for breach of its conditions.

In conclusion, on enforcement –

- the enforcement provisions must be realistic, and not impose unnecessary burdens on the public or the law enforcement authorities;
- sometimes the cancellation of a licence to operate (e.g., to import veterinary drugs) can be a more effective measure than prosecution for an offence;

- some breaches of the requirements are sufficiently serious, however, as to warrant prosecution for an offence.

Operational aspects

If a new veterinary drugs law is introduced, action will be required on a number of operational matters to implement the new law fully and effectively :

Rules, guidelines, forms, fees : Subsidiary legal documents (Rules, Regulations, etc.) will have to be prepared on various matters, e.g., the forms to be used under the law and the fees to be paid. Guidelines may also be useful to assist with certain matters (e.g., for completion of applications for the registration of veterinary drugs). In some countries the law provides for codes of practice to be issued, on the manufacture, import and sale of veterinary drugs, etc. These matters should be discussed with the relevant authorities, to facilitate introduction of the new legislation with the minimum inconvenience to the public and those who will be administering the law.

Transitional arrangements : A new veterinary drugs law will not come into operation in a vacuum. To take account of the fact that there will already be many veterinary drugs in use in the country, some transitional provision should be made in the new law, to allow time for people to adjust to the new law's requirements. One way by which this can be done is to allow a short period from the new law's commencement (say, 6 months), during which persons holding a licence to operate under the existing law must apply for a new licence under the new law. When such an application is made, the old licence can be "deemed" to be a licence under the new law until the application has been decided. If an application is not made within the specified time, the old licence is cancelled.

Public awareness: Farmers are the main users of veterinary drugs, and they usually buy their drugs from small rural outlets (including from paravets or community animal health workers). It is extremely important for a public awareness campaign to accompany introduction of the new law, targeted at farmers and small rural outlets as well as the big operators in the market. Any farmers unions or co-operatives can be very useful partners in designing and implementing such a campaign.

Staffing, facilities, funds, training, equipment: Some additional demands on administrative resources will be unavoidable, if the requirements of the new law are to be known and understood, and effectively implemented. Funds will be required for a public awareness campaign, and also for the necessary upgrading of facilities (laboratories, etc.), training and information kits for those involved in administering the new law. While every attempt should be made to avoid unnecessary duplication – especially of procedures, facilities and staff for testing and evaluation of drugs for use on humans – there will probably be the need, at least, for an upgrading of existing laboratories, to carry out the further testing of drugs for their use on animals. Customs officers at border posts and international ports and airports must be provided with the information necessary to enforce the new law's requirements with respect to drug importation.

Conclusion

It is worth repeating again that, in drafting a country's legislation for veterinary drugs control, a balance must be struck between –

- the goal of guaranteeing the quality, safety and efficacy of the drugs; and
- the goal of making the drugs reasonably available to the farmers in rural areas.

In many countries, the existing controls on drug availability are simply not enforced in rural areas. The first aim, in these circumstances, is to try to recover some respect for the law, and some likelihood that its requirements will be observed. That will not be achieved by bringing in tougher legislation, which seeks to control drug supply too strictly. What is needed is a combination of laws which allow farmers to have reasonable access to the veterinary drugs which they need to protect the health of their animals, together with a public awareness campaign which informs those in the industry - manufacturers, importers, vets and paravets, small-scale drug retailers and the farmers themselves - of the law's requirements, and how they can be met. After all, it is not in the farmers' interests to buy useless or dangerous substances to give to their animals.

In drafting the appropriate law, the veterinarians, livestock officers, pharmacists and drug administrators all have important inputs to contribute. One very important point-of-view to include, however, is that coming from the rural areas. Unless the farmer's perspective is included, and the views of those who service the farmer's needs (paravets, community animal health workers, village drug retailers, etc.), it is not likely that the law will strike the necessary balance between drug control and drug availability.

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FAO 1993 "Licensing of Veterinary Vaccines and Biologicals", by J. M. Rutter, in FAO Animal Production and Health Paper No. 116, FAO, Rome.

FAO 2001 "Final Report on Veterinary Pharmacology Legislation", by Dr Jim Fingleton, FAO report prepared for the Government of Mozambique, June 2001.

FAO 2002 "Law and Sustainable Development since Rio : Legal Trends in Agriculture and Natural Resource Management", FAO Legislative Study No. 73, FAO, Rome.

FAO 2003 "Revising Veterinary Legislation", FAO Terminal Statement prepared for the Government of Rwanda, January 2003.

FAO 2003a "Assistance in the Review of Agricultural Policy and Legislation : Veterinary Drugs Legislation", Final Report by Dr Jim Fingleton prepared for His Majesty's Government, Nepal, December 2003.

Annex: Legislation included in the study

Africa -

Botswana:

Veterinary Drugs Act (draft, 2000)

Malawi:

Pharmacy, Medicines and Poisons Act 1988

Mozambique:

Veterinary Medicines Law (draft, 2001)

Rwanda:

Veterinary Pharmaceuticals Act (draft, 2002)

South Africa:

South African Medicines and Medical Devices Regulatory Authority Act 2000

Zambia:

Pharmacy and Poisons Act 1978

Zimbabwe:

Medicines and Allied Substances Control Act 1969

Asia -

Nepal:

Veterinary Drugs Act (draft, 2003)

Sri Lanka:

Animal Diseases Act 1992

Pacific -

New Zealand:

Agricultural Compounds and Veterinary Medicines Act 1997

North America -

Province of Alberta, Canada:

Production Animal Medicine Regulation (made under the Livestock Diseases Act 1998)