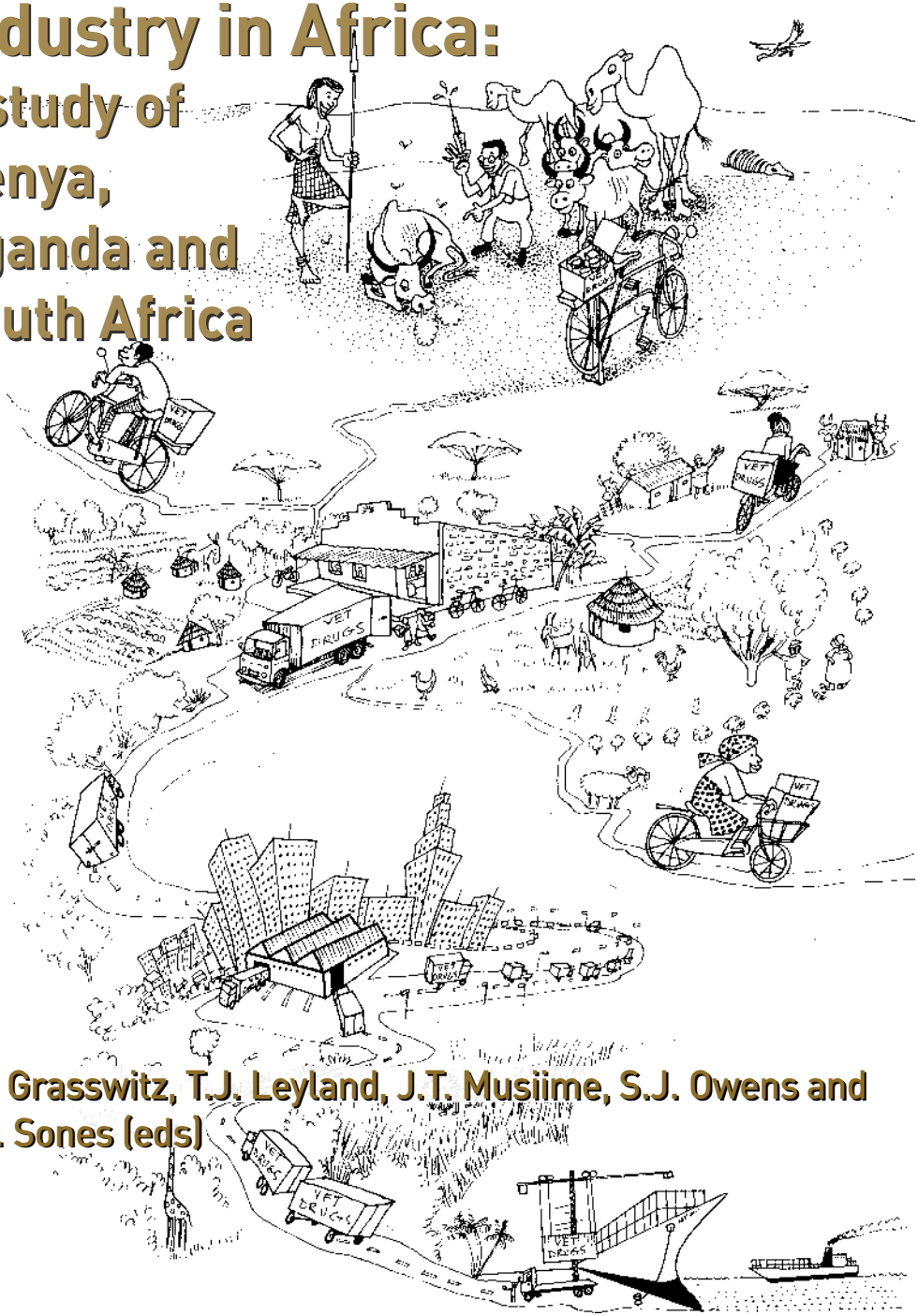
The veterinary pharmaceutical industry in Africa:

a study of Kenya, Uganda and South Africa



T.R. Grasswitz, T.J. Leyland, J.T. Musiime, S.J. Owens and K.R. Sones (eds)

The African Union/Interafrican Bureau for Animal Resources

The African Union/Interafrican Bureau for Animal Resources (AU/IBAR) is a specialist technical agency of the AU mandated by member states to promote livestock development in Africa. Based in Nairobi, Kenya, AU/IBAR implements major livestock development programmes including the Pan African Programme for the Control of Epizootics (PACE) and Farming in Tsetse Controlled Areas (FITCA).

The aims of AU/IBAR are to:

- Co-ordinate the activities of all AU member states in the field of livestock development;
- Collect, collate and disseminate information on all aspects of livestock development;
- Initiate, develop and execute livestock development projects;
- Liaise with appropriate authorities of member states, regional groups, inter-governmental and international organisations.

For many years, AU/IBAR has been an African success story, attracting donor funds and providing technical and policy support to the AU's member states, particularly for state veterinary services. The bureau understands that livestock issues are becoming increasingly complex due to forces such as globalisation, rapid technological advances and the demands of stakeholders. Stakeholders at all levels are becoming more vocal and influential, and now demand to be involved in all aspects of livestock development interventions, including priority setting, financing, governance and evaluation, in addition to planning and implementation. AU/IBAR provides effective responses to stakeholders' needs through a clear vision of its direction, policy and strategies.

For further information contact:

The Director, AU/IBAR, PO Box 30786, 00100 Nairobi, Kenya
Tel: +254 2 334550/251517/226651
Fax: +254 2 332046/226565
E-mail: jotham.musiime@oau-ibar.org

The Community-based Animal Health and Participatory Epidemiology Unit

Within AU/IBAR, the CAPE unit links field experience with stakeholder dialogue to create enabling policy and institutional settings for community-based animal health services. The unit also supports a range of government and non-government partners in their efforts to improve epizootic disease control in marginalised areas.

E-mail: tim.leyland@oau-ibar.org or andy.catley@oau-ibar.org
Website: www.cape-ibar.org

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African Union/Interafrican Bureau for Animal Resources, Nairobi, Kenya

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Contents

Acknowledgements

The initial study on which this report is based was commissioned by the Community-based Animal Health and Participatory Epidemiology (CAPE) Unit of the African Union/Interafrican Bureau for Animal Resources (AU/IBAR). For this, Sarah Jane Owens was invited to prepare an overview of the veterinary pharmaceutical sector in three countries, Kenya, Uganda and South Africa, to identify the key policies that influence the sector, and to assess the linkages between the veterinary pharmaceutical sector and private veterinary practitioners. Sarah did an excellent job of amassing a great deal of information, very little of which has previously been published. In conducting her study, Sarah met many representatives of the veterinary pharmaceutical industry, government officials, private veterinary practitioners, representatives of veterinary associations and many others – unfortunately too numerous to mention individually. All were extremely generous with their time and expertise and the co-editors would like to thank them all. Martin Mitchell of CEVA Santé Animale S.A. very kindly contributed a piece from his perspective within the veterinary pharmaceutical industry. Finally, Green Ink did an excellent job of working with the co-editors to turn a wealth of information into what we believe to be a unique, extremely useful and very readable report.

Foreword

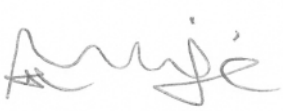
Appropriate and affordable veterinary drugs and vaccines are an essential component of any animal health service. However, there are particular challenges involved in providing reliable and efficient supplies of such products to the remote regions of Africa, particularly to the arid and semi-arid areas of eastern Africa that support approximately 60% of the region's livestock and a third of its people.

In recent years, much has been published on new approaches to delivering animal health services to remote areas, and AU/IBAR has been especially active in this regard. Most stakeholders now accept that in the more remote regions of Africa, community-based animal health services are the best – perhaps the only – option. There is now good evidence that, if properly trained, supervised and regulated, community-based animal health workers (CAHWs) can provide high quality services to their communities.

However, such services are dependent on a reliable source of veterinary medicines and this critical issue of sustainable drug supply has so far received less attention than it merits. In the past, when veterinary pharmaceutical companies concentrated mainly on large, donor-funded government tenders and direct sales to large commercial farms, pastoralist livestock keepers were not regarded as an attractive market. It was considered too difficult to distribute products to widely scattered, nomadic livestock keepers, many of whom were not then part of the cash economy. Times have changed, however, and pastoralists have gradually become more sedentary, better educated, and increasingly involved in the cash economy as a result of the need to pay school fees, medical bills and to buy food during times of drought. Of necessity, these pastoralists have become increasingly involved in livestock trading and are now viewed as a market with considerable growth potential by the veterinary drug companies, whose traditional markets have declined in recent years. Furthermore, networks of CAHWs, linked to vets and animal health

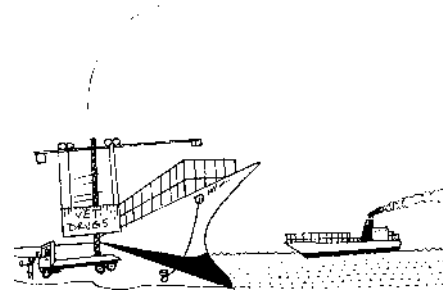
assistants (AHAs), appear to represent an effective supply route that could reach millions of pastoralist livestock keepers.

The twin objectives of establishing better animal health services in remote areas, and of finding profitable new markets for veterinary products, both demand that more effective ways are found of ensuring that community-based animal health services have adequate access to appropriate veterinary products. As a contribution towards this goal, AU/IBAR commissioned the study that forms the basis of this unique report. Governments, international agencies, non-governmental organisations (NGOs) and others involved in the provision of community-based animal health services would benefit from a better understanding of the views of the veterinary pharmaceutical companies, while the latter, in turn, need a greater appreciation of the problems, challenges and opportunities associated with the provision of community-based animal health care. I believe that there is considerable scope for innovative public–private partnerships in this area and I hope that this report may go some way to realising some of that potential.



Dr Jotham T. Musiime
Acting Director, AU/IBAR
March 2004

1 Introduction



This study was undertaken to review the status, structure and performance of the veterinary pharmaceutical industries in Kenya, South Africa and Uganda, with particular reference to the provision of animal health services in the arid and semi-arid lands. The report addresses the availability of products and services (particularly in rural areas), the role of the veterinary and allied professions, the current regulatory framework and proposed legislative reforms in all three countries. In compiling the report, information from published sources has been augmented by an extensive series of interviews with leading members of the animal health care sector in each nation.

The provision of adequate animal health care is of fundamental importance to Africa's present and future food security. On much of the continent, livestock productivity is low and current national needs for milk and meat are not being met. The demand for livestock products is expected to increase considerably in the next few decades as a result of increased population growth, urbanisation and increasing income levels, and unless the level of livestock production can be improved, the World Bank predicts severe food shortages throughout the continent by 2025 (de Haan and Umali, 1992). However, livestock productivity can only be increased if reliable animal health care is available. Annual losses due to preventable livestock diseases in sub-Saharan Africa have been estimated at US$4 billion, representing about a quarter of the total annual productive value of the continent's livestock (de Haan and Bekure, 1991). Furthermore, increased movement of people, animals and animal products across national boundaries has led to an increase in the geographical distribution of some livestock diseases. Given this background, it is perhaps not surprising that, of all development projects, investments

in animal health services have been shown to result in some of the highest rates of return.

Numerous attempts have been made to improve Africa's animal health services, particularly in the arid and semi-arid lands, where nearly one third of the continent's human population and approximately 60% of its animal population are found. In most African nations, state involvement in the provision of clinical veterinary services and the supply of veterinary drugs has declined in recent years. However, private or semi-private veterinary care is only slowly becoming established in the rural areas of Africa, and private veterinarians have so far played only a limited role in the import, distribution, sale and administration of veterinary pharmaceuticals. Establishing successful private practices capable of meeting the needs of widely dispersed pastoralist populations in the arid and semi-arid regions is particularly difficult.

In many African countries, the difficulty of providing adequate animal health care is compounded by an absolute shortage of practising veterinarians. Varying degrees of reliance are therefore placed on veterinary para-professionals[1], including community animal health workers (CAHWs). Concern has sometimes been expressed over the quality of the services provided by such individuals, but they have nevertheless been shown to be the best means of providing basic veterinary care in remote areas where private veterinary practices cannot survive. Attempts to legally define the roles and qualifications of CAHWs – and hence improve the quality of their services – are currently in progress in all three countries considered here.

The veterinary pharmaceutical industry has a critical role to play in improving the quality of Africa's animal health care. Most of the veterinary products used in Africa are manufactured in Europe or Asia and are imported by both multinational and local companies. In most African countries, the sale of many veterinary products is legally restricted to pharmacies but many pharmacists have little interest in (or knowledge of) products for animals, and the provision of animal health care for rural live-

[1] An *ad hoc* group of the Office International des Epizooties (OIE) recently defined a veterinary para-professional as a person who is authorised by a statutory veterinary body to carry out certain defined tasks under the direction and supervision of a registered or licensed veterinarian. The tasks authorized for various categories of para-professionals should be defined according to the training and qualifications of each group.

stock keepers has suffered as a result. In most African countries there are thus complex drug distribution chains which involve a large number of participants, both formal and legal, and informal or illegal. In most of Africa, the influx of poor quality drugs is a major threat to the provision of reliable animal health products at realistic prices. In this regard, the importance of an active state regulatory authority with strictly enforced standards cannot be over-emphasized.

The increasing availability of cheap Asian and generic drugs throughout much of Africa has resulted in a general reduction in product pricing, although there are still active niche markets for recognised brands and premium products. In terms of the global market for veterinary drugs, South Africa currently represents 1% of the total (estimated at US$13 billion per annum), with the rest of Africa together representing only 0.7%. South Africa houses the regional headquarters of many of the major European pharmaceutical companies, most of whom view exports to the rest of Africa as a potentially lucrative emerging market. South Africa's manufacturing and export sector is thus gradually expanding. In general, however, while the domestic South African market for products aimed at pets is increasing, that for livestock-related products is declining. Nevertheless, as elsewhere in Africa, rural smallholders are viewed as an important emerging market, and many companies have started to repackage their products in smaller sizes to accommodate the needs of this sector. On the whole, however, the veterinary pharmaceutical industry in South Africa faces the same difficulties as the rest of Africa in reaching poor rural communities, despite the existence of a very successful infra-structure for distributing veterinary products and services to large-scale commercial farmers.

Kenya and Uganda provide good examples of some of the problems related to the restructuring and decentralisation of veterinary services that has occurred in much of East Africa. Uganda has been more successful than Kenya in improving the overall provision of veterinary pharmaceuticals, in part due to the efforts of its national drug authority. Kenya's problems in this regard are compounded by the country's current economic difficulties and a relatively weak infrastructure for monitoring and enforcing pharma-ceutical quality standards; indeed, a veterinary drug inspectorate has only recently been established, with just eight inspectors to cover the entire country.

Government regulations sensitive to the needs of the veterinary sector, and of veterinary participation in the regulatory process, are also important to the future provision of animal health care products. In many African countries, the regulatory framework for veterinary products has its historical basis in legislation targeted at human medicines, and is often inappropriate for today's animal health industry. In all three countries covered by this study, programmes of regulatory reform are in progress which should help meet the needs of the veterinary sector. If nothing else, such reforms provide an opportunity to repeal older legislation currently restricting the further liberalisation of trade in animal health products. From a wider perspective, there is also a need to harmonise the regulatory procedures of different countries: at present, meeting the requirements of various national registration policies significantly limits international commerce in animal health products within Africa.

2 Background to the animal health care industry in Africa

2.1 The importance of livestock and animal health care to developing countries

In much of Africa, livestock productivity is low: in the least-developed countries (LDCs), average milk production per cow is less than 10% of that in developed countries, and a similar disparity is seen in the figures for meat production (Upton, 2001). Per capita consumption of milk and meat therefore falls well below international recommended levels. The Food and Agriculture Organization of the United Nations (FAO) estimates that, on average, Africans currently consume 13 g of animal protein per capita per day compared to the world average of 28 g per day. Energy intake from animal products is equally low – less than half the global average of 460 calories per capita per day. Increasing the productivity of livestock in developing countries is therefore considered a priority, since even small increases in the consumption of animal products can provide as much or more additional protein, fats and other nutrients as can be obtained only from much larger quantities of vegetables and cereals (Delgado *et al.*, 2001).

Improving livestock health is fundamental to improving overall productivity, since parasites and diseases are a major limitation in African livestock systems (Jemal and Hugh-Jones, 1995; Mukhebi *et al.*, 1995; Swallow *et al.*, 1995; Pegram *et al.*, 1996; Gatongi *et al.*, 1997). Overall, it has been estimated that annual losses of approximately US$4 billion due to livestock diseases could be prevented, representing about a quarter of the total annual productive value of African livestock (de Haan and Bekure, 1991). Apart from direct losses due to reduced milk production or the death of affected animals, parasites and pathogens can cause indirect losses by reducing the quality of animal products. For example, although hides often

represent the main economic value of pastoral livestock (since they are readily transported and stored), their quality is reduced by ectoparasites and disorders such as lumpy skin disease.

Animal health is also a primary concern for countries aspiring to export livestock products. Without established disease-free zones, for example, developing a significant export trade in live animals is generally impossible, particularly given increasingly stringent animal health requirements in many parts of the world. At present, the many animal diseases that occur in Africa are a major constraint on trade in animals and animal products (Thomson *et al.,* 2004). These diseases have not only prevented the majority of countries in Africa from participating in the more lucrative livestock and meat markets of the developed world, but also prevented free trade within Africa. However, for countries such as Ethiopia and Kenya, where much of the livestock population is mobile and scattered, maintaining disease-free zones is expensive and difficult, and alternative solutions (such as exporting de-boned or cooked meat) may be more appropriate (Hargreaves and Belachew, 2003).

In all developing countries, however, the potential value of a livestock export market must be carefully weighed against the expense involved in complying with the necessary international standards: in many cases, addressing regional trade standards may be more appropriate than aspiring to global markets. Furthermore, improving the value of livestock through production or trade is difficult without intensifying production, which may be difficult in some pastoral areas (Upton, 2001). Nevertheless, where a viable export trade can be developed, it would stimulate demand for veterinary services and provide private vets or state veterinary services with a means of generating additional income (e.g. through the provision of advisory or inspection services to meet and maintain higher animal health standards).

As mentioned previously, returns on investments in animal health services have been shown to be some of the highest for all development projects. In Ethiopia, for example, the benefit to cost ratio for one animal health programme (the Pan-African Rinderpest Campaign (PARC)) was estimated at 3:1 (1.68:1 when averaged over the whole of Africa). The net welfare gain for producers and consumers in 10 African countries over the lifetime of the PARC project was estimated at US$203 million (Tambi *et al.*, 1999).

Successful programmes aimed at establishing CAHWs are generally recognised to be even more cost effective and have been the focus of considerable research by the African Union/Interafrican Bureau of Animal Resources (AU/IBAR) over the past 12 years.

In view of the decline of many state veterinary services in much of sub-Saharan Africa, new models for the provision of veterinary care are urgently needed. In general, western models of private veterinary businesses are not readily applicable to the situation in Africa, where 70% of the land can be classified as arid or semi-arid and therefore unsuitable for intensive livestock production. Nevertheless, since more than half of Africa's livestock population is found in such areas, there is a critical need to improve veterinary services in these regions. The use of CAHWs and private veterinarians is likely to increase in these areas, although the prevailing political, legal and institutional environments may be a barrier to their successful establishment in some cases.

The provision and status of animal health care is the net result of sometimes complex interactions between government policy, livestock production and the veterinary pharmaceutical industry. Good animal health is directly connected to agricultural profit, but the reverse is not necessarily true: livestock value and market demand are not always reflected in the status of the veterinary pharmaceutical industry. A salutary example is provided by the situation in Brazil (Box 2.1), which illustrates the importance of government regulations sensitive to the particular needs of the veterinary pharmaceutical industry.

2.2 The role of the veterinary and allied professions in pharmaceutical distribution

The veterinary profession

Most of the veterinary pharmaceuticals used in Africa are manufactured in Europe or Asia and are imported by both multinational and local companies. In each country covered by this study, complex drug distribution chains exist that involve a large number of participants, both formal and legal, and informal or illegal. In most African countries, the state is no longer involved in the provision of clinical veterinary services and the

Box 2.1 The decline of the veterinary pharmaceutical industry in Brazil: a lesson for Africa?

In 2001, Brazil's exports of animal products increased by 45% compared to the previous year (from US$1.8–2.6 million), yet this was not reflected in the earnings of the veterinary pharmaceutical industry, which remained close to the levels attained in the preceding 3–4 years. At the time, Brazil was the third largest world market for veterinary pharmaceuticals, but it has subsequently fallen to fifth position and is still losing ground, despite having a livestock population similar in size to that of the US.

The Brazilian animal health industry is efficient, and produces good quality products, but it has been hampered by insensitive government policies. For example, a decision by the Brazilian Ministry of Health to tax veterinary pharmaceuticals at the same rate as those for humans, without granting the tax reduction on raw materials applied to the latter, resulted in an overall increase in taxation of 9% on veterinary products. Furthermore, registration procedures are stringent and subject to long delays, and the industry also faces competition from illegal and fake products, which are poorly monitored and controlled.

Source: Clements (2002)

supply of veterinary drugs; however, private veterinary professionals have so far played only a limited role in the import, distribution, sale and administration of veterinary pharmaceuticals. In Kenya, for example, where veterinary privatisation has received considerable support and is relatively advanced compared to some other countries, only about 100–150 veterinarians are in private practice and the majority of animal health services are provided by the informal sector, i.e. by the shops known as 'agrovets' in the higher-potential areas, and mixed-goods shops and informal traders in lower-potential areas.

There are many advantages of professional veterinary involvement in the provision of animal health care: compared to other service providers, veterinary professionals should have higher levels of expertise, be more accountable, and hence better able to safeguard public health. In most developed countries, veterinary professionals play an important role in the

supply and distribution of veterinary pharmaceuticals and services, but the same cannot be said of private veterinarians in Kenya and many other African nations, where their share of the retail market is relatively low. Strictly speaking, vets in Kenya are only permitted to supply veterinary drugs in response to clinical needs, but in reality, many veterinary practices derive up to 60% of their total income from (illegal) retail sales. Evaluations of various veterinary privatisation projects (including Operation Lifeline Sudan (Catley *et al.*, 1998), the Uasin Gishu Project in Kenya (de Haan and Bekure, 1991), and the pastoralist Simanjiro District in Tanzania (Owens and Stem, 2000; Nalitolela *et al.*, 2001) have all indicated the willingness of livestock owners to pay market prices for reliable drugs and treatments. In some cases, too, products restricted to sale by veterinarians command more respect from customers than do more widely available equivalents.

The failure of private vets to capture a larger share of the market has been attributed to various factors, including poorly developed partnerships with the pharmaceutical sector, a lack of political representation in regulatory authorities, the slow rate of privatisation of the veterinary sector, and the delayed establishment of regional business models – indeed, as mentioned above, functional models for very remote rural areas have only recently been formulated. One possible strategy for private vets might be to specialise in different technical services or husbandry regimes, tailoring their services to individual needs. A successful example of this type of approach is provided by the Vet Centre of Uganda, a parastatal organisation that employs retired government veterinary officers to provide services to smallholders, with free consulting but fees for drugs. The Centre's success is reflected in the fact that it is now the sole Bayer distributor for Uganda.

Parts of Africa are suffering from an absolute shortage of practising veterinarians – one study reported a shortage of vets in 27 of the 48 African countries (56%) (de Haan *et al.*, 1994) – and great reliance is therefore placed on veterinary para-professionals. In each of the countries included in this study, legislative reforms are currently in progress to legally define the roles of the various groups within the animal health sector – vets, para-professionals and product manufacturers – all of whom should be involved in the dialogue in order to realise their full potential in the service and sales chain.

Farmers' co-operatives and community animal health services

Farmers' co-operatives and livestock producers associations are one way of improving the accessibility of veterinary services to small-scale livestock owners. By joining such associations, owners of small herds can take advantage of economies of scale, since discounts are generally available only on bulk orders that most African veterinary practices are too small to require. In India, an association of smallholder dairy farmers established with the dual aims of improving animal health care and increasing milk production led to a doubling of milk sales in 5 years (Doornbos and Nair, 1990), partly through improvements in livestock health. In a similar way, when the government livestock service of the Central African Republic experienced serious operational difficulties in 1982, the National Federation of Livestock Producers successfully assumed responsibility for marketing and distributing veterinary pharmaceuticals to a large number of producers (de Haan *et al.*, 1994). Other such organisations have been less successful (Sylla, 1989; Bruggeman, 1993; Hesse, 2000). Nevertheless, in South Africa, farmers' co-operatives are currently the leading distributors of animal health care products, being responsible for 60% or more of total annual sales.

There have been various attempts by non-governmental organisations (NGOs) and development agencies to improve rural animal health care systems by recruiting members of local communities and training them as CAHWs. The success of these schemes has been rather variable: their value to rural livestock owners has often not been fully apparent, and some community animal health schemes have been viewed rather critically by other members of the animal health industry. However, although there have been a number of poor programmes, some of the better ones have been very successful, particularly in regard to vaccination campaigns and providing animal health services in areas of greatest need. In Sudan, for example, when CAHWs performed rinderpest vaccination they achieved the same level of effectiveness as government-based livestock services, with an average of 76% seropositivity in vaccinated cattle, sufficient to prevent further outbreaks of the disease. Perhaps of greater significance is the number of cattle that can be vaccinated with a CAHW approach – in Sudan, such vaccinations increased from 100 000 per year to over 1.5 million per year, and in Turkana, Kenya, over 80 000 vaccina-

tions were made in a period of weeks, halting an outbreak of rinderpest (Catley *et al.,* 1998).

However, despite these successes, some concern remains among veterinary professionals over the quality of services provided by para-professionals and the level of drug misuse that they may engender. Although professional vets may be biased against these potential competitors, they have genuine concerns over the poor training of some CAHWs, particularly in relation to diagnosis and drug dosaging. Anecdotal reports of poor practice by para-professionals are common, mainly because there is often no satisfactory mechanism for linking such practitioners with professional veterinarians. However, in each of the countries covered by this study, attempts are being made to legally define the roles and qualifications of the various veterinary para-professionals and to legislate for their supervision by qualified vets. A recent study in Kenya demonstrated that CAHWs can provide high quality services which are greatly valued by local livestock keepers (Box 3.3).

Some members of the veterinary pharmaceutical industry have expressed the view that CAHWs may have the same tendency as vets to turn into simple traders rather than using and expanding their rather limited expertise. While community-based para-professionals undoubtedly have the ability to identify local needs and priorities, there is some skepticism regarding their ability to act on a preventative rather than a curative basis (Nelson, 2001).

In spite of these concerns, however, CAHWs and other veterinary para-professionals have proved to be one of the best ways of providing veterinary services in some marginalised areas where traditional private practices cannot survive, and, despite continued resistance, are increasingly accepted by veterinary professionals as the only viable means of providing basic animal health care in these areas (AU/IBAR, 2004; Leyland and Catley, 2002; Ly, 2002; Sones and Catley, 2003). In many African countries, former government veterinary assistants are still the primary (albeit illegal) practitioners around many small towns and provide a much-needed, if unregulated, service.

An enterprising example of a small business that successfully links vets, CAHWs and the veterinary pharmaceutical industry is outlined in Box 2.2.

Box 2.2 Successful veterinary drug distribution in rural Uganda

Dr Opolot of Karamoja has combined intelligent pharmaceutical distribution with extension services to develop a very successful business in one of the most hostile parts of Uganda. Karamoja is a very isolated pastoralist area, plagued by cattle rustling and ethnic violence. Dr Opolot started a veterinary supply business on the edge of this region, with very little initial capital; it grew slowly, but sufficiently for him to obtain several successive bank loans. As the business continued to grow, so Dr Opolot was able to obtain larger stocks on credit with pharmaceutical companies, and began applying for government contracts. He also began to distribute drugs to the NGOs who were training CAHWs in the region; eventually the CAHWs came to him independently of the NGOs, allowing the latter to implement their phase-out plans.

As the business has continued to grow, so has the need for sound business management, and a young vet has now been hired for the bulk of the practical work, leaving Dr Opolot to concentrate on running the business. Dr Opolot has encouraged other vets to establish private practices in the area by supplying new graduates with their initial drug stocks on credit. He has subsequently retained them as clients and now supplies drugs, training and promotional items in large enough quantities for him to consider applying for a direct import license. This would further benefit local livestock owners by reducing the overall cost of drugs in the area.

2.3 Pharmaceutical suppliers: incentives for investing in least-developed countries

For the majority of veterinary products currently on sale in African countries, patent protection has expired and generic drugs dominate the market. There is currently little incentive for most of the major multi-national pharmaceutical companies to develop products targeted at the most important livestock diseases in Africa. In this respect, poor enforcement of intellectual property rights is one of the main disincentives. Where intellectual property protection is inadequate or poorly enforced,

pharmaceutical companies risk losing market share through the sale of copies, counterfeits and parallel-traded products from lower-priced markets. Under such conditions, there is no incentive for either multinational or local companies to invest in research and development targeted at strictly regional problems. Improved patent protection 'internationalises' the effort to find cures for diseases, spreading the effort to countries that have the core scientific skills but lack the necessary market incentives. Better patent protection would also encourage researchers in countries with emerging pharmaceutical industries to switch from a strategy of 'molecule copying' to more innovative research into new drugs or versions of existing ones specifically for LDCs (Bale and Kettler, 1999).

Various attempts have been made to try to encourage companies to invest in products which, while being greatly needed, represent only relatively small 'niche' markets. The provisions of the US orphan drug legislation (tax credits, research grants, guaranteed purchasing and market exclusivity), for example, are designed to address this need. Of these, various analyses have found market exclusivity rights to be the most important incentive (Peabody *et al.*, 1995), since research grants and tax credits together make little impact on the high costs involved (Shulman and Manocchia, 1997). However, as things currently stand, market exclusivity incentives are generally weaker for products targeted primarily at the problems of LDCs, for two reasons: firstly, as mentioned above, intellectual property rights are often inadequately protected and secondly, the poorest LDC markets are simply not an attractive proposition for most international companies. One alternative, suggested by Harvey Bale (President of the International Pharmaceutical Manufacturers Association), is to grant exclusivity rights for other products marketed predominantly in developed countries as an incentive for developing drugs and markets for LDCs. Better public–private partnerships might also increase the attractiveness of foreign markets to large pharmaceutical companies.

Some countries have introduced a system of compulsory licensing of products to competitors in an attempt to reduce prices. However, experience suggests that while this approach benefits new suppliers, it acts as a disincentive to major suppliers, inhibits innovation and is of little benefit to the end-user. For these reasons, such schemes have been abandoned in Australia, Canada and New Zealand.

2.4 Drug resistance and rational product use

Given the general lack of incentives for companies to develop new products for LDC markets, it is important that the efficacy of existing products is maintained for as long as possible by ensuring that they are used correctly. Consistent underdosing can lead to the development and persistence of chemoresistant populations of parasites and pathogens, while overdosing can lead to increased residues in tissues and faeces, which may further promote the development of resistant populations. In Africa, veterinary drugs causing particular concern in relation to resistance include anthelmintics, acaricides, antibiotics and trypanocides. Of these, resistance to anthelmintics, acaricides and trypanocides is clearly evident, and cases of mastitis resistant to multiple antibiotics are an emerging problem. Factors contributing to under- or overdosing (and hence to the development of resistance) include illiteracy, inability to estimate livestock body weights, dilution of product (e.g. spreading a small purchase over a large herd), unfamiliarity with the product and ignorance of the consequences of misuse (Boray *et al.*, 1990).

Poor quality-control during the manufacturing process can also contribute to the problem: if the concentration of active ingredient is inconsistent, then unintentional under- or overdosing will result. The difficulty of ensuring adequate quality control is illustrated by the fact that, of 21 African nations with a domestic pharmaceutical manufacturing industry, six have no national quality control laboratory and four lack a national drug inspectorate. A study conducted in Cameroon, Chad and Madagascar from 1992 to 1993 found that 18% of the sampled drugs failed quality control tests and, of those, 3.7% contained no active ingredient at all (Wondemagegnahu, 1999). Similarly, a study of nine anthelmintic products sold in Kenya found that the actual concentration of the active ingredient (levamisole) varied from 0 to 114% of that claimed on the label, and that the concentration in different batches of the same product varied from 0 to 85% of that claimed. These deviations could be due either to incorrect storage or to deliberate fraud (Monteiro *et al.*, 1997).

Resistance problems are not restricted to marginalised farming areas. In South Africa, for example, a representative survey of 26 farms in the country's most productive wool-producing district showed that, on 8% of sheep farms, the parasitic nematode *Haemonchus contortus* was more than 60%

resistant to drugs from all four groups available in South Africa (M.O. Stenson, personal communication cited in van Wyk *et al.*, 1998). While the development of resistance is more or less inevitable for all drugs, it is hastened by the fact that products are often used incorrectly. Pastoralists are generally good at diagnosing animal health problems, but often use drugs in a trial-and-error manner which is likely to contribute to poor efficacy and the consequent development of resistance. These problems in turn generate mistrust of the affected products, and further undermine product sales. Even experienced clients are often unaware of more subtle dosing concepts that can affect efficacy; for example, they may buy a 5% oxytetracycline formulation because it is cheaper than a 10% product, yet administer the same volume and hence inadvertently give half the recommended dose of active ingredient.

It is unclear which methods can best improve consumer awareness of quality and rational use issues. Commonly used methods include radio campaigns, extension via CAHWs and company-run 'farmers' days'. Other suggestions include creating different packaging for different product concentrations, with some additional customisation of labels. However, creating customised local labels in addition to those dictated by international standards is sufficiently expensive to deter some companies. In contrast, basic consumer education on issues such as weight estimation for accurate dosing could have a significant impact at relatively low cost.

As mentioned above, the development of resistance is of particular concern given the low rate of new product discovery and development. For example, despite growing resistance to current anthelmintics, there is little hope that any new, chemically unrelated products will be forthcoming in the next decade: it has been reported that, out of approximately 7 500 compounds shown to have anthelmintic activity each year, only three are eventually considered for registration and only one will ultimately be approved for commercial use. Of even greater concern is resistance to trypanocidal products, since the latter are of little concern to the wealthy countries with the facilities to develop and register new drugs. Even if new products are developed, they may be too expensive for African consumers: most veterinary drugs available in Africa are older products for which patent protection has expired, allowing cheaper generic products to dominate the market.

Sheep and goats, which are very important in rural Africa, are especially at risk from the slow rate of new product development: on a global scale, although parasiticidal products constitute approximately 25% of total veterinary pharmaceutical sales, sheep products represent only 7% of this figure (Soll, 1997).

In spite of these concerns, however, it is important to avoid over-emphasising resistance issues, and to keep in mind that improved rational use is the best way of alleviating the problem. Resistance to antibiotics in particular is a politically charged subject, which in several developed nations has resulted in legal threats to the use of veterinary antibiotics both clinically and as growth promoters. In the USA, regulations have become so stringent that few companies are now willing to invest in the research and development of new veterinary antibiotics. Although this situation has been generated more by media outcry and public concern than by solid scientific evidence, it nevertheless has the potential to severely reduce livestock productivity and increase consumer costs. Developing nations should endeavour to avoid such reactionary regulation and the resultant shortage of veterinary drugs.

2.5 Drug regulatory authorities: development, functions and resources

An efficient regulatory authority is essential if quality standards are to be achieved and enforced. Drug regulatory policies and authorities – though now considered central to health policy – are in fact a relatively new phenomenon: 20 years ago only a few countries had national drug policies, and even today only half of World Health Organization (WHO) member states have appropriate regulatory authorities, of which only 1 in 6 are fully effective. The WHO defines the term 'drug regulatory authority' as a body that administers the full spectrum of drug regulatory activities, including authorisation of new products, modification of existing authorisations, quality control testing, monitoring of drug use and adverse reactions, promotion of rational drug use, certification inspections (e.g. for Good Manufacturing Practice (GMP)), licensing of manufacturers, wholesalers and other distribution channels, and quality enforcement operations (WHO 1998; 2000). In most WHO member states, companies pay an administra-

tive fee to maintain their marketing authorisation, but unreasonable fees can encourage evasion.

Some drug regulatory authorities are expected to generate their own income by undertaking profit-making activities such as commercial -testing, providing advice to other governments and agencies, and providing expert witnesses for legal proceedings. However, undertaking such activities for profit is contrary to the purpose and ethics of a regulatory agency, and detracts from the authority's regulatory function. Providing training and supplying publications on a cost-recovery basis are acceptable. Wherever possible, state financial support for the regulatory authority should include provision for an expert advisory body.

In Africa, operational drug inspectorates are generally non-existent, and access to quality control laboratories is often poor. Various international health organisations are actively involved in improving regulatory authorities for human medicine, and most of their work can also be applied directly to veterinary medicine. The WHO, for example, is responsible for certification of premises under the GMP scheme, maintaining the *International Pharmacopiea* and register of international non-proprietary names, administering the certification scheme for products on the international market, and providing training and advice for national quality control laboratories and other authorities. However, in many nations (including Kenya and Uganda), those with the greatest interest in maintaining a high quality animal health industry are effectively excluded from active involvement in regulatory policy making and enforcement, since there is little or no veterinary or animal health industry representation on the regulatory councils.

2.6 Regulatory harmonisation

Harmonisation of regulatory procedures is fundamental to improving the supply and distribution of veterinary pharmaceuticals in Africa. Apart from research and development, the time and expense involved in repeating work in order to register the same product in different countries is the largest single resource drain on the veterinary pharmaceutical industry.

In many developed countries, registration problems are increasingly responsible for reducing the availability of veterinary medicines.

In an effort to overcome some of these difficulties, European attempts at regulatory harmonisation have resulted in three different licensing categories for veterinary products, a scheme that might serve as a model for Africa. The three levels – 'national', 'mutual recognition' and 'centralised' – provide the same level of public safety, but allow companies to choose the number of the markets in which their product can be sold – a single nation, several member states, or throughout the European Union (EU), respectively. The European system recognises that not only are both host species and their diseases often very localised, but also that husbandry systems (and hence veterinary requirements) may differ from region to region. Veterinary vaccines in particular are clearly 'niche' products, being both species-specific and disease-specific. However, despite this tiered approach to product registration, a recent study commissioned by the European animal health industry found that the regulatory framework governing the development, registration and licensing of medicines is still the main obstacle both to the development of new products and to making better use of existing ones (Business Decisions Ltd, 2002).

If a suitable framework for increased regulatory harmonisation can be found, then numerous benefits are likely to result, both from industrial and national perspectives:

- the enforcement of uniformly high standards should increase the accessibility of export markets
- the number of substandard products should be minimised (particularly relevant to Africa, which tends to be treated as a 'dumping ground' by other continents)
- bureaucratic demands on both industry and government should be reduced
- decision-making at a national level will be facilitated
- countries still developing their own registration systems will benefit from the overall framework
- wastage of obsolete stock will be minimised as a result of being able to move stock easily to different markets
- regional markets will be developed
- specialised knowledge can be consolidated within a region.

Regulatory harmonisation in Africa

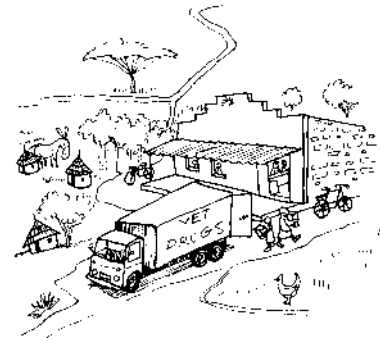
In contrast to the registration of crop protection products, relatively little progress has been made towards developing regional registration standards for veterinary products in southern and eastern Africa.

Nevertheless, some nations with no regulatory authorities of their own (Botswana, Lesotho and Swaziland) have already harmonised their standards with those of South Africa. Furthermore, although Namibia has its own National Drug Authority (NDA), it recognises the relative insignificance of its home market and so also bases its product acceptance decisions on those of the South African authorities.

In general, toxicological studies performed for registration in the northern hemisphere are satisfactory for most African regulatory authorities. However, country-specific clinical trials are generally required, and those products specific to the southern hemisphere (e.g. trypanocides, specialised vaccines, and products for the control of various endo- and ectoparasites) will inevitably require further local efficacy testing. A few African nations (e.g. Zimbabwe), still demand expensive and cumbersome repetition of complicated tests already completed in developed nations, as well as insisting on personal GMP inspections and so on. Ultimately, such over-regulation simply deters imports and reduces product choice and availability.

As a first step towards greater regulatory harmonisation in Africa, priority needs to be given to establishing a drug listing and classification system in nations with no regulatory authority of their own.

3 Status of the veterinary pharmaceutical sector in Kenya



3.1. The significance of livestock in Kenya

In the past, livestock production has comprised up to 25% of Kenya's total gross domestic product (GDP), but at present constitutes only about 10% (Anon, 2002), with agriculture as a whole contributing approximately 25% to total GDP. The recent decline in the importance of livestock is partly due to several years of drought, which are thought to have significantly decreased Kenya's cattle population from its previous estimated level of about 12 million. Relatively little of the government's budget is allocated to the livestock sector: in the years 1993/94 and 1997/98, for example, the livestock sector received less than 2% of Kenya's total recurrent agricultural budget (Aklilu and Wekesa, 2002).

Since Kenya became independent in 1963, the number of large-scale livestock producers has steadily declined: according to one pharmaceutical distributor, there are now only about 30 large ranches in Kenya, each with an average of 5000 head of cattle. Sixty per cent of the national herd is owned by pastoralists and agropastoralists, who comprise 25% of Kenya's human population and occupy 75% of the land mass (Silkin and Kasirye, 2002). The value of livestock in these pastoralist areas is estimated at over 70 billion Kenyan shillings (Ksh) (US$1 billion), but it is in these arid and semi-arid lands that livestock tend to be at greatest risk from disease and drought. Under drought conditions, offtake is more important to herd survival than are veterinary drugs. However, drugs can increase survival during times of stress, and if owners can pay for drugs with animals, both prevention and offtake are accomplished (Aklilu and Wekesa, 2002). Several NGOs have successfully implemented this novel strategy, although ideally local drug suppliers should be used so as not to undermine the latter's business – an important point often ignored in the past.

In the higher rainfall areas of the country, the smallholder dairy sector has grown in importance over the last 40 years, and Kenya now has the largest national dairy herd in Africa: larger than that of all the eastern and southern African countries combined. The market for milk and other dairy products was liberalised in 1992 and in non-drought years production exceeds demand due to seasonal gluts in the wetter months.

The production of other animal-based foods still does not meet national demand, although there is a small export market for processed meat products (e.g. sausages) (mainly to other African countries and the Middle East).

3.2 The animal health care industry

Industry structure and distribution networks

The Kenyan market for animal health products is shrinking, mainly due to a combination of national economic problems and the particular fragility of the agricultural sector. In recent years, profits throughout the sector have also been adversely affected by drought, which, as mentioned above, is thought to have significantly decreased Kenya's cattle population (although quantitative data are unavailable). After the drought in 2000, for example, several distributors reported a reduction in profits of up to 70%. Nevertheless, the major suppliers of veterinary products to Africa are still highly dependent on the Kenyan market and there is still some potential for growth by small companies. Overall, the large number of unregulated commercial entities makes it difficult to estimate the absolute value of the veterinary pharmaceutical industry in Kenya, but it is undoubtedly one of the most important markets and re-export sites for animal health products in Africa. It was estimated that Kenyan livestock farmers spent Ksh 0.64 billion (approximately US$8 million) on veterinary pharmaceuticals in 2000, although this is probably a very conservative estimate.

The Kenyan pharmaceutical industry was liberalised in the 1990s, and there are now numerous veterinary drug retailers across the nation, although it is currently illegal for anyone other than pharmacists (including veterinarians) to sell drugs wholesale. As in most of Africa (apart from

the francophone nations), large international pharmaceutical companies tend to work with a single main distributor, who in turn supplies retailers, large farms and veterinary practices (Box 3.1). This differs from West African francophone and European nations, where wholesalers act as distributors for 10–12 companies, and retailers therefore have a choice of suppliers. Kenyan main distributors either specialise in veterinary products, or sell both human and veterinary medicines.

The larger international pharmaceutical companies vary in the extent to which they have maintained their own marketing teams in Kenya and elsewhere in Africa. Many companies, including Merial and Pfizer, have completely withdrawn their local representatives (with the exception of South Africa) and rely completely on local distributors.

The largest clients of the main distributors are pharmacies and the shops known as agrovets (which stock both crop-related and veterinary products),

Box 3.1 Can exclusive distributors survive?

One company in Kenya now distributes its products via a network consisting of one main distributor in each district. These distributors were initially selected on the basis of their existing customer base, sales volume and turnover, and were subsequently required to restrict their sales to the company's products. In return, they received support in the form of vehicles, credit, business training, etc.

Nearly all of the distributors initially recruited have remained in the scheme, although in general they do not appear to have gained any notable advantage from operating under an exclusive contract. From the customer's point of view, the approach has various problems. Most customers tend to prefer outlets with a wide variety of products, and since the company's range lacks some key products, their distributors do not offer the full range of items required by rural clients. The restrictive nature of the system has also been criticized by other members of the veterinary pharmaceutical industry. Nevertheless, the company intends to persist with the scheme, and plans eventually to supply each district with products with separate batch numbers, both to improve traceability and to prevent competition between distributors in adjacent territories.

followed by private vets and large-scale farmers. Legally, vets are only supposed to provide products in response to clinical need, but the law is not rigorously enforced and for many vets profits from retail sales form a substantial part of their income. From an industry point of view, their professional expertise should give vets a competitive advantage as distributors. However, they often have poor commercial skills and some pharmaceutical companies therefore offer vets training in business and financial skills.

From a retail perspective, animal health products typically generate more profit than do other agricultural products. Regardless of the nature of the outlet (chemist, vet or agrochemical shop), more than 60% of shop profits usually come from veterinary pharmaceuticals. Of this 60%, 40–70% is typically derived from acaricides, which are by far the most important products. A typical veterinary retailer has an average distribution radius of 50–100 km, but the main distribution strategy (as in Uganda and South Africa) is to increase product range before expanding geographical range. For animal health specialists in higher-potential areas, livestock nutritional products and artificial insemination (AI) services are particularly lucrative. The value of AI services has more than doubled in the last four years, nationally generating approximately Ksh 90 million (US$1 125 000). Overall, however, profit margins are low and profits depend on volumes traded. Discounts (usually around 10%) are given on bulk purchases (and occasionally for cash payments), but while pharmacies and larger-scale ranchers often qualify for these discounts, vets are rarely able to order in sufficient quantity.

Apart from vets, agrovets and pharmacies, other retailers of veterinary goods and services include dairy co-operatives and large- or medium-sized milk processors, who also supply extension advice and services such as AI. There are also a few examples of both large- and medium-sized shops on the edges of towns, serving mainly pastoral markets with consistent profit. The relatively neglected pastoral market is viewed by the pharmaceutical industry as having great potential, and is currently being addressed in various ways, including switching from large to small pack sizes. Novartis, for example, has started working in partnership with local chiefs to sell small (100 ml) bottles of selected products together with free equipment (e.g. sprayers for acaricides) and information on correct use.

One of the most efficient rural distribution mechanisms consists of vans that visit local livestock markets, with sales being coordinated by a distributor in a local town. However, these van-based sales are only legal for over-the-counter materials such as anthelmintics and acaricides, and products are sometimes displayed in inappropriate conditions (e.g. in full sun). Veterinary medicines are certainly available in rural areas, but their quality is variable and advice on dosing and rational use is often lacking. The best way of distributing restricted products (so-called 'ethical' drugs) and of supplying accurate diagnoses and dosing regimes in remote areas are still largely unresolved issues, although properly supervised and regulated para-professionals have been shown to help (IDL, 2002).

Representatives from all levels of the animal health industry have repeatedly emphasised that the most important way to improve animal health in rural areas is to improve customer education regarding quality products and services. A variety of methods have been used to address this need, including some limited radio advertising. However, the most successful way of reaching local communities is via company-sponsored 'farmers' days'. Unfortunately, because many companies have a poor image of vets (as a result of an over-emphasis by some on sales at the expense of clinical services), they prefer to hold such events in association with feed producers, dairy co-operatives or NGOs. The information provided in the course of such events is, of course, biased towards the product range of the sponsoring company, but they are nevertheless very popular. Unfortunately, however, such events are almost never held in pastoralist or arid areas.

Product manufacturing and repackaging

Members of the animal health industry have expressed differing opinions concerning the feasibility and advisability of processing or repackaging products in Kenya. There is often no price advantage for in-country processing, since the Kenyan government taxes imports of the petroleum-based products needed for this purpose, yet fully formulated veterinary drugs are free from duty. There is thus no incentive for the establishment of a local industry, despite the potential employment and investment opportunities it could provide. Kenya has an export processing zone from which, theoretically, stock could be re-exported to the rest of East Africa,

but having tried this for several years, CEVA found that the strict zonal regulations, high rents and other overheads forced them to close and resume exporting directly from France. Ensuring adequate quality control is also an issue for some companies. CEVA, for example, eventually concluded that quality could not be guaranteed even for repackaging, much less for manufacturing finished products. However, Cooper produces products in pack sizes appropriate for local purchasers, and Pfizer and Novartis are partners in repackaging their South African imports in Kenya; they are sufficiently happy with the results to state that the ability to repackage would be a significant factor in deciding to import into other new markets.

There is only one Kenyan generics manufacturer: Cosmos. Unique in East Africa, Cosmos has 15 years experience in veterinary medicines and is generally considered to produce goods of equivalent quality to imports, although distributors have mentioned that their packaging is occasionally vulnerable to tampering and that their products are sometimes adulterated and show poor efficacy. Fifty percent of their market is in anthelmintics, with a growing presence in the poultry sector. They have not yet entered the acaricide market (the largest market in eastern and southern Africa). Cosmos representatives believe that their internal manufacturing strategy gives them a competitive advantage: their products are significantly cheaper than those of most other companies, they have a widespread distribution network and an excellent client base. The only other manufacturer of animal health products in Kenya is the Kenya Veterinary Vaccine Production Institute (KEVEVAPI), which produces vaccines for various diseases (including foot-and-mouth disease (FMD), rabies, and several others), despite competition from imported products.

3.3 The role of the veterinary and allied professions

National structure

Only about 5% of veterinarians in Kenya are in private practice and, of these, very few practice in the arid and semi-arid areas which are of such significance to the livestock industry. There are considerable

obstacles to establishing a private practice, including lack of security, a shortage of banks willing to guarantee credit sales and a general lack of recourse in the event of non-payment of bills. The capital necessary to start up a private veterinary practice in Nairobi and the Mount Kenya area has been estimated by veterinarians and other industry members to range from Ksh 600 000 to 2 million (approx. US$7 700–26 000). These estimates reflect the amount needed to compete well enough to overcome any initial competition, and even at the lower end of the range are well in excess of the funds available to most Kenyan vets. However, the Kenya Veterinary Association Privatisation Scheme (KVAPS), a development project initiated in the early 1990s, is able to provide individual loans of up to Ksh 1.2 million (US$15 400) (Box 3.2). So far the scheme has supported nearly 60 vets in 20 districts, although none are based in the arid or semi-arid areas. The support offered by the KVAP scheme can help vets acquire the most important inputs for a new practice (e.g. a vehicle, a shop with a wide range of products and an employee to run the shop when the vet is out on call).

Officially, off-duty government vets are only allowed to provide private services in areas where there are no private practitioners; they can be disciplined for infringement by the Kenya Veterinary Board (KVB), with penalties up to and including deregistration. In practice, however, these regulations are rarely enforced and both government vets and para-professionals can be a major threat to legitimate private practices.

The Kenya Veterinary Association (KVA) is the professional body for the country's veterinary surgeons, but only a minority of qualified vets are members; many now earn their living from other professions as a result of the lack of opportunities in the public sector and the difficulty of establishing private practices.

The statutory body responsible for both veterinary laboratory services and the registration, discipline, education, and practice standards of all of Kenya's vets is the KVB, formed under the provisions of the Veterinary Surgeons Act (CAP 366). Veterinary drug distribution is regulated by three sections of Kenyan law: the Veterinary Surgeons Act, the Food and Drug Act, and the Pharmacy and Poisons Act, the provisions of all of which are administered by the nine-member Pharmacy and Poisons Board (PPB). However, veterinary representation on the PPB is limited to the Director

of Veterinary Services (DVS), with the other members representing the pharmacy and human medical professions.

Box 3.2 The Kenya Veterinary Association Privatisation Scheme (KVAPS)

The Kenyan state veterinary service is under-resourced and the range of services that it provides is declining. There is general agreement amongst veterinarians and other industry professionals that most animal health care should be provided by private vets, leaving the government service only with specific responsibilities related to regulation, vaccination and the control of notifiable diseases. If necessary, these latter services could also eventually be contracted out to private veterinary practices. Successful veterinary privatisation is thus one of the keys to improving the provision of rural animal health care in Kenya.

Veterinary privatisation is progressing at a similar rate in Kenya as it is in many other African countries, although start-up capital is often harder to obtain. It was to address this need for venture capital that the KVAPS initiative was first proposed in 1984 and implemented in 1991. KVAPS is a credit scheme initiated by the KVA, funded by the EU and administered in association with the Kenyan Ministry of Finance, the Co-operative Bank of Kenya and AU/IBAR. The KVAPS trust provides loans at favourable rates (up to 4% better than commercial bank rates), up to a maximum of Ksh 1.2 million (US$15 400). If the loan is repaid on time, with documented accounts, a rebate of 50% of the interest is paid. Approximately 95% of recipients of KVAPS financial support use their funding to establish a retail outlet for veterinary drugs.

Compared to privatisation support schemes in other nations, one of the strengths of the original KVAPS system lay in the fact that the trust's capital funds were invested, allowing the project to be funded from interest payments; furthermore, any surplus was reinvested, so that the capital reserve increased rather than diminished over time. The main advantage to vets of the KVAPS scheme was its relatively low interest rates, although the project's insistence on small business training and field experience was (and is) also beneficial: all but one loan recipient interviewed for this study were enthusiastic in their pursuit of business training.

From 1996 to 1998, the failure rate of businesses funded by the project was about 10% (i.e. within acceptable international standards for start-ups). In recent years, the scheme has been adversely affected by falling interest rates and hence reduced income from its capital. Nevertheless, the third round of loan offerings is currently being planned and implemented, with the dual intention of focusing on marginalised areas of Kenya (including the arid/semi-arid lands), and on providing an enabling environment for vets (e.g. by lobbying for legislative changes and by offering continuing education and research opportunities).

Veterinary auxiliaries and para-professionals

In addition to professional veterinarians, varying levels of animal health care are provided by AHAs, junior animal health assistants, animal health technicians (AHTs) and CAHWs. The government has a 1–3 year training programme for AHAs and AHTs, who until the 1980s were commonly employed by the state to help veterinarians with primary animal health care and extension services. CAHWs serve a similar purpose but are selected by and work within their own community after being trained by various NGOs or private or government vets. The training programmes for CAHWs are in the process of being standardised, but at present are quite variable. Both AHAs and CAHWs are supposed to operate only under veterinary supervision, but many are currently operating illegally on their own. Often they work in remote areas far from the nearest 'supervising' practitioner. Some holders of AHA certificates and diplomas have set up unlicensed agrovet shops, and some CAHWs provide both over-the-counter and restricted products. They are thus open to the same criticism leveled at vets – i.e. that they can show a tendency to turn into simple traders rather than using their expertise to the full.

The perceived value of these veterinary para-professionals is thus rather variable, although many view them as the best way in which veterinarians can extend their outreach and improve rational drug use. Both diagnosis and dosing by livestock owners could be enhanced by well-trained AHAs and CAHWs: for example, while pastoralists are often excellent at diagnosing common local diseases, they have less experience of administering modern veterinary medicines. Under- or overdosing are chronic problems, and drug resistance or lack of efficacy due to misuse have been witnessed by many of the vets interviewed for this study. CAHWs are an obvious way of improving the informed use of veterinary medicines, although vets in the Mount Kenya area interviewed for this study reported that, at present, many AHAs and CAHWs have poor practical skills and poor training in diagnosis and correct drug use. They also expressed some concern over the possibility of being undercut by these practitioners, although most stated that they would make use of a CAHW-based distribution system if it was linked to their business and further training was provided.

Despite these rather negative views, however, in most of the marginalised areas (where private veterinary practices have yet to be established and government services are overstretched), CAHWs have been found to be the

best means of providing primary animal health care, and are increasingly accepted as such by veterinary professionals (Box 3.3). Furthermore, where CAHWs have access to a good range of drugs and are well supported, they are usually preferred by clients over local, untrained dealers (Catley *et al.*, 1998; Owens, personal observation). Even without adequate professional supervision, client satisfaction with CAHWs tends to be higher than with any other service provider. In Huri Hills, for example, CAHWs became the sole providers of animal health care despite a thriving black market, mainly because they were able to supply a wide range of drugs and acted responsibly in dispensing and administering them (Owens, personal observation). The Kenyan Government is currently considering a revision of the Veterinary Surgeons Act which proposes licensing and regulatory procedures for veterinary para-professionals; better training and regulation would undoubtedly improve the status of these veterinary auxiliaries and enhance their value as providers of rural animal health care.

Veterinary services[2] in relation to the veterinary pharmaceutical industry

The Pharmacy and Poisons Act (CAP 244) denies veterinarians the legal right to trade in veterinary medicines except for therapeutic purposes: neither wholesale nor retail sales are permitted. However, the Act is nearly impossible to enforce, and most private vets make 60% or more of their profit (illegally) from sales of animal health products. Many members of the industry (including representatives of pharmaceutical companies, farmers and laboratory personnel) have expressed the opinion that retail sales can compromise the professionalism of vets, shifting their focus away from rigorous diagnostic, therapeutic and preventative services to selling the cheapest products at the highest margins. A common perception is that vets would rather sell merchandise and knowledge over the counter in volume than undertake time-consuming diagnoses in the field. Pharmaceutical companies have also expressed some dissatisfaction with the poor business skills of most vets.

[2] The term 'veterinary services' includes all veterinary authorities, the state veterinary administration and all persons registered or licensed by the statutory veterinary bodies.

Box 3.3 Successful community animal health services: a case study from Mwingi District

Mwingi District in the Eastern Province of Kenya is a predominantly semi-arid area where there is a 66% probability of crop failure and livestock products constitute, on average, approximately 70% of total household income. Prior to 1992, when the first community-based animal health services were initiated, livestock owners had to rely on traditional healers or untrained individuals since the area was poorly served by both state and private veterinary services.

The CAHWs currently working in Mwingi District are trained, deployed and supervised by the district veterinary officer. The training consists of two separate 7-day courses with additional updates as required. Many CAHWs have established good relationships with government-employed AHAs (many of whom own agrovet shops) – which embrace drug supply, referral and support. There are also very complementary linkages between CAHWs and other staff employed by the state veterinary service.

The CAHWs carry good quality products and derive sufficient income from their services to want to continue to provide them. A study commissioned by AU/IBAR in 2002–3 found that 80% of all those who had been trained under the scheme were still practising, and of these, 95% considered their businesses to be successful and expanding. During the study, the CAHWs were tested to assess their knowledge of disease symptoms, notifiable diseases, zoonoses and correct drug use. Of the CAHWs who took the test, 90% passed and were considered to show a sufficient level of technical proficiency to limit the emergence of problems such as drug resistance. Their main weaknesses were in record keeping and knowledge of zoonoses.

Local farmers rated the services provided by the CAHWs very highly, describing them as timely, accessible, affordable and effective, with treated animals showing good rates of recovery. As a result of these positive perceptions, there is now an increasing trend for farmers to choose CAHWs over competing service providers such as the traditional healers and various untrained, unsupervised and illegal operators.

Source: AU/IBAR (2003)

Nevertheless, their professional expertise gives vets a competitive edge over other retailers, although it is not sufficient to allow them to charge a premium in poor rural areas. In order for veterinarians to compete as retailers with small, high-volume shops selling cheap generic products, they must offer a full range of products including acaricides, anthelmintics,

antibiotics, and, increasingly, other products such as agrochemicals, animal feeds, and so on. Buying in cash, direct from manufacturers can increase their profit margins and competitiveness, but some suppliers (e.g. Bayer and Cooper Kenya) will only supply via an intermediary main distributor. All pharmaceutical distributors interviewed for this study were willing to supply vets on credit, although a few prefer more established clients and larger bulk orders. The distributors generally agreed that veterinarians are far superior to pharmacists in terms of ensuring rational use of animal drugs, and most feel that vets play a key role in fostering acceptance of new products. Many private veterinary practices in the higher-potential areas are now specialising in expanding sectors of the livestock industry (e.g. poultry, pigs or dairy cattle), or are diversifying into new enterprises such as feed manufacturing. However, although many see possibilities for expansion, their opportunities are often constrained by a lack of available capital. Their potential income is further reduced by the fact that some essential vaccinations (e.g. for rinderpest and contagious bovine pleuropneumonia (CBPP)) are still provided free of charge by the Kenyan Government. In developed nations, such vaccinations can have high profit margins and are one of the most dependable components of a vet's annual income. Contracting-out services traditionally performed by state veterinarians to private practitioners (such as vaccinations, disease surveillance and meat inspection) would both help to increase the viability of private practices and ease the burden of over-stretched government services. This approach has been adopted successfully by other nations (e.g. Uganda) and in emergency (outbreak) situations in Kenya itself.

Proposed amendments to the veterinary legislation

In addition to the proposed revision of the Veterinary Surgeons Act mentioned previously, a proposal to amend the Pharmacy and Poisons Act to limit the dispensation of veterinary medicines to veterinary professionals has been pending for approximately 10 years. A legal monopoly on retail would allow many vets to expand the geographical scope of their businesses, which, at least theoretically, should improve the overall infrastructure and integrity of the Kenyan animal health care system. However, the proposed amendment faces serious opposition from some pharmacists, who argue that they could meet the needs of the

legislation by increasing the veterinary component of their training. This, however, would undermine a key aim of the proposal, namely to ensure that the responsibility for correct treatment lies with those for whom animal health is a priority and who are present at the point of use, not just at the point of sale. At present, pharmacists in Kenya are notorious for selling restricted veterinary products without proper prescriptions, despite training to the contrary. Perhaps somewhat surprisingly, many of the larger and more successful pharmacists interviewed for this study supported limiting the supply of veterinary drugs to veterinary professionals, and the better quality distributors expressed a willingness to hire vets to supervise the sales of their animal health products should it become necessary.

However, opposition to the proposal has also been expressed by many animal owners, who fear that restricting sales to vets would result in higher prices, either because pharmacies would be forced to employ vets, or because they themselves would have to pay veterinary call-out and treatment fees each time one of their animals needed medication. In fact, however, observation suggests that in both Kenya and Uganda (in both rural and urban areas), prices tend to decrease when private vets enter the market, and treatment costs in towns in which a veterinarian is the sole provider are no different from elsewhere. If confusion and mistrust are to be avoided, therefore, the potential effects of the proposed legislation must be properly explained to consumers.

Veterinarians are probably those best qualified to regulate the quality of animal health services and products. However, in order to promote legislation such as the proposed changes to the Pharmacy and Poisons Act, they need stronger political lobbying powers and greater professional solidarity.

3.4 Regulatory authorities and processes

National structure and quality control

Legal control of drug quality falls under the mandate of the PPB, while the DVS, as overall coordinator of animal health, is mandated to improve service delivery. As mentioned previously, the PPB focuses primarily on

quality control of human medicines and agrochemicals, and has only one veterinary representative. Perhaps as a result of this imbalance, shops selling a mixture of products report that while both human medicines and agrochemicals are regularly inspected, the same cannot be said of veterinary products, which are rarely (if ever) checked. In order to counteract this inaction on the part of the PPB, the DVS has begun to appoint provincial veterinary inspectors whose duties include inspecting wholesale and veterinary drug outlets; the first eight inspectors were recruited and trained in 2003. With a minor amendment to the Veterinary Surgeons Act, these officers will be given the power to arrest offenders, although their ultimate value will be restricted by the fact that multiple agencies and laws are involved in the prosecution of such cases. Ideally, the new inspectorate should be consolidated into a designated body with full prosecutionary powers, run by experienced veterinarians committed to providing high quality animal health services. With the help of AU/IBAR, donor funding has recently been secured by the KVB for legal help in proposing and lobbying for such changes.

At present, however, Kenya faces a serious problem with counterfeit and adulterated drugs and has significant quality control issues. Estimates by industry members suggest that approximately 30% of all drugs in Kenya are substandard, and a recent study by the Kenya Agricultural Research Institute (KARI) found that although injectible products were generally of good quality, many anthelmintics and pour-on acaricides were substandard. Some products (e.g. the therapeutic trypanocide diminazene) have been found with levels of active ingredient significantly lower than the amount declared on the pack. Monitoring product quality and enforcing standards have been made more difficult by the increasing number of companies involved in the provision of veterinary drugs, mainly as a result of trade liberalisation and the expiry of patents, both of which have allowed new manufacturers to enter the market. In some areas, livestock owners have encountered sufficient problems with ineffective drugs (especially cheap generic products) that they are increasingly seeking new products, education and advice from 'reputable' companies. Adverse reactions or product failures are generally reported directly to the supplier by the distributor, although most suppliers feel that such events are rarely product-related and often blame misuse or adulteration by either the retailer or end-user.

A National Drug Quality Control Laboratory (NDQCL) was established in 1995. It has the capacity to carry out 1 500 tests per year, but is currently very underutilised, running on average only 100 samples per year, about half of which are commissioned by the private human health care sector and 15% by the PPB; only two veterinary samples have ever been submitted. Fees range from Ksh 600 to 15 000 (US$8–192), depending on the tests required. However, the laboratory's analyses tend to be of a relatively low standard, due to poor access to reagents and outdated protocols. Perhaps for this reason, the PPB has not given the NDQCL the mandate to carry out pre- and post-registration product analyses. In contrast to the NDQCL, the privately run Analabs conducts over 320 acaricide analyses per month for European manufacturers, either to verify quality at the retail level as part of their service to distributors, or in response to customer complaints. There is thus a widespread perception among industry members that they have been left with the bulk of the responsibility for preserving the integrity of their brand names, with very little support from the Kenyan Government. Prosecutions are rarely publicised, fines are generally too low to act as deterrents (ranging from US$30 to 500), and, although there is legal provision for imprisonment, such sentences are rarely, if ever, imposed.

Registration requirements

The registration of veterinary drugs is the responsibility of the PPB, while acaricides are classified as pesticides and are registered by the Pest Products Control Board. There is a US$1 000 fee for registering veterinary products, renewable every 5 years. However, many smaller importers 'avoid' paying it, since it significantly increases their costs and reduces their competitiveness. The costs of funding the NDA therefore tend to fall mainly on the larger companies who are more concerned with meeting international standards of accountability.

There is an urgent need to improve Kenya's drug registration and enforcement procedures, specifically to address the following:

- revision of registration forms to include more details on the pharmaceutical aspects and clinical formulation of products
- revision of the registration guidelines to improve their compatibility with the application forms

- expansion of product classification to include, for example, medical devices and herbal products
- updating of existing drug schedules
- enforcement of product registration requirements
- strengthening the pharmaceutical inspectorate
- initiating strategies for market surveillance
- implementing standard evaluation procedures.

4. Status of the veterinary pharmaceutical sector in South Africa

4.1. The significance of livestock in South Africa

Compared to their role in other African nations, livestock are less important in South Africa, contributing less than 5% to the national economy. In the past, there have been up to 12 million cattle in South Africa, but their numbers have been decreasing since 1980 as a result of severe drought conditions over much of the country, and the present population is estimated to be approximately 8–9 million. Beef cattle are reared mainly under extensive conditions, although some intensive units are found in the high-potential areas of Mpomalanga, KwaZulu-Natal and Eastern Cape. The emergence of these intensive feedlots and the removal of restrictions on the numbers of animals being marketed at any one time has encouraged the sale of animals at about a year old compared to the previous norm of 2–3 years, so that cattle owners now have a higher turnover of younger animals. However, cattle still function as 'bank accounts' for many smallholders, as well as providing dietary protein, forming dowries and fulfilling other cultural functions.

As far as livestock diseases are concerned, in contrast to the situation in the disadvantaged pastoral areas of Kenya and Uganda, poor livestock owners in South Africa have little knowledge of drugs and diseases and do not diagnose their own animals (although they usually administer all of their own treatments). Better extension services are needed to improve the flow of information to these farmers. For example, local pharmacists in KwaZulu-Natal have publicised the risks of trypanosomiasis and worms, and as a result local livestock keepers tend to overdiagnose these conditions while other maladies (including various tick-borne diseases, brucellosis and salmonella) go unrecognised and untreated. Furthermore,

while there is usually little cash available for commercial products in rural areas, there is often a thriving trade in traditional plant-based medicines. Ondestepoort University's veterinary pharmacy department is presently researching the composition and efficacy of traditional medicines and new products may eventually arise from this initiative.

4.2 The animal health care industry

Industry structure and distribution strategy

South Africa is currently ranked thirteenth in global sales of animal health products. Most products are imported from the USA or Europe, and most of the main multinational pharmaceutical companies (including Merial, Novartis and Pfizer) are represented in South Africa. The principal companies trading in products for the large animal market are Intervet (the market leader) and Bayer (which has about 20% of the market share in both the large and small animal sectors, and has the widest range of products).

Unlike the situation in the rest of Africa, the market for products aimed at small animals is growing very rapidly while that for large animal products is declining (with the possible exception of a small but growing sector associated with game farming). Pet products are the fastest growing market, with pet foods and other retail items (mainly sold through vets) generating high profits. Nevertheless, the majority of animal health products are still destined for the large animal market, with some of the most important being acaricides, endectocides (avermectins, pyrethrins, etc.), and anti-infectives. Brand name is important, but many of the major distributors feel that price is more critical, particularly in many niche markets. Furthermore, since the patents for most products have expired, competition from cheap generic products is becoming increasingly important.

Although there are no government incentives for manufacturing, there are ten pharmaceutical manufacturing plants in South Africa, all of which import their basic chemicals and active ingredients for further processing and export finished products to the rest of Africa. The export trade benefits

from a good regulatory infrastructure, and the sector is likely to increase in importance in the future.

Among the wholesalers, the largest is Lakato, with a 60% share of the animal health market (by value); most of their products are pet foods, and they supply exclusively to vets. The largest wholesaler of generic products is Eco Animal Health, who currently employ their own vets as company representatives, although they are also willing to work with private vets.

Average growth rates for companies within the animal health sector range from 5–10% per annum, with the highest rates being recorded by those distributing speciality pet foods or by large suppliers exporting to the rest of Africa. However, profits from traditional product sales are declining: global competition has reduced margins, and the costs of transport to rural areas have become progressively more difficult to absorb. As elsewhere in Africa, increasing costs are often absorbed by the distributor and are not necessarily reflected in the end price to consumers. Some of the distributors interviewed for this study viewed contract sales to large-scale farmers as a potentially profitable area; at present, however, these clients are supplied directly by manufacturers.

Another potentially valuable emerging market is for products targeted at small-scale farmers. Most of the major suppliers are now starting to produce small packs designed specifically for these customers. Lionbridge Veterinary Distributors, for example, has built a very successful business based entirely on supplying small packs to farmers and rural pharmacies. However, they have experienced problems as a result of the generally poor infrastructure in rural areas, and in recruiting enthusiastic rural distributors. The rural smallholder market is not being fully exploited: if the local availability of drugs could be improved, livestock owners would buy smaller packs or single doses (Gehring *et al.*, 2002). Only Alphapharm (a distributor based in Natal) has been actively trying to improve its smallholder distribution network, albeit with only limited success. The main rural smallholder areas where veterinary needs remain largely unmet include Zululand (north of Durban to Mozambique), selected areas in the Northern Province, and the Eastern Cape.

In smallholder areas, successful marketing strategies include translation and/or pictorial adaptation of labels and package inserts, and specialised training of sales representatives (Gehring *et al.*, 2002). Company-run

farmers' days are also popular and usually attract large crowds. However, such events are typically run in conjunction with community officials or agricultural extension offices rather than the state veterinary service; making better use of state AHTs for field days would help strengthen the connection between the veterinary pharmaceutical industry and the state service. Other successful promotional strategies include running annual cattle shows and sponsoring champion wool clubs in subsistence areas in order to increase the value of the local livestock.

The principal retail distributors of veterinary products are shown in Table 4.1. Unlike the situation in other African countries, there are almost no local mobile traders, and farmers' co-operatives are more important than veterinarians as distributors of over-the-counter products for livestock because they qualify for bulk discounts. Co-operatives can therefore sell

Table 4.1 Principal distributors of animal health care products in South Africa

Major distributors of livestock products	Market share (%)
Farmers' co-operatives	≥ 60% of total national sales
Wholesalers and pharmacists	25%
Veterinarians (Veterinarians are major distributors of products for small animals)	10–15% Products distributed exclusively by veterinarians represent 25–30% of sales by value (but not by volume)
Government tenders for free distribution to stock owners	5–10%

Note: 5% of 'Act 36' (over-the-counter) products are sold through vets, and of the remainder, 50% are sold through co-operatives and 50% through pharmacists.

at much lower margins than can vets (around 20%, compared to 50–100% for vets), even without passing on the full discount to their customers. The co-operatives have the additional advantage of being able to operate credit systems, allowing farmers to pay for products after harvest or after a fixed term. Veterinarians complain that the co-operatives are undercutting their businesses without offering the benefit of animal health expertise: representatives of the co-operatives generally have good product knowledge, but have no relevant practical skills and cannot offer personal diagnostic or treatment services. Nevertheless, most industry members feel that, overall, co-operatives are perfectly acceptable primary distributors of over-the-counter products to farmers, particularly since many vets are reluctant to distribute low-profit products such as dips, anthelmintics, vaccines and some antibiotics. There is a perception that some tribal communities have been excluded by the co-operative infrastructure, but there is no evidence to support this view. On the contrary, in some parts of the Northern Province, co-operatives were found to be the primary source of veterinary drugs and the only source of information regarding treatments. In many cases, too, they are better equipped to store and sell pharmaceutical products than are the state agricultural or veterinary outlets. However, the focus of many co-operatives is changing: some have been badly affected by the general decline of the agricultural economy, and many have become too profit-orientated to truly serve disadvantaged, small-scale farmers. Thus there is some doubt that the existing co-operative infrastructure is adequate for the distribution of animal health products to underdeveloped farming communities, particularly given the post-apartheid influx of thousands of new small-scale farmers into the agricultural sector (Catton, 1996).

There is some controversy over the number of products that should be limited to vet-only distribution: reducing the number would increase their accessibility to poor and/or rural communities, but might decrease the viability of private veterinary practices in marginal areas. Some distributors (e.g. Alphapharm) have targeted the rural subsistence population by educating local pharmacists about animal health issues. However, few pharmacists are interested in veterinary pharmaceuticals: in general, they have little knowledge of the products and their prices are high, so that farmers tend to use them only to acquire restricted products (Gehring *et al.*, 2002; Owens, personal observation). Some rural pharmacists have

even been described as a danger to the rational use of drugs because of their lack of familiarity with livestock problems and products.

A recent study of rural animal health care in Northern Province found that the few community outlets carrying veterinary drugs had largely untrained staff and were little used by local customers. Most farmers appeared to be unable to recognise important livestock diseases, and numerous examples of the misuse of veterinary products indicated that the information supplied to farmers was not sufficient to ensure safe and effective use. Furthermore, although the majority of products sold appeared to be appropriate for the livestock diseases prevalent in the area, small outlets often lacked adequate facilities for the correct storage of products. In addition, since product choice was limited and prices relatively high, customers preferred to take a bus to the city to buy pharmaceuticals than to take a taxi to a small local outlet (Gehring *et al.*, 2002).

Apart from various commercial outlets, a large number of NGOs distribute veterinary drugs for welfare purposes. Drugs supplied by these organisations (which include the International Fund for Animal Welfare (IFAW), the Society for Prevention of Cruelty to Animals (SPCA) and community vet clinics run by the South African Veterinary Association (SAVA)) are generally free, although a few groups use profits generated in the more lucrative areas to fund free drugs elsewhere. Very few of these organisations work extensively in livestock systems, although the SPCA efforts in Natal are an exception. An SPCA project run in conjunction with Novartis and the local state vet concluded that the most important need was to re-establish dipping, followed by basic herd health inspections and treatment for trypanosomiasis. The SPCA has tried distributing veterinary products through the tribal authorities in this area but has found it too inefficient; they now aim to appoint a dependable person at each dip to be responsible for local drug distribution.

Thus, despite the comparatively advanced state of some aspects of the South African animal health industry, it suffers from many of the same rural distribution problems as does the rest of Africa. The underlying reasons for the lack of veterinary services and poor pharmaceutical distribution in rural areas are similar to those elsewhere on the continent: insecurity, large geographical areas with scattered populations, poor transport, lack of reliable outlets, low value livestock, poor local cash flow

and low levels of consumer education, with a consequent lack of effective demand.

The export sector

South Africa is a regional research and development centre for several international pharmaceutical companies, and the export market to the rest of Africa is considered potentially lucrative. The latter is well monitored and relatively transparent: low quality, excess, or expired product cannot be 'dumped' at low prices into the rest of Africa and parallel trade (i.e. buying products cheaply elsewhere and re-importing them into South Africa at a profit) is prevented. Supply gaps left elsewhere on the continent by the departure of some of the major European companies are now increasingly being filled from South Africa. Bayer's exports to the rest of Africa, for example, have grown significantly over the past 3 years, while Intervet's export sector has grown at three times the company's overall growth rate, prompting plans for the development of an all-Africa warehouse. In general, European parent companies are supportive of their South African subsidiaries' pursuit of external markets, although they often face competition from counterfeit and adulterated goods from elsewhere.

In spite of a lack of government incentives, there are ten pharmaceutical manufacturing plants in South Africa, all of which export to the rest of Africa. For human drugs, South African manufacturing quality is considered to be close to that of Europe, with a strict inspection and regulatory framework enforced with support from the WHO. Unfortunately, for animal health products, only Bayer's plant in Pietermaritzburg is currently up to the standard required by international GMP, although Virbac is also applying for certification for its new factory. Global markets create a need for such standards, but the cost of meeting the requirements is extremely high and most older plants were not built with such demands in mind. At present, there is only one recognised GMP inspector for Act 36 (over-the-counter) products in the Ministry of Agriculture. The Ministry of Health, on the other hand, has a full GMP inspectorate for Act 101 (prescription) products. The international manufacturing sector is likely to increase in future, although it is hard for South African companies to compete with the low production costs in China and India.

Some South African companies repackage their products in importing nations in order to provide pack sizes better suited to the local market. Pfizer and Novartis, for example, both use their Kenyan distributor (Ultravetis) to repackage their products, although many South African companies feel that other African nations may not be capable of meeting quality standards in either formulating or packaging products. Outside of East Africa, logistical problems in any case prevent such processing, despite occasional tax incentives for creating new jobs.

There are no standard criteria by which South African suppliers appraise potential foreign markets. Few African nations offer investment incentives for pharmaceutical companies (e.g. import rebates, tax incentives for in-country manufacturing, etc.), and since profit margins are low (typically about 20–35% for commercial markets and less for the smallholder market), likely sales volumes must be sufficient to justify the expenses associated with exporting. Of these, the principal cost is freight, while the greatest problem associated with entering a new market lies in finding a suitable distributor. Other potential obstacles include a lack of veterinary expertise, laboratories or cold chains, poor infrastructure and poor customer awareness of animal health issues. Market size compared to the cost and effort of registering the product is also critical. Tanzania, and occasionally Uganda, are thus sometimes avoided due to the expense and complicated nature of their regulatory procedures. Political insecurity is another issue which in the past has deterred companies from attempting to export to some countries (e.g. Angola, Eritrea, Ethiopia, Rwanda, Uganda and Zimbabwe), while in some parts of Africa, lack of a reputable banking system may deter companies from applying for major international tenders, despite the fact that many nations rely on grants and monies from international organisations for drug purchases.

With increased regulatory harmonisation, both Uganda and Tanzania could be potentially lucrative markets for the South African export sector. Other nations (e.g. Botswana, Mozambique and Zambia) are considered valuable markets by individual companies, depending on their market presence in the country and on the diseases targeted by their products. Sudan and Ethiopia tend to be supplied directly from Europe and the Middle East, and are in any case difficult to serve since they have no banks suitable for providing payment guarantees. The francophone countries are still served mainly by French companies.

4.3 The role of the veterinary and allied professions

National structure

The veterinary profession is governed by the South African Veterinary Council (SAVC), a statutory body founded under the provisions of the Veterinary Act of 1933. Council officials are independently elected by vets and are responsible for the regulatory and registration requirements of the profession. Other animal health issues are addressed by the Medicines Control Council (MCC) and SAVA. The latter was founded in 1920 with 80 members and currently has about 1 470 members. There is also a 'Vets in Industry' group, but it is little more than a fraternity of veterinarians employed in the veterinary pharmaceutical industry. Overall, despite the existence of these various organisations, South African vets have little professional solidarity or political influence.

There are a total of 2 400 registered vets in South Africa, but only an estimated 1 500 are actively practising, and many of those work mainly with small animals. The number of rural private practices is declining, and there are few black vets. There is a severe overall shortage of veterinarians, especially in government service and in rural areas: approximately one-third of state veterinary positions are vacant, and the remaining state vets are overworked as a result. Attempts have been made to address this issue by means of a scheme in which veterinary students in receipt of government funds are required either to repay their bursary on graduation or to work for the government for several years. However, most new graduates are deterred from entering the state service because of its poor resources and chronic underfunding. The government is therefore considering the possibility of mandatory community service for vets. The SAVC has responded to this proposal by trying to impose various conditions (e.g. that the vets are employed only to gain experience, are given adequate protection in marginal areas and can defer payment on their debts). No decisions on the scheme have been made at the time of writing.

Overall, the lack of veterinary services in rural areas gives serious cause for concern. Not only has state veterinary provision declined, but there are no incentives for private vets to practice in rural areas. Various factors prevent vets from profiting from retail enterprises in such areas: livestock

numbers have declined as profits have fallen, and the remaining farmers are becoming more industrialised and self-sufficient. Furthermore, there is strong competition for retail sales from farmers' co-operatives (and also to some extent from government services). As a result, vets in rural towns can usually only survive if they have a small animal component to their practice.

Theoretically, state vets should be available to cover all geographical regions, allocated as needed by a regional veterinary authority. In areas with no private practitioners, clinical services are supposed to be provided by state veterinarians; in areas with a private practitioner, however, local agreements are usually negotiated whereby the government vet refrains from practising. Government supplies of free drugs and veterinary expertise to marginal communities has had only a slight deterrent effect on the establishment of private practitioners, since state vets tend to have few available products and little time for consultations. There have been no reported instances of subsidised government products 'leaking' onto the regular market. However, many of the state vets feel that rural services would be greatly improved if they had the freedom to order and charge for drugs. A few have already begun doing so, and have found a ready demand for the additional services that they are consequently able to provide. However, other state vets have expressed reservations regarding the likely success of a semi-privatised structure, given the current infrastructure and entrenched feeling against private practice within the state service. They also express concern that clients would resent being charged by someone already receiving a government salary. If the state vets were to be given more entrepreneurial freedom, their services would have to be regulated in some way to prevent them from undermining private veterinary practices.

Veterinary auxiliaries and para-professionals

There are various para-professionals associated with the state veterinary service, but since livestock are relatively unimportant to the national economy, livestock-related government extension services have declined along with government funds. Nevertheless, each state vet is assisted by several state-employed AHTs who are based at government-run dip-tanks and whose role is to assist with disease monitoring, basic treatment and

advice on preventative care. In the past, the AHTs suffered from a lack of both discipline and incentives, and became notorious for selling government drugs (especially livestock dips) which were supposed to be free. However, in response to the need to regulate and improve the service, the SAVC has spent the past 5 years working with the state Department of Agriculture to develop suitable qualifications and legally defined codes of conduct for AHTs. State registration of the first cohort of 600 AHTs is about to take place: from now on, they will be formally registered after at least 5 years in practice or after a 2-year course leading to a recognised diploma. As in Kenya, the government is seeking to ensure that AHTs operate only under veterinary supervision and do not infringe on, or compete with, professional practices. However, there is some concern that the need for a high level of supervision would undermine their value as extension agents in areas where qualified vets are scarce. The pharmaceutical industry in general views AHTs as an essential component of the animal health industry, since South African consumers are often very poorly informed with regard to animal health issues. Industry is therefore heavily involved in supporting on-going AHT training, seeing it as a way of improving diagnosis, rational product use and the effectiveness of vaccination and dipping treatments.

Animal welfare technicians (AWTs) will also be formally recognised under the proposed revisions of South Africa's veterinary laws. AWTs work mainly in townships or rural areas and undertake primary care such as dressing wounds and caring for unwanted animals. With an appropriate permit, they can also dispense some prescribed drugs, although restricted products must be supplied by a vet. Under the new regulations, all AWTs must be evaluated by designated vets, after which they will be 'authorised' (rather than registered) for a period of 2 years, with subsequent re-evaluation every 2 years.

Farmers' needs for information are met by extension officers based at Field Service Units (FSUs). These officers are not involved in diagnosis or treatment and are not in regular communication with veterinary officers. Nevertheless, agricultural extension officers with some experience of the community (along with fellow farmers) have been reported by consumers as being amongst the best sources of information on animal health products. State vets and employees of farmers' co-operatives are regarded as being somewhat useful but less accessible or concerned, while

pharmaceutical representatives and traditional practitioners are regarded as being of relatively little use. It has been suggested that, since farmers often look to their peers for help and advice, it may be worthwhile training respected community members to act as 'local experts' and distributors of over-the-counter veterinary products. There is certainly a need for informed advice: almost all rural consumers express a desire for more written or oral information concerning veterinary products (Gehring *et al.*, 2002; Owens, personal observation).

The role of veterinarians in relation to the veterinary pharmaceutical industry

The veterinary pharmaceutical industry is very supportive of vets, providing training and funding for meetings and conferences. Several companies provide vets with business training, while Pfizer, for example, sponsors seven regional scientific meetings each year specifically for veterinarians, with 200 vets attending each one. The company hopes eventually to have these conferences accredited as part of the professional development programme required by the veterinary registration authorities. Industry support also extends to promotions such as a recent voucher system administered by SAVA. Under this scheme, vouchers for a free veterinary exam were sold by SAVA to pharmaceutical companies, who in turn gave them to clients. SAVA then reimbursed the vets at slightly less than the original price of the voucher, making a net profit for the association.

As elsewhere in Africa, industry opinions vary as to whether it is better to invest directly in educating animal owners, or to use veterinarians in this role. Most companies tend to target separate marketing campaigns at consumers and vets, rather than using the latter as their primary conduit to the community. However, representatives of two companies interviewed for this study claimed that 90% of their sales could be attributed to investment in veterinary education, and the fact that pet food and vaccine manufacturers also consistently limit their products to vets further attests to the importance of veterinary distribution. Lakato, the largest distributor of animal health products in South Africa, supplies only vets and believes that this strategy is fundamental to the success of their business, arguing that more readily available products do not command the same level of consumer respect. An example in support of this argument is provided by

'Program', a systemic flea control product for dogs and cats, which was initially marketed only through vets, and then subsequently through grocery stores, decreasing in popularity thereafter. The larger animal health care companies tend to be of the opinion that vets offer the dual advantages of good quality control and direct access for their customers to the newest products and information. On the other hand, some farmers and industry representatives condemn vets for concentrating too much on easy profits from sales of cheap products at high margins, rather than capitalising on their professional skills.

In general, state vets have a mixed view of industry involvement in rural communities. Overall, they would welcome more support from pharmaceutical companies but are wary of marketing campaigns that promote products that they consider unnecessary.

4.4 Regulatory authorities and processes

Regulatory framework

The sale and supply of veterinary drugs is regulated according to the provisions of Act 36 (1947), Act 101 (1965) and the Veterinary and Paraveterinary Act of 1982. Veterinary pharmaceuticals are categorised under various schedules, ranging from Schedule 1 (over-the-counter), through 4 (prescription only), to 7 (addictive). As a general rule, medicines listed under Schedules 1 to 6 are distributed through pharmacies, and a pharmacist may supply any medicine in Schedules 1 and 2 directly to the public for use on animals, without a veterinary prescription. Paraprofessionals may only use and sell drugs up to and including Schedule 4 on the instructions of a veterinarian for a specific patient. Registered vets may compound or dispense any medicine prescribed by themselves (or by any other person with whom they are professionally associated), for treating an animal under their professional care, but are not permitted to keep a retail shop or pharmacy. Only vets and pharmacists are allowed to repackage drugs to sell in different volumes.

Act 36 is administered and enforced by the Ministry of Agriculture and is concerned with general agricultural over-the-counter products (including farm feeds and feed supplements, crop protection chemicals and animal

medicines such as anthelmintics, acaricides and some antibiotics). The livestock products regulated under Act 36 are differentiated from ethical medicines on the grounds that they are preventative, that the problems they address can be easily diagnosed by farmers (e.g. tick-borne diseases) and/or whether rapid administration is usually necessary (e.g. tetracycline for tick-borne diseases). The South African legislation regarding over-the-counter products tends to be more permissive than that in many developed countries because of the relative shortage of vets and the comparatively long distances between vets and their clients. About 1 040 animal health products are currently registered under Act 36.

Act 101 regulates the provision of medical and veterinary prescription products (including all veterinary vaccines), and is administered by the MCC of the Ministry of Health. Overall, about 520 animal health products are currently registered under Act 101. Under the provisions of the Veterinary and Paraveterinary Act, practising a veterinary profession is in part defined by supplying or selling Act 101 veterinary medicines.

Over time, there has been some transfer of products between the two main regulatory instruments: veterinary vaccines and some other products, for example, were originally classified under Act 36 but are now regulated under Act 101. Conversely, in 1983, a number of previously prescription-only veterinary medicines were transferred to Act 36, and the two regulatory authorities (i.e. the Ministry of Agriculture and the Ministry of Health) have been increasingly in conflict ever since. Furthermore, since technical reviews of products falling under both Acts may apply conflicting standards, there is an urgent need to reform South Africa's regulatory procedures to bring them into greater alignment with international standards (Catton, 1996).

The pet food industry attaches great importance to their vet-only products, and for this reason would like to have their products policed by the veterinary regulatory authorities. However, although their position is supported by the vets, the authorities are reluctant to undertake this task since there are no animal welfare or public health implications associated with these products.

The animal health industry is represented in the regulatory process primarily by the Association of Veterinary and Crop Associations of South Africa (AVCASA), whose members include more than 80% of companies

participating in the South African crop protection and animal health industries. The Association is a full member of the International Federation of Animal Health (IFAH) and actively promotes the industry at all levels, consulting and negotiating with government and NGOs and with the private sector. As mentioned previously, there is also a 'Vets in Industry' group, but this is more of a fraternal organisation of vets employed by the veterinary pharmaceutical industry than a policy-making forum.

Registration requirements

While recognising that the quality of medicines cannot be compromised, the regulatory authorities acknowledge that the southern African market is not large enough in international terms to justify making unrealistic demands on companies developing or registering new products. Efficacy testing requires a minimum of three trials over a minimum of two seasons in different climatic regions. If two seasons are needed for trial work, it will take at least 3 years to get a new product registered, since at least 1 year must be allowed between submission of the application and final approval for products which include a new active ingredient. The local efficacy trials and residue testing required for anthelmintics and acaricides make them much more expensive to register than other products (approximately US$14 000–16 000 for an acaricide compared to US$300 for other over-the-counter products). Registration fees for Act 101 drugs depend on whether the product is locally manufactured or imported, but in general both fees and turnaround times are very reasonable. Guidelines have recently been established for measuring the bioequivalency of generics to facilitate their registration.

A total of approximately 400 applications for the registration of animal health products are received each year.

Quality control and monitoring

There is an eighteen-member government quality control inspectorate with personnel distributed throughout the nation, and adequate policing of borders and retail outlets ensures that there are few problems with poor-quality drugs reaching South Africa from elsewhere on the continent. Furthermore, there seems to be little or no 'leakage' and re-sale of free

government drugs – in marked contrast to the situation in the rest of Africa, where subsidised products often travel across national borders for re-sale. The main problem with the use of veterinary medicines in South Africa appears to lie with the end-users themselves, either diluting the product or underdosing to the point of inefficacy.

The quality testing service run by the government is realistically priced, with a reasonable turnaround time. Random sampling is contracted out by the NDA 5–7 days prior to product releases, but in the event of a customer complaint, the distributor normally recalls the product and sends a sample to the manufacturer for testing. As far as enforcement is concerned, there is a perception amongst international companies that the regulatory authorities tend to concentrate on the larger members of the industry, at the expense of adequate checks on smaller local competitors. On average, about 20 cases are prosecuted each year.

Ondestepoort Veterinary Faculty has recently established an adverse event database for veterinary drugs, but as yet there is no official national equivalent. The MCC inspectorate keeps records of its findings with respect to the quality of Act 101 products, but no comparable figures are kept for products regulated under Act 36. There is an urgent need to upgrade and maintain standards for the latter products, since they tend to be highly variable in quality. Most violations of Act 36 tend to be associated with the wildlife management sector.

Proposed amendments to veterinary legislation

The primary goal for regulatory reform is to harmonise the requirements of the two Acts, even if two ministries remain jointly responsible for their enforcement. This process has been ongoing since approximately 1990, but so far little progress has been made.

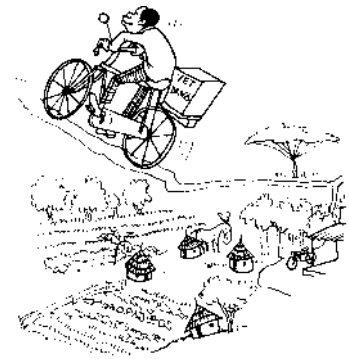
Nevertheless, it has been recognised for some time that the unique status of veterinary medicines warrants a dedicated governing body. The Veterinary Products Committee (VPC) was therefore established in 1996 to harmonise and strengthen the regulation of veterinary products. The committee is based on the British Veterinary Medicines Directorate, which also (in contrast to the situation in most other countries) combines the responsibilities of the British Ministries of Health and Agriculture.

In 1997 the Ministry of Health began reforming the national drug policy to reflect concern for supplying 'previously disadvantaged individuals' (e.g. those marginalised by apartheid). In 1999 the South African Medicines and Medical Devices Regulatory Act (SAMDRA) was drawn up with the aim of establishing an independent drug regulatory authority. However, various proposals to increase drug affordability (including, for example, attempts to legalise parallel imports), led to vociferous protests from industry and a major court case which led to the withdrawal of SAMDRA before it ever became law. Mechanisms for price control are still being proposed in new legislation, but so far veterinary medicines have been excluded.

Priorities for further reform include improving the quality control process, establishing essential drug lists and protocols for their use, improving the supply of veterinary drugs and services to users and improving the drug registration classification system.

South Africa leads the regional effort to standardise its regulatory procedures and plans to expand pharmaco-vigilance and residue monitoring. As such, representation on various bodies concerned with global livestock and pharmaceutical standards (e.g. the Codex Commission, International Technical Consultation on Veterinary Registration, Veterinary International Conference on Harmonisation, and the OIE) is keenly sought.

5 Status of the veterinary pharmaceutical sector in Uganda



5.1 Significance of livestock in Uganda

The livestock industry in Uganda accounts for 17% of agricultural GDP and 9% of national GDP. In recent years, the sector has been the target of several strategic government initiatives, the ultimate goal of which is to increase the volume of exports and the value of animal products to US$282 million by 2006. At present, however, the domestic demand for livestock products is not being met: the average annual per capita consumption of milk is 22 litres and of meat is 5.6 kg – very low compared to the 200 litres and 50 kg recommended by the FAO. There are various constraints on the industry, including poorly organised facilities and markets, abandoned or destroyed stock routes and quarantine stations, and the occurrence of notifiable diseases such as FMD, CBPP, tuberculosis and brucellosis. At present, approximately 90% of the cattle population are indigenous breeds of low productivity, although there is increasing interest in exotic breeds and high-input husbandry.

The dairy sector has been the focus of considerable development effort, which has given Uganda a comparative advantage in this area. Nevertheless, the private dairy sector remains relatively undeveloped: poor enforcement of regulations has led to the widespread sale of adulterated milk at the expense of legitimate vendors, and Uganda's geographical advantage has not been fully exploited in exporting to neighbouring markets. Government intervention is needed in order to overcome the relative weakness of the private sector and stimulate exports of dairy products.

5.2 The animal health care industry

Industry structure and distribution strategy

In contrast to the situation in Kenya, the Ugandan animal health industry is growing. The economy is stable and there is increasing interest in exotic breeds of cattle and high-input agriculture. The veterinary drug supply was liberalised in 1976 as a result of a growing black market when government systems collapsed in the wake of major civil unrest. More recently, the Ugandan Government has drawn up a new national policy to encourage private sector investment in the production, importation and distribution of veterinary drugs, including vaccines, biologicals and other products. Acaricides currently represent the largest and fastest-growing sector of the market.

For distribution purposes, each pharmaceutical company tends to be associated with a single local import partner (main distributor) who, on payment of an annual registration fee, can supply retailers with everything except vaccines for the four notifiable diseases, namely CBPP, FMD, rabies and rinderpest. The main distributors are generally based either in Kampala's 'container village' (an area in which a variety of products are sold from disused shipping containers, often in an informal and largely unregulated manner) or in Nakivubo (site of a former government distribution centre for seeds and veterinary drugs). Many Ugandan main distributors also serve Burundi, Rwanda and Tanzania, but even so, competition between distributors is so intense that at times they may sacrifice some or all of their profit margin in order to retain customers. Remoteness is not a limiting factor for the larger distribution companies, although the expense associated with long-distance transport makes it more difficult for smaller companies to compete.

As far as retailers are concerned, the main outlets for over-the-counter (class C) products are currently the agrovet shops, followed by large-scale farmers and vets. Such outlets must pay the required annual registration fees and have at least one employee with a qualification in the medical, pharmaceutical, veterinary, nursing or paramedical fields. Registration as a primary importer significantly reduces prices, but the process is complex and expensive, deterring all but the very largest companies. The sale of restricted (class A and B) products is limited to pharmacists, veterinarians and similarly licensed individuals, with infringements punishable by fines

up to 1 million Ugandan shillings (Ush) (approx. US$500) or up to 5 years in prison. A government-run radio campaign has helped to increase consumer awareness of unregistered products and merchants.

There are niche markets at all levels for expensive brands associated with high quality products. For example, as in the Mount Kenya region, a strong demand for Pfizer's relatively highly priced Terramycin® antibiotic persisted for several years following its withdrawal from the market, despite the availability of cheaper equivalents. On the other hand, there is little opportunity for market growth for products with a well established brand name and a long history in the country (such as those of Cooper and Norbrook), although such products tend to have a long and relatively stable market life. Sales figures usually increase greatly in response to advertising and aggressive marketing, since buyers are often readily influenced by sales advice. As elsewhere in Africa, all the veterinary pharmaceutical companies run field days to educate farmers about their products and animal health in general. In contrast to the situation in Kenya, some companies organise such events in conjunction with vets, viewing vets as important sales advocates and established sources of knowledge. They are more than willing to assist in training vets with regard to drug dosing, safety and ethical issues.

Legally, vets can only sell drugs for therapeutic purposes (i.e. to treat specific cases), although in practice this requirement is readily circumvented. Vets are also required to be on the premises of every shop selling restricted animal health products, but since they are frequently called out to clients, sales are often left to minimally trained employees. In addition, in every town visited for this study, it was reported that in many shops, a vet will sign the registration papers each year in the role of legal owner, but will rarely, if ever, participate in the day-to-day running of the business.

Most retailers stock a wide range of brand names and product types. European and South African products are generally perceived to be of higher quality than Asian, local or generic products, and farmers show considerable brand awareness. The retail perception of Kenyan products is variable: while most retailers consider that Cosmos products are of a quality comparable to more well-known brands, about 20% of interviewees reported either first- or second-hand experience of poor packaging and/or adulteration of Kenyan products.

Prices paid by consumers have changed little over the past few years: as a result of intense market competition, even government taxes and inflation have been subsumed into shrinking company margins. The decentralisation of government veterinary services and the corresponding increase in private practitioners have also had little effect on prices.

5.3 The role of the veterinary and allied professions

The statutory veterinary body, the Uganda Veterinary Board (UVB), is responsible for establishing and revising professional guidelines, developing undergraduate and postgraduate training, and for disseminating information on proper drug use both to members of the profession and to the public. However, because the UVB is underfunded and poorly developed, most of the legal issues facing the veterinary profession are dealt with by the professional organisation, the Uganda Veterinary Association (UVA). However, this presents problems for the UVA, since they lack recognised legal powers. Policy revisions designed to strengthen the UVB and to fully separate veterinary from human medical policy are likely to become law in the near future.

As in Kenya, funding for state veterinary services has declined and efforts are being made to encourage the growth of private practices, including contracting-out vaccine provision and other routine government tasks to private practitioners. The UVA is technically responsible for fostering privatisation, but many private practices are being established without their help. By 1998, 80 private practices had emerged in high-potential farming areas, and their numbers continue to grow. There is a loan scheme similar to that in Kenya, from which 12 vets have so far received funds.

One of the greatest obstacles to the success of private practices is reported to be competition from various unregistered veterinary auxiliaries, including retired government animal health officers (AHOs) and various other para-professionals, all of whom have the advantage over licensed vets of fewer overhead expenses for proper equipment and licensing fees. Often, too, private vets find it difficult to obtain the initial capital to establish their practice, whereas the owners of agrovet shops may have

access to capital from other successful businesses and can afford to buy in bulk, obtaining volume discounts by doing so.

The decentralisation of government services has left Uganda with a large number of unemployed AHOs, who, although not qualified or licensed to practice, often provide basic veterinary care in rural villages. They are also employed by some veterinarians and agrovet shops, some of which send them out to conduct field work and dispensing, despite their general lack of expertise. However, since animal owners do not pay for such call-outs, their services undercut the vets, reducing the prices that they can charge for their travel expenses and time.

Vets and industry representatives generally agree that relatively few areas are suitable for CAHWs, and in the past, the UVA has been hostile to them: at present, their use is endorsed only in Karamoja and the insecure areas of the north, although some NGOs in the south of the country are still (illegally) training them. Again, there is general agreement within industry that they should be closely monitored, trained to a standard curriculum, and their operations restricted to particular geographical areas. Amendments to the Veterinary Surgeons Act (CAP 265) to legally regulate them are currently pending. A livestock development forum composed of regional veterinary services and the NGOs working with CAHWs is supposed to meet every 3 months, but there are few incentives for it to do so. However, the Ugandan Director of Animal Resources has recently endorsed the establishment of a specialised unit to coordinate NGO activities and advise on community-based animal health care systems.

Extension services are now largely the responsibility of local government and are run under the auspices of the National Agricultural Advisory and Development Service (NAADS), which is charged with further decentralising such services and promoting greater involvement by the private sector.

5.4 Regulatory authorities and processes

Regulatory framework

Overall control of the regulatory framework falls under the remit of the Ministry of Agriculture, Animal Industries and Fisheries (MAAIF), which

presides over various other government ministries and commissions involved in the sector.

Prior to 1993, the pharmaceutical industry in Uganda was regulated by the Pharmacy and Poisons Act of 1970, which was primarily designed for human medicines and which was therefore poorly suited to the needs of the veterinary sector. In 1993, however, the Pharmacy and Poisons Act was superceded by the National Drug Policy and Authority Statute, which resulted in the formation of the NDA, the body now responsible for all matters relating to pharmaceuticals. The veterinary profession was consulted during the policy development stage, but is currently under-represented on the board of the NDA.

The MAAIF has recently developed a new national policy on the delivery of veterinary services which addresses drug registration, quality and importation, as well as retail guidelines and legislation governing the prudent use of veterinary products. The new policy encourages the privatisation of various aspects of the regulatory process by making provision for sub-contracting inspection, quality assurance, registration, licensing and monitoring to the private sector. Under this new policy, MAAIF will establish an information management system for veterinary drugs and a monitoring system for the verification and disposal of both veterinary waste and expired and unwanted products.

Registration requirements

Products are classified into three classes, A to C, according to their potential for abuse and the danger of overdosing. In 1997, 1 728 human drugs and 171 veterinary products were listed as provisionally registered, with full registration proceeding gradually since 1998. MAAIF maintains an essential veterinary drugs list, and there is sufficient flexibility to import unlisted products. There are no price controls but the import price must be indicated when the drug is registered.

With the exception of acaricides, it generally takes about 6 months to register a new product; 2 years are needed for acaricides because the NDA requires them to be field tested under local conditions. (Local testing is theoretically required for all products, but in practice the cost is often too high considering the size of the market. However, since the market for

acaricides is relatively large, enforcement of the testing requirement for these products tends to be stricter.) Registration fees are relatively high (US$500 for each product except acaricides, for which the fee is US$2 000); however, there is general agreement within the industry that the NDA functions well and that the fees are worth paying. Enforcement of regulations is consistently good, and registration usually proceeds smoothly provided that the necessary documentation is in order. At present, the NDA is funded almost entirely by user fees, prompting several industry representatives to recommend that it should be supported to a much greater degree by government funds. There have been some complaints from the industry regarding the requirement for product labels to include the manufacturer's address for tracing purposes, since manufacturers often change and some companies consider production contracts a trade secret.

Ugandan standards for manufacturing plants are so high that there is currently no in-country manufacturing and only one company has expressed a possible future interest in doing so. While such high standards help to ensure quality products, financial incentives for the establishment of a home manufacturing industry might be in order, since it would benefit employment and the economy as a whole, as well as reducing the retail prices of veterinary products. As it is, the NDA requires GMP inspection of foreign manufacturing plants, and has audited over 30 Indian sites; South African plants usually meet all of their standards because of the vigilance of the MCC of South Africa.

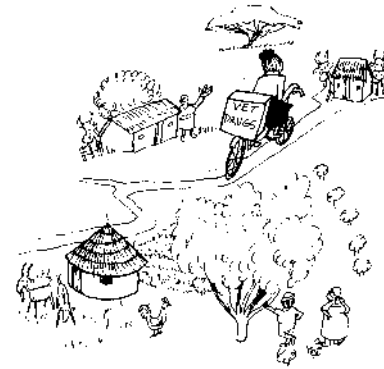
Quality control and monitoring

Uganda does not as yet have a national pharmaceutical quality control laboratory. The state service generally either analyses samples at a local factory laboratory, or sends them to Kenya or Tanzania for analysis. Some residue testing is conducted by the Uganda Bureau of Standards, and MAAIF is currently trying to improve the national facilities for both residue testing and quality control analysis. Makarere University is collaborating with the government in establishing a quality control laboratory, but given the small volume of drugs handled in Uganda, the present arrangement of sub-contracting to Kenya may be more cost-effective – another good argument in support of regional collaboration and harmonisation.

Overall, Uganda has a very good quality-enforcement system. Applications to import drugs must be accompanied by the manufacturer's GMP certificate, although this can be waived at the discretion of the NDA. Distribution facilities have been regularly and reliably inspected since 1993, and retail outlets are visited 3–4 times each year. Penalties for selling adulterated or misrepresented products can include a fine of up to 5 million Ush (approx. US$2 500) and/or up to 10 years imprisonment. During the course of this study, interviewees based in rural areas reported relatively few cases of adulterated animal health products, although the problem tends to be worse close to the Kenyan border. There are many unqualified distributors, and although they are generally caught, many often re-establish themselves following prosecution. In general, however, distributors are satisfied with the NDA's enforcement procedures, although some shops and veterinarians expressed a wish that steeper penalties were invoked more frequently, with complete closure of rogue outlets in particular being imposed more often. Many distributors would also like the NDA to conduct continuous quality analysis by random sampling, which would help to prevent undercutting of legitimate products by poor-quality or adulterated goods. Smuggling from Kenya significantly undercuts profits for both large and small companies, and fake products are more commonly found near the Kenyan border. Some retailers have found Kenyan products to be poorly sealed and frequently adulterated, with acaricides (especially expensive pour-ons) and anthelmintics being most at risk. Improving border policing, though difficult, is critical to improving quality control.

One weakness of Uganda's inspection and enforcement procedures is the lack of veterinary involvement. Competition from poor-quality providers tends to be a significant obstacle to successful practice and members of the profession therefore have a very real incentive for taking quality control seriously. At present, however, there is only one veterinary representative on the board of the NDA.

6 Public–private partnerships in Africa: an industry perspective[3]



In Africa, as elsewhere in the world, the veterinary pharmaceutical industry is inextricably linked to public sector veterinary services, either through formal contracts with governments or via more informal links (for example, via donor-funded projects or NGOs). Much has been written on the need to develop public–private partnerships to better serve Africa's livestock owners, but in practice few such partnerships currently exist. From the perspective of the private sector, the major difficulty appears to be that representatives of governments, NGOs, and so on, are understandably reluctant to be too closely associated with particular companies in case their impartiality is questioned. This obstacle must be overcome if successful public–private partnerships are to be developed.

As it is, the roles of the public and private sectors often overlap to a significant extent, with considerable duplication of effort and expenditure. In spite of this, however, services to livestock farmers in many parts of Africa have declined in recent years. In some countries, although state support for veterinary services has been reduced, the private sector has neither the mandate nor the capacity to compensate. NGOs with budgets for specific projects may also feel frustrated by government representatives who delay granting necessary approvals because of a perceived threat to their own role.

Given these difficulties, is there really a genuine interest in promoting public–private partnerships in relation to veterinary supplies and services? Some might argue that governments should play no part in the supply of veterinary products other than to regulate their use and distribution.

[3] Contributed by Martin Mitchell, CEVA Santé Animale S.A., La Ballastière BP 126, Libourne 33501, France.

Rather, the role of government should be restricted to product registration, disease surveillance and the control of notifiable diseases. Demand for products and services would then be generated by the needs of livestock owners, which in turn would drive supply. This type of demand-driven situation was observed to some extent in Uganda and Kenya when state support for tick control measures was withdrawn: many farmers chose to persist with relatively intensive programmes of tick control – and met the costs themselves. In contrast, the Government of South Africa (for the time being at least) has taken the opposite view: with the support of industry, it continues to provide acaricides for routine tick control in designated areas dominated by small-scale farmers. For the South African Government, there is an additional benefit from this service – it provides them with vital disease surveillance at relatively low cost.

The situation is not always so clear-cut. For example, few would argue that the state should play no part in controlling trypanosomiasis, since the disease has such a significant impact on both humans and animals. Yet one of the most important techniques for controlling the disease is to treat cattle with insecticides to kill the vector (tsetse fly), and this is generally carried out by livestock owners on a purely private basis. The treatments are not subsidised, despite the potential benefits to the wider community.

A good example of a very practical public–private partnership is provided by the situation in Uganda in the late 1980s, when the government was still committed to a national programme of tick control for cattle. At that time, the ticks were becoming resistant to the organophosphate (OP) products that were then prevalent. However, the new synthetic pyrethroids had just been launched and had been shown to be highly effective against both ticks and tsetse flies. The President of Uganda tested the pyrethroids on his own cattle and the government subsequently replaced OPs with pyrethroids in the national tick control programme. The pyrethroids were more expensive, but because of the wider public benefits of the treatments, the government chose to meet the difference in price rather than passing on the full cost to the farmers. At the time, the private sector was just beginning to re-emerge after years of war and, rather than importing products itself, the government decided to put the contract out to tender and supply the products privately via the successful bidder. As a result, Cooper Uganda Ltd. administered a successful 'revolving fund' on behalf of

the government and in less than 5 years the scheme evolved from the provision of highly subsidised products to a completely free-market situation. In this way, the Ugandan Government was able to meet several objectives:

- it reduced its costs by withdrawing from the direct supply of dips and insecticides
- it helped to demonstrate the effectiveness of a new technology which farmers were eventually willing to pay for
- it helped to strengthen the private sector: as a result of the scheme, Cooper Uganda Ltd. was able to expand its distribution network and open new branches in areas which had not been serviced since before the war.

There were additional benefits of the programme, the most notable of which was the construction of a number of communal 'crush pens' which gradually replaced the government-run dip tanks which had fallen into disrepair. These pens are simple, communally managed facilities to which livestock owners regularly bring their animals for spraying with pyrethroids. The costs of the facility and the chemicals are met by fees paid by the farmers. The system was based on a similar method used in Zimbabwe and first introduced by Cooper Uganda Ltd. The approach was popular with farmers and the idea spread rapidly, helped by the EU-funded Farming in Tsetse Controlled Areas (FITCA) project in south-eastern Uganda. The leaders of the FITCA project also introduced the idea to Kenya, where over 300 such facilities have now been built – mostly by the farmers themselves.

The FITCA team also worked with other private sector partners (e.g. Vestergaard and Bayer) to develop the novel idea of protecting zero-grazed cattle with vast 'mosquito nets'. As a result, dairy cattle can now be profitably kept in the Lake Victoria basin region, improving the lives of both the livestock owners and those benefiting from the increased supply of fresh milk.

One could argue that the companies involved in these schemes received an unfair advantage by working with the relevant governments, projects or NGOs, but by knowing their markets and having the faith to invest in new ideas, they helped to bring about significant changes that might otherwise never have occurred.

But can such public–private partnerships play a larger part in improving the distribution of veterinary supplies and services to the poor livestock owners of Africa? The vast herds of the African pastoralists have never been viewed as a significant market by most major pharmaceutical companies. Nevertheless, they have considerable potential, despite being far from easy to reach (in more ways than just geographically). Public–private partnerships may play an important role in meeting the needs of pastoralist communities, but if the logic of a market economy is to be believed, then the first step must be to ensure a secure market for their animals and animal-derived products. Demand for both animal and human health-care products will increase as the value of the livestock increases and as their owners are increasingly drawn into the surrounding cash economy.

As far as CEVA is concerned, Africa is an important market, representing approximately 14% of the company's total sales. As such, the company is committed to finding new products (and means of delivering them), that specifically meet the continent's needs. CEVA's involvement therefore includes the following:

- basic research (in collaboration with public institutions), some of which may result in the first new trypanocidal drugs in many years
- production of a sterile, injectable form of the trypanocide diminazene (at the request of the Kenyan Government), together with the development of a unique weigh-band system designed specifically for zebu cattle, which facilitates easy and correct use of the drug
- a planned new programme (VET ASSIST) which CEVA hopes will train thousands of CAHWs, AHAs, lay staff and livestock owners in the best animal husbandry practices. The aim is to collaborate with both governments and NGOs to ensure the best use of the latest veterinary extension materials
- the development of more affordable products for livestock owners, both by reducing costs (e.g. by using high-quality, but less-expensive generic raw materials), and by making products available in pack sizes suitable for small-scale farmers.

In addition to the efforts of a single company, however, there are numerous ways in which government policies could encourage the private sector

to participate in public–private partnerships. The following suggestions have been developed as a result of numerous discussions with many colleagues and competitors in the veterinary pharmaceutical industry in different parts of Africa:

- **Support local companies.** Government tenders are often awarded to 'outsiders' at the expense of companies that already have an established local 'presence'. Although it is hard to quantify the value of the latter, at the very least it demonstrates an active interest in the market and such companies should be among the first to be considered for new contracts.
- **Establish reasonable registration fees.** There is a general perception within the pharmaceutical industry that the costs of product registration in some countries are becoming prohibitive. The situation is compounded by the lack of progress towards regional harmonisation of registration requirements, which often results in the need to register products (and repeat efficacy trials) in several adjoining countries with very similar climatic and farming conditions. This is both cumbersome and expensive – and ultimately increases the cost of the products to livestock owners.
- **Ensure adequate quality control.** Recent studies of commercial samples of diminazene in Kenya found a worryingly high proportion with concentrations of active ingredient significantly below the level declared on the label. Quality control should not simply be a question of evaluating the sample submitted for registration purposes, but should extend to correct storage, provision of advice, and so on. Public and private sectors should work together to improve overall standards and ensure more rigorous enforcement of current legislation.
- **Define the roles of public and private sectors.** There are some services – such as livestock disease surveillance, control of notifiable diseases and meat inspection – that are clearly public goods and should be paid for by the government, and others – such as the provision of clinical services – that are private goods and should be paid for by individuals. However, public goods could nevertheless be sub-contracted to the private sector, as is common practice in Europe and the Americas. Such contracts could be crucial to the viability of privatised veterinary practices in more marginal areas.

- **Ensure equal access to funding.** All businesses and NGOs with viable proposals should be able to access funding specifically allocated to the support of public–private partnerships. Everyone with a genuine interest should be invited to contribute.

Addressing these various issues would contribute much to meeting the evolving needs of Africa's livestock keepers by creating an environment conducive to the formation of innovative public–private partnerships in the veterinary sector.

7 Summary and conclusions

7.1 Summary

Almost all veterinary activities are ultimately dependent on the availability of good-quality, reliable inputs. In much of Africa, the procurement and distribution of veterinary pharmaceuticals was once the almost exclusive preserve of the state veterinary services, but in recent years their involvement in these activities has decreased dramatically as their operational budgets have declined. As a result, this function is being increasingly taken over by the private sector. The involvement of private vets in this capacity has generally increased the availability of veterinary products (FAO, 1997) and has had the additional benefit of adding value (in the form of professional expertise) without increasing prices. At present, however, in the competitive and cash-poor economies of many African countries, most private vets are found in urban and peri-urban areas; the poor financial prospects associated with pastoral and smallholder areas has acted as a deterrent to the establishment of private veterinary practices in these regions.

The veterinary pharmaceutical industry has responded positively to the increased importance of private veterinary practitioners by supporting veterinary meetings and conferences and by providing some limited training in business skills. However, because intense competition has reduced profit margins on veterinary products to very low levels, financial support via discounts is limited: such discounts can only be offered on bulk orders, which most African veterinary practices are too small to require.

Nevertheless, the sale of drugs can represent up to about 60% of veterinary income. The professional expertise of private vets gives them a business edge as retailers, but, except in South Africa, it is not generally

sufficient to enable them to charge more than shops. In any case, too great an emphasis on retailing has resulted in a perception that some vets have compromised their professional standards by concentrating too much on sales at the expense of clinical services. This issue could perhaps be addressed through the proper training and licensing of veterinary para-professionals to manage retail outlets, leaving the vets free to concentrate on clinical practice. The rather ambivalent industry view of vets is reflected by varying attitudes to the role of vets in consumer education, which is generally viewed as a key element of marketing: while some companies see vets as a valuable means of targeting customers, many prefer to by-pass them and instead focus their educational and promotional campaigns directly on the final customer.

An increasing body of evidence indicates that, if properly regulated, veterinary para-professionals such as CAHWs can be a more effective, dependable and sustainable means of delivering veterinary services in marginal, low-potential areas than either public or private vets (FAO, 1997; Catley *et al*., 2002; IDL, 2002; AU/IBAR, 2003). Their effectiveness is enhanced if they can be incorporated into an infrastructure that provides technical support, advice and guidance from professional veterinarians. Legislative reforms that clearly define their roles and training should help prevent or reduce misuse of products, competition with veterinary professionals and substandard service. Improving the effectiveness of veterinary para-professionals would benefit industry by facilitating access to the rural smallholder and pastoralist sectors, which are viewed as increasingly important emerging markets. The veterinary pharmaceutical industry has been addressing smallholder needs by repackaging products in smaller sizes, but in general has shown little initiative in facilitating drug distribution to this sector. At present, the most efficient way of targeting the pastoralist market is via sales of small, affordable packs from vans stationed at local livestock markets. Only relatively few products, however, can legally be sold through such outlets, although sales of acaricides (which are often the most lucrative animal care products) are permitted.

Profit margins for final distributors (including vets) are very low throughout most of East Africa and are further reduced by distribution expenses, which in general are borne by the distributors themselves rather than by the end consumer. Price competition within the industry is intense, and

overall prices have been lowered by the increasing availability of cheap Asian and generic drugs. However, price is not necessarily the most important element in capturing a share of the market: various pharmaceutical companies have shown that there are niche markets for branded products and premium animal health care services. The animal health industry in general needs to increase consumer awareness of quality standards, and 'branding' for quality might be a useful promotional strategy not just for products, but also for the services supplied by vets and others.

In many African countries, the influx of poor-quality or adulterated drugs remains a major threat to the provision of reliable animal health products at realistic prices. In this regard, an active national regulatory authority with good enforcement powers can make a tremendous difference (compare, for example, the situation in South Africa to that in Kenya). In addition to strengthening national regulatory processes and authorities, there is also a continuing need for increased harmonisation of regulatory procedures between African nations. Although there have been several conferences on this subject, only in South Africa (where a large number of international companies are based) have serious attempts been made to address this issue. At present, the various national registration processes present a significant barrier to greater international commerce in animal health products.

7.2 Principal conclusions for each country

Kenya

In recent years, the status and importance of both the livestock and animal health sectors have been badly affected by Kenya's national economic difficulties and by prolonged periods of drought. However, there are other, more fundamental challenges facing the industry. Tax burdens and the lack of adequate product protection are significant barriers to the development of a local drug manufacturing base, and the large number of informal, unregulated suppliers of veterinary products – at all levels of the supply chain – is a considerable hindrance to legitimate trade. If the distribution and availability of animal health products is to be improved, then

urgent attention must be given to improving both the current regulatory infrastructure and the degree of veterinary participation within it. The recent establishment of a new cadre of veterinary inspectors (whose responsibilities include inspection of retail and wholesale veterinary drug outlets) is a positive development, particularly if their role in enforcement can be strengthened and supported by proper penalties and an adequate level of quality control testing.

As elsewhere in Africa, Kenya faces problems in providing adequate animal health care in rural areas. There are relatively few vets in private practice, and fewer still in the pastoralist areas, so that improving the training and regulation of veterinary para-professionals is an obvious way of strengthening rural outreach. The proposed amendments to the Veterinary Surgeons Act that will introduce proper licensing and regulatory procedures for these individuals will help by better defining their roles and qualifications. In drought-prone areas, the viability of private veterinary practices could be greatly enhanced by contracting-out some of the services currently provided by the state system (e.g. vaccination and disease surveillance). Furthermore, the proposed changes to the Pharmacy and Poisons Act should increase the viability of private veterinary practices by giving them a monopoly on the sale of veterinary products. However, this will only occur if customer fears can be allayed, industry opposition overcome and any new legislation properly enforced.

South Africa

South Africa is becoming increasingly important as a regional centre for the manufacture of animal health products for export to the rest of the continent, although nearly all of North Africa and the francophone countries are still supplied mainly from Europe. South African manufacturing quality is approaching European standards, labour is inexpensive and it is a cheaper base than Europe from which to ship to the rest of Africa, although in some countries it can be hard to find a suitable distribution partner. Some animal health companies undertake repackaging in the importing country, although the difficulty of ensuring adequate quality control acts as something of a deterrent.

Product registration in South Africa is characterised by very reasonable fees and prompt processing times. Quality enforcement for prescription products (so-called 'Act 101' products) is excellent, and although

over-the-counter products ('Act 36' products) are subject to less stringent registration and quality control requirements, good border patrols and import controls ensure that there are few problems with counterfeits.

In contrast to other African nations, South Africa has a growing market for small animal products, including pet foods. Many of the latter are restricted to vet-only distribution, and suppliers see this exclusivity as an important component of their marketing strategy. As far as livestock products are concerned, as elsewhere in Africa, subsistence farmers and the small pack market are viewed as important growth areas, especially since the large-scale farmer market is now essentially saturated.

The main distributors of non-prescription products are farmers' co-operatives, which have the dual advantages over vets of being able to buy in bulk (and hence sell more cheaply) and of offering deferred payment plans for members. There is some controversy over the extent to which products should be restricted to distribution by vets only – while some companies benefit from the high-quality image attached to vet-only products, many small outlets feel that this limited distribution creates an unfair price monopoly.

As elsewhere in Africa, it has been difficult to get rural pharmacists interested in veterinary products, and distribution of products and services to smallholders and remote areas is almost non-existent. In regions where there are no private vets, clinical services are supposed to be provided by state veterinarians and animal health technicians, but the state service suffers from the same problems here as in the rest of Africa: one third of government veterinary posts are vacant, the AHTs are generally not functioning well and budgets for government vet departments have been greatly reduced. As a result, most customers in remote areas currently obtain their animal health products by making bus trips to urban centres – a cheaper and more reliable option than purchasing from government-run community outlets. There may be scope for the pharmaceutical industry to make better use of properly supervised CAHWs in this respect.

Historically, the legislation governing the South African veterinary industry has fallen either under the remit of the Ministry of Health or the Ministry of Agriculture. Current plans to revise the regulatory framework to create a single dedicated authority for the control of veterinary drugs should help to streamline regulatory procedures and improve efficiency. In addition, legislation to formally register and define the roles of veterinary para-

professionals should help improve the provision of animal health care to the rural poor.

Uganda

Historically, Uganda has had relatively few large-scale commercial farms and the needs of Ugandan smallholders and pastoralists are similar to those of their counterparts in Kenya and South Africa. The Ugandan market for animal health products, although small, is relatively well regulated and is expanding. The NDA has been restructured in the past decade and has achieved very respectable quality standards, although it still has some weaknesses, notably expensive user fees and a lack of severity in enforcement. These issues are being addressed through the broader involvement of the veterinary profession in enforcement and regulation, and by strengthening the UVB. Better policing near the Kenyan border and steeper penalties would help to deter persistent illegal traders.

The government veterinary service has suffered somewhat from the effects of decentralisation but still has a clearly defined role. The number of private veterinary practices is growing; contracting-out former government services to private practitioners has worked well, and appropriate animal health systems are emerging in each production area. As in Kenya, there is a perception amongst some industry members that private vets have 'sold out' professionally (although to a lesser extent than elsewhere), and companies are generally willing to work with private practitioners.

In recent years, improved distribution, governance and infrastructure has resulted in increased profits for all sectors of the animal health industry, and in many respects Uganda provides an excellent example of what can be accomplished with good governance.

7.3 Overall conclusions and recommendations

The changing face of animal health care in Africa

Over the past few decades, there have been significant changes in the animal health care sector in many parts of Africa. As mentioned previously, in most African countries, the state veterinary services have declined in the past 20 years and have progressively withdrawn from the

provision of free or subsidised clinical services and/or the distribution of most drugs and vaccines.

Other changes in the agricultural sector have affected the market for animal health products. In South Africa, for example, after decades of neglect, small-scale farmers (so-called 'previously disadvantaged individuals'), are now being targeted by both public and private sector providers of animal health products and services. In Kenya, one of the most significant changes since independence has been the steady decline in average farm size, both as a result of a gradual reduction in the number of large-scale commercial farms and the repeated sub-division of family farms with each successive generation. There has been a corresponding increase in the number and economic importance of small-scale farmers, most of whom own their own land. In the dairy sector, for example, small-scale producers now own a total of more than three million cattle and account for over 80% of all marketed milk.

There has also been an increasing trend for pastoralists to move away from subsistence-level livelihoods towards a more cash-based economy, fuelled by the need to pay school fees and medical bills and to buy additional food in times of drought. As a result, many pastoralists have become more actively involved in livestock trading and now represent a significant emerging market for animal health care products.

Livestock are thus widely acknowledged to be particularly important to the household economies of the poor in developing countries and the demand for livestock products is predicted to continue to increase rapidly. Healthier, more productive livestock, reduced exposure to the risk of zoonoses and fewer barriers to local, national, regional and international trade in livestock and livestock products are all important if significant progress is to be made in reducing poverty throughout Africa.

Suppliers of veterinary pharmaceuticals

The most lucrative African markets for most multinational veterinary companies used to be the large-scale commercial farmers and state veterinary services. With the demise of these markets, most companies reorganised and rationalised their operations: some relocated their African headquarters to South Africa, and many ceased to maintain

resident representatives in most African countries, relying instead on local distributors. There are very few local manufacturers of veterinary products in Africa (with the exception of those in South Africa).

As their traditional markets declined, the multinational companies were faced with an additional problem in the form of the increasing number of generic products which began to appear as patent protection on key products expired. The presence of numerous fake and sub-standard veterinary products is also a major problem, particularly in Kenya.

In all three countries covered by this report, both smallholder and traditional extensive livestock keepers represent increasingly important markets for animal health products and services. However, the systems that effectively supplied large-scale commercial farmers and state veterinary services are not well suited to their needs. Nor are traditional western models of private veterinary practice appropriate for arid and semi-arid lands. The challenge is to find cost-effective, sustainable ways to meet the needs of rural livestock keepers that are compatible with their culture and the constraints and challenges imposed by their environment. New approaches, new services and new products are required, since a reliable supply of appropriate drugs is essential if rural animal health services are to be effective.

Poor and small-scale livestock keepers are extremely sensitive to price and in most cases good-quality generic veterinary products will be the most appropriate and affordable products for their needs. Safe, effective products are needed that are simple to use and which are available in small packs suited to the herd size and budget of small-scale livestock keepers. Local language labelling is also desirable, although the cost implications must be carefully considered before this is made mandatory.

Methods of delivering effective animal health care

Both the public and private sectors should be involved in the development of better ways of meeting the needs of livestock keepers in the arid and semi-arid lands. The new, streamlined state veterinary services need to be reorganised to better accommodate both private sector veterinarians and para-professionals. At present, much of the development, testing and promotion of new ways of delivering animal health care is undertaken by NGOs and donor-funded projects, but there is considerable potential for

the veterinary pharmaceutical industry to become more actively involved in these endeavours.

Veterinary para-professionals, including CAHWs, can provide high-quality and affordable animal health services that are responsive to the needs of poor livestock keepers. Such practitioners are essential given the shortage of fully qualified vets and their general reluctance to work in remote areas and difficult situations; even in areas where qualified vets are available, poor and small-scale livestock keepers often cannot afford their fees.

CAHWs can also form the frontline of disease surveillance networks for state veterinary authorities – an important consideration given that such surveillance systems are currently a prerequisite for increased participation in regional and international trade in livestock and livestock products.

Policy and legislative review

Proper enforcement of existing legislation, coupled with revision of the policies and legislation defining the role of veterinary para-professionals, would do much to overcome the problems of poorly trained animal health care providers and fake or sub-standard veterinary products. AU/IBAR, in conjunction with various state and NGO partners, has already developed suitable models and guidelines to meet these needs.

Legislative changes designed to increase the number of products available exclusively through vets would help to make private veterinary practices more viable in remote rural areas. As demonstrated in Kenya, however, such legislative changes are likely to be met with opposition from other veterinary retailers (especially pharmacists) and from customers concerned about potential price increases. The long delay in implementing the proposed changes in Kenyan law testifies to the difficulties involved in this approach. The same ends may more easily be achieved by contracting-out services formerly provided by state veterinary services (e.g. vaccinations).

The veterinary profession should be encouraged to show a more active interest in quality enforcement and policy issues. The Kenyan initiative in appointing veterinary inspectors is a positive step in this direction, particularly if such officers are supported by a stronger approach to enforcement. Professional veterinary organisations also have key roles to play: not

merely in representing veterinary views to governments, but also in increasing morale and fostering continuing professional development.

Regulatory requirements need to be revised to ensure that, while all products offered are safe and effective, the registration requirements themselves are neither unreasonable nor excessively expensive; any additional costs incurred in the registration process will inevitably be passed on to end-users and decrease the availability of affordable products. Regional harmonisation of registration requirements for veterinary drugs and vaccines (and acceptance of registration trials conducted in neighbouring countries) would greatly reduce costs and ultimately make more products available. Conversely, any increase in the complexity of registration procedures will act as a deterrent – particularly to those companies marketing products which, whilst locally important, are of low profitability.

The creation and enforcement of appropriate policies and legislation will in many cases require institutional changes within the relevant government departments and ministries, but will ultimately result in better quality animal health products and services which are both accessible and affordable.

Development of new products

The development and registration of new products for diseases which are important regionally but not globally is an important issue. For some regionally important diseases, either there are no treatments available at all, or the products currently available are inadequate. Regional manufacturers of generic products generally lack the capacity to develop new, improved drugs and vaccines, and while the large, research-intensive multinational companies may have the necessary capacity, they currently have little incentive to develop products targeted at such diseases.

Sources of funding must be identified and secured to fund research into these diseases and the development of new treatments – perhaps even to subsidise their production and marketing. Such efforts would be well-suited to the types of innovative public–private partnerships that are gradually emerging in the human health field. The rapid advances currently being made in the biological sciences also offer increasingly powerful tools with which to tackle animal health challenges, and

the market for new products would be much more attractive if effective, sustainable ways can be found of delivering animal health care to the many millions of small-scale and pastoralist livestock keepers in Africa.

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Acronyms and abbreviations

AHA	Animal health assistant
AHO	Animal health officer
AHT	Animal health technician
AI	Artificial insemination
AU/IBAR	African Union/Interafrican Bureau of Animal Resources
AVCASA	Association of Veterinary and Crop Associations of South Africa
AWT	Animal welfare technician
CAHW	Community-based animal health worker
CAPE	Community-based Animal Health and Participatory Epidemiology
CBPP	Contagious bovine pleuropneumonia
DVS	Director of Veterinary Services
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FITCA	Farming in Tsetse Controlled Areas
FMD	Foot and mouth disease
FSU	Field Service Unit
GDP	Gross domestic product
GMP	Good Manufacturing Practice
IDL	In Development Limited
IFAH	International Federation of Animal Health
IFAW	International Fund for Animal Welfare
KARI	Kenya Agricultural Research Institute
KEVEVAPI	Kenya Veterinary Vaccine Production Institute
Ksh	Kenyan shillings
KVA	Kenya Veterinary Association
KVAPS	Kenya Veterinary Association Privatisation Scheme
KVB	Kenya Veterinary Board
LDC	Least-developed country

MAAIF	Ministry of Agriculture, Animal Industries and Fisheries
MCC	Medicines Control Council
NAADS	National Agricultural Advisory and Development Service
NDA	National Drug Authority
NDQCL	National Drug Quality Control Laboratory
NGO	Non-governmental organisation
OIE	Office International des Epizooties
OP	Organophosphate
PARC	Pan-African Rinderpest Campaign
PPB	Pharmacy and Poisons Board
SAMDRA	South African Medicines and Medical Devices Regulatory Act
SAVA	South African Veterinary Association
SAVC	South African Veterinary Council
SPCA	Society for Prevention of Cruelty to Animals
Ush	Ugandan shillings
UVA	Uganda Veterinary Association
UVB	Uganda Veterinary Board
VPC	Veterinary Products Committee
WHO	World Health Organization

Annex 1

Primary animal health care in the 21st century:

recommendations from an international conference

In October 2002, AU/IBAR hosted an international conference that brought together a wide spectrum of animal health specialists and senior government officials from Africa, Asia, the Middle East, South America, Europe and the USA. The conference was attended by more than 100 delegates, who together drew up the following observations and recommendations for improving the provision of primary animal health care in the 21st century (Sones and Catley, 2003).

1. Institutional change

The meeting recognised that institutional changes are needed in order to improve animal health care services, and made the following recommendations:

- the formation and development of farmers' and herders' organisations should be encouraged
- international agencies, such as AU/IBAR, should endeavour to strengthen the capacity of national governments to understand and manage change in the livestock sector
- national governments should raise awareness of such changes and attempt to engage civil society in the process.

The meeting acknowledged that while change at the community level can be rapid, institutional change occurs at varying speeds and can be slow. However, once stakeholders have agreed the need for change, there are various ways in which the process can be facilitated.

2. Policies and legislation

There is an overall need to increase the capacity of governments and other stakeholders in relation to legislative reform, policy formation, co-ordination and management. Policies related to livestock issues are generally formulated in isolation from national development strategies, and there is thus a need to raise the profile of the livestock sector and improve its integration with other sectors. Efforts should also be made to ensure that smallholders and pastoralists are involved in policy development.

3. Training

Veterinary curricula should be updated to respond to the new demands being placed on the profession. Topics such as privatisation, participatory approaches and the provision of primary animal health care should be included.

4. Privatisation of veterinary services

The benefits of privatisation have been poorly exploited in the livestock sector. There is evidence to suggest that most poor livestock keepers are willing to pay for high-quality animal health services, but often need better access to service providers. In order to facilitate the latter, a better understanding of veterinary privatisation and its benefits is needed at all levels from livestock keepers to local and central government. The latter should also consider increasing incentives to attract service providers to remote areas (for example, through long-term contracts for disease surveillance and other services).

5. Disease surveillance

There is considerable evidence that community-based disease surveillance and participatory epidemiology can be very useful in complementing and strengthening national disease surveillance and epidemiological systems. This approach should be developed further and increasingly integrated with existing strategies.

6. Community animal health services

CAHWs are proving increasingly useful, but their management and integration into existing systems must be improved. More effective links are needed between veterinary surgeons, veterinary para-professionals and farmers if the delivery of veterinary services at the community level is to be improved. There is also a need to improve the regional integration and harmonisation of primary animal health services, particularly in cross-border areas.

7. Roles and terminology

At present, a number of terms are used for various categories of veterinary service providers. The OIE was therefore asked to analyse the current terminology and to define terms such as 'veterinary para-professional', as well as to clarify the roles, links and regulations required to incorporate private veterinarians and various para-veterinary staff (including CAHWs) into the structure of national veterinary services.

Source: Sones and Catley (2003)

Annex 2

Cross-country comparison chart

Annex 2. **Cross-country comparison chart**

	South Africa	Kenya	Uganda	USA
Number of manufacturers of veterinary products	10 (raw materials imported)	1 (+ vaccines at KEVEVAPI)	0 [1]	Unknown
Issues addressed by relevant legislative control/national drugs policy	Parallel trade, intellectual property rights, compulsory licensing to competitors, extra-label use and product disposal	Drug registration, quality, import, retail, prudent use and disposal	Drug registration, quality, import, retail, prudent use and disposal	Parallel trade, intellectual property rights, compulsory licensing to competitors, price controls, export incentives, drug registration, quality, import, retail, prudent use and disposal
National drugs inspectorate and quality control laboratories	Good. Records of inspections of restricted products ('Act 101' drugs) are maintained by the Ministry of Health. No records for over-the-counter products ('Act 36' products). Strong links with OIE laboratories in the rest of the world	Poor. The NDQCL was established in 1995 but is poorly resourced and under-utilised A veterinary drugs inspectorate has recently been established	No national quality control laboratory at present; some residue testing by the Uganda Bureau of Standards	Good. National Veterinary Diagnostic Laboratory in Ames, Iowa. Strong links with OIE laboratories in the rest of the world
Implementation/ inspection for GMPs	Yes	No	Yes: applications to import drugs must include the manufacturer's GMP certificate	Yes

[1] Extremely high legal standards have inhibited manufacturing in Uganda

Annex 2. **Cross-country comparison chart** (continued)

	South Africa	Kenya	Uganda	USA
Essential veterinary drugs list	No	No	In preparation	No
Adverse drug reaction monitoring?	Currently being implemented	No	No	Drug sponsor is responsible for compiling relevant records and submitting them to the Food and Drug Administration (FDA)
Price monitoring	No	No	No	No
Evidence of abuse, misuse or fraudulent products	Rare, although use of antibiotics without culture or sensitivity checks is common	Common	Common	Rare, although use of antibiotics without culture or sensitivity checks is common
Penalties for malpractice	Various. For manufacturers, penalties range from a 500 Rand fine and/or 3 months in prison to 2 000 Rand and/or up to 1 year in prison. Second offences are proportionately higher	Licenses may be revoked at any time. Illegal distribution of schedule one poisons is punishable by fines of up to 5 000 Ksh and/or up to 1 year in prison. Illegal distribution of other products is punishable by fines of up to 2 000 Ksh and/or up to 3 months in prison (up to Ksh 4 000 and 6 months in prison for second offences)	Licenses may be revoked at any time by the NDA. Illegal distribution of class A or B drugs is punishable by fines up to 1 million Ush and/or up to 5 years in prison Supplying adulterated or misrepresented products is punishable by fines of up to Ush 5 million and/or up to 10 years in prison	Various, depending on offence. Range from fines (up to US$500 000), suspension of licenses or certification, product recall or criminal prosecution with up to 3 years in prison

Annex 2. **Cross-country comparison chart** (continued)

	South Africa	Kenya	Uganda	USA
Initial registration fees[2]	US$220 for locally manufactured restricted ('Act 101') products, more for imports US$300 for over-the-counter ('Act 36') products US$14 000–16 000 for acaricides plus cost of residue trials	US$1 000 per product (more for acaricides)	US$500 per product US$2 000 for acaricides	—
Timescale for product registration	1.5 to 2 years	—	6 months (2 years for acaricides)	—
Fees/timescale for registration renewals	US$150 Annual	Every 5 years	US$200 Annual	—
Import requirements	Government license needed	Import and sale under the supervision of a pharmacist, on premises separate from any other business	Importers are licensed for 1 year and must already hold a license for retail, wholesale or manufacture. Pre-import verification for each consignment, applications for which must include the Ugandan product registration, manufacturer's GMP certificate and Free Sale Certificate from the regulatory authority in the nation of origin. Products must comply with international standards for labelling and sealing	Importing facility must be registered and the product approved. Shipments may be inspected on arrival

[2] Acaricides must undergo local efficacy trials

Annex 2. **Cross-country comparison chart** (continued)

	South Africa	Kenya	Uganda	USA
Distributor/ retailer requirements/ qualifications	Registered business must be principally veterinary and manager must be a vet or pharmacist	Distributors are licensed annually by the PPB for drugs listed under schedules 1 and 2 Legally, vets are restricted to dispensing drugs only for treatment of specific cases	Registration required, with annual fee. Owner/partner of retail outlet must be a pharmacist and must be present for all prescriptions filled. Under new regulations, all veterinary service providers will be required to undertake periodic refresher courses UVB and NDA are currently drafting guidelines for drugs sold through non-registered service providers	Must have a pharmacy, medical or veterinary degree to distribute prescription drugs
Involvement of NGOs and public–private partnerships in policy and sales	SPCA but few others with regard to livestock	Much of rural livestock sector	NGOs are supposed to work with local government vets but often work independently. Some are distributing products legally in some areas (e.g. Karamoja), but others are operating illegally via CAHWs (especially in the south of the country)	Occasionally in Native American communities and inner cities (mainly for pets)
Estimated amount of veterinary drugs supplied by NGOs	Insignificant	Significant but unknown (40% for human medicines)	Significant but unknown (25% for human medicines)	Insignificant

Credits:

Cartoons: Joseph Kariuki

Copy-editing: Tess Grasswitz, Green Ink, UK

Design and layout: Christel Blank, Green Ink, UK

Printing: Pragati Offset Pvt. Ltd, India in collaboration with Sue Hainsworth

AU/IBAR, PO Box 30786, 00100 Nairobi, Kenya
Tel: +254 2 334550/251517/226651
Fax: +254 2 332046/226565