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Legal Control of Sale and Distribution of Drugs in Kenya

A Dessertation subitted in partial fulfillment of the requirements for the LLB Degree University of Nairobi

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Nairobi April, 1981

Acknowledgements

I take this opportunity to acknowledge my indebtedness to my Supervisor, Mr. T.A. Mweseli. I do express my sincere appreciation to him for his a advice, guidance useful critisisms and discussions throughout my work under his supervision.

I also wish to thank my husband Phelix Majiwa for his continuous encouragement and his co-operation during the time I was writing this paper. His suggestions on this paper have been very useful to me.

I especially wish to thank Ms. Janet Ochola Mrs. Lea Agina, and Ms. Consolata Magunga for typing this paper.

Finally, I wish to thank those who freely gave useful information for the paper, especially by answering the questionaires.

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ABBREVIATIONS

AER	All England Reports	1944 - 1952
C.A.	Court of Appeal	1932 - 1969
KB	Kings Bench	1950
QBD	Queens Bench Div.	1878 - 1963
JP	Justice of the Peace and Local Goverument review	1896-1905

CASES

List of statutes

1. Foreign Investments Act .. .. cap. 254 Laws of Kenya

2. Sale of Goods Act .. .. cap. 31 Laws of Kenya

3. Dangerous Drugs Act .. .. cap. 245 Laws of Kenya

4. Pharmacy and Poisons Act .. .. cap. 244 Laws of Kenya

5. Food Drug, and Chemical Substances Act. .. .. cap. 254 Laws of Kenya

6. Price Control Act .. .. cap. 504 Laws of Kenya

7. Public Health Act. .. .. cap. 242 Laws of Kenya

LEGAL CONTROL OF SALE AND DISTRIBUTION OF DRUGS IN KENYA

Introduction and Brief Historical Background

The paper examines some aspects of law relating to control of sale and distribution of pharmaceutical drugs in Kenya, with special reference to substandard drugs. The examination will include the relevant legislation pertaining to drug control. This includes the Food Drugs and Chemical Substances Act[1], its aims, enforcements mechanisms and accomplishments. Secondly the paper will define the subject matter of control. Thirdly it will examine the functions of law and the extent to which it is utilized as a means of control and then proceed to analyse the necessity for legal control. Next, the paper will identify the problems relating to legal control of sale and distribution of drugs. The paper will then evaluate the adequacy of existing techniques as a means of control and finally there will be conclusionsand recommedations of alternative ways of dealing with the current problems.

Kenya has been linked to the world market forces since the late 19th Century. This was done through British colonialism.[2] The initial steps in this process where Britain aquired control over Kenya, thus linking it to the world market forces, was done by a favourite colonial device, the chartered company. In Kenyan case, it was the Imperial British East African Company[3], (IBEAC) started by William Mackinon in 1877 and granted A Royal charter in 1888. The granting of the charter was an annoucement that the company was an arm of British imperial policy.[4] The company carried on this duty until 1895 when Kenya was declared a protectorate. This declaration marked the beginning of official British rule which was to last until 12th

December, 1963.

After the declaration of a protectorate over Kenya, the colonial authorities acquired power and used it to establish their strength in Kenya and thus created a colonial society. By this period, Kenya was increasingly being incorporated into the rapidly expanding world of trade. The coastal area and the interior to the south of Kenya had been fully incorporated into this rapidly expanding trade, but the interior of Kenya was to be incorporated in a different way. Incorporation of the interior was as a result of building the railway from Mombasa to Kisumu.

The completion of the railway from Mombasa to Kisumu in 1901 provided a straight access to the headwaters of the Nile, and gave the administrators the idea of establishing an extensive white settlement to bring land into full commercial production. As a result of implementation of this policy, Kenya began to play the classic role of a country at the peripphery of a capitalist system, exporting the primary commodities and importing manufactured goods.[5]

Commercial agriculture, introduced with European settlement, was dominated by European settlers and foreign firms. Africans and Asians were effectively excluded and Africans were forced to provide cheap labour in the European farms. Since colonial development was designed to increase supply of raw materials to British industry and at the same time encourage growth of 'captive' markets for British manufactured goods, local manufacturing became impossible apart from the basic process of commodities[6]. As a result Kenya had very few indigenous markets and very little assistance was given to industry and manufacturing. Emphasis was placed on agriculture and basic processing rather than domestic

industrial capital accumulation.[7] This was the position until 1945 It explains the limited number of industries in Kenya at the time and also the

> 'desire of British industrial capital to discourage any manufacturing for export which would threaten her own metropolitan capital' [8]

After 1945, however, there was a substantial change. This change was especially noticeable in the growth of the manufacturing sector; whereas historically, it had been concentrated on the agricultural sector and training, foreign investment after 1945 increasingly concentrated on the manufacturing sector. This change has been attributed to two main reasons, first in the fact of global competition the inefficient British capital was driven to invest behind a protective wa ll in order to maintain the Kenyan market, and secondly, merchant capital was facing intense competition and firms were forced into primary production to maintain their competetive positions.[9] Thus the world economic pressure forced the merchant capital to industrialize in the period after the second world war.

By the late 1950s, following the ravages of the second world war, industrial capital in Europe was turning outwards because of international competition. At the same time Kenya was seeking to deversify her economy and sources of foreign capital. The result in Kenya was an inflow of predominantly industrial capital from not only Britain but also United States, Germany, France and other countries.[10]

As a result of these trends, foreign investment has come to play a very important part in the Kenyan Economy.

> 'Foreign investment is substantially concentrated on import substitution of final consumer product modelled on similar products sold in other parts of the world by subsidiaries of the same and competing multinational corporation. [11]

In Kenya

> "these companies' position largely follows from the relationship with the host state and the absence of an African Industrial bourgeoise" 12.

Today much of Kenya's industrial activity is dominated by multinational corporations and their subsidiaries or non-citizen enterpreneurs who produce import substitutes of lower value for local consumption For instance the pharmaceutical subsidiaries confine their activities to mixing imported inputs, forming them into pills and packing them. These companies negotiate for heavy protection from overseas firms while frustrating any intention of competition by local firms.[13] In their campaign against competition, the companies use differentiation in brand names backed with heavy expedditure advertisement. Most of the goods produced by these firms are those that have been made to suite the home economy.

Apart from protection 'negotiated' directly by these companies with the government, further protection of investment is provided for by the Foreign Investments Protection Act[15]. This Act provides for application of a certificate for foreign firms to be 'approved' firms. After the issue of such a certificate, the firm to which it is issued can bring assets to Kenya and freely repatriate the profits outside Kenya. The Act also provides for protection from deprivation or compulsory acquisition of any property of an approved firm; this guarantee is a reproduction and exphasises the basic guarantee of the constitution.

As regards the sale of products, the Sale of Goods Act[17] allows and sets conditions for sale of goods in Kenya. The principle of Nemo Dat allows the subsidiaries to act as agents for parent firms.

Like the Foreign Investments Act, there are acts of partiament providing for imports of certain goods into the country. Among them is the Customs and Tarrifs Act.[18] This Act provides for imposition of customs duties on goods imported into Kenya. Condition for importation of goods including drugs are provided for in the schedule of the Act.

The foregoing shows how Kenya was integrated into the world market forces through British colonisation. The main roles imposed on her by her colonial and post colonial demands of international finance capital are: to export agricultural and other raw materials, to provide outlets for foreign capital directly or through subsidiaries of foreign multinational firms and to provide markets for foreign industrial products. The foregoing further shows that the laws of Kenya provide for the performance of the roles imposed upon her by the colonial and post colonial demands of international finance capital. These laws include laws relating to manufacture of goods by multinational subsidiaries and local firms, importation and sale of goods. Apart from the above mentioned laws there are tother legislation dealing specifically with drugs The following is a brief history of drug legislation.

Brief hisotry of drug legislation in Kenya

Drug Legislation in Kenya began in 1933 with the enactment of the Dangerous Drug Act.[19] However, control of quality of drugs did not start until 1948 when the Food and Drugs Adulteration Act was passed to prevent sale of adulterated food and drugs. Since the passing of the Act, there have been two other acts passed in relation to control of drugs. The following brief summary

will show that the legislation have been fragmentary, inadequate inflexible and of limited application.

In 1933 the Dangerous Drugs Act[20] was passed. The aim of this Act was to regulate importation, sale, manufacture and use of opium and other dangerous drugs. In addition, effect was being given to international conventions on opium. In 1912 the Hague Convention was signed and by this convention, import and export of opium for smoking was prohibited and import, export production and dealing in narcotic drugs were subjected to a scheme of control. In 1925 the first General Convention was signed for the purpose of complementing and strengthening the Hague Convention and in 1931 another Geneva Convention was signed for limiting manufacture and regulating distribution of narcotic drugs. By these conventions it was hoped that the wide spread misuse of drugs would be curbed, but in fact misuse of drugs has increased considerably.

The next drug legislation passed in Kenya after the 1933 Act was the Food and Drug Adulteration Act of 1948. The aim of this Act was to prevent sale of adulterated food and drugs to the public. With the expansion of commerce and industries, it was felt that the scope of the Act should be expanded to cover new drugs and chemicals locally manufactured or imported into Kenya. Secondly it was meant to ensure that products conform to the laid down standards. This Act continued in force until 1965 when it was repealed by the Food Drugs and Chemicals Substances Act of 1965.

While the 1948 Food and Drug Adulteration Act was still in force, the Pharmacy and Poisons Act[21] was passed in 1957. The aim of this Act was to make provisions for control of the profession of pharmacy and to control trade in drugs and poisons.

The Act established a Pharmacy and Poisons Board with powers of registering or deleting from the register pharmacists. Secondly, the Board could recommend to the minister to prohibit or control certain medicines. This Act however did not deal directly with control of substandard drugs although it did in many ways supplement the Food, Drugs and Chemical Substances Act which dealt directly with standards of drugs.

The Food Drugs and Chemical Substances Act[22] was passed in 1965. It repealed the Food and Drug Adulteration Act of 1948. The aim of this act as regards drugs is to control standards of drugs, it prohibits sale of certain drugs, and provides for preparation of drugs under sanitary conditions. The Act establishes a statutory board known as Public (Standards) Board. This Board is responsible for advising the minister who may make legislation controlling the preparation, packing, labelling and sampling of drugs and chemical substances for sale whether imported or locally manufactured.

After 1965, there has been no legislation providing for control of standards of quality of drugs. This is not in keeping with the fact that in the last few decades, there has been a great increase in manufacture and importation of drugs. The existing legislation providing for control of sale and distribution of drugs are inadequate to control standards and qualities of new drugs that have poured into the markets as a result of the enormous advancements in the field of pharmacology. The legislation is further not adequate to counter the manouvres used by businessmen to try and sell substandard drugs in this country. Thus even after the attempt by the government in 1965 to try and deal with the problem of quality and standard of drugs, one still finds the existing drug legislation, fragmentary

inadequate and inflexible.

The Acts are fragmentary because they do not knit together sufficiently to provide a comprehensive and flexible scheme for controlling sale and distribution of substandard drugs. The Acts are inadequate because, although the 1965 Act was passed to counter the problem of standards of drugs, it was never intended to control the widespread sale and distribution of substandard drugs as it is understood today. As a result, the Act is very limited in scope and the procedure is too slow to keep up with the pace of new developments. The Act is inflexible because the courts cannot administer it readily. It does not provide speedy methods for dealing with irresponsible over prescription or promotion of substandard drugs by doctors and salesmen. Similarly the Act does not provide for obtaining of information from doctors and pharmacists about the possible side effects of drugs. Finally these acts have many loopholes that can be exploited by salesmen and drug agents in order to sell substandard drugs. Thus the Act does not provide adequate protection to the consumer and has failed to accomplish intended goals.

As a result of the outlined factors, it becomes imperative to re-examine and re-assess the Kenyan Legislation on drug control with a view to positing the solutions that could be found to remedy the inadequacies.

CHAPTER ONE: PART ONE

Definition and Discussion of subject matter of control

There has been a great advance in the field of pharmacology in the last two decades. This has enabled the introduction of a wide range of new drugs. The quantity of drugs introduced after the second world war is without parallel. For instance, it is estimated that more than eighty percent of drugs now in active use by physicians were not available twenty years ago.[1] The ever growing quantity and variety of pharmaceutical drugs has been reflected in the vastly increasing numbers of pharmaceutical companies moving into international trade. While Kenya is not one of the largest users of drugs in the world, modern drugs have become cosmopolitan articles generally available world-wide[2] and Kenya has been affected by them.

Man's attempt to cure illness through intake of foreign substances is as old as man himself, but the modern era of pharmaceutical development dates from the nineteenth century. The foundation to this era was laid by Paul Erlich, a German Physician, who propounded the concept that pharmaceutical research should be directed towards finding chemical agents which would be taken up by targeted bacteria in lethal dosage but would be tolerated by the host organism, man, without damage[3]. This opened way for new drugs, and together with isolation of penicillin in 1939, revolutionized medical treatment and pharmaceutical industry. By early nineteen forties, the mechanism of drug action and effect of drugs in specific organs begun to have a major impact on drugs being produced for general use. Since 1970, a variety of drugs estimated at 20,000 have been in existance. The progress in the development of new drugs has provided effective and other routine treatment of a wide range of diseases

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previously considered beyond treatment.

Modern drugs are end products of a complex industrial production process and since they are intended to be used in man, the drugs should satisfy demanding standards as to their proven efficacy, safety and pharmaceutical quality. A lot of these modern drugs, such as antibiotics, contraceptives and analgesics are potent and the difference between the required therapeutic dosage and the dosage that would be toxic is very small. While modern drugs enable the treatment of diseases previously considered beyond treatment, they also pose a possibility of harmful side effects. Although the potential dangers posed by modern drugs have been widely recognised in the scientific field, it was not until the 1962 Thelidomide disaster that this potential became a major issue in public policy[4]. Following this, many nations have introduced stringent controls demanding substantial evidence for performance of the drugs.

Control of Standards

Concern with the quality of drugs started almost as early as the discovery of drugs. In the fourth century A.D., a Greek physician Dioscordes was able to identify forty generally adulterated drugs[5]. In the modern times, this concern has become even more serious. In Britain, the first drug regulatory Legislation was passed in 1785[6], as a result of public concern over quality of drugs. In the United States concern over drug quality led to the passing of a regulatory Act in 1906[7]. In Kenya this concern led to the passing of a regulatory Act in 1948[8]. The 1948 Act was repealed by another regulatory Act in 1965. This was the Food, Drug and Chemical Substances Act[9].

THE FOOD, DRUG AND CHEMICAL SUBSTANCES ACT

Purposes of the Act

The Food, Drug and Chemical Substances Act (herein referred to as the Act) was passed in 1965 to widen the scope of the 1948 Food and Drug Adulteration Act.[10] The purpose of the 1948 Act was to prevent the selling of adulterated food and drugs to the public. It was considered that food and drugs should be sold to the public in the purest form. The 1965 Act was passed in order to cover new drugs both Locally manufactured and those imported into Kenya, in order to ensure that they conform to laid down standards.[11]

The main purposes of the Act as regards drugs are to provide a means of controlling standards and qualities of drugs and to ensure the safety and efficacy of drugs sold to the public. The Act was aimed at taking into account modern developments and its purposes include control of manufacture and sale of drugs. The Act also seeks to prohibit sale of certain drugs.

A significant feature of the Act is the establishment of a statutory board known as the Public Health (Standards) Board (herein after called the Board). The members of the Board are intended to represent a cross section of the community reflecting the interests of the Government, Local Authorities, and commercial concerns. The Board is responsible for advising the Minister for Health who may make regulations controlling the preparation, packing, labelling, sampling and sale of drugs whether imported or of local origin.

The Act gives a new definition of Health inspectors and also defines the powers of authorized officers. These officers include Medical Officers of Health, the Health Inspector, Police Officers of the rank of a sub inspector or above, and other persons authorized by the Municipal Council.

Prohibited Sales and Offences

Section 8 of the Act provides that:-

"Any person who sells any drug that
(a) is adulterated; or
(b) consists in whole or in part of any filthy, putrid, disguisting, rotten, decomposed or diseased or substances or foreign matter, shall be guilty of an offence".

This section aims at protection of the consumer. The offence here is the sale perse of drugs affected in the manner specified. Under this section agreement to sell does not itself constitute a sale, the passing of the property is necessary[12]. The word "sell" is defined as including

"offer, advertise, keep, expose, transmit, convey, deliver, or prepare for sale or exchange, dispose of for any consideration whatsoever, or transmit, convey or deliver in pursuance of a sale, exchange or disposal as afore said".13

The definition of the word "sell" is very broad and may cover many kinds of transactions. A sale may, for the purpose of the Act, be completed before payment is made for the goods[14]. However, the mere fact that a customer may pick up goods marked with their price and exposed for sale does not amount to an offer to sell by the shopkeeper; the customer offers to buy goods and the contract for sale is completed only when the cashier has accepted the purchase price.[15]

For the purpose of this Act, "person" includes limited companies or association of persons, corporate or incorporate[16]. An action can be brought against a company for an offence under this section.

Drug is defined to include

"(a) any substance included in the publication mentioned in the schedule of this Act; and
(b) any substance or mixture of substances prepared,

sold or represented for use in
(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or symptom thereof, in man or animal; or
(ii) restoring correction or modifying organic function in man or animal". 17

Difficulty may arise under this definition with regard to those substances which have commercial as well as medicinal use for instance sulphur or sulphuric acid. In Fowle v Fowle[18] a grocer sold a quarter of a pound of Beescoak which was adulterated by paraffin. It was proved that the substance was used in preparing medicine and that it was included in the British Pharmacopaeia. The court held that it is a question of fact for the justices to decide whether in all circumstances of each case, the article is a drug and that in the circumstances of this case, the article was not a drug. It should also be a question of fact to be decided on the circumstances of each case whether an article is a drug or food. Although the term "drug" should not be restricted or confined to the statutory difinition for the purpose of this Act, drugs mean drugs used for the benefit of human beings and includes drugs used for veterinary purposes.

Whenever adulterated drugs are sold contrary to the provisions of this section, proof of adulteration need not be by a public analyst. The responsibility of enforcing this section is upon the Board although an individual can bring proceedings in his own name if he has been affected. It is however difficult for an individual to bring proceedings in his own name, as an ordinary person would hardly, if ever, find out that the drug was adulterated. In effect there have been no prosecutions brought by individuals under this section in this country. This should not mislead one to imagine that no offences under this section have ever been committed but rather implies that this

section does not give much protection to the consumer because of the difficulty of finding out whether the drug is adulterated.

This section can only be brought into use by an individual who has been affected or by authorised officers. In case of authorised officers effective sampling and analysis of drugs already in market can only be carried out if their attention is drawn to them. This is difficult because ordinary people will not find out that drugs are adulterated so as to alert the officers' attention. This therefore leaves room for adulterated drugs to be sold to the public.

Section 9 of the Act seeks to protect the consumer from deception. It provides that

> "Any person who labels, packages, treats, processes, sells or advertises any drug in contravention of any regulation made under this Act, or in any manner that is false, misleading or deceptive as regards its character, constitution, merit or safety shall be guilty of an offence". 19

The authority responsible for enforcing Section 9 is the Board[20]. However, permissive powers to institute legal proceedings are conferred on other authorized persons[21]. This section is one which if implemented, would offer a great protection to the consumer. However it had not been rigidly enforced and offences under it have not been prosecuted. The most important point in this section is that it prohibits misleading advertisement as to character, consitution, merit and safety of drugs which can be very damaging if left unchecked.

Advertisement as defined, includes:

> "any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of ... drugs ...".22.

This has infact been done in various ways by the promoters of drugs while knowing very well that their drugs are substandard. The drugs are often promoted by aggressive sales campaigns that may tend to over-

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state their merits and fail to indicate the risk that may be involved in their use. Complicated advertising techniques are used to sell drugs that are either dangerous or of little use to the country. This is further verified by the number of drug representatives in the country. There is an average of one drug representative to every eight doctors in Kenya while there is only one drug representative to every twenty doctors in Britain[23]. Many drug advertisements in this country are misleading. This is supported by the fact that some of the drugs that are promoted in Kenya have been restricted in use or have been totally rejected in their countries of origin[24]; for example antibiotic penalba, alias Albamycin, which was banned in United States in 1970 is being promoted and sold in many developing countries without publishing the effects[25]; the controversial injected contraceptive, Depo-provera which is unavailable and has never been accepted for use in the United States is avidly promoted and sold in this country[26]. It is clear that any attempt to promote such drugs as is done here is a misleading and deceptive attempt and any person who tries to promote such drugs should be prosecuted under section 9. There are however no decided cases as to what is a misleading advertisement in Kenya. In the U.K. the test of whether a description is misleading has been held to be whether an ordinary man will be misled by it[27]. This test negates the burden on the prosecutor to prove that any particular person was in fact misled. However, since Kenya has her own perculiar conditions "what will mislead an ordinary man in Kenya" should be decided bearing in mind those conditions.

Another important protection section 9 purports to give to the consumer is against

> "false labelling, packaging, treatment or processing drugs, so as to deceive or mislead the purchaser as regards the character constitution, value potency,

quality, composition merit and safety of drugs".

Label is defined to include

"any legend, work or mark attached to, included in, belonging to or accompanying any .. drug ..".28

Package is defined to include

"anything in which any ... drug ... is wholly or partly placed or packed".29

Treatment or processing is not defined by the Act; however, the treatment referred to here is the treatment in relation to manufacturing. Similarly the processing is the process of manufacturing.

Section 9 has been violated by some "back street" drug sellers to sell drugs that have been rejected in their countries of origin. An example of such violation is the case where a drug 'Nikon', banned in the United States where tests indicated it contained carcinogens and caused two types of cancers, found its way into Kenya and was sold under labels of various popular drugs[30]. The 'Nikon' dealers, in order to mislead the public, sealed their tablets in the container of a popular drug 'algon' which had'disappeared' from the market, and distorted the word 'Nikon' to make it 'Aafkon' which is the name of another popular drug. This is a case of double cheating, a wrong drug bearing a false name and packed in a wrong container, all done deliberately to 'dump' an outlawed drug in this country.[31] People who buy such drugs are therefore misled and deceived as regards the character, constitution, value, quality composition merit and safety of drugs which they purchase. This is clearly done in contravention of section 9.

Section 11 attempts to further protect the consumer by making it an offence to sell to the prejudice of the purchaser any drug not of the nature, substance or quality demanded. The Board is responsible for the enforcement of this section and Authorized Officers have power

to institute proceedings under this section. In Kenya, there are no decided cases regarding drugs sold to the prejudice of the purchaser, but in the U.K. decided cases illustrate two main propositions, namely: that a purchaser cannot be prejudiced when notice is given to him at the time of the sale that the article sold is not of the nature, substance or quality of the article he demands; and that in order to show that an article was sold to the prejudice of the purchaser, it is not necessary to prove that he has sustained actual prejudice or damage.

With regard to the first point, and considering decided cases, no such question can arise unless the notice given has actually been received by the purchaser. In Sands v- Small[32], Lord Cockburn in giving judgement, said

> "The provision seems to me to apply to cases where a seller professes to sell to the purchaser an article as being of certain denomination, whereas the article has been altered ... when the article is so altered it must be considered to have been done to the prejudice of the purchaser unless it is duly and sufficiently brought to his knowledge and he chooses to purchase not withstanding ...".33

In some instances, multinational companies change the name of drugs that have been banned or found to have bad effects and give scant information to their potential dangers[34]. This was the case with Bendictin, an anti-nausea drug which is said to have caused birth defects in many children and which was sold in Kenya without information about the possible side effects. As the public learnt the dangers of this drug, the manufacturers purported to replace the drug with a similar one called "Debendox" which is essentially the same as the "Bendictin"[35]. Thus the drug companies violate the law by overstating the merits of the drugs while withholding information as to their potential dangers.

This leads us to consider the words "... nature, substance and quality demanded ..." by the purchaser. In every case, it is necessary to decide which of the three words is most appropriate to use. It is not necessary that all three qualifications be met in each case. The wording in this section alleges three offences as was held in Baskin v- Davies[36].

The phrase 'article demanded' in the section has been held to be the article as it is known commercially in Pasher v- Stevenit[37]. Thus if a person demands a drug by its patent name, which is often the case, then it seems the section does not offer him any protection.

However, if the drug demanded has some recognized standard of quality or composition, it is an offence under section 10 to sell it not conforming to this standard if it is likely to be mistaken for another drug. In the absence of a statutory standard, it has been held in Roberts v- Leeming[38], that the judges must set one for themselves as a matter of fact to be founded upon the evidence presented.

With regard to the second point, namely that in order to show that the article was sold to the prejudice of the purchaser, it is not necessary to prove that the purchaser has suffered actual prejudice or damage, Lord Mellow J. has said in the case of Hoyle v- Hitchman[39]

> "if a purchaser whoever he may be gets an article inferior to that which he demands and pays for, it seems to me that he is necessarily prejudiced within the meaning of the section ...".40,

and Lush, J. said that:

> "Prejudice is one which an ordinary customer suffers, that which anyone suffers who pays for one thing and gets another of an inferior quality ...".41

Using the tests laid down by justices Mellor and Lush, it seems that many purchasers or consumers of drugs in this country are prejudiced within the meaning of section 9, by any sale of low quality drugs that maybe in the market[42] and, from the foregoing, these drugs are sold to their prejudice.

Standards

Section 10 provides that:

> "where a standard has been prescribed for a drug, any person who labels, packages, sells or advertises any substance in such a manner that it is likely to be mistaken for that drug shall be guilty of an offence unless the substance is the drug in question or complies with the prescribed standard".43

This section seeks to protect the consumer by prohibiting sale of drugs of different standards where appropriate standards have been prescribed. The wording of the Act suggests that standards prescribed are absolute. There are instances where this section has been violated by distributors and manufacturers of drugs. These are cases like the one already mentioned where dealers sold an unaccepted dangerous drug 'Nikon' in the packet of other popular drugs like "Algon" and name "Aafkon"[44]. Another instance where this section has been violated is where certain drug manufacturers copy the drugs already in the market and come up with cheap imitations whose qualities cannot be guaranteed[45]. This has been the case with locally manufacturered drugs such as 'asprin'. Thus even though standards laid down are absolute there are instances where they are violated.

Section 10 (2) continues to state that:

> "where a standard has not been prescribed for a drug but the standard of the drug is contained in any of the publications specified in the schedule of the Act, any person who labels, sells or advertises any other substance or article in any other manner that is

likely to be mistaken for such drug shall be guilty of an offence".

The publication specified in the schedule are pharmacopoeaia Internationalis, the British pharmacopoeia, the Pharmacopoeia of United States of America, Codek Francais, the Canadian Formulary, The British Pharmaceutical Codex, The National Formulary and the British Veterinary Codex.

The question arising here is how effective these publications can help ensure quality, safety and efficacy of drugs and to what extent they have actually done so. Unfortunately these publications have given very little help in ensuring the standards of drugs imported into this country.

To begin with, the principal difficulty is that at least four major drug exporting states, the U.K. (whose standards Kenya tends to rely on a great deal) Switzerland, France and Italy, drugs produced for export are exempted from national regulatory requirement[46]. With these exemptions it will be practically impossible for Kenya to enforce Laws from which the drug companies are exempted in their own countries. The section does not give much protection unless it is enforced and as yet, it has proved very difficult to enforce it. Thus it is known practice that pharmaceutical companies deliberately label "For Export only" drugs that cannot meet the registration requirements for use in the countries where they are manufactured.[47] Another problem arising out of relying on the publications is that conflicting values may prevent the countries in which the drugs are manufactured from controlling trade elsewhere in substandard drugs. For instance in the United States

> "some influential circles ... view drugs ... dumping in the third world markets as export business and therefore an intergral component of the U.S. balance of trade equation.

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> "Other U.S. circles view the Government's attempt to control export of hazardous drugs ... as unacceptable interference with free enterprise system ..." 48

While this kind of conflict is going on, it is unlikely that the drug exporting countries will strictly require drugs 'for export' to comply with the standards laid down in the pharmacopoeias. Thus the provision that the standards of drugs should comply with those laid down in the foreign pharmacopoeias does not offer much protection incase of imported drugs from these countries.

As regards Pharmacopoeia internationalis, it was intended to harmonize standards of drugs in various national pharmacopoeias and to be a means of exchanging information of national data on drugs. It is submitted that it has not been an effective technique for carrying on both these aims[49], it has been slow to incorporate newly introduced drugs. For instance the second publication of International Pharmacopoeia was published sixteen years after the first publication. The pharmacopoeia internationalis lacks the advantage of speedy availability of drug information, and completeness of data[50]. Lacking these advantages, it has not proved to be an important international technique for exchange.

The foregoing shows that the publication in the schedule are of little use since in most countries the drugs for export are exempted from national regulatory requirements and Kenya lacks quality control facilities with which she can check if the drugs comply with the standards laid down in the publications in the schedule.

Thus although there have been many violation of this section by the intentional sale of substandard drugs that do not comply with standards in the publications, the section has given very little help in trying to curb these offences. Also the section is one which by its very nature is very difficult to enforce. This is because it seeks to enforce in Kenya standards from which drugs are exempted in their countries of origin. The drug sellers have succeeded in avoiding this provision by changing the names of drugs so that even if a standard has been prescribed for a particular drug, the change of the name will effectively exclude it from the scope of stipulated standard. This practice constitutes an offence which ought to be prosecuted under this section.

Since many countries do not require drugs for export to meet national regulatory requirements, the publications in the schedule are of little use to the country. This leaves Kenya to rely on the standards she has to set down herself. These standards have not been set.

Section (10) (3) further purports to protect the consumer by providing that:-

> "Any person who labels, packages, sells or advertises any drug for which no standard has been prescribed or for which no standard is contained in any publication specified in the schedule to this Act shall be guilty of an offence unless such drug
>
> (a) is in accordance with the professed standard under which it is labelled, packaged, sold or advertised, and

> (b) does not resemble in any manner likely to deceive, any drug for which a standard has been prescribed or which is contained in any of the publications specified in the schedule to this act 51".

The little protection offered by this section is reduced by its proviso. The section deals mainly with new drugs since it is those drugs whose standards are likely to be absent. To allow sale of drugs without laid down standards is tantamount to allowing testing of drugs in this country. Since the section allows sale of drugs whose standards are not prescribed provided they are in "accordance with the professed standards", the firms selling the drugs can always argue that the standard they have mentioned is the standard they profess. This problem is made even more serious by the fact that Kenya, like most other developing countries, lacks quality control facilities, and therefore has to rely to a large extent on the good faith of the drug manufacturers who are usually outside the country[52].

Section 10 (3) (b), has constantly been violated by drug firms especially as regards drugs that are imported into the country. As has been mentioned, the requirement that drugs meet standards laid down in the publications in the schedule is not of much assistance if the countries from which the drugs are exported exempt the drugs from their national regulatory requirements. In the past and at present, the consequence of the legal exemption from drug exporting countries is that many drugs have been sold in this country that do not meet the required standards in their own countries of origin.

The foregoing shows that the provisions concerning standards of drugs have been of very little help in protecting the consumer, and that drug companies have been able to evade restrictions laid down by the provision and continued to sell substandard drugs.

Section 12 seeks to ensure that drugs are processed under sanitary conditions. It provides that:-

> "Any person who sells, prepares, preserves packages, stores or conveys for sale any drug under unsanitary conditions shall be guilty of an offence " 53.

It would seem that this section refers to preparations of drugs in this country firstly because it is difficult to know under what conditions imported drugs are prepared and as such, sanctions will be difficult to enforce against those who violate this provision outside the country. Secondly, because it presumes that the drug exporting countries have their regulations regarding conditions under which drug preparations should be carried on.

Many small pharmaceutical manufacturers in Kenya have no modern facilities for ensuring maximum quality control, and are therefore not able to ensure that drugs are manufactured under the highest possible sanitary standards.[54] They have pointed out the expense involved in ensuring quality and ensuring that drugs are manufactured in the highest possible sanitary standard, and admitted that they cannot afford these expensive facilities.[55] The crucial point however is the hazards posed by lack of such facilities, and more particularly when the companies cannot guarntee quality of drugs manufactured under such conditions as the companies can afford.

It is also contended that the small local manufacturers not only lack modern quality control facilities, but they also lack proper storage facilities[56]. This means that in many local pharmaceuticals, preparation, preservation and storage are not done under the highest, let along acceptable, possible sanitary conditions as required by the Act.

It is the duty of the Board to see that the provisions of section 12 are enforced, to ensure maximum standards in preparation of drugs. Control should further be extended to include packaging, labelling, storage or conveying. Evidence, however, shows that

> "pharmaceutical industries have been allowed to mushroom uncontrolled, thus posing health hazards to the lives of many uninformed consumers of the cheap drugs". 57

Administration and Enforcement of The Act

Section 27 of the Act establishes the Public Health (Standards) Board consisting of ten members appointed by the minister herein-after referred to as the Minister. The intention of parliament in creating such a board was that its members should represent a cross-section of the community. Hence section (27)(2) provides for the composition of the Board to consist of

(a) "a chairman who should be the Director of medical services ...
(b) a vice chairman who shall be the Public Health Officer
(c) four members appointed to represent the Government.
(d) one member with special knowledge in food packing industry
(e) one member nominated by the Pharmaceutical society of Kenya.
(f) One member representing the National Assembly".58

The tenure of office of members appointed under paragraphs (d), (e), (f), and (g) of section 2 sub section 2, is three years; after

the expiry of the three years, the members shall retire but are eligible for reappointment. However during the three years in office, the above mentioned members may resign by writing a letter to that effect addressed to the chairman. The quorum of the Board is four. The Board is empowered to invite any person to attend any meeting for the purpose of assisting or advising the Board, but voting rights are denied to any such person. The Board regulates its own meeting, subject to the Act or special direction in writing by the minister for Health.

The Board is responsible for advising the Minister under section 28 of the Act, the Minister in consultation with the Board has power to make regulations.

> "(a) declaring that any .. drug .. or class of .. drugs .. is adulterated ... If any prescribed substance or a class of substance is present therein or has been added thereto or omitted therefrom". 59

In addition to this power, the section gives the minister power to make regulations relating to the labelling, packing, offering exposing, advertising, and selling of drugs. Under section 28 (i) (b) (ii), the Minister may make regulations restricting sizes, dimensions and other specifications of packages of drugs. Under section 28 (i) (b) (iii) the minister may make regulations respecting sale or condition of any drugs and under section 28, (i) (b) (iv), the minister may make regulations respecting the use of any substance as an ingredient in any drug.

These provisions are intended to protect the consumer or the purchaser of drugs from being deceived or misled as to quality, character, value, quantity, composition, effect, merit or safety of drugs, or to prevent injury to health of the consumer or purchaser.

This section to a large extent has failed to achieve its purpose. Drugs are often promoted and sold, whose merits are overstated through

advertisement and whose side effects are often not mentioned. For instance, the case of injectable contraceptive depo-provera which is considered "appropriate for use in developing countries"[60] has never been approved for use in the United States because of its many side effects. This contraceptive is promoted and sold here liberally and its effects are often not indicated. This is also the case with many other drugs like ovulen (pill) tetracycline (antibiotic) and imipramine (anti-depressant)[61].

This section gives the minister adequate powers to make regulations to protect the consumer from deception as regards standards of drugs. The number of substandard drugs sold in this country are increasing[62]. Much of the responsibility for ending or curtailing this problem is with the Government through the Minister for Health who may use his powers under section 28 to make necessary regulations.

Section 28 (c) further gives the minister power to make regulations

> "prescribing standards of composition strength, potency, purity or other property of any drug".

This section could be used particularly to check the standards and qualities of drugs manufactured in this country. It can also be used to check the "backstreet Manufacturers" who copy drugs already in the market and come up with cheap imitations. Under section 28 (d) of the Act the minister is given power to make regulations respecting the importation of drugs. The minister can use this power to make regulations necessary to stop the importation of substandard drugs to this country. This section can further be used to stop the "dumping" of drugs which are banned in the west and yet sold to this country or given "to hospital as 'aid' from European nation"[63] by making appropriate regulations.

The minister has further powers under section 28 to make regulations

respecting method of preparation, preservation, packing, storing conveying and testing of drugs. This section is intended to prevent injury to health of the consumer, users, or purchasers of drugs. The section is complementary to section 12 of the Act which requires preparation of drugs to be done under sanitary conditions.

Section 28 (g), (h), (i), (j), and (k) gives the minister powers to make administrative regulations. Such regulations include those requiring the manufacturers of drugs to maintain such books and records as the Board may consider necessary for enforcement and administration of the Act and any regulations made under the Act, requiring drug manufacturers to submit test portion of any batch of such drugs, to make regulations providing for analysis of drugs, regulations for providing for taking of samples of any articles for the purpose of the Act of any other Act or exempting drugs from all or any provision of the Act. In addition to these powers, the minister after consultation with the Board, has powers to make regulations generally for the carrying of any purposes or provision of the act into effect.

This section gives the minister extensive power which if used, would decrease the sale and distribution of substandard drugs. Unfortunately the Regulations made under this section have not been implemented in respect of drugs. This being so, the section has failed to play the role for which it was intended, namely to protect the consumer from worthless medicine and lethal drugs.

Under section 30, an authorized officer has powers to enter any premises, examine any articles and take sample of such articles reasonable for proper performance of his duty. If the Act or any regulation made under it applies to such article, an authorized officer also has power to stop, search, detain any aircraft ship or vehicle if he believes that any article subject to the provision of this Act is

being conveyed. He may examine the article and take samples. He may also open and examine any receptacle or package which he believes contains such articles, or examine any books or documents he finds in the premises or area of search. He also has power to seize and detain any article he believes is in contravention of the Act. The power given to the authorized officers has rarely been used in connection with control of substandard drugs. This is because of lack of qualified manpower and laboratory facilities and also because of unwillingness of the Government to acknowledge the extent of sale of substandard drugs. As a result of these, authorized officers have done very little to exercise powers given to them under this section as regards sale and distribution of substandard drugs.

Apart from the power given to Authorized officers, under section 31, the Director of Medical Services, in any matter appearing to him to affect the general interest of the consumer, has power to order a public officer to procure for analysis samples of any drug and thereupon such officer shall have the same powers as an authorized officer. This section is complementary and supplements section 30. However, both of them have not been used in control of substandard drugs and therefore have done very little towards achieving their aims.

Under S. 32 (i) the municipal councils are given a duty to enforce the Act like any other authority under this Act, there is very little evidence to show that the Municipal councils have done anything to provide safeguards for the sale of drugs or to direct its officers to procure samples for analysis.

Under section 32 (2) in the event of Municipal councils failure to act, the Minister may by order empower an officer to execute and enforce those provision or procure the execution and enforcement thereof in relation to any article mentioned in the order and recover expenses

incurred under such order from the Municipal Council. Thus a mandamus would not issue to compel the Municipal councils to perform their duties since there is an effective remedy for the breach of the duty.[64] Under section 33, the Minister may direct any person who carries on bussiness that includes production, importation, use of any substance of any class to which the Act applies to furnish him as he may direct, such particulars as maybe so specified of composition and use of any such substances sold or for sale in the course of his business or used in preparation of drugs.

The intention of this section is to ensure proper standards of drugs, hence the direction made under the section may require data showing the evidence of the performance of a drug for the purpose for which it is intended that is known to the person carrying on the business in question, and pre-marketing test known to the person carrying on the business for the purpose of determining the cumulative effect on the health of a person consuming the substance in ordinary quantity.

Section 34 gives power to the courts to order the cancellation of a licence in addition to, or in lieu of any penalty, lawfully given to any person convicted of any offence under the Act. It has been held in United Daries Ltd v - Beckenham Corporation[65] that the phrase 'under the Act' meant under the statute as distinct from under the regulations made under the Act. Section 35 provides for prosecution where a public analyst has given certificate that an offence has been committed under the Act. Section 37 provides for a certificate of analysis purporting to be signed by a public analyst to be accepted as prima facie evidence of the facts therein provided the person against whom it is produced may require the presence of the public analyst for cross examination and the intention to use it as evidence has been made known to the accused

person together with a copy of the certificate. If the public analyst's certificate shows that an offence is likely to have been committed under this Act, an authorized officer may take proceedings under this Act before any magistrate having competent jurisdiction in the place where the drug was delivered or where the sample was taken. In this country very few prosecutions have been carried out under this Act as regards drugs.

Section 36 sets out the penalties for the offences under the Act. It sets out the penalties for offences under the Act for which no special penalty is provided. In case of a first offence, the section provides for a fine not exceeding two thousand shilling or imprisonment for a term not exceeding three months or both such fines and such imprisonment. In case of a subsequent offence, the section provides for a fine not exceeding four thousand shillings or imprisonment for a term not exceeding six months or both such fine and imprisonment. Although only a few cases have been prosecuted in respect of drugs and thus very few penalities have been imposed, in practice, the Act is contravened in many ways. This is supported by the number of substandard drugs sold in this country together with mispromotion and general deception of the consumers of these drugs.

Section 38 of the Act provides that its provision shall be in addition to and not in derogation of the provision of the public Health Act[66] and the Dangerous Drugs Act[67]. Both these acts have direct link with the Act, under the Public Health Act the Minister and the Director of Medical Services have general powers in relation to any matter concerning public health but these are too general and since under the Act, the same people have specific powers concerning drugs, it is better to use provision of the Act.

The Dangerous Drugs Act also has no direct bearing on the Act

since it deals with regulation of importation, exportation manufacture, sale and use of opium and other dangerous drugs such as coca leaves, indian hemp, cocain and morphine which are outside the scope of this paper.

The pharmacy and Poisons Act[68] seeks to make better provisions for the control of the profession of pharmacy and the trade in drugs and poison. This act has more bearing on the Act under discussion. It lists some of the publications in the schedules and defines them. British Pharmaceutical codex and British Veterinary codex are defined as

> "The editions for the time being current of the books published under those names by the phamaceutical society of Great Britain and any other addenda thereto".

The British Pharmacopoea is defined as

> "The edition for the time being of the books published under that name parsuant to section 54 of the medical Act 1858 of the United Kingdom".

International Pharmacopoeia is defined to mean

> "The edition for the time being current of the book published under that name by the world Health Organization and any addenda thereto".

The Pharmacy and Poison Act, under section 3, establishes a pharmacy and Poison Board. The members of the Board are appointed by the Minister. The Chairman is the Director of Medical Services - and its members include Chief Pharmacist, four other pharmacists, two medical practitioners and The Director of Veterinary Services or a veterinary surgeon appointed by him. Other conditions and terms of office are the same as those of the Public Health (Standards) Board and the purpose of this Board is to advise the Minister. Section 43 of the pharmacy and poisons Act gives the minister power, on recommendation of the Board, to prohibit or control the manufacture, sale, advertisement or possession of any secret, patent proprietory or homoeopathic medicine, preparation or

appliance. Under section 44, the minister may after consultation with the Board, make rules prohibiting, regulating or restricting the manufacture, sale or advertisement of drugs. He may also make rules respecting importation of drugs.

The pharmacy and poisons Act also prohibits advertisement that certain drugs, or advertisement that certain drugs will cure diseases listed in the schedule. Section 39 prohibits misleading advertisement of any drugs which in the opinion of the pharmacy and poison Board are considered to be extravagant and to bear little or no relation to the pharmacological properties and action and ingredients or components thereof.

Offences under these sections carry a sentence or fine not exceeding one thousand shillings in case of a first offence and in case of subsequent convictions a fine not exceeding two thousand shilling or imprisonment for a term not exceeding three months or both such fine and imprisonment. Prosecutions under these sections must be instituted with the consent of 'The Attoney General'.

Under section 45, a magistrate may issue a warrant to a police officer to enter and search any premises, vehicle or vessel, if he is satisfied by information on oath that there is reasonable ground for suspecting that an offence under the Act or any rules thereunder has been or is being or is about to be committed. An authorized officer may on the same grounds as above, if necessary, enter, search any premises or may detain, enter and search any vehicle and may seize any drugs articles and documents, without a warrant, if he has reasonable cause to believe these to be evidence of commission of any offence. Seizure of any drug or article under this section must be reported to the magistrate.

Section 50 provides that if a corporate body is convicted under this Act or any rules made thereunder, it may either cease ... to be a

seller, or be disqualified for a period of time. Incase of a conviction of a registered pharmacist, he shall be unfit to be registered. An appeal may be made by a corporate body to the Minister against a direction given under section 50, the decision of the Minister under such appeal is final.

Offences under this Act unless otherwise provided, carry a sentence of a fine not exceeding two thousand shillings or imporisonment for a term not exceeding three months or both such fine and imprisonment. In addition to any penalty imposed under this Act, the court has power to order the forfeiture of any article in respect of which such offence has been committed or which has been used for the commission of such offence.

Most of the prohibitions and punishments are reproduced in the Pharmacy and Poisons Act and reproduced in the Food Drug and Chemical Substances Act.

Analysis and conclusions of the Functions of the Act

Control of sale and distribution of drugs through the Act is to a large extent an executive function. The enforcement officers must therefore have knowledge of trade practices and commerce in a wide range of drugs. The work demands the art of public dealing which finds a solution for every difficulty.

> "The essence of administration is that it should be known to be powerful, efficient, helpful, incorruptable and alert". 69

Secondly it must be noted that as the administration of the Act involves enforcement of complete Laws with Legal Sanctions, there arises need for expertise in practice in dealing with infringement both in perfecting techniques of investigation and assembling evidence and launching and conducting procecutions. Sanctions are generally absolute

modified slightly by defences and if these were imposed or implemented, would make traders more careful in their sale, preparations as well as limit the sale of worthless or harmful drugs. Unfortunately the sanctions have been prescribed but hardly enforced vigorously through prosecutions.

Thirdly, functions conferred on the authorities under the Act have very wide areas of discretion. This makes policy making very important in this area so as to bring uniform enforcement which is vital in administration of the Act. Here again, very little policy has been made about the sale and distribution of substandard drugs. The tendency has been to warn drug firms

> "not to break contract terms by supplying substandard drugs to Government hospitals". 70

Beyond this very little has been done to stop the sale and distribution of substandard drugs.

Forthly, the enforcement of the Act needs highly specialised manpower to protect a large population, since the function is specialised and technical there is need for manpower whith expertise, experience specialization and knowledge in the field of drugs. In addition to these, the authorities must be active and alert. The public Health (Standards) Board has people with great expertise and experience but the Board does not seem to have been very active as regards their duty to advise the Minister to make regulations on sale of drugs especially as regards restricting the use of certain drugs and banning those that have been rejected in their countries of origin.

Fifthly, the functions demand knowledge without local influence in the officers, because quasi-criminal matters are involved. Enforcement of this Act must be completely uninfluenced by unfair personal consideration.

Finally, the function regularly calls for unity and promtude of action over the whole enforcement area in respect of for example, common fault in a particular brand of drugs or faults of a particular trader. This unity and proptitude of action has never been achieved in enforcement and administration of the Act. As a result, very many faults and contraventions of the Act have escaped punishment and thus multiplied.

The foregoing shows that the Act has failed to achieve its purpose which is fair trading in drugs, prevention of deceit and promotion of safety. The basic protection given to the consumer has not been enforced. Enforcement involves legal sanctions to secure complience with the law. The authorities have failed to enforce the Act and as a result traders have taken advantage of this to exploit the consumer and other traders by selling worthless and harmful drugs to the public.

CHAPTER TWO: PART ONE

An Analysis of the Function of Law

Introduction

The potential dangers of modern drugs have for a long time been recognized in the scientific field. However, much analysis has been done without reference to law. In the developed world for instance, it was not until the 1962 thelidomide disaster, that the potential dangers posed by modern drugs became a major issue in public policy.[1] This has led to the passing of more stringent legislations demanding substantial evidence of performance of drugs for the purpose for which they are designed. In the last two decades, although much analysis has been done as regards drugs without law playing any substantial role, there are good reasons why law should not be reticent. One of these reasons is that many forms of drugs in use are controlled by law in one way or another and thus the question of interpretation arises which requires legal analysis of provisions of the law in relation to drugs.

Apart from the problems which derive from a particular provision of the law relating to drugs, is the more important question of the legitimate function of law in respect of sale and distribution of drugs and the extent to which it can be utilized as a means of control

At the most general level, the function of law have, it would seem, is to protect the health of individuals and to prevent exploitation of such individuals by either drug manufacturers or

those in a position to endanger consumer's health. The law however has failed to achieve this goal. The following examination of a few branches of law will confirm this:-

Criminal Law

Criminal law aims at punishing those who violate the law; the extent to which it is deemed necessary to punish the offenders depends on the value judgement as to what constitutes harmful behaviour and on the acceptibility of using criminal law as a means of regulating that harmful behaviour. Protection of the public is the object of punishment in criminal law and it can either be achieved by deterring, isolationg or reforming the offenders and/or potential offenders. Imposition of such punishments however should take account of socio-economic conditions in which they are to operate. Certain circumstances may call for stringent rules and therefore harsh punishments. Legal controls may be resorted to in order to achieve the desired goals. In the case of drugs, stringent control is essential to ensure that the consumer receives drugs of high quality.

The extent to which criminal law has been used to protect drug consumers has not been satisfactory. Criminal law has proved least effective in dealing with offences created under the Food Drug and Chemical Substances Act [2]. This is mainly because drug offences are by their nature difficult to discover and prove, and because the masses of the people are ignorant of the presence of substandard drugs and thus cannot find out that drugs are substandard and report to the appropriate authorities. In addition to these, the need for

legal intervention is not well defined. A clear example of this contention can be seen in parliamentary debates on the safety of the injectible contraceptive Depo-provera, where in a motion to ban the drug use in Kenya because of its potential dangers, the Minister for Health defended it saying it was used in several other countries and therefore should be good enough for use in Kenya.[3] Thus in this instance there was no agreement as to what constitute danger to health. Another example of lack of consensus as to what constitutes danger to health or what is a safe and acceptable drug can be seen in the case of Bendictin, a drug sold here in Kenya for the relief of nausea during pregnancy.

It has been claimed by lawyers in a joint lawsuit against Richardson-Merrell Incorporation, that the manufacturers of this drug, that Bendictine is a new thelidomide. The manufacturers and and some medical scientists on the other hand urgue that there is no clear and sufficient evidence that the drug is harmful[4]. The point at issue here is whether lack of evidence that a drug is harmful should be taken to mean that it is not harmful. A consensus has not been reached as to

"how safe is safe"

The need for legal intervention is not clear thus making criminal law ineffective. Even assuming that there is a consensus as to what constitutes danger to health and exploitation, it is not clear how far criminal law should go in imposing controls, for instance whether or not control is necessary beyond the minimum needed to prevent danger to health and exploitation. The right position is that the law should aim both at totally banning certain undesierable drugs and restricting the use of others not known to be safe. However there has been very

few attempts at taking either of the above measures and thus offences have been committed contrary to the provisions of this Act but have often passed unnoticed or unchallenged. Criminal law is also rendered ineffective in controlling sale and distributions of drugs by the fact that some high level government officials have interests or dubious connections in drug trade[5] and therefore the course that would be taken by criminal law by such individuals or against them is considerably weakened. An example of this is the corruption trial in 1973 where senior health officials were implicated in the importation of certain drugs that were known to be dangerously substandard. The drugs were imported from an Asian country and yet they were packaged and marked as products of a major British Pharmaceutical Company, Burroughs Wellcome[6]. Conflict of interest on the part of health officials can weaken and even undermine the law, if that official is able to influence the enforcement of the law.

Another fact rendering criminal law ineffective is the absence of facilities for controlling quality. In the absence of modern quality control facilities many of the offences created by the Act cannot be discovered or proved and thus again, criminal law as regards drug sales has been considerably weakened and so does not offer the protection it was intended to offer.

The offences created under the Act as regards standards are not effective. This is because various standards for drugs have not been laid down as was contemplated by the Act and the pharmaceuticals in effect have to be 'taken for their words'

The same case applies to imported drugs. Since there are no quality control facilities, imported drugs are taken to be what the literature contained in their labels says they are, only the literature is compared with the relevant requirement in the pharmaceutical but the drug itself is not checked thus there is no way of knowing whether there is an offence.

The Law of Torts

The law of torts is concerned with rights of injured person to compensation. Many personal injury actions are based on the tort of negligence. Negligence has been defined as a breach of legal duty to take care which results in damages.[7] This branch of law can be used to protect those who suffer a certain amount of injury as a result of using substandard drugs, thus holding companies or their subsidiaries liable for such injuries. Liability in tort will depend on whether there is damage, negligence and the right to sue. In the case of damages, the suite must be brought by one who has suffered, and in negligence, the requirement is that there must be duty of care. The starting point of this concept is still found in the classic exposition of Donoghue V-Stevenson,[8] wherein Lord Atkins formulated the neighbour principle that :

> you must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour... (that is)... persons who are so closely and directly affected by my act that I ought to reasonably have them in contempletion as being so affected when I am directing my mind to the acts or omissions which are called in question.."[9]

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> "the manufacturer of an article food, medicine or the like, sold by him to a distributor in circumstances which prevent the distributor or ultimate purchaser or consumer from discovering by inspection any defect, is under legal duty to the ultimate purchaser or consumer to take reasonable care that the article is far from defect likely to cause injury to health." 11

Following Donoghue V-Stevenson, courts have tended towards inferring negligence if satisfied that a defect arising from error or carelessness in the process of manufacture caused injury[12]. In the case of most companies that promote and market drugs in this country, negligence or carelessness can be inferred easily since the companies are aware that certain drugs they sell here are defective.

A problem arises where it is not clear whether the defect arose from the designer of the drug or whether it arose while the manufacturer was making use of a third party's formular. In such a case, the right position would be to provide a remedy to the consumer injured without having to prove negligence, provided that it can be shown that the defect arose before the product left the manufacturer.

In this country however, not many claims have been brought against manufacturers of drugs. This is not to say that substandard drugs have not caused any harm, but rather it seems to imply that since most people do not know the dangers of substandard drugs they may not even realize that the injury they have sustained is due to the use of a substandard drug.

Another problem which may arise regarding claim for compensation

is in connection with the fact that most drugs in use in this country are imported. Certain drugs are imported with the government's knowledge that they are potentially harmful. The issue that arises here is whether a person injured by such drugs can successfully sue the company or its subsidiary manufacturing these drugs or whether such a company is able to disclaim liablity by saying that the government knew about the dangers of such drugs and went on to purchase them, or licensed their importation. Such a question is debatable. It would seem however that considering the facts that make the government purchase such drugs, for instance weighing of the benefits against the risks, the manufacturers or sellers of such substandard drugs should still be liable since they promote these drugs knowing, and sometimes concealing, their potential dangers. A partial answer to this question can also be found in commercial law, as it also determines who may be liable.

I iv Sale of Goods

The case of sale of drugs is somehow peculiar in that a seller may not necessarily be liable for sale of a defective drug. Thus it would seem that a chemist who has sold a defective drug may not be held liable to an injured person since his function, a part from any skill required in making up prescriptions, is essentially mechanical. Secondly, he is not under a duty to carry out tests on the drugs which he dispenses and this rules out the question of negligence. It may be argued that even in the absence of negligence as an issue, there may be a basis for a claim in contract. Such a claim may be difficult to sustain if a drug is

supplied on prescription. There is no Kenyan decision on this point, however, the House of Lords, in the case of Pfizer V-Ministry of Health[13] has held that the supply of drugs to a member of public under the National Service Scheme, whether by a hospital or pharmacist, was not a sale even though a prescription charge was paid. Lord Reid said that:

> "... in my opinion there is no sale in this case. Sale is a consensual contract requiring agreement, express or implied. In the present case there appears to me to be no need for agreement. The patient has a statutory right to demand the drug on payment of two shillings. the hospital has obligation to supply it on such payment, and if the prescription is presented to a chemist he appears to be bound by his contract with appropriate authority to supply the drug on receipt of such payment." 14

It would seem from this that a patient would have no remedy even if a dangerous drug was sold to him and thus strict liability on seller of defective goods which causes injury, imposed by the sale of goods Act would seem to offer no protection to a person who is supplied with defective drugs in the absence of negligence, since the transaction is not a sale. Atiyah has however urged that:

> " ... it would be a mistake to conclude that patients would necessarily be left remediless in such circumstances if defective drugs were supplied, even in the absence of negligence". 15

He bases his arguement on the House of Lord's approach in the case of Young and Matten Ltd V-McManus Childs Ltd.[16], where though the

the contract was for supply of labour and materials and thus not sale of goods, the court was prepared to hold that the supplier owed the same obligation as to the implied quality of his materials as if the transaction had been covered by the Act. However, this case is distinguishable because it envisages the existance of a contract while the fact that there is a statutory entitlement as regards prescription may rule out any sale or contract as regards supplier of drugs and the buyer.

As regards drugs sold 'over the counter' without prescription, if the analogy of sale of goods is accepted there would be contract for which sale of Goods Act[17] would apply. Sale of Goods Act[18] requires that the seller's goods should be of merchantable quality. It can be argued that a drug with disastrous secondary consequences is not of merchantable quality even if it performs the act for which it was originally intended. If however, such a drug is deemed merchantable, which is unlikely, another possible requirement of the sale of Goods Act is that goods must be reasonably fit for any purpose made known by the buyer [19]. Thus if a buyer makes known his purpose for a drug and the drug produces harmful (serious) secondary consequences, it seems that it cannot be argued that the drug is fit for the purpose made known to the buyer. In deciding such cases, the courts should weigh unsuitability for human use against gravity of consequences for the user.

The foregoing account of contract and negligence principles shows that the gravity of risk may in certain circumstances be the

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overriding criterion of liability. Thus a place such as Kenya where drug sellers sometimes sell drugs knowing their dangerous secondary consequences, liability should be inferred easily and appropriate action taken

Apart from manufacturers and pharmacists selling drugs, there is the doctor, who is in many cases most 'immediately instrumental' in choice of a particular drug which is taken, To an extent it can be said that it is on the doctor's judgement that the patient, the drug consumer relies. It is debatable whether a doctor can be held liable if he knowingly prescribes a substandard drug and that drug causes harm to the patient. It can be argued that negligence can be inferred in such a case; but while this is true in case of carelessness in diagnosis or treatment, it is arguable that a doctor, like a chemist, is not under duty to test the drugs he prescribes and thus cannot be held liable if a drug he prescribes causes harm. It would seem however, that if a doctor is aware of the dangers posed by a certain drug, as is the case most of the times, and he goes on to prescribe it, then he should be held liable. A typical example of such a case is where doctors are encouraged to buy , prescribe or recommend the use of drugs, whose dangers they know, and in so doing are given discounts and "kickbacks" by the manufacturers. In such cases there is carelessness for which liability should be inferred.

Another issue which arises regarding liability is the question of whether there is a case for imposing liability on the government authority that licences or purchases drugs, knowing or not that certain drugs are substandard. This question has not arisen in Kenya nor has the parliament debated on it. If they did

however, it would seem that the same stand as on thalidomide would be taken namely, that compensation is not for the government to provide and that "there is no legal liability on the government... compensation is a matter for the company[20]". Again in Kenya since there is no scrutiny system for controlling quality of drugs especially those imported, it would seem that the government authority would not be held liable if the drugs they authorise to be imported causes harm. The question may be extended as to whether an authority can be held liable if they authorise importation or marketing of drugs knowing that such drugs are substandard, and harm is actually caused by the drugs. In certain circumstances it would seem that the authority would not be held liable for instance, if the government through the Minister for Health has approved that drug. Such is the case of Depo-provera which is known to be substandard and yet the minister for health has approved of its importation and use. On the other hand, authorities may be held liable if there is corruption involved in the importation of drugs.

Much of the drugs used in this country are imported from various countries, the major ones being West Germany, Britain, India, Switzerland and France. Thus the past and certainly future development of drug control in this country are closely bound up with international law. The Food Drug and Chemical substances Act, for instance, apart from including other nations' pharmacopoeias like those of Britain, France and United States

also includes the International Pharmacepoeia and requres that standards of drugs meet the requirement laid down in these pharmacopoeias. Secondly, Kenya being a member of World Health Organization and other International Bodies concerned with Health and population like International Planned Parenthood Federation (IPPF) and United Nations Fund for Population Activity (UNFPA), it is necessary to mention International Law and its relevance in this study.

International Law

> "At international level, concern with the quality of drugs moving into international commerce initially emerged in the 1950's 21".

In 1960's the main concern at international level because the dangers posed by drugs of low quality moving into international commerce, especially those destined for the third world countries. The World Health Assembly of WHO has thus made many resolutions to try and ensure good quality of drugs moving in international commerce but the export of substandard drugs to third world countries has continued to increase.

A few multinational companies based in United States, United Kingdom, West Germany, Switzerland and Japan produce most of the World's drugs. In these countries especially in the United States and United Kingdom, consumer politicization has driven the multinational companies to find foreign market for drugs that are either banned or restricted in these countries. It is condended that

> "Not only are the largest and most prestigeous names in the pharmaceutical industry engaged in the 'drug dumping' but international development agencies like the UN Fund for Population Activity, the International Planned Parenthood Federation and the US Agency for International Development have been distributing the harmful products 22".

An example of this is the distribution of an injectible contraceptive Depo-provera. This drug is banned in the United States but is used by both the Fund for Population Activity and the Planned Parenthood Federation, and also used widely in US sponsored programs. Such international bodies do not only distribute this drug but also advocate its use in developing countries claiming that its benefits for these countries outweigh its risks to the individual consumers. In fact the World Health Organization is currently working out its potentials for wide distribution particularly to developing countries as a family planning aid[23].

The third world states have requested the World Health Organization to take an action to ensure quality of drugs moving into international commerce, and although many resolutions have been passed, exportation of substandard drugs to less developed countries has continued to increase. This is because WHO, like other international organizations, has weakness in that it depends on the member states increasing their payment of funds before it takes any new action and this is not usually easy. Thus WHO though aimed at guarding health internationally, seems to operate different standards, one for developing countries and the other for developed countries.

CHATER TWO: PART TWO

Examination of Necessity for Legal Control

Introduction

The era in which we are is one in which many different types of drugs are manufactured and used increasingly. Whereas there has been a little politicization as regards dangers posed by substandard drugs, law has been raticent in the debate. Yet in such a situation, it is law that should intervene to protect the consumer. To a large extent the need for legal intervention arises out of practices of pharmaceutical companies which was raised in World Health Assembly in 1975 namely that:-

> "Drugs not authorized for sale in the country of origin - or withdrawn from the market for reasons of safety or lack of efficacy - are sometimes exported and marketed in developing countries; other drugs are promoted and advertised in those countries for indication that are not approved by regulatory agencies of the countries of origin. Products not meeting the quality requirements of the exporting country, including products beyond their expiry date, may be exported to developing countries that are not in a position to carry out quality control measures. These practices ... are unethical and detrimental to health 24".

It was further claimed by the Director of World Health Organization that:-

> "developing countries were wasing scarse resources in purchasing expensive drugs that were at best only marginally useful and at worst totally irrelevant to their health needs 25".

In 1977, there were over 8,000 drugs in Kenya's market, this is very high compared to 1,200 drugs registered in Yugoslavia and 1,500 drugs registered in Sweden.

It is in the light of the above claims that stringent legal control is needed to protect the public from harmful drugs and to protect them from exploitation resulting from selling drugs that do not meet the health needs.

Control of Importation and Marketing of Drugs

Multinational companies have been accused of marketing hazardous drugs in the developing countries. Drugs which are banned or available on prescription only in the United States or Europe are today freely available over the counter in many African and Asian countries. Often the drugs have been banned or restricted in use because of their dangerous secondary consequences. Such drugs may come into the country as "hospital aids", but often they are exported by multinational companies who fear heavy losses of the ban of the drugs in the developed world. The amount of time and money spent in the development of new drugs that do not meet Western standards of drug safety may influence "drug dumping". This together with the fact that the government sometimes buy drugs fully aware of their being banned in their countries of origin may encourage pharmaceutical companies to continue manufacturing and exporting drugs which should otherwise be phased out because of their undesirability. Thus there is need for stringent laws prohibiting purchase of any drugs if there is knowledge that such a drug has been banned in its country of origin.

A list has been complied of fourty four drugs which

are still prescribed in developing countries, but which are prohibited in western countries. This list include drugs like melsedin, anakoline, lomitie, tetracycline, and lymramine. It has become dangerously easy to buy antibiotics from street peddlers. The result of this is a wide spread bacterial resistance to the more common products, thus 'cracking' a market for more advance and expensive products. Since the harmful effects of drugs are often gradual and difficult to link back to their source, there is an urgent need for legal intervention so as to control the importation of these dangerous drugs and to stop them from getting into wrong hands.

Importation of low quality drugs is another area in which there is need for urgent legal intervention. Drug companies have been accused of operating in double standards. For instance British companies have claimed that they are being forced to lower their standards in order to compete rival drug companies 26 This competition resulting in production of low quality drugs could have serious consequences on the health of people who use these drugs. Coupled with this, is the problem of recommendation of excess dosages by companies. For instance, Wellcome, a British Drug Company, has been accused of aggresively marketing the drug Migril to releve migraine and the dosage they recommend is more than double the dose suggested for the same drug in the USA[27]. Overdosage encourages increased consumption which in turn induces more headaches. This is also the case with Glaxo's guanimycin used for the treatment of severe digestive

sickness. It is tragic that only particular 'dumps' come to light, yet they go on all the time in the course of international trade. This kind of operation is often protected by both the exporting government, which does not require the drugs for export to conform with laid down standards, and importing ones influenced by production and marketing interests of the multinational drug manufactures based in the developed countries.

Sales Methods

There is a great need for legal intervention in the area of promotion and advertisement of drugs. The 'social audit' a London based independent research organization, has found that drug multinationals use unscruplous sales methods in the promotion and sale of their drugs. This same fact has been recognized by the international organizations such as WHO, namely that drug companies promote and advertise drugs for indications that are not approved by regulatory agencies in their countries of origin[28] and that patent drugs are promoted by very aggressive sales campaigns that overstate their merits while failing to indicate the risks involved in their use. In many instances, drugs that should be restricted in use or banned totally are sold liberally without mentioning the possible fatal side effects.

A lot of promotion is done by sending free drug samples to doctors; in addition to this, the doctors may be given discounts and 'kickback' in drugs, which they thus sell. Drugs

are also very heavily advertised in developing countries, for example in 1973 ,nearly a quarter of Swahili radio advertising in this country was devoted to the advertisement of patent medicices.[29] This trend has continued steadily. Drug promotional methods are to a large extent misleading and do not comply with the requirements under the Food Drug and Chemical Substances Act. Also methods to curb mispromotion and recommendation of excessive dosages in the"normal cause of business" have not been devised. It is possible for doctors to be influenced by sales representatives to prescribe their brand of drugs. This can be very dangerous since doctors may be influenced to prescribe substandard drugs. There is however no law to deal with this situation and thus no measures have been taken against this practice. The total number of drug representatives in Kenya is over two hundred and fifty distributed amongst the two thousand practicing doctors and dentists. This means that there is one drug sales representative to less than ten doctors. Thus through these excessive sales promotions there are reasons to believe that practices such as 'kick-backs', pressure and possibly bribery are relatively prevalent among medical practitioners to prescribe certain brand of drugs. No measures have been taken to ensure that drug representatives do not corrupt doctors to prescribe certain types of drugs especially substandard drugs. This is mainly because the two people, the doctor and the drug seller, involved in this practice gain and therefore cannot complain, yet it is the third party, the consumer, who suffers if the drugs are defective.

Some of the methods used by multinational companies are ones that could never be used in their home markets. Business interests should not be allowed or encouraged to spend large sums of money telling 'ignorant' people to buy products which may by default or otherwise do them incurable harm. The multinational companies have failed to act responsibly by encouraging patents of 'wants' that are irrelevant to real health needs of the country. Since most people are far from being well informed about health, drug companies do a great deal of advertisement that exploit the people's consciousness. It is for the law to step in and protect these people.

Price Control and Bried Conclusion

The Companies that produce drugs have often raised the problems of expenses involved in research as the reason for the drugs being expensive. However, there is also the question of industries performance in its marketing of existing drugs. In marketing existing drugs, drug companies deploy large resources in order to reach individual practitioners that there are eight doctors to one drug representative in Kenya. The methods used by these representatives induce and influence doctors to prescribe their drugs. This in turn means that the drugs must cost more than they cost in Western countries where there is only one drug representative to about twenty to thirty doctors[30]. Secondly, this high spending has the result of doctors and hospitals purchasing drugs that are more expensive and yet less essential.

The major factor behind over charging of drugs is the idea of brand names. The cost of drugs varies widely depending on whether they have brand names or whether they are simply sold under generic names. Since brand named drugs cost a lot of money to promote, it follows that they will cost more. Brand named drugs can sometimes cost as much as ten times its generic equivalent[31], and still sell better because

> "the appeal for brand names is so strong that big drug producers can charge whatever prices the market will bear[32]"

The prices charged as regards drugs in the market have little relation to the cost of product[33] or prices that are charged by smaller competitors. This problem is not present only with imported drugs. The production of drugs in this country is controlled largely by multinational corporations through licencing arrangements or local subsidiaries and thus they continue the practise of their holding companies.

Overpricing of drugs is not only practised at international level, but may also be practised internally. For instance, the Price Control Act[34] has a loophole in that it allows pharmaceutical dealers to increase their prices without written authority. This loophole has been used extensively.

The foregoing are some of the malpractices of drug manufacturing companies that call for urgent legal control. They show that there is a need to devise a method for controlling prices at the time of importation and at the time of marketing. The

effect of uncontrolled "drug dumping" and uncontrolled promotion may be very detrimental to health. Legal Control of malpractices of the pharmaceutical companies is also needed to save the scarse resources that are being spent on drugs.

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CHAPTER THREE : PART ONE

IDENTIFICATION AND EXAMINATION OF PROBLEMS RELATING TO LEGAL CONTROL

Introduction

The problems relating to legal control can be seen as arising from the fact that Kenya is a developing country. She still has the inevitable task of meeting the health needs of her growing population. This creates a large potential market for modern pharmaceutical drugs. Since Kenya does not produce many of the drugs, she has to rely heavily on imported drugs. In so doing another problem is encountered, namely that there is a very small amount of foreign exchange available for spending on the purchase of the drugs and hence there is pressure to get the most advantageous prices available. Once the drugs have been imported, the task of testing them brings yet another problem namely lack of domestic capacity to monitor the quality of these drugs. We shall examine briefly some aspects of each of these problems.

LACK OF FUNDS

To a large extent many problems encountered in legal control of sale and distribution of drugs emanate directly or indirectly from the fact that the financial resources of the countries wherein they are used, are scarse. Since Kenya has to meet her health problems on the small available foreign exchange, she theoretically has to buy pharmaceutical drugs at the lowest price available in the market. This increases the probability of importing drugs of unacceptable quality. In practice however, multinational companies have

been known to overcharge developing countries.[1] Indeed certain British companies have admitted lowering drug standards sold to the developing countries so as to compete with their rival multinational companies.[2] The probability of importing drugs of unacceptable quality is enhanced by the fact that domestic quality regulations of the major drug exporting countries, from which Kenya imports her drugs do not apply to the drugs produced for export.

Similar problem is also encountered in respect of locally manufactured drugs. Once drugs come into market, it is easy to copy such drugs and produce cheaper imitations whose qualities cannot be guaranteed. Generic equalence sometimes differ from therapeutic equivalance mainly because of manufacturing methods. Failure to recognise this distinction has in the past resulted in the Ministry of Health purchasing drugs purpoting to be cheaper but which in fact do not serve the intended purpose. In the long run, this is more expensive than purchasing the correct drug initially. Thus the problem of lack of funds in itself embodies two inherent problems. On the one hand, there is need to take the most advantageous terms while purchasing drugs, and on the other hand low prices may mean that drugs sought to be purchased are of low quality.

LACK OF QUALITY CONTROL FACILITIES

Modern pharmaceutical drugs, by their nature and the nature of their production system, have a special characteristic deriving from their intended use in and by man. This is the requirement that drugs must satisfy certain standards with respect to their proven efficacy and therapeutic quality. There is also need for substantial

evidence for the performance of a drug in the purpose for which it is intended. These can be achieved through pre-marketing tests to eliminate those drugs whose secondary effects out weight their therapeutic benefits to the consumer. It is in this area that developing countries are rendered almost helpless and have to depend on the good faith of representations of the drug manufacturing countries.

Owing to lack of quality control facilities and qualified personnel, the law embodied in the Food Drug and Chemical Substances Act[3] and the Pharmacy and Poisons Act[4] cannot be effected. Tricks used by drug representatives to sell substandard drugs have not been detected. Doctors and Patients have had to rely on literature containing information on the drug provided by the manufacturers. This information is relied on despite the accusations that have been made against drug manufacturers, that they sell drugs without publicising possible fatal side effects and giving scanty information as to the secondary consequences of drugs sold in third world countries[5]. Standards of existing drugs are not monitored. Drug offences are not easily discovered or proved. In other instances differences in opinion as to quality of drugs arise because of lack of data showing both benefits and potential dangers of drugs. It thus becomes evident that in the absence of quality control facilities, law alone cannot be effective in controlling sale and idistribution of drugs.

LACK OF INTERNATIONAL CO-OPERATION

Problems here include some relatively straight forward issues like lack of common international system of drugs nomenclature or lack of adequate exchange of information among the different countries. Common

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problems are more complicated by the fact that there is no concensus in procedures that should be used in pre-market testing and evaluation of new drugs.

While it is recognized that in order to ensure quality, safety and efficacy of drugs, they should be thoroughly tested prior to their introduction in the market, national specifications as to tests differ enormously. There is no agreed checklist of the factors that should be considered in the testing of the drugs in order to ensure their standards. As a result of the different registration and evaluation requirements of major drug manufacturing countries, during importing countries are at a dilema. They cannot tell which evaluation is better than the other. Attempt by W.H.O to recommend standard methods for clinical and pharmacological evaluations of pharmaceutical preparations has neither come up with an approved list of tests nor indicated an acceptable range of results. Thus no solution has been found for this problem.

The problem of lack of funds is not only experienced at national level, but is also at international level. As a result of funds, WHO has not been able to respond positively to the request of third world countries for assistance in establishing internationally supported regional testing facilities. Such facilities would make up for the deficiency of local quality control efforts.

Large multinational companies have not supported internationally aided quality control facilities. These companies deny the existance of any significant problem with the drugs they produce. They contend that serious problems in respect of quality of drugs in international commerce have arisen only in connection with

the companies export funds by charging their subsidiaries inflated prices for products supplied by parent companies.[8] The subsidiaries in turn sell these drugs to the consumers at more inflated prices. In such cases national regulations on prices cannot really be effective, in the absence of international support of the national price controls.

Drug problem being mainly of international nature, national control is rendered ineffective in the absence of additional international co-operation. There is real need for aid and collaboration at international level. Assistance is not only needed from international organizations but also from multinational companies themselves which at the moment are unwilling to commit 'drug suicide'.

CHAPTER THREE : PART TWO

EVALUATION OF THE ADEQUACY OF THE EXISTING TECHNIQUES AS A MEANS OF LEGAL CONTROL

Introduction

Much of what has been said indicates that the techniques employed in control of sale and and distribution of drugs are not adequate. Control of drugs can be classified into two general groups namely national control and international control. While national control is implimented through legislation, and subsidiary legislation, international control is carried on mainly by resolutions and recommendations by international organs such as the W.H.O.

The Food Drug and Chemicals Substances Act: Successes and Failures

This Act is the major means for controlling sale and distribution of drugs. As has been seen it deals with foreseable instances of adulteration, standards of drugs, passing off, and or misleading labels or advertisements.

The major weaknesses of this Act is that whereas it contains broad and simple prohibitions, many of the cases it seeks to prohibit against never come to light because they are usually not detected due to domestic incapacity to monitor drug qualities. Also for this reason drugs are not tested physically by an independent body, but instead a lot of reliance is placed on manufacturers information which the Act seeks to control. This leaves most prohibitory provisions lying in disuse and as dead letters of the law. In the circumstances, the authorities are left to do only that which is in the domestic

capability. This includes checking the literature containing the information against the relevant standards by various pharmacopaeids to ascertain their standards, seizing and detaining drugs that have gone beyond their expiry dates and carrying on limited analysis.

In many instances regulations required to supplement the Act have not been made and where they have been made, they have not been implemented. For instance, the Act requires that drugs comply with the laid down standards.[9] These standards have not been prescribed as required by the Act and thus there is no reference point for standards laid down in the country. Other standards required to be complied with are outside the country and in the absence of physical testing it cannot be known certainly whether these standards have been complied with.

The offences created under the Act need constant checking and reviewing because of the development of new circumstances that were not foreseen by the Act at the time of enactment. For instance drug promotional methods have developed to such an extent that legal intervention is now necessary. There is no section in the Act aimed at controlling mispromotion as it is today, neither have methods been devised for use against unscruplous methods used by companies to sell their drugs. Again, the Act does not provide any legal tool with which to beat the drug companies from influencing doctors to promote and sell their brand of drugs, these being substandard or otherwise, or to control the sale to doctors through 'kickback' methods and to limit excessive sales promotion where doctors are pressed and possibly bribed by numerous drug representatives. Although

such practices are unethical there are no laws to curb them. As a result of these the consumer is left without protection from those who are more interested in selling drugs than in his welfare.

While other countries are making their drug legislation stringent, the Act allows drugs whose standards have not been set to be sold and distributed provided that they conform to the standards professed.[10] This is a loophole in this section that can easily attract drug testing on consumers.

Other provisions relating to nature, substance and quality demanded[11] does not offer much protection in a society where masses of the people are ignorant as to the nature, quality and substance of drugs, also in the presence of free enterprise and patent names, reference of drugs by their patent names as is often the case will take consumer out of the protection offered by the section.

Thus although the Act itself may seem fairly comprehensive, there are loopholes in it that can easily be exploited by the drug manufacturers. Viewed with the background of the society in which the Act is meant to operate in, namely where the masses are ignorant of the law and where economic factors do not allow for rigid control of drugs, the Act does not offer much protection to the consumer. Under the Act[12], the Minister for Health has wide powers to make regulations necessary for effectuating the purposes of the Act. Such regulations are to be made after consultation with the Public Health (standards) Board. The section gives the Minister very wide powers for making regulations. The ultimate decision on any advise by the Board lies on the Minister. He is not bound to follow the

recommendations of the Board. The effect of this section is that a minister's decision is final even if it is erroneous. Indeed this has been the case where the Minister has been unwilling to acknowledge the extent of harmfulness of certain drugs such as Depo-Provera. He has infact defended it despite the protest by members of the board and certain Members of Parliament. Thus although wide powers are given to the Minister to make regulations for the carrying on of the purposes of the Act, this wide discretionary power can actually operate and does operate negatively.

Other Acts of Parliament

Apart from the Food Drugs and Chemical Substances Act, other legislation whose provisions seek to control sale and distribution of drugs are the Pharmacy and Poisons Act[13], The Dangerous Drugs Act[14], and the Public Health Act.[15]

The Pharmacy and Poisons Act regulates the profession of pharmacy and trade in drugs and poisons. It simly reproduces certain prohibitions contained in the Food Drugs and Chemical Substances Act and powers given to authorized officers are the same under both Acts, namely domestic incapability to monitor the quality of drugs. Thus although this Act may seem to complement the Food Drug and Chemical Substances Act, its control of sale and distribution of drugs is very limited.

The Dangerous Drugs Act controls trade and use of narcotic drugs. It does not deal directly with control of pharmaceutical drugs. The public Health Act is also complimentary to the Food Drug and Chemical Substances Act in that it gives the Minister for Health wide powers to make regulations in any matter concerning public health.

These powers are too general and in view of the fact that special powers are already given to the Minister under the Food Drug and Chemical Substances Act, this Act does not add any power to the Minister to do anything that cannot be done under the Food Drug and Chemical Substances Act.

At the end of 1980, it was announced by the Director of Medical Services that a new legislation would be passed requiring registration of all new drugs both imported and locally manufactured. The purpose of the proposed legislation is to reduce unnecessary oversupply of various types of drugs in the country. However, the legislation has not been enacted.

Liability and Compensation

Liability and compensation either under the law of torts or under the law of contract does not relate directly to control except in so far as they warn the drug manufacturers to avoid acts or omissions that can cause injury to consumers. The major effect of liability and compensation comes after the occurance of certain consequences like injury.

There are long procedures involved in cases of claims for injuries and compensation. A case may take years before it is heard. This intricacy in the procedure is advantageous to the party who can best afford time and money involved. In Kenya where a large percentage of the population are unaware of their rights and usually cannot afford cost of litigation, most people cannot afford to fight large companies with money and who can afford the best lawyers through legislation.

Thus the whole machinery, though meant to protect the consumer has a built in advantage for the drug manufacturers because they can afford to hire the best legal staff as they financial interest to protect. The majority of the people are ignorant of their rights and even if they were not, they will not usually litigate as the procedure is expensive and slow. This is in addition to the fact that there is risk of ultimately losing the case. Thus the machinery of compensation and liability of manufacturers does not really operate in favour of those it purpotedly seeks to protect.

International Control

Since 1950s when W.H.O started to concern itself wih the quality of drugs moving into international commerce, it has made several efforts. These efforts on inter-alia include requiring good manufacturing practice, providing for drug information on common problems and setting up international pharmacopoeia as a reference source of acceptable standards.

International control however has failed to establish regional quality control facilities for monitoring drug imports within the countries that import the drugs. In this area W.H.O has been incapacitated by financial consideration. W.H.O has to rely on member countries to donate funds and this is not always easily accepted. This is a persistent weakness of most international organizations as a means of control. Another inherent weakness posed by international control is that only recommendations are made while enforcement of such recommendations are left totally to the manufacturing countries. Thus developing countries are left in no better position than to rely on the good faith representations of the drug exporting countries.

Where a third world country buys drugs or accepts it as aid, fully aware that it is banned in the country of origin, the international mechanism for control can do nothing. Again as with the Government international control has been unwilling to acknowledge the harmfulness of certain drugs, it has maintained that instances of drug dumping are very few and that third world countries do not have to ban drugs simply because they are banned in their country of origin.

The developing countries lack specific data to show as examples of importation of drugs of inadequate qualities and they lack sufficient monitoring capability to develop such data so as to convince W.H.O of importation of drugs of unacceptable quality.

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CHAPTER IV

CONCLUSION AND RECOMMENDATIONS

Conclusion

The present law has not developed sufficiently well to solve the problem of control of pharmaceutical drugs as they are understood today. To a large extent the failure of the law can be attributed to lack of domestic capacity to monitor safety, quality and efficacy of the drugs before their purchase, sale and distribution. Even in foreseable instances however, the law has not been very active. The wide powers available to control composition, labelling, use, sale and advertising of drugs have been used only to the extent that a few subsidiary legislations have been made. Implementation and enforcement of these subsidiary legislations have been very limited. Standards of various drugs have not been laid down as required by the law and no national statistics have been compiled.

Other measures like torts and contracts have been of very limited use since the society in which they purport to operate in, is one in which the masses of the people are ignorant of their rights and cannot afford costly suits. Other measures sought to be relied on are only of limited help since they are in most cases advisory.

The developed countries have made stringent their laws regarding manufacture, importation, distribution and testing of drugs. This in turn has driven drug companies to use third world countries with weak drug legislations to test and distribute those drugs that do not meet requirements of the country of origin. Thus the third world's role has continually become that of 'test beds' and 'dumping grounds' of drugs

by multinational companies driven out of the marketing structure in the western countries. Large measures are deployed by these multinational drug companies to reach individual practitioners and consumers. This effort is very controversial especially in a country where the government health infra-structure is still being developed because of confusion and the lack of proper flow of information. There are many forms of malpractices done by multinational companies which, although they may conform to the law of countries of origin, are inethical and detrimental to health of the individual drug consumer. Many of these malpractices can be discouraged by enactment and enforcement of stringent drug laws. The absence of any stringent law and instead the buying or accepting as aid, drugs that are banned in the country of origin may encourage the manufacture and exportation of drugs that would otherwise be phased out.

Existing activities in pharmaceutical field have not been fully responsive to the expressed problems of developing countries. Developing countries have continued to concern themselves with quality of imported drugs yet the response of WHO and its member states have been slow, generally half-hearted measures taken and sometimes even tainted with bias. Regional quality control facilities have not been developed and efforts at creating regional training facilities for national quality control personnel has never taken root. Other efforts like the international pharmaceutical, Principles of Good Manufacturing Practice and Certification program have not been pushed forward with vigour. WHO has also paid inadequate attention to the necessity of developing standards especially for transit and storage drugs and this may be a source of substandard drugs. The assistance of WHO has not led to the growth of national capacity to monitor the use of drugs as regards quality or overall strategy of better health case. In addition to this, the government has not viewed pharmaceutical drugs and related problems as sufficiently

important to justify the investment of the scarce resources in the establishment of a monitoring facilities. It is therefore not likely that international action by itself will ever be able to ensure that quality of drugs moving into international commerce, nor is it likely that international action can be taken effecting the composition of drug imports. International action would only appear to be appropriate in assisting to develop national competencies in both areas.

Recommendations

The drug problem is an international problem and needs some form of international or regional collaboration in order to improve efficiency of national efforts. Each country however must find solutions suitable to her own peculiar drug problems circumstances. In Kenya the first solution should take the form of law reform.

The present law imposes penalty for adulteration of drugs, a few statutes control advertising, labellingaand sale of drugs[2] or prohibit the advertisement to the public of drugs which purport to help in treatment of serious diseases like cancer or venereal diseases[3] or control the exercise over drugs of dependance like opium and cocain[4]. However, there is no law ensuring the safety of pharmaceutical drugs. Thus it is possible for dangerous or inadequately tested drugs to be brought into the Kenyan market without registration and without an independent body being satisfied as to its safety. For this reason the first recommendation is to pass a law aimed at controlling the safety of drugs marketed in the country.

The new law should require manufacturers, especially those submitting new drugs for approval, to provide suitable reports on relevant experiments on animals (and human volunteers if any) which should show the mode of action, toxity, efficacy and physio-chemical properties. The experiments should include testing of drugs on the foetus of appropriate pregnant

animals to avoid possible bad effects on unborn children.

The same law should set up a board composed of people with relevant knowledge and qualifications in the pharmaceutical field to act as independent body assessing the data submitted by the drug manufactures and should have the powers to approve or disapprove drugs after the assessment of the data. Such a system would be desirable because it does not transfer the responsibility of drug testing to the board; instead the manufacturers continue to be responsible for laboratory testing, with the board only reviewing the data and the results of clinical trials. The board should also collect reports from general practitioners as to the possible adverse reactions of the drugs in their clinical use.

A commission of experts should also be set up who should from time to time report on use of drugs, report on drugs that should be for general sale and those whose sale should be restricted. The commission should also report and advise on importation, marketing and distribution of drugs.

One weakness of the method of reviewing data submitted by the manufacturers is that most drugs used in this country are imported and therefore there is still dependance on manufacturing country's good faith in providing the correct information. Thus although the responsibility of testing of drugs should basically remain with the manufacturer, the commission should have the power to arrange for independent testing whenever it is doubtful of the information submitted by the manufacturers. Therefore there is need to set up drug control laboratory adequately equipped and staffed to make full analysis of any drug.

The law should make it a mandatory pre-condition to obtain a licence to market new drugs. Technically the granting of such a licence should be by the Minister for Health, but incase of ministerial refusal to grant such a licence an appeal should lie with the commission who would

review the decision. A situation where the ultimate decision lies with one person would be avoided. The rules for granting a licence especially as regards new drugs should be stringent enough so as to exclude all drugs with disastrous side effects. However, where benefits may outweigh the losses, safety rule should be relaxed only as far as is absolutely necessary. For instance in a case of a disease that kills a victim a drug that is effective in treating such a disease should be accepted even though it may have a high level of toxity. In such cases however the commission should take the task of monitoring the adverse action through reports by medical practitioners and hospitals.

For drugs that are already in market their safety standard and efficacy, chemical, clinical and manufacturing data should be submitted to the commission for review. An investigation should be initiated if an allegation that a drug is substandard exists. If the allegation is proved, the drug should either be removed from the market or its use should be restricted according to the finding of the investigations initiated by commission. Higher standards should be established for assessing the drugs safety, quality and efficacy.

The licence for importation and marketing of new drugs especially should be denied if manufacturing data, submitted for assessment, are inconclusive or if proposed labelling is false or misleading. In certain circumstances where necessary manufacturing data should be submitted with tenders for supply of drugs, especially where a large consumer like Ministry of Health is concerned, in deciding whether or not to grant a licence, the commission should have power to review any other relevant information apart from that submitted by the drug manufacturer.

It should be mandatory for the manufacturer to furnish the commission with information on the side effects and clinical information after a drug has been put into market or give any other information which

would assist the commission in continuing the evaluation of quality safety and efficacy of the drug.

Where necessary the commission should be given power to choose an official name for any drug. This is to avoid manufacturers evasion of the law by changing names, relabelling or re-circulating through other countries drug that have been banned elsewhere. This official name together with the genetic name should appear in visible print in the label and all advertisments. All literature on advertising or labelling should contain a brief summary of the side effects and effectiveness of a drug. This will provide the consumer with a fair and balanced information.

In order to counter 'drug dumping' a legislation should be introduced which would make it impossible for drugs to enter this country unless that drug is used as it is in the country of origin. It should further be required by law to show the use for which the drug is intended in this country, and an indication of dosage should be that approved by regulatory agencies of the countries of origin. This will be a check on the companies that "dump" rejected drugs or recommend excessive dosage of the drugs they sell.

This law should however be adopted with caution because it has a weakness in that a manufacturer with a substandard drug can escape it by getting a country with a weaker legislation to approve such a drug, possibly through bribery, and then have that country become the country of origin. Hence, together with the 'country of origin' legal requirements, the authorities should know something about the history of the drug and that of the company manufacturing and selling it. The only exception which should be made to the 'country of origin' law is where a drug cannot possibly be used in the country of origin, for instance where a drug is manufactured in a temperate climate for diseases that are only found in

tropical climate. Such will be only a few instances.

The second recommendation is for the country to establish a comprehensive drug policy based on understanding of priority of health problems. An essential start for such a policy would be to establish the type of drugs that are needed and register them. In doing this a list of three or four categories of drugs may be a start. The first list should contain a list of drugs that can be used by paramedicals even in the smallest clinics in the health needs. The second list would be available at district or regional hospitals and the other one or two categories would be a specialist drug whose use would be severely restricted, and perhaps the largest list of those drugs explicity excluded. These drugs would be categorised by their great expenses but their relevance only to trivial disorders, or by there being cheaper drugs of equal efficacy. This would avoid overstocking of drugs as well as help check the life span of drugs so that they would be used before they reached their expiry dates. Secondly it would help to limit the unnecessary oversupply of drugs. Supervision and checks on possible errors will be made considerably easy and thus reduce neglegence and corruption that has always accompanied lack of registration and over stocking.

There should be an abolition of brand names and a reduction in patent protection so that the real price competition may be fostered. The basic list should be made of generic names.

The establishment of a basic list for drugs that are needed should in itself help reduce the cost of drugs to the health authorities. Cost effective purchasing is hampered by abundance of branded products and confusion as to their composition. By listing generic products, a lot of funds can be saved. Funds further could be saved by inviting tenders for generic drugs rather than brand name products.

Health authorities, however, have been prevented from buying cheap generics because of concern over quality while big multinationals who sell brand named drugs at relatively high prices frequently point to the guarantees of quality they offer. In fact multinationals mark on pill is no guarantee of its quality. For instance, the case has already been mentioned where dangerously substandard drugs imported from an Asian country were packed and marked as products of Borrough Wellcome, a major British Company.

A general conclusion can be drawn that the danger of substandard drugs are more likely to arise from the fact that enormous profit margins are earned on brand names that attract small dishonest imitators. Listing of and inviting tenders for generic names may solve this problem.

The proposed policy is unlikely to develop along the idealized line in the context of free enterprise ethics which allows the traffickers in patent medicines to divert consumer spending to products which satisfy very little or only illusory health needs. Hence there is need to put stringent control on advertising and promotion of drugs.

The third recommendation is the reform of the present law of tort. Two major criticisms can be made as regards liability and compensation in tort. The fact that the consumer must prove negligence in order to succeed against the manufacturer of defective drugs and the defects of the procedural frametoral within which the parties operate is an obstacle to redress, a solution to which may be found in the imposition of strict liability on the manufacturer. In this case the injured party does not have to prove negligence on the part of anyone but only that his injury resulted from negligence.

The imposition of strict liability on the manufacturer may create further anomalies without removing the inherent weakness like costly court

procedures. It is therefore arguable that what is really needed is a form of comprehensive insurance entitling all provenly injured persons to compensation from a central fund. Such a solution however has further mental, political and social difficulties in addition to assessing its economic and administrative viability.

The fourth recommendation concerns international control. International aid should coincide with national drug policy. WHO has tried to establish a scheme of control of pharmaceutical drugs moving into international trade. This scheme relies however on certification by the exporting country that drugs meet local standards. This system is clearly open to abuse in the absence of additional international control and it is especially so since most drug exporting countries do not require that drugs produced for export meet the standard requirement. WHO however could be of great help in control of drug trade. It could set up regional agencies which would advise on drugs which are suitable for the country's needs, bearing in mind relevant climatic, sociological and economic factors which it would be able to monitor closely. Such an agency would also be able to advise on,even control, prices in view of the exhorbitant prices charged for drugs especially in developing countries. Such advice however, should also be reviewed by national agencies as they may be tainted with racial bias.

WHO should also look into ways and means of assisting in establishing natural or regional testing facilities to monitor the quality of drug imports. Since WHO has from time to time given the excuse of lack of funds, there is need for greater co-operation from member states to commit additional resources to WHO for the establishment of such facilities. Support should also be drawn from the large drug manufacturing companies. Developing states should also be able to rapidly reach agreement on the desirable regional groupings and strongly support the location of facilities

in agreed sites. If WHO cannot operate a national or regional quality control facilities, it should assist more in training and upgrading national regulatory authorities.

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A P P E N D I X

Questionaires used in collecting materials.

Part one of the questionaire are general questions relating to sale and distribution of drugs.

Part two are questions relating to the adequacy of law relating to drugs.

PART ONE

Legal Control of Sale and Distribution of Substandard Drugs

1. What is the percentage of drugs
   i) imported into Kenya?
   ii) manufactured?
   iii) manufactured by Kenyan owned companies?

2. Which are the major countries which export drugs to Kenya?
   i) which companies manufacture these drugs?

3. Are new drugs in the market evaluated for:-
   i) safety
   ii) efficacy for their intended use in Kenya
   iii) efficacy for their intended use by the exporting countries.

4. Are the drugs imported into Kenya used (widely, moderately or hardly if any), in the countries where they are manufactured and subsequently exported to Kenya?

5. Are there any measures taken to show that drugs approved for marketing continue to meet specific standards of:-
   i) quality
   ii) efficacy

6. What measures have been taken to show that drug labelling and advertising informs, but does not mislead physicians or patients?

7. Are new data obtained on the impact of an existing drug promtly made available to physicians and to the regulatory authorities?

8. What methods are used to
   i) withdraw drugs from the market
   ii) to restrict the use of an approved drug if new data warrants such action?

9. Have there been any cases as in (8) involving

i) imported drugs?
ii) locally manufactured drugs?

9(a) in your opinion, was the action taken effective and / or necessary?

(b) have there been any prosecutions?

10. What sector (proportion), urban, rurual etc) of the population mostly use

i) imported drugs
ii) locally manufactured drugs?

11. What are the methods, i.e creteria for tenders, used for purchasing drugs from:-

i) overseas manufacturers?
ii) local manufacturers

12. What methods are used for refusing or withdrawing tenders from:

i) overseas manufacturers?
ii) local manufacturers?

a) have there been such cases
b) which drugs, sold primarily by which company / companies
c) when?

13. What measures have been taken against any 'tricks' to sell substandard drugs?
'Tricks' such as

i) change of name after a drug has been rejected
ii) mislabelling of drugs that cannot meet registration requirements
iii) circulation of drugs through countries with weaker legislations
iv) ineffectual change of manufacturing formulae

14. Are there any measures taken against those people who copy and come up with cheap imitations whose qualities are not guaranteed?

a) have there been any such cases?

b) how were they handled?

15. How does the government ensure that doctors get the right information as to:

i) effects
ii) side effects of drugs?

16. Are there any measures taken to show that the drug companies while competing with others do not

i) lower the standards of the drugs?
ii) suggest that their drugs, though considered dangerous to the developed countries, is good enough for use in Kenya.

17. What are the measures taken against:-

i) mis-promotion of drugs
ii) recommendation of exessive dosages
iii) misprescription?

18 What measures have been taken against unscruplous methods for sale used by drug companies?

19. Is it possible for a drug company to influence doctors to prescribe their brand of drug, the drug being substandard or otherwise?

20. Is it possible for doctors to buy drugs from these companies through 'kick-back' method? Is there a possibility of doctors being corrupt through this?

21. Is there a possibility that through excessive sales promotion doctors are pressed, possibly bribed, by the numerous drug representatives to use / sell their drugs?

i) what measures have been taken against this?
ii) how many drug representatives are there for every number of doctors?

22. What measures are taken to ensure that these drugs sales representatives do not:-

i) corrupt the doctors in any way so as to promote their substandard drugs

ii) misinform the doctors in any way so as to promote their substandard drugs?

iii) influence the doctors in anyway so as to promote their substandard drugs?

23. Is there over-pricing of drugs in Kenya as compared with other markets? Is this under any regulation?

24 Is there a possibility of pharmaceuticals withholding information about possible side effects of drugs?

i) have there been any such cases? Was anything done about them?

25. What is usually the reaction of government / drug companies to new data showing possible bad effects of drugs in the market?

26. Are there instances where drugs, officially determined to be worthless and potentially lethal in domestic markets in developed world, have found their ways into Kenya.

i) what drugs would you say is such an example?

ii) how did they find their way into Kenya, and from which countries did these drugs come?

THE ACT & LEGISLATION (PART TWO)

(The Act means Food Drug and Chemical Substances Act)

1. Is there a need for legal intervention and distribution of:-

   i) imported drugs
   ii) locally manufactured drugs

2. Is the present Law adequate in controlling:-

   i) standards
   ii) efficacy
   iii) safety of drugs (a) manufactured in Kenya
   (b) imported into Kenya

3. If not where does it fail?

4. How can it be improved?

5. Is the consumer well protected by the Act?

6. Does this Act facilitate exploitation of masses by not providing for their protection?

7. Does this Act respond adequately to drug problem as it is understood today?

8. What is the effect of uncontrolled sale and distribution of drugs?

9. Are there other Acts which can help this Act to be more effective?

10. What is the social attitute

    i) mass ignorance
    ii) ignorance of dangers of side effects
    iii) unwillingness to acknowledge the extent of harmfulness of substandard drugs.
    iv) institutionalization by i.e chemicst, clinics hospitals - have created marked resistance to perceiving them bad?

11. Is the present law adequate in ensuring that imported drugs are safe and effective?

12. Is the law adequate to reject goods banned in domestic markets of exporting countries?

13. Does the law require exporting countries to label both potentially:-

i) useful effects of their products?

ii) harmful effects of their products?

iii) is this practice adhered to?

14. Does the act give effective protection against harmful drugs?

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