Drug Information and Advertising in Nigeria

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ABSTRACT

Orthodox drugs especially prescription drugs as well as traditional medicines are presently hawked and advertised in public with little or no restriction from the proper regulatory agencies. And in almost all the cases, the advertisements are generally misleading because the perpetuators are quacks. Uncontrolled advertisement is likely to fuel cases of product imitation, pass-offs and other forms of faking/counterfeiting which are dangerous to public health. The advertisement of drugs in Nigeria is a breach of the various laws regulating the proper distribution and sale of drugs. The aim of this review is to set out the position of our laws as regards advertisement of drugs, show how it differs from communication of product information and to define the basis for the legal prohibition of advertisement of drugs. The focus is also to emphasize the need for effective regulation and control of advertisement by the appropriate regulatory agencies.

KEY WORDS: Drug information, advertisement, learned intermediary rule, neighbour principle, drug laws.

INTRODUCTION

Everyone that gets sick (patients) approaches physicians, pharmacists or other health care providers who are termed learned intermediaries, to profer solution to their problems. The treatment options available to such patients include carrying out a surgical operation, advice to control diet and other non-drug remedies such as reduction of alcohol intake, prescription and administration of a drug or combination of drugs, referral of patients to other specialists for further treatment and so on.

Generally, drug treatment is the easiest and favoured option in all of these cases and it is resorted to in nearly every case of the management of ill-health and when it is not the only mode of treatment, it is normally added as an adjuvant to other forms of therapy.

Different types of people who are knowledgeable are involved in the manufacturing, compounding, mixing, production, prescribing, dispensing, distribution, sale, and administration of drugs. The activities of all these persons are important to ensure that the sick patient gets the right kind of drug which is safe and efficacious.

What is most important is the consumer's well being which depends on the skills of the physician to diagnose the particular sickness as much as it does upon the skills of the pharmacist to produce and dispense the drugs and other health professionals that provide other medical services as well as upon the efficacy, safety and quality of the drug relied on to effect the cure.

WHAT IS A DRUG?

The term drug has been defined by health bodies, dictionaries and statutes. The World Health Organization Scientific Group defined a drug[1] as: "any substance or product that is used or intended to be used to modify or explore physiological or pathological states for the benefit of the recipient." This definition is not exhaustive since it does not explain the states and the nature/type of recipients, whether they are humans or animals.

The World Health Organization went further to distinguish between a drug and a medicine. A drug is a single chemical substance that forms the active ingredient of a medicine, while a medicine contains many other substances used to deliver the drug in a stable, acceptable and convenient form to the patient. The word medicine or drug is used interchangeably. Generally, the word medicine is usually preferred for therapeutic drugs to distinguish them from addictive and controlled drugs[1].

The Black's Law Dictionary[2] defines a drug as: "a substance intended for use in the diagnosis, cure, treatment or prevention of disease, and also as a natural product or synthetic substance that alters one's perception or consciousness e.g. controlled substances like cocaine"

The Black's Law dictionary went further to classify drugs as prescription drugs, non-prescription or over-the-counter (OTC) drug, addictive or controlled substances (which includes alcohol and tobacco).

Drugs are statutorily defined as: "any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof manufactured, sold, or advertised, for use in the diagnosis, treatment, mitigation or prevention of any disease condition in man or animal or used for disinfection or control of ▶

pests and contraception".[3]

Also the NAFDAC Decree No. 15 of 1993 (as amended) defines a drug as[4] "any substance of vegetable, animal or mineral origin or any preparation or a or a mixture thereof manufactured and sold or advertised for use in :-

(a) The diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal;
(b) restoring, correcting or modifying organic function in man or in animal;
(c) disinfection or the control of vermin, insects or pests; or
(d) contraception.

The control and regulation of drugs is important because drugs on their own can cure diseases and even where they cannot, they are able to relieve symptoms and alleviate suffering when properly selected and used. However, when improperly used or when fake and counterfeit drugs are used, they can cause or worsen disease and hence endanger lives.

DRUG INFORMATION

Information is defined as the act of informing or communicating knowledge as news or advice communicated by word or writing[5]. All pharmaceutical companies are expected to provide detailed information regarding all aspects of their drugs and medicines. The labels and packages are intended to provide basic information for the public while qualified suppliers, prescribers and dispensers are to have neutral and objective information about drug products.

An adequate drug product information is one that a reasonable, prudent person in the same and similar circumstances would have provided with respect to the dangers and that communicates adequate information on the dangers and safe use of the product, by taking into account the characteristics of the product, the ordinary knowledge that is common to the persons by whom the product is intended to be used; and in the case of prescription drugs, by taking into account the characteristics of product and the ordinary knowledge common to the prescribing physician, the production and dispensing pharmacists and other health professionals.

DRUG ADVERTISEMENT

Advertisement may be defined as the mechanism(s) by which any purveyor of goods and services may seek to influence prospective purchasers or consumers in the purchasing or consumption of those goods and services.

Advertisement is a passive tool by which a manufacturer or distributor or retailer of products draws the attention of a would-be consumer to the goods or services he offers for sale.
The Black's Law Dictionary[2] defines the word "advertise" as: "To advise, announce, appraise, command, give notice of, inform, make known, and publish. To call a matter to the public attention by any means whatsoever. Any oral, written or graphic statement made by the seller in any manner in connection with the solicitation of business and include, without limitation because of enumeration, statements and representations made in a newspaper or other publication or on radio or television or contained in any notice, handbill, sign model, catalogue, placard, or letter or printed or contained on any tag or label attached to or accompanying any merchandise".

The focus of the regulation and control of advertisement by NAFDAC is to stop misleading advertisements. Statutorily, advertisement includes every form of advertising, whether in a publication, or by display of any notice, circular, label, wrapper, invoice or other documents; or any public announcement by display of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents; or by words inscribed on an article, by exhibition of a photograph or a cinematograph film, or other forms of advertising made orally or by means of transmitting light or sound, or in any other way[6]. Therefore, leaflets, booklets and other promotional materials are regarded as advertisements.

The aim of advertising a product is to draw the attention of the public to the availability and utility of a product or service, thus creating demand for it, and to keep the product or service in the purview of the public so as to maintain or increase its marketability. Advertisement is, therefore, a passive form of promoting products meant to appeal to the senses and thus develop product awareness without necessarily providing an immediate opportunity for the purchase of the product.

While drug information should be readily available and accessible, it is important to understand and draw a distinction between drug information and drug advertising with regards to legal controls. Promotional activities and dissemination of information are complimentary and closely related, but they are different in terms of marketing value and thus subject to different measure of control and regulation. There are laws and statutes to ensure that adequate information of drug products are given to the public and there are also laws and statutes to prevent the giving of misleading information in the form of advertisements so as to safeguard the health of the public.

LEGAL ASPECTS OF ADVERTISEMENT

An advertisement is seen legally as a commercial offer and once there is an unequivocal and unconditional acceptance, a contractual relationship exists between the advertiser or the manufacturer that he/she represents and the customer. It is not in every situation in law that an advertisement will be held to be an offer. For example, a trader stating that he is willing to sell some goods is merely an offer to chatter as illustrated in the case of Partridge v. Crittenden[7] where Mr. Partridge was charged with unlawfully offering for sale a certain wild bird, to wit a brambling contrary to Section 6 (1) of the Protection of Birds Act 1954. He had inserted in a periodical called Cage and Aviary Birds, an advertisement which read "Bramblefinch cocks, bramblefinch hens, 25s. each". Mr. Thompson, having seen the advertisement, wrote up for a hen and enclosed the money. Mr. Partridge sent him the hen and it was on these facts that Mr. Partridge was charged. It was held by the Divisional Court that the Advertisement was an invitation to treat and not an offer for sale so the offence charged was not established. The odd thing is that he could have been charged under the same section ▶

with selling, rather than offering for sale; and he would have been convicted if he had been so charged.

However, where an advertisement offers a reward as in the case of Carlill v. Carbolic Smoke Ball Co.[8], a unilateral contract is created where one party binds himself by a conditional promise and then leaving the other party free to perform the condition or not, as he pleases. In Carlill v. Carbolic Smoke Ball Co., the Defendants were the makers of a medicinal item called "The Carbolic Smoke Ball". They issued an advertisement in which they promised to pay £100 to anyone who caught influenza after having sniffed at the smoke ball for a specified period in a prescribed manner. They stated that they had deposited £1000 with their bankers (Alliance Bank, Regent Street) "to show their sincerity in the matter".

Mrs. Carlill having seen the advertisement, bought a smoke ball, sniffed at it in the prescribed manner and then caught 'flu. She sued for the £100 and succeeded.

One of the points taken by the defense was that the advertisement was not a true offer, but the Court of Appeal held that it was by holding that by the terms of the contract, there was no need to notify the Defendant company of the fact of acceptance (acceptance which does not require communication in the ordinary sense) which took the form of performance when the plaintiff sniffed at the smoke ball for two weeks, and the performance constituted consideration. Mrs. Carlill knew of the offer of a reward but certainly her motive at sniffing at the smoke ball was presumably to avoid catching 'flu rather than to get the reward by getting 'flu.

Lord Justice Bowen in the above case said: "An offer can be made not only to an individual or a group of persons, but also to the whole world. "It is an offer made to the world which is to ripen into a contract with anybody who comes forward and performs the condition. Although the offer is made to the world, the contract is made with the limited portion of the public who comes forward and performs the condition on the faith of the advertisement".

Therefore, a contract can arise from an advertisement and a person making an advertisement becomes liable to anyone who, before it is retracted, performs the condition. This is different from an invitation to treat that includes a mere offer to negotiate or to receive offers, or offers to chatter.

The advertisement of drugs which is regulated by laws and statutes depends on the nature of the drug product, whether the drug product is an over-the-counter (OTC) medicine or a prescription only medicine (POM); and these regulations vary from country to country. But generally, most countries prohibit the advertising of prescription only medicines to the general public. However, the new trend in the United States is Direct-to-Consumer Advertising of Prescription drugs[9].

Under the Nigerian legal system, the advertisement of drugs is dependent on the type of drug product. Over-the-counter (OTC) medicines are simple household remedies that can be purchased without prescription from a physician or obtained from pharmacies and patent/proprietary medicine stores.[6] They are remedies for minor cases which can be purchased from drug stores without doctors prescriptions.

On the other hand, prescription only medicines (POM) comprises complex medicines that are esoteric in formula and varied in effect[11] and are sold or supplied in accordance with a prescription given by an appropriate practitioner and appropriately dispensed by a pharmacists in pharmacies only. Prescription drugs as the name implies should only be obtained with the prescription of a qualified health practitioner and these drugs are classified as Part III poisons under the Poisons and Pharmacy Act Cap 535, 1990.[6]

The advertisement of prescription drugs will therefore be a breach of the law since the consumer (patient) needs a learned intermediary (physician, pharmacist or some other health professionals) to recommend the use of such, make it available and perform other relevant services leading to therapeutic treatment.

As part of duty of care, a manufacturer must supply adequate information about these drug products including any relevant warnings, and failure to do so will amount to negligence especially if the manufacturer knew or ought to know of any latent dangers inherent in the product. There is a continuing duty on the part of the manufacturers and suppliers of medicinal products to monitor the safety profile of their drug products and to ensure that they are fit for their purpose and are still reasonably safe.

On occasion, a medicinal product or a particular batch of the product may have to be recalled and/or there may be a duty to issue further warnings or information about the product in the light of emerging knowledge and surveillance data about a drug product.

Because it is only in exceptional cases that products are defective due to design, liability resulting from the use of a product (product liability rule) does not only focus on the manufacturer, but on all those who are interposed between the manufacturer and the ultimate consumers. In the case of drug products, the health workers such as physicians, pharmacists, nurses and others who are termed learned intermediaries make the decisions on product use or application.

The principles underlying the doctrine of "informed consent" apply to the relationship between manufacturers of medical products and consumers. The manufacturer-consumer relationship (unlike the doctor-patient relationship) is characterized primarily by a lack of direct communication that is able to create a relationship of complete dependency between manufacturer and patient.

Manufacturers, therefore, are reasonably required to make clear, complete and current informational disclosure to consumers concerning the risks inherent in the ordinary use of their products. A high standard for disclosure protects public health and yet does not place an onerous burden on manufacturers.

The manufacturer of drug products therefore rely on the learned intermediaries who have close contact ▶

with the patients to be able to effectively warn the patients about the latent dangers and risks associated with the use of their products. The "learned intermediary" rule applies where an intermediate inspection of the product is anticipated because the product is highly technical in nature or where a consumer is placing primary reliance on the judgment of a "learned intermediary" and not the manufacturer. In such cases, a warning to the ultimate consumer may not be necessary and the manufacturer may satisfy its duty to warn the ultimate consumer by warning the learned intermediary of the risks inherent in the use of the product. The learned intermediary rule is supported by the practical fact that manufacturers may find it difficult or impracticable to provide direct warnings to patients whose identities are unknown to them and the fact that patients may not understand written warnings if not explained. The learned intermediary rule presumes that the intermediary is "learned", i.e., fully apprised of the risks associated with the use of the product.

Therefore, a learned intermediary is that expert who can take into account the propensities of the drug as well as the susceptibilities of the patient. He takes the risk of weighing the benefits of the medicines against its potential dangers by making individualized risk/benefit analyses of medical therapies for a particular patient, monitor the use of prescribed products and decide which warnings particular patients should receive or which they should not. The choice he makes is an informed one, an individualized medical judgement bottomed on knowledge of the patient and the drugs. The rationale for the rule was outlined by Justice Wisdom in Reyes v. Wyeth Laboratories (supra) [10], a suit against a manufacturer of oral polio vaccine and the father of Anita Reyes (an injured vaccinated child). In the United States, the "learned intermediary" rule was first elaborated in Sterling Drug, Inc. v. Cornish[11], a suit brought by a patient blinded after taking the drug, chloroquine phosphate. On page 85 of that case, it was emphatically stated that where the learned intermediary are properly warned, there are chances that harm to the patient can be avoided.

The learned intermediary rule was later reaffirmed and developed in a series of American cases involving the liability of manufacturers of prescription drugs. For example, applying Arkansas law in the case of Schenebeck v. Sterling Drug Inc.[12], the manufacturers were held liable because of their failure to warn in a timely manner that Aralen (a brand of chloroquine phosphate) could cause blindness. Applying Pennysylvania law in the case of Hoffman v. Sterling Drug, Inc.[13], the court held that manufacturers need to adequately warn the prescribing physicians; applying Tennessee law in the case of Dunkin v. Syntex Laboratories, Inc.[14], it was stated that warning the learned intermediaries satisfies the manufacturer's duty to warn and that attempts by manufacturers to give detailed warnings to patients could mislead patients and might tend to interfere with the physician/patient relationship. Applying New York law in the case of Lindsay v. Ortho Pharmaceutical Corp.[15], it was held that the inclusion of warning materials in the package provided adequate warning, and in a more recent case of Motus v Pfizer Inc.[16] (applying California law), it was held that the adequacy of the manufacturer's warning was irrelevant since the prescribing physician in this particular case testified that he did not read the warning label that accompanied Zoloft before prescribing the drug. Applying Louisiana law in the case of Timm v. Upjohn Co.[17], it was held that a manufacturer is not expected to give warnings to each consumer if the learned intermediaries receives adequate warnings of the potential adverse effects. Applying Virginia law in the case of Stanback v. Parke, Davis and Co.[18], the fact that the physician made no individualized judgement during the mass vaccination of people with Fluogen vaccine did not stop the application of the learned intermediary rule. Applying Georgia law in the case of Walker v. Merck & Co.[19], it was held that other health professionals like the nurses may also act as learned intermediaries. Applying California law in the case of Plummer v. Lederle Laboratories[20], it was held that a manufacturer should not be held liable for damages caused by its products if the user of the product engages in practice where there is an already known risk, like in the case of Edwards v. Basel Pharmaceuticals[21] where a man died from the effect of overdose. In Canada, the rule was first considered in an obiter passage by Justice Linden in Davidson v. Connaught Laboratories[22] by stating that, it was the duty of the learned intermediary to inform the patient about the seriousness of a procedure or the risks inherent in it when recommending a medical procedure or product.

Pharmaceutical companies must warn ultimate purchasers of dangers inherent in drug products sold over the counter and then to warn the prescribing physician and dispensing pharmacists (acting as learned intermediaries between manufacturer and patients) in selling prescription drugs. The manufacturers also have a continuous duty to warn learned intermediaries of dangers incident to using their drug product and must keep abreast with scientific developments touching their products and then notify the learned intermediaries appropriately.

As learned intermediaries, the prescribing physicians are expected to take into account the propensities of the drug, as well as the susceptibilities of his patient in making an informed choice of prescription drug to use based on knowledge and skill, while the dispensing pharmacist is expected to provide information and answer questions (e.g. questions on drug interaction, adverse drug interactions, response of patients with renal failure to drugs etc.) which are of concern to the patient. It is evident, therefore, that the dispensing pharmacist must be kept fully informed of all (both good and bad) developments about the patient's drugs.

This learned intermediary rule generally applies either where a product is highly technical in nature or is intended to be used only under the supervision of experts, or where the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product.

The rule, which is in essence an application of the common law ▶

principle of intermediate examination and intervening cause, is an exception to the general manufacturer's duty to warn the consumer and operates to discharge the manufacturer's duty to the ultimate consumer, who has a right to full and current information about any risks inherent in the ordinary use of the product.

Accordingly, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary's knowledge approximates that of the manufacturer. To allow manufacturers to claim the benefit of the rule where they have not fully warned the physician, pharmacist or other health professionals, would undermine the policy rationale for the duty to warn, which is to ensure that the consumer is fully informed of all risks. Since the manufacturer is in the best position to know the risks attendant upon the use of its product and is also in the best position to ensure that the product is safe for normal use, the primary duty to give clear, complete, and current and easily understood warnings must fall on the shoulders of the manufacturer.

The rationale for the manufacturer's duty to warn can be traced to the "neighbour principle", which lies at the heart of the law of negligence, and was set down in its classic form by Lord Atkin in Donoghue v. Stevenson[23].

When manufacturers place products into the flow of commerce, they create a contractual relationship of reliance with consumers, who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the products are not safe. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.

While the "learned intermediary" rule was originally intended to reflect, through an equitable distribution of tort duties, the tripartite informational relationship between drug manufacturers, physicians and patients, the rationale for the rule is clearly applicable in other contexts. Indeed, the "learned intermediary" rule is less a "rule" than a specific application of the long-established common law principles of intermediate examination and intervening cause developed in Donoghue v. Stevenson (supra)[23] and subsequent cases such as the Holmes v. Ashford[24] case.

In the case of Vacwell Engineering Ltd v. BDH Chemicals Ltd[25], the words "harmful vapours" did not give adequate notice of the explosive properties of the product on its contact with water. In this case, the defendant supplied the chemical boron tribromide to Vacwell in glass ampoules labelled "harmful vapour". It was not known to the suppliers that the chemical reacted violently with water. A scientist accidentally dropped an ampoule into a sink containing other ampoules and the resulting explosion killed him and caused great damage to the plaintiff's factory. The manufacturers were held liable to have been negligent in failing to give an adequate warning of the dangerous properties of the chemical, which had been pointed out in scientific journals and therefore ought to have been known. In the case of Devilez v Boots Pure Drug Co.[26], the plaintiff accidentally spilled corn solvent on his genitals and recovered damages from the manufacturer on the ground of the failure to warn, although the plaintiff was also held to have been [25] percent contributorily negligent.

Thus in the case of Holmes v. Ashford[24], the manufacturer of hair dye were not liable for injury caused to the plaintiff's scalp because the container in which it was supplied to the hairdressers and the accompanying literature, warned of the danger. The hairdresser was held responsible as an intermediary and in the circumstances, a warning to the hairdresser was sufficient. It is clear that a dispensing pharmacist may be liable for damages where he or she neglects to warn a patient about the risks associated with the use of a drug.

THE NEED TO CONTROL ADVERTISEMENT OF DRUGS

Sales promotion has become one of the most popular and powerful tools for products and services marketing. The forms of sales promotion include advertising, provision of free samples, sponsorship of programmes etc., and all these have the potential to influence people's beliefs, guide them towards thinking in a particular way so that they may buy goods and services offered for sale.

As have been stated earlier, the advertisement of prescription drugs is prohibited because unlike OTC drugs, prescription drugs are normally dispensed from bulk containers rather than unit-of-use packages in which the manufacturer may have enclosed a general label. Also many manufacturers provide the consumers with diluted variation of the risks associated with the drug product and usually give warnings that are of a general nature only to patients, e.g. see your doctor. Since it is the physician that determines the type of drug and the eventual adjusted doses depending on age, weight and some other factors, direct-to consumer advertisement of drugs is prohibited in Nigeria and some other countries. Even in the US where Direct-to-Consumer advertising has become an essential part of pharmaceutical manufacturer's marketing plan, the manufacturers are subject to claims by consumers if the advertising fails to provide an adequate warning of the drug's dangerous propensities.[9]

Since advertisement play a major role in consumer's choice, manufacturers now budget large sums of money to influence consumers favour for their products. This has led to distortion or exaggeration of information, competitive promotion of products and eventually high prices of drug products. An advertiser must be aware that he or she is not free to describe the goods and services that he wishes to promote in any manner he deems fit because legal controls have been put in place.

Although an advertisement is not false in itself, it may be misleading and this can make the advertiser to be liable. In the case of Director-General of Fair Trading v. Tobyward[27], the respondent advertised a product called "speedslim" claiming that its use could result in permanent weight loss, that success was guaranteed, that the product contained an ingredient that was a medical and scientific breakthrough and that the product was 100 percent ▶

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