*Maintaining Qualitative Pharmacy practice in a depressed economy

By
WILSON O. ERHUN
Faculty of Pharmacy,
Obafemi Awolowo University,
Ile-Ife.

INTRODUCTION

A definition of Pharmacy practice can be derived from the role of the Pharmacist in Health care delivery as spelt out by the World Health Organisation (WHO) as follows:

* Ensuring the quality of pharmaceutical products at the time of manufacture, importation, exportation and at all stages of distribution chain.
* Managing the procurement and supply system to ensure quality and cost effectiveness.
* Advising and promoting rational use of pharmaceutical products from the prevention of illness and the enhancement of health.
* Promoting relevant regulatory issues relating to pharmacy in heath care.

Qualitative pharmacy practice can thus be said to be provided when the aforestated roles of the pharmacist are optimally performed. Essentially the practice of pharmacy is aimed at providing and promoting the best use of drugs and other health care services and products by patients and members of the public. The basic interest of the pharmacist is the welfare of the patient.

The depressed economy currently in Nigeria is characterised by low capacity utilisation in the industry, high unemployment rate, high mortality and morbidity rates, extremely low levels of disposable income in a large segment of the population, high cost of loanable funds, high crime rates, and a general sense of insecurity particularly in the urban centres; unpredictable industrial disputes; very unstable educational calendars particularly at the tertiary level; high cost of essential commodities, very high transportation costs amongst other features. The list is unending.

The above factors constitute a challenge to the practise of pharmacy if quality is to be of major consideration. An attempt would be made in this presentation to examine those areas in pharmacy practice that should be watched in a depressed economy like ours. In particular we shall examine the issues of pharmaceutical manpower, cost of drugs, counterfeit and fake drugs, patent and proprietary medicine vendors and ethical practice.

PHARMACEUTICAL MANPOWER

Basic training: The Pharmacist is trained in any recognised university that has a school/faculty of Pharmacy. It is a 4 year (post-preliminary) degree programme.

To date there are seven recognised training institutions for pharmacists in Nigeria. They are, University of Nigeria, Nsukka, University of Lagos, University of Jos, University of Ibadan, Ahmadu Bello University and the Obafemi Awolowo University, Ile-Ife. The University at Uyo is also training pharmacists, but the picture at the Ogun State University is not quite clear. In all of these institutions, the story remains the same. Shortage of staff, shortage of laboratory equipment, shortage of laboratory reagents, shortage of classroom seats, low morale of lecturers and laboratory staff and an increasing pressure for increased intake of students. These are fall outs of economic depression. The consequence is that the students are not properly trained. Pharmacy is a life science and practical based. But what do you now find?

Experiments specifically designed for individual students are now carried out in groups with many students not having the opportunity to try their hands. The situation is depressing, and needs to be addressed.

The current industrial action embarked upon by the Academic Staff Union of Universities needs to be mentioned. The thrust of the dispute is a review of an agreement entered into by two parties. (Government and ASUU). Instead of addressing the substantive issues, government took a panic measure of banning ASUU at the national level. Recently, we are told that individual unions would negotiate with their employers (governing council). By implication there would be some disparities in salary structures, betweeen Universities. I see this development as drawing back the hand of the clock in the educational sector. In the early days of university education in the country with less than 5 universities, all owned by the Federal Government and no tangible form of university autonomy this may have worked.

But we now have federal and state owned Universities with the gross imbalance in the available facilities. What I forsee is a situation in which there would be a drift of lecturers from the state to the Federal Universities and the private sector. This would lead to significant fall in the already poor quality of university education. Some university departments may have to fold up or resort to the use of part-time lecturers and its attendant problems. In such a situation only poor quality pharmacists would be trained in the universities

that would survive the mass brain drain.

The implication of this for the overall health of the nation is obvious.

The Pharmacists Council of Nigeria (PCN) must take a decisive action on the quality of Pharmacists produced in our universities. Section 15 of the Pharmacists Council decree of 1992 clearly indicates that the responsibility for approval of institutional courses of Pharmaceutical training rests with the PCN. It is the PCN that can withdraw this approval as it thinks fit.

A major deficiency in the training programme is the fact that Pharmacist lecturers do not have opportunities for private practice. The knowledge acquired from practice could be quite valuable in illustrating lectures. Apologists of sustaining the ***status quo*** have continued to argue against registration of pharmaceutical premises by academic Pharmacists. They maintain that academic Pharmacists should be involved in locum. Meanwhile, most community Pharmacists cannot afford to employ the services of locum Pharmacists. They also argue that there is a need for a continuous supervision of the Pharmacy by a Pharmacist, a situation that may not be possible when the lecturer goes for his lectures and laboratory work. One however, wonders about who supervises the retail Pharmacy outlet when the community Pharmacist in Ile-Ife, travels to Lagos, for stock replacement.

It would be desirable for further thought to be given to these issues during the course of this pharmacy week.

INTERNSHIP: Before a Pharmacist's name can be entered into the register of Pharmacists, it is expected that the Pharmacist would have successfully undergone a period of 12 months continuous internship in a recognised Pharmacy under the supervision of a Pharmacist of not less than the rank of a senior Pharmacist or equivalent.

It is the responsibility of the Pharmacists Council of Nigeria to approve premises for the purpose of internship. Internship is a period of training and it would normally be expected that as the Pharmacy student is graduating he would be able to make a choice as to an internship site. Unfortunately, however, we have observed that many graduate Pharmacists waste weeks searching for internship placements.

Hospital Pharmacy normally absorbs most of the internee Pharmacists. It is sad to note that many of the hospital pharmacies are in very poor conditions in terms of facilities and manpower. This would tell on the quality of experience gained during the internship period.

It is expected that the internee Pharmacist should have an all round exposure to hospital, industry and community Pharmacy practice. The Pharmacist Council of Nigeria, may need to review and update the list of approved premises for internship.

PRACTISE LICENSES: Registered Pharmacists are expected to renew their licenses to practice on an annual basis. Infact, Decree 91 of 1992 specifically states in section14(i) that no registered person shall practice as a pharmacist in any year unless he has paid to the Council in respect of that year the appropriate practising fee which shall be due every January. Section 14(3) further states that every fully registered Pharmacist who has paid his registration fee, shall be entitled to an annual practising license authorizing him subject to any regulations in force to import, mix, compound, prepare, dispense, sell and distribute drugs and poisons. The inference from the above is that the payment of fees is not what authorises the Pharmacist to practise but the license he is issued after payment. It is against this background that the non issuance of practising licenses to pharmacists in the first half of this year should be viewed. A situation where Pharmacists are forced to practise illegally by reason of the inability of the PCN to issue them with licenses is simply unfortunate.

In the first quarter of this year a circular emanated from the PCN to the effect that registration fees had been reviewed upwards on the directive of the Honourable Minister of Health and Social Services. Section 14 sub-section 4 of decree 91 of 1992 states that "The Council may with the confirmation of the Minister from time to time vary the practising fees". it is inconceivable that the Honourable Minister acting as Council could take a decision of changing practising fees which is tantamount to amending section 14(1) sub-sections- (a) (b) (c) (d) and (e) of the Pharmacists Council decree. If the Council were in existence, this particular decision would be subject to confirmation by the Pharmaceutical Society of Nigeria at its next meeting or at any special meeting of the Pharmaceutical Society of Nigeria convened for that purpose, and if then annulled shall cease to have effect on the day after the date of annulment. In a situation where the Council does not exist, a decision of such a mature should have been deferred.

RE-CONSTITUTION OF THE PCN COUNCIL

The Council of the PCN was dissolved alongside those of other professional bodies and parastatals over a year ago. They are yet to be reconstituted. It however appears that the Council of the PCN should pose no problem whatsoever to government in respect of re-constitution.

Section 3 sub-section 1 of the Pharmacists Council decree lists the composition of the Council as;

(a) the Chairman who shall be a registered Pharmacist of not less than fifteen years post registration experience to be appointed by the President, Commander-in-

Chief of the Armed Forces on the recommendation of the Minister.
(b) a representative of the Federal Ministry of Health, who shall be the head of the Food and Drugs Administration and Control Department in that Ministry.
(c) the President of the Pharmaceutical Society of Nigeria.
(d) the Director of the Pharmaceutical Services (or however called) of each State Ministry of Health including the Federal Capital Territory.
(e) the Deans of the recognised Faculties or Schools of Pharmacy in Nigerian Universities.
(f) eight members from such of the States of the Federation appointed by the Minister on the recommendation of the Pharmaceutical Society of Nigeria, but no state shall in any event, be entitled to more than one member.
(g) one representative of the Armed Forces who shall be a registered Pharmacist and
(h) the Executive Director of the National Institute of Pharmaceutical Research and Development.

From the composition of the Council, the Head of State is to fill only one position with a Pharmacist. I do not think this should take years to accomplish. The non existence of the Council cannot promote qualitative Pharmacy practice. I wish to call on the Federal Government to reconstitute the Council of the PCN.

COST OF DRUGS:

Internationally, Pharmaceuticals are priced based on four types of pricing policies and regulations. They are:
(i) Product price control which is practised in France, Italy, Portugal and Spain.
(ii) Reference pricing as in Germany and the Netherlands
(iii) Profit control as in the United Kingdom
(iv) No control as in the United States.
(v) A hybrid of product price control and reference pricing as in Canada.

In product price control countries, there is virtually no market for a product until a price has been established. First, the product is approved for marketing (i.e. must be safe, effective and of good quality) before determining price. After marketing approval a price application is made to government, this is reviewed to determine whether to grant the request or seek a lower price. Reference pricing is strictly not a price control. The producer is free to seek a price for a product not higher than the established reference price for a group of drugs regarded as interchangable. The German experience has shown that products priced above the reference price will experience a major reduction in market share. Profit control as practised in the United Kingdom permits producers to set prices at any level but must limit company profitability on sales to the National Health Service (NHS). Current target profit in the UK is less than 25% return on capital. Any profit in excess of the target is considered to be in the "grey area" and may be kept by the company under certain circumstances. Under no conditions will the "grey area" be more than 50% of the company target profit. The no control pricing policy is operated in the United States of America. There are no restrictions on new products or price increases neither is there any government body that must set or approve a product price before it is available to consumers.

In Nigeria, a no control policy is operative which is subject to market forces. Basically, we are operating a free market economy where there is no price control policy on commodities, (food and drugs inclusive). The result is that over the last 3 years, the prices of some drugs have risen by upward of 500 to 1000%. This has very serious health implications. Where a prescribed drug cannot be purchased by the patient and the disease is life threatening, it is only a miracle that can save such a patient. The introduction of essential drugs policy in the nation does not seem to have had any significant effect on generic drug prices. The irony is that pharmaceutical manufacturers are complaining of a very harsh economic climate but their book profits appear to be increasing daily and declared dividends are not on the decline.

Drugs and drug products meant for the amelioration and mitigation of disease conditions should be available and affordable to the average citizen. Government should consciously set up a machinery to ensure this. I would wish that this issue be visited in our discussion to establish whether a drug price control policy would make a difference to the rising cost of drugs in Nigeria.

COUNTERFEIT AND FAKE DRUGS

One of the greatest challenges in the provision of qualitative pharmaceutical service in the country is the preponderance of counterfeit and fake drugs. Government's concern for the dangers posed to the Nigerian populace by the consumption of these spurious products led to the promulgation of decree No 21 of 1988, which was repealed by Decree 17 of 1989 which is the substance of Cap 73 of the laws of the Federation of Nigeria (1990) known as counterfeit and fake drugs (miscellaneous provisions) act. This was fine tuned in the amendment contained in Decree 99 of 1992.

It is generally agreed that fairly appropriate laws are in place to check the proliferation of fake drugs but it may appear that the situation is not getting better.

In a recent study, we sampled the views of the drug regulatory bodies/agencies; pharmaceutical organisations and manufacturers on why fake drugs appear to be on the increase in the Nigerian drug market. The following reasons were adduced:
(i) Ineffective enforcement of existing laws. In the

quoted words of a past president of PSN "It is disturbing that in spite of the existence of appropriate legislation, illegal distribution of medicines continue to fluorish giving the impression that the government is insensitive to the harmful effect of the people to the country, of medicines distributed unlawfully, some of which are of doubtful quality, safety and efficacy".

(ii) Non professionals in the pharmacy business. The Pharmacist is the only health care professional that is authorized to manufacture, sell, distribute, import, export, dispense and compound drugs. But Pharmacuetical business is now everybody's business.

(iii) Loose control systems at the ports arising from poor working facilities and sophisticated corruption.

(iv) High cost of genuine drugs

(v) Love of money. Importers colluding with overseas manufacturers to produce substandard drug products in a bid to get rich quick.

(vi) Ignorance on the part of consumers.

(vii) Corrupt officials in some regulatory bodies.

The role of task forces in the control of counterfeit and fake drugs needs to be re-appraised.

Task forces are generally regarded as specially recognized units for a special purpose. The task forces on counterfeit and fake drugs came into existence about 7 years ago. The situation before the establishment of the task forces is obviously much better than what we now have. This does not imply that they have not been working but to the common man this would mean that the experiment has been a failure. Our studies have identified some of the factors responsible for the poor performance. These are:

(i) Leadership by military personnel who would normally not want to take directives from or report to a "bloody civilian" who is the chairman of the Federal Task Force.

(ii) An industrial Pharmacist once said "some task forces work on the principle of settlement and favouritism thereby compouding the problem it is expected to solve.

(iii) Intra-task force conflicts.

(iv) (i) Arising from (ii) many spuriods products seized by some task forces tend to go back into circulation.

(v) Lack of incentives and facilities such as motor vehicles and laboratories for quick analyses of suspected samples.

(vi) Running after shadows: Task forces harassment of community Pharmacies and allowing the drug markets to fluorish with their fake drug products.

There is a need for government to revisit the issue of task forces. I would suggest the following:

(i) The control of fake and counterfeit drugs should not be centrally co-ordinated by the National Agency for Food and Drugs Administration and Control. One of the main functions of Decree 15 of 1993 which established NAFDAC is to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices bottled water and chemicals. Consequently, the presence of these fake and counterfeit products in the Nigerian drug market isan index of NAFDAC's capability or otherwise to carry out the stated function.

In my opinion, the Pharmacists Council of Nigeria empowered by law to regulate and control the practice of the Pharmacy profession in all its aspects and ramifications should take over this central function from NAFDAC.

(ii) The formation of state regulatory bodies on fake and counterfeit drugs should be centrally determined after recommendations are received from the states. And military presence should be de-emphasized despite the notion that only the use of force can properly address the problem. Experience does not support this notion. Those in military uniform are as equally prone to temptation and corruption as those in civilian dresses because the problem is with the heart of man.

(iii) Sale of drugs in drug markets located in Lagos, Aba, Onitsha, Kano amongst others that are very well known to the regulatory bodies should be ***completely banned.*** Sale of drugs in mass transit buses should alsq be banned.

PATENT AND PROPRIETARY MEDICINE VENDORS

Another significant challenge to the maintenance of qualitative Pharmacy practice is the issue of patent and prioprietary medicine vendors licenses.

The issuance of patent and proprietary medicine vendors licenses is now carried out at the state level on behalf of the Pharmacists Council of Nigeria. The guidelines on the process are clear. The drug products expected to be sold by the vendors are also well known. But the unfortunate aspect is that most PPM vendors sell prescription drugs. In some of the patent medicine stores which are regarded as clinics by many unsuspecting ignorant members of the public, minor surgical operations are carried out including abortion. Injectables are freely administered by persons who are not knowledegeable in the art. The harm being done to members of the public by many of these vendors is better imagined.

The historical principle behind the introduction of patent and proprietary medicine vendors licence in the early days of Pharmacy practice in Nigeria is sound. The number of registered pharmaceutical premises was not enough to satisfy the needs of the people. But the situation has since changed. What we now have is an over-concentration of Pharmacies in the urban areas. In most urban centres the pharmaceutical needs in terms of drug supplies can be met by the Pharmacist population. There is therefore no need to

settle for anything less than qualitative pharmaceutical service. However, this may not apply to the rural areas. This conference may wish to discuss this matter particularly to determine whether PPMV licenses should be issued in such areas where there are enough Pharmacies.

It is ironical that while two pharmacies cannot normally be sited less than 100m apart; there are many instances of over 10 patent medicine stores in a 100m radius. Drugs should not be seen as items of trade that could be sold primarily for profit. The only reasonable profit in drug sales is that derived from the provision of adequate patient care. The trend where state and local governments see the issuance of PPMV licenses as a veritable source of revenue is far from ideal and should be discouraged.

ETHICS

The ethics of a profession has been described as the principles written or unwritten which are accepted in any profession as the basis for proper behaviour. The Pharmacists Council of Nigeria has code of ethics for Pharmacists in Nigeria. The maintenance of qualitative pharmaceutical service in a depressed economy may not be possible if pharmacists do not practice ethically. In our studies of the pharmaceutical market in Nigeria we have been able to identify some worrisome areas in the matter of ethical practice in Pharmacy. I would simply list some ethically disturbing points which this conference may wish to further reflect on.

(i) It is ethically wrong for a pharmacist to connive with his employer or such other persons/institutions to imports by-standard, fake or adulterated Pharmaceuticals for sale in Nigeria.

(ii) It is morally wrong amongst other wrongs for government (or its agency) to say that patent and proprietary medicine vendors licenses should not be issued at particular levels only to observe that the number of such premises are increasing daily.

(iii) It is ethically wrong for persons to ride on buses and advertise pharmaceuticals of which they know next to nothing thereby convincing the unsuspecting passengers to waste their hard earned monies buying medicinal products that may turn out to be injurious to their health.

(iv) It is ethically wrong for medical doctors, dentists, veterinary doctors, nurses and midwives operating registered professional premises to delegate the responsibility of dispensing (sale) of pharmaceuticals to auxilliary nurses, ward orderlies and attendants.

(v) It is ethically wrong for a Pharmacist with an unregistered premises to convert the boot of his car/van as a mobile premise for the sale of pharmaceuticals.

(vi) It is wrong for non Pharmacists to detail ethical pharmaceutical products irrespective of whether the employing organization has a superintendent Pharmacist.

(vii) It is ethically wrong for Pharmacist manufacturers to condemn the sale of drugs in open markets only for one to observe that most of these manufacturers have their delivery vans frequent the same markets to sell their medicinal products.

(viii) It is unethical for a marketing manager to encourage his medical representative to sell medicinal products at unauthorised places and sometimes to unauthorised persons and institutions in a bid to meet up with projected sales figures.

(ix) It is unetical for a Pharmaceutial promotion effort in respect of ethical drugs to include giving of free samples, temporary price reductions, bonus, money off etc.

(x) It is unethical for a Pharmacist to honour a bribe request on drug imports.

It was the wise biblical king Solomon that wrote:

"Treasures of wickedness profit nothing;
But righteousness delivereth from death"

CONCLUSION

In the course of this presentation, I have attempted to sensitize us to some of the factors that may inhibit the maintenance of qualitative Pharmacy practice in Nigeria particularly at a time when the economy is depressed. It is my hope and prayer, that the issues would serve as adequate tonic to energize us during this week as we reflect on Pharmacy practice and its relevance in the provision of adequate healthcare for the Nigerian people.

Permit me to end with these words written by a profound legal luminary and scholar, named Paul who wrote a letter to the Romans and I quote:

"But unto them that are contentious and do not obey the truth, but obey unrighteousness, indignation and wrath, tribulation and anguish, upon every soul of man that doeth evil: of the Jew first and also of the Gentile, But glory, honour and peace to everyman that worketh good to the Jew first and also to the Gentiles; for there is no respect of persons with God. For as many as have sinned without law shall also perish without law, and as many as have sinned in the law, shall be judged by the law. For not the hearers of the law are just before God, but the doers of the law shall be justified".

I thank you very much for your patience and kind attention. May the Lord God Almighty bless you richly.

**** Being text of the keynote address delivered by Dr. W.O. Erhun on the occasion of the 1996 Pharmacy week of the Ogun State branch of the Pharmaceutical Society of Nigeria held at Gateway Hotel, Abeokuta on19th June, 1996.***