WORLD HEALTH ORGANIZATION
REGIONAL OFFICE
FOR THE EASTERN MEDITERRANEAN

ORGANISATION MONDIALE DE LA SANTE
BUREAU REGIONAL
POUR LA MEDITERRANEE ORIENTALE

TRAVELLING SEMINAR ON QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS

Islamabad/Lahore/Karachi/Teheran/Cairo
9 - 21 March 1970

EM/SEM.QUAL.CTR.PHARM/7 Rev.1
25 March 1970

ENGLISH ONLY

IMPACT OF DRUG LEGISLATION ON DRUG CONTROL IN DEVELOPING COUNTRIES

by

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Mr. Bisharah discussed with me the necessity for a paper to be presented at the WHO Travelling Seminar to stimulate Drug Research in the Eastern Mediterranean Region. I would like to discuss my views, which are purely personal, on the role played by the Government in improving drug control in a developing country according to the deficiencies in the existing system. I would like to begin with the quotation by Mr. Harvey W. Wiley about "life and the coming time" presented at the Hanover College in 1867. "We are carefully to preserve that life which the author of nature has given us for it was no idle gift". Drugs of today are like dangerous weapons if not used carefully, and thus, it is the responsibility of every Government to regulate its use by the medical profession as well as by the trade and industry. Drugs are invariably used to alleviate sufferings but at times these are used primarily to make profits My main theme in this paper would be about steps which could be taken by the authorities in a developing country towards the improvement in drugs used by the medical profession.

I would like to comment on the term "developing countries". The economists will classify countries according to the per capita income and thus, the developing countries lie at the lower end of the line. Thus, there is a scarcity of money for purchase of drugs as compared to other national projects. Diseases are more prevalent in a developing country and thus, more care is needed by the authorities to make drugs available at cheaper rates by using the local raw material to the maximum.

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The other important characteristic of developing countries is their diseases pattern. In the West, communicable diseases have been well controlled and it is even difficult at times to find even a single patient for demonstration to the medical students. While on the other hand tuberculosis, typhoid, smallpox, cholera, etc., usually occur in epidemics in the developing countries; thus, special drugs are needed to control these diseases.

Climate: I held discussion with Mr. Kolb, who has founded the famous Karl Kolb Instrument Company in Frankfurt. He was of the opinion that relationship exists between the climate in a country and its scientific advancement. Mr. Kolb's hypothesis was that it is because of the longer spell of winter in Japan and China that they are today classified as developed countries than the rest of Africa and Asia having very warm climate. I disagree with him and can say that if we can work hard, according to a good programme, there is nothing in the way of improvement not only in the field of drugs but in every sphere of our national life.

Public Opinion: Public opinion can contribute a lot towards the improvement in a society. If you park your car without keeping the lights on, in a street of Edinburgh, passerbies would certainly condemn you for doing something illegal and the police is sure to give you a ticket. While in the developing country many people could get away with such an irregularity very easily. I wish to bring out one point that in a society where certain irregularities are not prone to condemnation by the public it makes the job of a government machinery very difficult.

I noted in the United States during my visit to the Headquarters of the American Medical Association at Chicago that the opinion of the American Medical Association is so binding and vital for the United States Government that the President of the United States will not sign any document relating to the profession of medicine without having the views (concurrence) of the American Medical Association. The situation in Pakistan is different. Although, the Pakistan Medical Association at the centre as well in the various zones have organized themselves and are concentrating their views on the various problems relating to the practice of medicine in this country. There is a lot more to be expected from the Pakistan Medical Association

to come out with concrete plans and suggestions to the Government and help its members to get effective, safe and cheaper drugs available for their patients. I would also like to say that general public in Pakistan though critical at times about the sporadic incidence of spurious drugs have no opinion of their own. I invariably find foreign residents in Pakistan and especially their women folk criticising the availability even of a drug like Sulphadiazine at the Chemist shop without prescription because they are not used to this easy axcess to drugs in their own countries. On the other hand, Pakistanis going to the United States or other developed countries criticise their system where Chemists will never dispense even a drug simpler than Sulphadiazine. One would expect in the developing countries that the opinion of members of the medical profession in particular and that of the public in general would form a great force in helping the Government in Drug Control.

The subsequent speakers will be discussing the various steps which the drug control administration at the government level has to take and to scrutinize the details about medicines and drugs. Thus, I need not give these details and will concentrate on a few areas in the drug control in Pakistan which could offer improvement in our drug therapy. I will use Pakistan as a model of the developing countries. My observations are based on my personal experiences of the last 11 years as a teacher of Pharmacology and Therapeutics both at the undergraduate as well post-graduate level, for the students of Pharmacy, Dentistry and Medicine in Pakistan. I have also played a small role in the drug control administration in the form of heading laboratories as well I have maintained an active interest in the subject. My career is an example for the medical men in the developing countries to specialize yet in another branch of medicine, called drug control which can

have far reaching effects on the practice of medicine in a developing country rather than restricting oneself to the teaching of Pharmacology and Therapeutics at an under-graduate medical school for decades. My comments on various steps of drug control are as follows:-

Product Registration. It was on the 14th of August, 1947 that the newly created Government of Pakistan started its activities in hutments in Karachi. There were no records about the drug control as these were left over at New Delhi - Capital of British India. Improvement has been made in the Drug Rules, thus, inherited. A number of obsolete drugs which were official in the past and were considered as miracle drugs continue to stay with us in official capacity even today. The pharmaceutical houses, continue to sell the products not only in the large cities but also in the far flung rural areas. These obsolete drugs are usually used by the large number of quacks in Pakistan.

Every new drug has to be registered with the government as an important safeguard for the public. Switzerland has introduced a system where after every five years the manufacturers have to produce evidence about the safety and efficacy of their drugs to be allowed for continued sale for another period of five years. We are also aware of the noble efforts of the Food and Drug Administration in the United States in the form of KEFAUVER HARRIS amendment to the United States Pure Food and Drug Laws. It is for the first time that such amendment since 1938 has been initiated after thalidomide tragedy. Food and Drug Administration today rigidly requires proof of efficacy and safety of new drugs to be registered with F.D.A. But the second and important provision of this amendment was that all drugs permitted between 1938-1962 in the United States were to be

re-evaluated by F.D.A. for the newly required proof of efficacy as well as safety. In case of questionable efficacy the drug has to be withdrawn from the market. About 4000 drugs were involved in this venture. It was in 1966 that Dr. James Goddard, Commissioner of Food and Drug Administration requested president SEITZ of the National Academy of Sciences who in turn approached their drugs research board which was composed of Clinicians, Pharmacologists, Toxicologists, Pathologists and Scientists from drug industry to do this gigantic job. I wish to quote that BIOFLAVONOID, a drug included in this list has the following ambiguous and doubtful therapeutic indications:-

Habitual and threatened abortion, nose bleeding, little strokes, diabetic retinits, bleeding gums, gingivities, pyorrhea, menorhagia, Rh. incompetibility, cold and influenza and post operative bleeding. They also had drugs which claim to produce effect on various systems of human body when given by mouth but these were actually not absorbed from the Gastrointestinal tract (Prof. Gillman, 1968). I considered this a unique experiment carried out in the United States. I hope that description of this experiment will provide food for thought during this seminar with special reference to the developing countries.

Examination of the Drug Samples. You have learnt the procedures adopted in Pakistan about the examination of Drug Samples. I wish to bring out one essential amendment in our drug rules that a drug control laboratory both in the province and at the Centre need to have a theoretical permission to inspect the pharmaceutical industry, Chemist shops, Hospitals, etc., for collection of samples of drugs for analysis. This step will certainly remove the long standing objection which we have while working exclusively

in the laboratories with no direct approach to the field and thus, are in a way slaves of the Drug Inspectors or Assistant Drug Controllers who usually send the drugs specimens to us.

Evidence of efficacy and safety to humans by the Pharmaceuticals.

Upto the end of First World War and before the present Drug Revolution, most of the pharmaceuticals were neither harmful nor produced any marked effect. The drugs available today are very effective and are liable to produce toxic effects even in smaller doses if given injudiciously. Thus, a great responsibility lies on the manufacturers to prove the efficacy and safety of their products to the drug control administration in any country. In a developing country like ours where facilities for carrying out clinical trials are limited, I arranged a special session in August, 1968 during the 7th Annual Symposium at the Jinnah Post-graduate Medical Centre, Karachi on the "Need, Scope and Development of Clinical Evaluation of Drugs in Pakistan". The primary aim of this session was to see whether it was necessary to carry out clinical evaluation of drugs in Pakistan or shall we allow the sale of new products which have been approved by the Food and Drug Administration/Dunlop Committee etc. Representatives of the Pakistan Pharmaceutical Manufacturers Association, Pakistan Medical Association, Drug Control Administration and other independent Scientific Profession presented their views. One point came out very clearly after the 2 1/2 hours discussion that there is a need for strict scrutiny by academicians of the data presented by the manufacturers to the Government of Pakistan with regard to the efficacy and safety of new drugs. Decision was taken that the Government of Pakistan be requested to set up a Committee of Clinical Scientists who should take this responsibility. The

manufacturers agreed with this suggestion after some initial reservations (Khan 1969).

A special symposium was also held on the "Impact of Drug Regulations on Drugs Research" at the 4th International Pharmacology Congress held at Basel, Switzerland in July, 1969. Whether in a developing country, the drug control administration is justified to ask the pharmaceutical industry to obtain fresh evidence regarding effectiveness and safety of new drugs intended to be introduced was discussed. Professor Gross of the Heidelberg University (formerly with CIBA, Basel) in his paper did not consider any need for repetition of Clinical Trials if a drug has already been cleared by the Food and Drug Administration/Dunlop Committee etc. I argued with Professor Gross that his statement cannot be considered true in a generalized way as areas do exist where a country can offer some facilities keeping in view the disease pattern as well some minor pharmacological race variations. Professor Raskova of Czechoslovakia strongly supported my views. Professor Gross later modified his stand and said that it is for the drug control administration to decide whether some limited clinical studies on the imported drugs could be carried out at least to prove their suitability, dosage, etc. as well their effectiveness. India requires definite evidence for effectiveness and safety of the new drugs, obtained in India.

I am very glad to inform you that I received a letter from the Ministry of Health, Government of Pakistan recently signed by Mr. Fazlur Rahman/Drug Controller about the formation of a Drug Evaluation Committee as suggested during August, 1968 symposium at Karachi. The terms of reference for this committee are to evaluate the safety, efficacy and quality of new drugs

before permission to import is granted. The committee consists of Pharmacologists, Clinicians and Pharmaceutical Chemists, etc. It will be through the deliberations of this committee with the co-operation of the pharmaceutical industry in Pakistan that clinical research on drugs to the advantage of our industry and of medical profession in Pakistan will be developed in future.

Improvement in Drug Standardization facilities. We have recently reviewed this subject (Khan et al, 1968). The incidence of drugs being sub-standard or spurious will continue in any developing society unless the government sets up institutes, in all respects, to carry out complete analysis of drugs. Pakistan during the last two years has gone well ahead in improving its analytical laboratories. The establishment of the Drugs Research Institute, at National Health Laboratories, its facilities and staff with the active help of WHO is a unique example. The people usually ask me about the efforts on the part of the Government of Pakistan about ensuring the availability of standard drugs to our medical profession. My reply is straight-forward and I assure them that the availability of sophisticated equipment and well trained staff in our quality control laboratories is the most essential step in this direction. In these laboratories very small quantities of drugs can be spotted out even when present in a mixture and this, is a great safeguard against the evil designs of criminals who sometimes try to gain money through the production of spurious drugs. I will add at this stage that the punishment to these criminals should be made exemplary.

Planning for the Drug Development. I wish to repeat my suggestion presented at the seminar "on the role of Drug Research Institute at

Islamabad" in June, 1969 at these laboratories. There is an urgent need for proper planning of the drug industry according to the need of the country. The disease pattern in our country is different from that of the West. One would expect that we should stimulate drug research towards the solution of our own problems. The government always guides the activities of the pharmaceutical industry who wishes to do business in Pakistan. There is not much need for the vitamin preparations or hormones which stimulate growth, preserve vitality and sex, but should very much like to eradicate the communicable diseases. It is also the responsibility of the government to plan and create basic chemical industry and facilitate pharmaceutical industry to carry out basic manufacture of drugs by giving them all facilities and protection. In developing countries like ours, 5 years development plans are regularly prepared. Our 4th Five Year Plan is going to start from 1 July 1970. It is necessary that a full chapter on the development of pharmaceutical industry in Pakistan meeting the requirements of our people be incorporated in this plan. I have suggested for the creation of an Inter Departmental Committee for drugs, where representatives form the Government, Ministry of Health, Commerce, Export Promotion, Trade and Industry and other relevant departments like Agriculture, Forestry and Research Organizations on the pattern of our Inter Departmental Committee on Nutrition, be established to advise the Planning Commission about our drug needs in the session to come.

Medical and Pharmacy Education. The Pakistan Medical Council which is located at this campus controls our medical education and practice of medicine. Modification in our syllabi at the under-graduate level continues to improve medical education of our doctors. A time has come

that through the Pakistan Medical Council an effort should be made also to improve the knowledge of Clinical Pharmacology of the practising doctors long after they qualify from the medical schools. This is an area where WHO can help us in educating our practising doctors in using the drugs safely after the Government provides them safe drugs. It is heartening to say that the Government of Pakistan has established a Pharmacy Council similar to the Medical Council. This council is considering standardization of Pharmacy Education at the undergraduate and postgraduate level. This is another field where WHO can assist in the developing countries.

S U M M A R Y

In the developing country, the role of the Government is more important in development of safe and effective drugs as well as its use by the medical profession as compared to the developed countries where the opinion of the medical man as well as of the public is an important safeguard.

R e f e r e n c e s

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