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REPORT

URGENT NEED FOR DEVELOPING CLINICAL PHARMACOLOGICAL SERVICES IN PAKISTAN

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On the 14th of August, 1997, Pakistan celebrated its 50th anniversary of gaining independence. The present population is 130 million people. The pharmaceutical industry began from a scratch and presently has a large drug market of 650 million dollars. Pakistan has 25 schools of medicine and 5 post-graduate medical institutions and a college of - Physicians and Surgeons (CPSP). There are 9 schools for pharmacy. There is one doctor for 1,880 people. The growth of the pharmaceutical manufacturers has gone up to 275 out of which 31 are multinational companies who earn up to 70% of the profit. There are at least 1,200 pharmaceutical products registered in Pakistan.

The Pakistan Drug Act of 1976 is now 28 years old and it requires carrying out of clinical trials on new drugs prior to registration in Pakistan. Although the regulation does not make this compulsory but only desirable to undertake clinical trials. It is a fact that, based on reality that no expertise exists in clinical pharmacology in the entire country, that means academia, pharmaceutical industry and governmental institutions who provide and manage drug supplies. There are only two clinical pharmacologists, one of them has just retired, and the other one is responsible for the expanded programme of immunization at the National Institute of Health in Islamabad. Only Phase IV trials are carried out, with some very few Phase III trials.

During 1995-96, I visited Pakistan five times, each visit lasting 3-4 weeks. This was under invitation of various organizations; WHO Headquarters, EMRO, UNDP and national and regional authorities. The aim was to strengthen national and institutional efforts to promote the rational use of drugs in Pakistan. I specifically investigated the existing clinical pharmacological facilities, primarily in the educational institutions, and as to how to strengthen these facilities. I made visits to most of the schools of medicine, selected schools of pharmacy, and district headquarter hospitals in NWF Province. I had discussions with health administrators in the Federal and all the four provincial governments. I also visited the Pakistan Medical and Dental Council and officials in the trade, industry and professional organizations of doctors, nurses and pharmacists. A drug utilization study group was able to carry out a study in 3 university hospitals in Rawalpindi and Islamabad.

In January 1997, a new drug policy for Pakistan was approved and I have collaborated with the Ministry of Health in preparation for the implementation of this policy.

NEW PERSPECTIVE

1. I have learnt that during the third biennial conference on Pharmacology and Therapeutics held at Karachi on 16-17 January, 2005, the participants appreciated the efforts of the Pakistan Pharmacological Society in the regular publication of Pakistan Journal of Pharmacology, its recognition at the international level and holding the biennial conferences. However, it was felt that Society has not given due attention for the promotion of Clinical

Pharmacology in Pakistan. The participants suggested that Society should try hold a conference on this topic in Pakistan in November/December, 2005. Accordingly, the Society has planned to hold a Conference on Promotion of Clinical Pharmacology in Pakistan in 3rd week of December, 2005.

I am happy with this decision and wish all the success for this important conference. the European Association of Clinical Pharmacology and Therapeutics and the British Pharmacological Society and WHO will respond positively when invited for participation.

2. The drug utilization study was carried out in the Pakistan Institute of Medical Sciences, Islamabad, Rawalpindi General Hospital and the Military Hospital, Rawalpindi. During the autumn of 1995, 601 prescriptions from medical, pediatric and psychiatry units, from in-patients and out-patient units were analysed. The mean number of drugs was 2.97 per prescription. 23.6 per cent were prescribed by generic names. 80.25 per cent were from the national list of essential drugs. 17.12 per cent were injectables. 20.42 per cent were antimicrobials. The average cost per treatment per day was 26.10 Rupees in out-patients and 88.36 in in-patients. Treatment did not co-relate to the diagnosis in 24.63 per cent cases. Doses of drugs were inappropriate in 30.62 per cent cases. The duration of treatment was not specified in 73.38 per cent cases.

3. The Ministry of Health, Islamabad, has taken significant steps to promote rational drug use during the last two years. Training seminars were organized in individual institutions all over the country for doctors, pharmacists and nurses. The national essential drug list was revised in 1995, containing 250 drugs. A book was published, containing Pakistan Drug Information Sheets, with support of WHO. Above all, the new drug policy was approved by the Government.

4. Doctor International Publication and now its successor is a bi-weekly paper which informs doctors and pharmacists on steps to promote rational use of drugs. It can be a further help in these efforts.

5. The Newsletter of the Network for the Association of Rational Use of Medications in Pakistan has informed the health care professionals and now the public, on the need for reducing the number of drugs on the market as well as to reduce the price of drugs. I do hope that they will also include education of doctors and, in particular, creating expertise in clinical pharmacology to enable doctors to offer opinion on issues which they often raise with the authorities regarding adverse drug reactions. One of their paper on chlormazanone creating severe skin reactions and urging banning the production of this product. In this briefing, one factor is significantly lacking. That is the views of the Pakistani specialists working in the country. Let us hope that network will address itself to the training of manpower in Pakistan and generating data in the country. They obtain significant financial support from abroad. The network should also acknowledge the positive efforts made by the authorities in Pakistan in promoting the rational use of drugs.

6. CPSP has initiated a fellowship programme in clinical pharmacology four years ago. What they urgently need now is qualified staff in clinical pharmacology, laboratory facilities and hospital beds. The College has also initiated a programme for monitoring adverse drug reactions but their effort has so far been to organize national conferences and dissemination of information. What is lacking is actually qualified staff to go to individual hospitals and generate data, validate it and publish it. The example of drug utilization study should be followed.

7. Aga Khan University in Karachi has an excellent pharmaceutical supply system. They are also entrusted with adverse drug reaction monitoring, but their efforts are limited to collecting date from the literature. It is regretted that in the conference organized in Lahore by CPSP and the Royal College of Physicians in Glasgow, which was dedicated to adverse drug reaction monitoring, but no data was presented from Pakistan.

New Drug Policy

The important features of the new drug policy are; (1) to develop and promote the concept of essential drugs, and to ensure regular, uninterrupted and adequate availability of these drugs of acceptable quality at reasonable prices, (2) to inculcate in all related sectors and personnel the concept of the rational use of drugs and safeguarding public health from overuse, misuse and inappropriate use of drugs; (3) to develop adequate trained manpower in all fields related to drug management and to develop a reasonable base, particularly for operational and applied research; (4) for registration of new drugs, the fact that the drug is registered in one of the specified countries, that is the USA, European Union particularly the UK, Switzerland, Japan and China, would be necessary, using also their criteria for post-registration activities; (5) improvement in hospital pharmacy, community pharmacy and aiming to have at least one pharmacist for 50 hospital beds. Major efforts will be made to promote rational drug use, which will include regulation of promotional activities. Ethical criteria will be developed by monitoring drug promotion, using WHO guidelines. More copies of the national formulary will be published and made available to every health care professional in all categories. Standard treatment guidelines for important diseases will be published and circulated widely; (6) drug information and adverse drug reaction monitoring, through computerized drug information and poison centres and adverse drug monitoring centres will be created. Post-marketing surveillance studies of newly marketed drugs will be undertaken and data will be made available to health care professionals. In human resource development, availability of qualified clinical pharmacists and clinical pharmacologists are the most important factors which will be attended to. Undergraduates, post-graduates and in-service training programmes for all categories of doctors, pharmacists and other health care professionals are an important area of the new policy; (7) preference will be given to operational and applied research, in the following areas, in particular; (i) exploitation of local resources for basic manufacture of drugs, (ii) development of new drug from local resources, (iii) studies in rational drug use and drug utilization studies, and (iv) traditional medicine.

RECOMMENDATIONS

1. A major effort is needed to outline ways and means to promote the rational use of drugs in Pakistan through the creation of expertise in clinical pharmacology. This can be done by organizing a meeting by Pakistan Pharmacological Society, Ministry of Health, CPSP, and Pakistan Medical Association, European Association of Clinical Pharmacology and the British Pharmacological Society. WHO should be asked to co-sponsor this meeting. The modified Programme of WHO can play a leading role in this efforts.

2. Fellowships must be offered to Pakistani clinicians in clinical pharmacology abroad. At the same time, positions must be created in schools of medicine and drug control administration for clinical pharmacologists.

3. Pakistan Medical and Dental Council can, without delay, revise its teaching programme in clinical pharmacology and therapeutics for undergraduate, post-graduate and in-service training for re-registration of doctors.

4. The pharmaceutical industry has now a good opportunity to come up and assist the Government in the new drug policy implementation by training clinical pharmacologists through their efforts.

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