THE NETWORK'S

NEWSLETTER Rx

Association for Rational Use of Medication in Pakistan

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Herbal Medicines

A large segment of our population still visits hakeems and homeopaths for getting remedies for their illnesses. As a matter of fact it has been estimated that in the rural areas 80% of them visit traditional hakeems who dispense medicines supposedly extracted from herbs roots etc.

With the advent of modern therapeutic products, these drugs also have become part of armamentarium of traditional healers. The lax control of these potent pharmaceutical agents by the government has put these drugs in the hands of those people who are not qualified to use it. Most of these drugs are given in the guise of herbal medicines.

The Drug Act of 1976 does not consider substances or mixture of substances prepared for use in accordance with Ayurvedic, Unani – Homeopathic or Biochemic system of treatments. Therefore these would not be included in the definition of "drug" of the Drug act. The functionaries of Ministry of Health are not empowered to seize these product for analysis. This serious loophole has allowed the practitioners of these systems of treatment to use drugs like steroids, antibiotics, psychotropics to be used in the guise of herbal drugs.

In the present issue Dr. Balasubrmanium has raised very pertinent issues concerning consumer protection, regulation, pattern of consumption and consumers perception of herbal medicines. The use of traditional medicines in selected countries including Pakistan has been lucidly discussed.

The use of modern medicines under the garb of herbal medicines may be a phenomenon peculiar to Pakistan. The Ministry of Health needs to change the Drug Act to include all substances used as drugs in the traditional system of medicine to regularize their use for protection of consumers.

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The Network's mission is to promote rational use of medication and essential drugs concept in Pakistan in order to optimize the usefulness of drugs and help bring equity in their access.

Drug manufacturers pay no heed to Cabinet's decision

In complete violation of the Cabinet's decision to reduce the prices of drugs by four per cent, dauntless manufacturers have instead made an arbitrary increase of 18 per cent in the prices of Regular Insulin injection and Protamine Zinc Insulin. Both the U40 Regular Insulin Injection as well as Protamine Zinc Insulin are manufactured by Lilly pharmaceutical company. The prices of these drugs have been raised from Rs. 63 to Rs. 75.60 and from Rs. 76 to Rs. 93.40, respectively.

After Reckitt & Colman, Lilly is the second manufacturer to have raised the prices of drugs, and the first to have flouted the Government's decision. Reckitt & Colman had increased the prices of Disprin and Paracetamol by 83 per cent and 50 per cent, respectively. Despite a lot of hue and cry, authorities in the Ministry of Health failed to reverse the increase.

Not a single pharmaceutical company has honored the Government's decision of not charging sales tax with effect from August 15, 1997. The way things are going, it will be unwise on part of consumers to expect any kind of relief. Drug manufacturers have already flooded the market with their products, and until the current stocks are exhausted, there will be no change in the situation.

The Pakistan Chemists and Druggists Association has sought the Government's intervention in the matter. It has called for the establishment of an efficient drug monitoring system so that the prices and availability of drugs can be scrutinized. Moreover, it has also sought the withdrawal of increase in prices of Disprin, Paracetamol, Regular Insulin Injection and Protamine Zinc Insulin.

Source: Saad Khan, The News International, Friday, August 22, 1997

9th Five Year Plan: report of the working group on essential drugs

In May and June the Network participated in various preparatory meetings for 9th Five Year Health Development Plan. Professor Tariq Iqbal Bhutta was invited in the first meeting in Lahore in which a strategy was developed to work on various aspects of Primary Health Care (PHC). Nine groups were formed to work on various components of PHC. Executive Coordinator was invited then to serve in the working group on Essential Drugs. After various meetings in Islamabad and Lahore a final report was submitted by the group. Following is the full text of the report:

Development Of Essential Drug Package

There is a comprehensive National Drug Policy in place, which forms the foundation of 9th Five Year Plan for essential drugs. Over the recent past, the Ministry of Health and Provincial Health Departments have formulated essential drug lists, Procurement Via Medical Store (PVMS) list and formularies. Indenting, procurement and distribution system, along with medical store depots are in position. However, there is a general complaint by public and health care providers that essential medicines for treating common ailments and emergencies are usually not available in government health facilities and some available drugs are not relevant. Also, there are concerns about irrational use of drugs.

The 9th Five Year Plan aims to provide free medical treatment of common diseases and emergencies to all patients; ensure regular supply of very essential drugs; promote rational use of drugs; and give free treatment at all levels to patients coming in casualty, labor room and operation theater for at least the first 24 hours.

The main strategy is to provide the most important services to the maximum number of people at minimum cost. The Ministry of Health has finalized a national list of 470 essential drugs.

This will be adopted and updated periodically to keep the number at a minimum. The load of patients and the available resources may not be able to cope with the needs of people. Therefore, a list of very essential drugs and equipment for all levels of PHC will be formulated based on the load of diseases with highest incidence, mortality and complications. These few drugs/vaccines and items will provide free preventive and curative treatment to more than 80% of patients with less than half the already available resources. All drugs outside this list but on the national list may be procured and provided from the remaining resources. Those outside the national list may be purchased by the user. Essential drug lists for various levels of care will also be prepared.

The specific operational plan is as follows:-

Drugs Requirement Estimate

Initial drugs requirement will be worked out annually for each health facility on the basis of disease burden and catchment population for OPDs, while for causality, labor room and operation theater it will be estimated on basis of previous year's patient load and requirement. This will be consolidated district wise/hospitals wise, well in advance, for coming year. From second year onwards, it will be updated according to facility wise consumption and utilization.

Procurement System

The drugs will be procured at the provincial level and distributed to the district level. Requirement worked out as above will be consolidated before February for the next financial year. The process of tendering, technical scrutiny, finalization of purchase proposals at respective level, award of rate contract and purchase orders will be completed by the first of June at the provincial level. The distribution should be in-built in the procurement award.

Distribution/Payment Plan

At the district level, distribution of procured drugs will be quaterly by the manufacturers /sales agents.

The quantity and physical quality on the bill will be verified by the respective authority of the district. The verified bills will be attested by respective Director Health Services for payment from Director General Health Services Office.

Quality Assurance

The proposed quality control will be carried out at manufacturing level by the incumbent as well as by the health authorities. The district/divisional drugs inspector (who will be provided distribution list along with batch number) will draw sample of different batches at district level. The capacity of Drugs Testing Laboratory will be enhanced and it will be decentralized.

Rational Use of Drugs

Policy of prescribing specific and minimum drugs for a particular disease will be strictly implemented for economic use of essential drugs as well as to prevent the drugs resistance and incompatibility. The list of disease specific very essential drugs will be published and displayed in all OPDs. The specialists will be informed regularly by Government circulars to refrain from prescribing costly and non-specific drugs. The drugs showing severe side effects, or recommended for ban by World Health Organization or not used by the country of origin, will be immediately de-registered and their sale in private and public sector will be stopped.

The policies of drug registration and issuance of drugs sale licenses will be reviewed in order to minimize the number of registered drugs and drugs sale licenses respectively.

Work Plan for 1998-2003

1998-1999

- Approving and implementing the essential drugs and equipment plan.
- Approving the essential drugs/equipment lists.

1999-2003

Annual

- Revising/updating the essential drugs /equipment lists
- Estimating drug requirements for districts
- Preparing rational drug use plans/educational materials

Quarterly

- Preparing distribution and payment plan for district

Continuous Process

- Procuring essential drugs/equipment
- Conducting quality assurance

Non-availability of essential drugs

Essential drugs are further diminishing from the market place. People in Pakistan have less and less choice to buy effective, safe and yet cheaper drugs for their more common medical problems. In other words, they have to buy expensive alternatives to essential drugs by spending their very scarce resources. Not infrequently, people first have to sell some thing to buy the "necessary" medical care (of which drugs form a major part) and in doing so, many a times, they have to compromise on other necessities of life.

In this case the role of the Health Ministry, as provided in the statute, is to ensure the regular supply of all the registered products in the market. Obviously, the MoH has failed to fulfil its legal responsibility. Economic imperatives are ruling the scene. If a company can earn more by making expensive alternatives to the essential drugs, why should it even consider offering cheap alternatives to the people and spoil the market for their goodies especially if it also knows that the MoH can keep its eyes shut to the aftermath. And this is what is happening.

Where should people turn to in this case? One has to knock at the door of justice. And that is what the Network decided to do eventually.

Following is the step by step account of the efforts of the Network to raise this issue of non-availability of essential and life saving drugs with the authorities concerned:

The Network wrote a letter to the Director General Health, Ministry of Health, Islamabad in which the Network directed the attention of authorities towards the non availability of life saving drugs and the steps that could be taken in order to improve the situation. Copies of this letter were sent to the following.

President of Pakistan
Chief justice of Pakistan
Prime Minister of Pakistan
The Federal Ombudsman
The Federal Secretary for Health

In return the Ministry of Health did not bother to respond. However, the Federal Ombudsman acknowledged the receipt of the letter sent by the Network and drew the attention of Secretary Health division towards this vital issue.

It was only after recieving a letter from the Federal Ombudsman that the Director General contacted us, thanking us for pointing out this important problem! He mentioned that they have sent show cause notices to drug companies responsible for the non non-availability of essential life saving drugs and that further action will be taken in due course.

Again the Federal Ombudsman has sent us the copy of the letter that they received from Health Ministry depicting the so called "improvement" in the situation. However, the Network again, contested the MoH view of presumed improvement and asserted with evidence that the situation had not substantially improved and needed an institutional action, rather than quick-fix-solutions. The most interesting solution to the problem suggested by MoH is that they have made up a list of non-available drugs and they are asking more companies to apply for registration!

Our current survey shows the non-availability of almost sixteen very essential drugs from the market. We have prepared a detailed table about the situation in which our team has not only identified the non-available and drugs in short supply but we have also worked out details about the available therapeutic alternatives and most importantly the price differentials between the two. As you will see, consumers are paying much more than they should in case of availability of these essential drugs.

Request to supporters

We request all our supporters to help us in monitoring the market situation about the availability of essential drugs. When you find an essential drug missing please do inform us and we will continue to compile the latest situation and present it in the newsletter and to the authorities for remedial action.

Details about non-available essential drugs

No.	Trade Name	Generic Name	Dose Formulation	Manufacturer	Included in *PNEDL	Price in Pak Rs.	Closest available Alternat	
							Trade Name	Gene
1	Lanoxin	Digoxin	.25mg; tab	Glaxo Wellcome	Yes	Rs. 6.63 per 25 tablets		nil
2	Neonaclax	Bendrofluazide	2.5mg; tab	Glaxo Wellcome	Yes	Rs. 3.55 per 25 tablets		Indapan
3	Adalat	Nifedipine	10mg; caps	Bayer	Yes	Rs. 111.89 per 30 tablets		Nifedipi
4	Saventrine	Isoprenaline	30mg; tab 2mg/2ml; inj	Pharmax Ltd.	Yes	Rs. 189.75 per 30 tablets		nil
5	Pencillin V Syrup	Phenoxymethyl penicillin	125mg/5ml syrup	Glaxo Wellcome	Yes	Rs. 22.53 per 60 ml bottle		Erythror
6	Ventolin	Salbutamol	100 mcg. per actuation inhaler	Glaxo Wellcome	Yes	Rs. 76.10 per aerosol canister		Salbutan
7	Isoket	Isosorbide dinitrate	11 ml; spray	Schwarz	Yes	Rs. 148.65 per bottle of spray		Nithrogl
8	Insuline regular	insulin (beef)	.10 ml vial	Lilly	Yes	Rs 63.78 per vial		Beef insu
9	Ventolin	Salbutamol Sulphate	5 mg/ml; sol	Glaxo Wellcome	Yes	Rs. 25.49 per sol		Salbutan
10	Norcan	Naloxone Hydrochloride	.02 & .4 mg/ ml; inj	Boots-Knoll	Yes	.02 mg. 12 ml-pack of 10 @ 124.5/inj. .4 mg. 11ml-pack of 10@ 139.7/inj		nil
11	Polyvealent	Anti snake venome	10 ml vial	National Institute of Health (NIH)	Yes	Rs. 558 per vial		Anti sna
12	Dextran 70	Dextran	500 ml; drip	Otsuka	Yes	Rs 65.07 per drip		Plasma l Osscua (
13	Coumadin	Warfarin	5 mg; tab	Sandoz Pak. Ltd.	Yes	Rs. 756.06 per 100 tablets		Warfarir
14	Camcolit	Lithium Carbonate	400 mg; tab	Norgin Limited England	Yes	Rs. 113.84 per 100 tablets		Lithium
15	Dilantin	Phenytoin sodium	100 mg; caps & 30 mg/5ml	Parke Davis & Co. Ltd.	Yes	Rs. 51.30 per 100 tabs		Phenyto tab. by Mere
16	Calan	Verapamil	40, 80 & 240 mg; tabs	Searle Pak. Ltd.	Yes	Rs. 70.33 per 50 tablets Rs. 48.82 per 20 tablets. Rs. 62.79 per 10 tablets.		Verapmi

Source of information is market survey, available drug compedence and d

...ative ...neric Name	Price in Pak Rs.	Price Difference	Comments
	nil	nil	Lanoxin (.25 mg), an essential drug for heart patients has been missing from the market for about six months. Lanoxin is a relatively cheaper drug, manufactured by Wellcome. When asked Wellcome says that they are producing enough quantities "but it is being smuggled." Unfortunately, there is no substitute for" this essential medicine in the market.
...mide	169/30 tabs	+5.49 for each tab	Neonaclax for congestive heart failure and hypertension is not available now for a long time. Pakistan is the only country where it is not available. It is the most important and firstline treatment of hypertension all over the world.
...pine	175/50 caps	-0.2	Adalat remains most effective Nifedipine preparation for prophylaxis and treatment of angina and has bee absolutely not available in the market for a long time.
	nil	nil	Saventrine, is also missing from the market and it is said that the manufacturer has allegedly stopped producing it. All formulations are missing.
...omycin	nil	0	Penicillin syrup by Glaxo Welcome is absolutely not available in the market for quite some time now.
...amol	78/aerosol canister (200) inhlations	-1.90	Ventolin inhaler is not openly available in the market and is being black marketed. The alternative Vanex is also in short supply.
...oglycerine	246.40/10 gm aerosol	-13.16	Isoket spray by Schwarz is not available.
...nsulin	vial 40 iu/ml 10 ml is Rs 40	-16.6	Insulin regular for diabetic patients by Lilly is not available.
...amol sulphate	75.13 / 5 injs.	See Comments	Ventolin Respirator solution is not available. In its absence Ventolin injections are poured in the repirator. 1 dose, if made by sol. (5mg/1ml), cost Rs. 1.271/dose, if made by pouring injs., 10 injs. of .5mg are required which cost 75.13x2= 150.26 each dose cost excess of Rs 149 to consumers just because of non-availability of the solution which is allegedly short supplied by the manufacturer precisely due to above mentioned profitability.
	nil	nil	Norcain, antidote for morphine is not available. Many other antidotes are also not available.
...nake venome	558 / vial	0	Polyvalent anti snake is very important as it provides immediate relief to patients and is not available.
...a bag by ...a (500 ml bag)	242 / per drip	+177	Dextran has not been available in the market for a long time now. Its alternative in the market is double in price.
...rin	240 / 5 tabs.	+46.86	Coumadin, a life saving anti-coauglant is not available in the market for long time now and its alternative is extremely expensive.
...m carbonate	277.41/100 tab	+163.57	Camcolit is used for manic depressive illness. It is not freely available.
...toin 100 mg ...re-Doa	143 / 300 tabs	+.037	Dilantin, a cheap remedy for epilepsy patients is not readily available in the market. Other alternatives (Tegretol, Epilim etc.) are far more expensive.
...mil	39 / 40 tabs 20 / 81 tabs	+0.4316 +2.194 +6.0321	Calan (Ca Antagonist) is absolutely not available ,and its alternative in the market is double than its price.

...d direct from manufactureres and retail sellers.

* Pakistan National Essential Drug List

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Dr. Bala is a great inspiration for all those working for rational drug policies in developing countries. He is a long standing friend of the Network.

This article is an abridged version of a paper presented by the author at International Symposium on Herbal Medicines, Honolulu, Hawaii, USA, June 1-4, 1997

Herbal Remedies: Consumer Protection Concerns

Introduction

There is now ample documented evidence that people in both developed and developing countries are purchasing and consuming herbal remedies and traditional medicines in increasing amounts. There is also evidence that some of the herbal remedies in the market are not safe, effective and of good quality. This raises the issue of consumer safety.

It is useful to classify herbal remedies into the following three categories:

1 Phytomedicines or Phytopharmaceuticals sold as over-the-counter (OTC) products in modern dosage forms such as capsules, tablets and liquids for oral use.
2 Dietary supplements containing herbal products, also called nutraceuticals, available in modern dosage forms.

These two types of herbal remedies are used by consumers in developed countries and those in urban areas of developing countries.

3 Herbal remedies consisting of either crude, semi-processed or processed medicinal plants and herbs. These remedies are available at two levels:
- Traditional beliefs, norms and practices based on centuries old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and may be called, "people's health culture", home remedies or folk remedies. These have a vital place in primary health care in developing countries.
- A codified system of traditional medicine at the level of the traditional healer.

Consumer concerns about herbal remedies are the same the world over. These include: safety; efficacy; quality; costs; unethical promotion, and irrational use of traditional medicine and herbal remedies.

Consumers believe that sharing of information on consumer protection measures between developed and developing countries would be advantageous to both due to the following reasons:

- Developed countries have effective and efficient regulatory control over modern pharmaceuticals. These may serve as useful models to enact appropriate legislation to regulate herbal remedies;
- Developing countries have had several centuries of experience with the use of traditional medicine in health care. Developed countries may find this experience useful;
- Neither developed nor developing countries have an effective regulatory mechanism to ensure the safety, efficacy and quality of herbal remedies;
- Almost all herbal remedies marketed in developed and developing countries are OTC products, although some of these are known to be toxic;
- In both developed and developing countries a herbal medicine, if marketed as food, is not regulated; but if the same product is marketed as a traditional medicine, it is regulated;
- In all developed and most developing countries, there are no systems, self-regulatory or otherwise, for the training, certification and registration of traditional healers or herbalists. Consumers have no guarantee that the traditional healers or the herbalists whom they visit to obtain health care have the necessary qualifications.

There is need to develop guidelines for national policies on herbal remedies which can serve as a model to enable countries to develop their own national policies on traditional medicine.

Regulation, patterns of utilisation and consumers' perceptions of herbal remedies and traditional medicines in selected countries

In the developed countries, consumers are making a deliberate choice in opting for herbal remedies. Their popularity is widespread in North America, Western Europe, Japan and Australia. In the developing countries, on the other hand, a vast majority of the people use traditional medicines because modern health care services are not accessible, available or affordable to them. (1,2,3,4,5)

International market prices of top-selling herbs have been published. Some of the more popular herbs such as Echinacea and Goldenseal sell for quite a high wholesale price of about $30-$50 per pound for their roots. The most expensive herb in the world is wild Chinese Ginseng. It sells for $1000 a gram and is traded in the market place. (6a) There is very little published data on retail prices of herbal remedies and how much consumers pay out of pocket for them particularly in developing countries.

Adverse reactions to herbal remedies reported in developed countries

There is a long list of medicinal plants that are toxic to the liver (38-41). Germander has been used with apparent safety for centuries. It was in the early 1990s, that Germander was first identified as a hepatotoxic drug.(42) In May 1992, all preparations containing Germander were withdrawn from the market and banned in France. This lead was not followed in Canada, where the first two cases of hepatitis were reported recently.(43)

Four cases of acute hepatitis attributable to single plants or mixtures were reported in British patients taking Vallerian and Scutellaria.(44) Valerian is one of the top selling herbs in the US.(45)

In Belgium 70 cases of renal impairment attributable to preparations based on Chinese plants were recently reported.(46)

A neonatal death where mother had been drinking herbal tea was reported in 1988.(47)

One research field that has been neglected and poorly studied is the potential interaction between herbal remedies and modern pharmaceuticals.(48) This is another consumer concern since many people both in developed and developing countries take herbal remedies and modern drugs together and do not reveal this to their physicians or pharmacists.

Developing Countries

Traditional systems of health care and herbal remedies were freely available in developing countries for several centuries. WHO came into existence in 1948. But only in 1976 WHO decided that traditional healers and midwives, previously seen as an obstacle to progress, must play their part.(49) The Traditional Medicines Programme under a Director was set up in 1978.

What is WHO's policy on traditional medicine? Does the WHO consider traditional medicine as merely a substitute for modern medicine when the latter is either not accessible, available or affordable to the poor in the Third World? Or is traditional medicine a valid health technology in itself?

In the mid seventies, it was estimated by the WHO, that about 80 per cent of the world's people had no

Worldwide Phytomedicine Market, 1994

per Dr Grunwald, PhytoPharm, Phytotherapeutics market

Country	Million US$ @ retail
European Union	6,000
Rest of Europe	500
Asia	2,300
Japan	2,100
North America	1,500
Total	12,400

Source: *Brevoort, P. "The Current Medical & Dietary Uses of Botanicals: A market perspective" In July 1996 USP Open Conferences on Botanicals for Medical & Dietary Uses: Standards & Information Issues. Proceedings of the Conference. United States Pharmacopeial Convention Inc.*

access to modern health care. As recently as 1993, it was reported by the Director of the WHO Traditional Medicine Programme that 80 per cent of the world's inhabitants rely chiefly on traditional medicines, mainly plant based, for their primary health care needs.(50) It is difficult to understand how this precise numerical value was arrived at and the particular research methodology used to determine it. It is relevant to note that this figure fits very well with the other side of the coin. More than 80 per cent of health budgets in developing countries are directed to services that reach approximately 20 per cent of the population.(51) This figure refers to modern health services.

Malaysia and Pakistan

Regulatory systems for the control of traditional medicine vary widely among developing countries. Malaysia, for example, introduced the Drugs & Cosmetic Control Act (1984) to regulate and control traditional medicine.(59) Only those preparations that are processed and presented in modern dosage forms such as tablets, capsules and oral liquids will be subjected to evaluation, approval and registration. Raw materials such as seeds, or any parts of plants will not be registered.(60) These will include herbs sold as food or drinks such as herbal teas which are not regulated. For example, the advertisement for "Tea of Longevity" states, "suitable and beneficial to many ailments including migraine, weak heart, hernia, menstrual pain, kidney stones, rheumatism, arthritis, sexual stress, impotence, frostbite, internal and external cancer and infections". A retail pack of 150 mg costs between 160-240 Malaysian Ringgits (US$62-96). (60b) This is equivalent to 10 days wages of an unskilled worker in Malaysia.

The mandatory registration of traditional medicines is not intended to give recognition to traditional healers, who are not recognised in Malaysia.(61).

Projected phytomedicine annual growth rate 1993-1998

Region	Projected phytomedicine annual growth rate in percentage 1993-98
North America	12++
European Union	8++
Rest of Europe	12
Japan	15
South East Asia	12
India/Pakistan	15

Source: *Brevoort P. op. cit.*

In Pakistan, on the other hand, traditional healers are registered by the Ministry of Health. They are responsible for the safety, efficacy and quality of the medicines they prescribe and dispense. There is no regulatory control of traditional medicines.(63) Not all the traditional medicines consumers use are purchased from the traditional healers. Regulating the traditional healers and not the traditional medicines will therefore, not ensure consumer safety.

Thailand

The Ministry of Health promotes the use of 66 traditional medicinal plants in primary health care (PHC). This is based on the scientific evidence of efficacy of these plants as well as on traditional patterns of utilisation. The Ministry of Health also promotes the use of traditional medicine in state-run hospitals and health service centres.

However, herbs are available in the market in various forms of commercial products, including cosmetic lotions, creams and soaps as well as a vast pharmacopoeia of herbal preparations in modern dosage forms. Food and dietary supplements with medicinal properties are also available. About 100,000 traditional healers were involved in the preparation of herbal medicines in 1987(69).

Republic of Korea

The Republic of Korea is unique in that traditional medicine is favoured equally by all levels of society. Health insurance coverage is available for traditional medicine and traditional medical practitioners typically earn more than modern medical practitioners due to the popularity of the traditional approach to health care. However, only 15 to 20 per cent of the national health budget is allocated for traditional medical service.(70)

The traditional medicine market is estimated at about $2 billion a year or per capita consumption of $46 per year.

It would appear that the Republic of Korea is perhaps the only country where pharmacists have to be licensed in traditional medicine before they can stock and sell traditional medicine.

India

Traditional medicine in India is regulated by the Drugs & Cosmetic Act 1940 (Act No. 23 of 1940). This Act regulates the import, manufacture, distribution and sale of drugs. A separate section deals with traditional drugs. There are three well known and widely used systems of medicine in India, namely Ayurvedic, Unani-Tibb and Siddha. Each system uses its own variety of herbal remedies. For the purpose of this Act, all herbal remedies belonging to these three systems are collectively known as Ayurvedic drugs.

Drugs & Cosmetics (Amendment) Act 1982 defines Ayurvedic drugs as follows:

"Ayurvedic drugs include all medicines intended for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative texts of Ayurvedic, Unani-Tibb & Siddha systems of medicine specified in the First Schedule".

Evaluation of traditional medicines

Clinical pharmacologists and other scientists working on medicinal plants focus all their attention on isolating and identifying biologically active ingredients in medicinal plants and herbs.

Traditional pharmacologists argue that the efficacy of herbal remedies is due to the synergistic activity among the several ingredients of herbal mixtures. Complex mixtures of plants or herbs form the basis of traditional medicines. The mixtures are usually subject to crushing, heating, boiling, etc. It is possible that this process may change the chemical structure of the active ingredient in the plants.

Traditional healers do not accept that the efficacy is necessarily due to the active ingredients in the plant. According to them, modern clinical pharmacologists by their "active ingredient" approach, take the knowledge from the plant but throw away the wisdom of centuries.

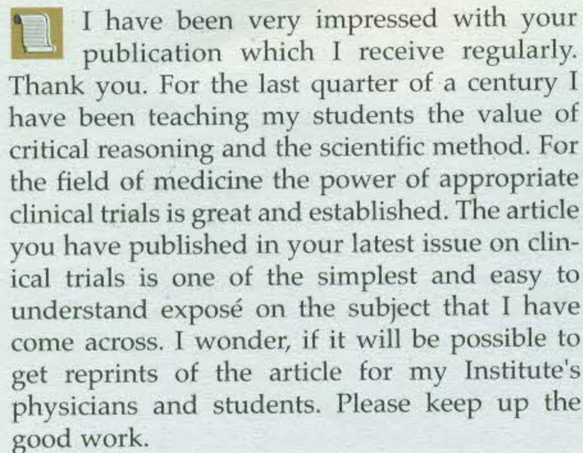
If there is acceptable historical evidence that traditional herbal remedies have been effective in the treatment of certain diseases, but neither their active ingredients nor the mechanisms are known, will it be ethical or moral not to accept and use that treatment? Some examples of successful treatment by traditional medicines will be useful to answer these questions.

In the late 1980s children attending the Dermatology Department, Hospital for Sick Children, London' showed marked improvements in their eczema symptoms. These improvements were due to oral treatment with aqueous decoctions of a mixture of 10 Chinese medicinal herbs.(77) Clinical experimentation and pharmacological testing revealed that a mixture of the 10 herbs were necessary and that the efficacy could not be attributed to any single active ingredient from any one of the 10 Chinese herbs.

I wish to conclude this section with a philosophical question. Is medical science one universal and uniquely expressed (Western) paradigm - a biomedical paradigm? If it is possible to conceive of alternative methodologies, theories and practices in other domains such as music, logic, linguistics, art and politics, is it not possible to consider possibilities of alternative methodologies in medical science, knowing that doctors practice medicine within a biopsychosocial paradigm?

Is it possible for research scientists to examine other methodologies, for example, using experiential methods - an inductive approach, to evaluate traditional herbal remedies?

Dialogue



I have been very impressed with your publication which I receive regularly. Thank you. For the last quarter of a century I have been teaching my students the value of critical reasoning and the scientific method. For the field of medicine the power of appropriate clinical trials is great and established. The article you have published in your latest issue on clinical trials is one of the simplest and easy to understand exposé on the subject that I have come across. I wonder, if it will be possible to get reprints of the article for my Institute's physicians and students. Please keep up the good work.

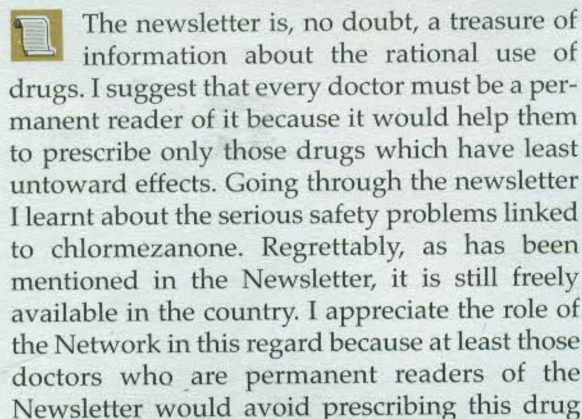
Prof. Azhar Masood A. Faruqui
Executive Director & Professor of Cardiology
National Institute of Cardiovascular Diseases, Karachi

Thank you very much for your encouraging letter. We would be very willing to send you the reprints of the article on Clinical Trials at the price of Rs.15 per copy (just to cover the actual costs). Please let us know about the quantity you require. Others can also ask for copies of the reprint on the same terms.

On Chlormezanon

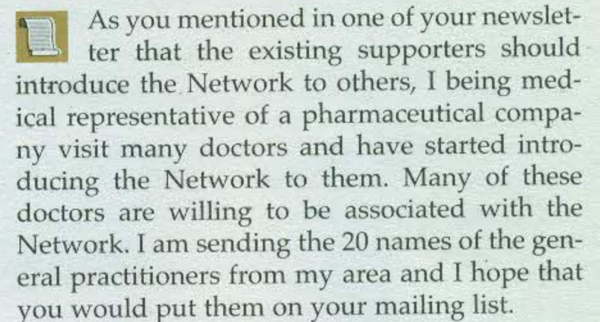
I run a medical store in Arifwala. In your last newsletter I read that Chlormezanon (Beserol®) is banned in other countries and its use can be very dangerous to the consumers. After reading this vital information I threw away all the stock of this drug from my medical store. My father was happy that such a source of information is available in the country.

Mahboob Ali Booby, Awan Medical Store, Arifwala.



The newsletter is, no doubt, a treasure of information about the rational use of drugs. I suggest that every doctor must be a permanent reader of it because it would help them to prescribe only those drugs which have least untoward effects. Going through the newsletter I learnt about the serious safety problems linked to chlormezanone. Regrettably, as has been mentioned in the Newsletter, it is still freely available in the country. I appreciate the role of the Network in this regard because at least those doctors who are permanent readers of the Newsletter would avoid prescribing this drug in future though it is not banned yet.

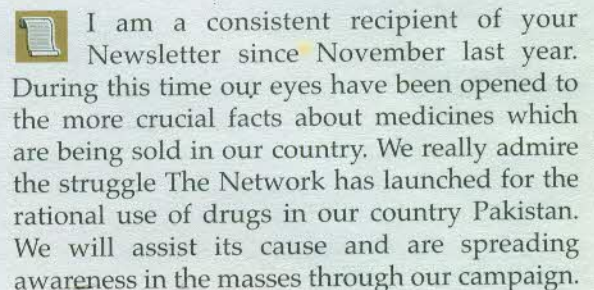
Muhammad Irshad Khan.



As you mentioned in one of your newsletter that the existing supporters should introduce the Network to others, I being medical representative of a pharmaceutical company visit many doctors and have started introducing the Network to them. Many of these doctors are willing to be associated with the Network. I am sending the 20 names of the general practitioners from my area and I hope that you would put them on your mailing list.

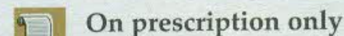
A Medical Rep.

Thank you very much for the names. We have temporarily put all the names on our mailing list. I hope all the GPs would complete the enclosed forms on receiving this newsletter and send these back to us so that we can put them on our regular mailing list. Others are also encouraged to spread the word around.



I am a consistent recipient of your Newsletter since November last year. During this time our eyes have been opened to the more crucial facts about medicines which are being sold in our country. We really admire the struggle The Network has launched for the rational use of drugs in our country Pakistan. We will assist its cause and are spreading awareness in the masses through our campaign.

Riaz Mohammad, Nowshera.

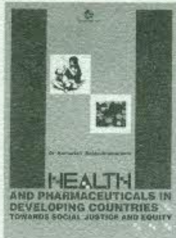


On prescription only

In other countries, no drug, except the OTC (over the counter) drugs is available to the patient without prescription. But in our country every kind of drug is available to the patient any where through out the country without any prescription. This is due to lack of interest and negligence by the Government. So I may very kindly request the government and authorities concerned to take strict action against the violators which will be in the favour of human life. And this is one of the problems which is a hurdle in the way of proper medication.

Dawood Kamal, Peshawar

Health And Pharmaceuticals in Developing Countries: Towards Social Justice and Equity.



This collection of articles by Dr. K Balasubramaniam, Pharmaceutical Adviser at Consumers International Regional Office for Asia-Pacific, makes a convincing case for Primary Health Care and the achievement by developing countries of the goal of health for All. The author advocates the need for formulation and implementation of national Health and drug policies based on the concepts of Primary Health Care.

This 215 page book costs US$ 15.00 and is available from: CI ROAP P.O. Box 1045, 10830 Penagn, Malaysia.
Tel: (+60) 4 2291396, Fax: (+60) 4 2286506
e-mail:ciroap@pc.jaring.my

Training Course in Managing Drug Supply for Primary Health Care

A training course in Managing Drug Supply for Primary Health Care is being organized jointly by Management Sciences for Health, Boston, USA and International Dispensary Association in Amsterdam, The Netherlands from 6-17 October 1997.

This is a very well regarded course on the subject. The target audience for the course include physicians, pharmacists, senior health system managers, and technical assistance professionals from ministries of health, non-governmental organizations, and donor agencies. And the objectives of the course are as follows:

- Expose participants to modern management principles of drug supply systems and to teach how to apply them in their own specific situation.
- Provide practical tools to decision makers in essential drugs programs to improve their level of performance.
- Exchange views and experiences between senior decision-makers.

The course is designed for two weeks and consists of presentations, discussions, group activities, and field visits.

Major topics include:

- Drug Policy and Regulation
- Selection and Quantification of Drugs
- Procurement Methods and Strategies
- Quality Assurance
- Kit Distribution
- Financing Drug Supply
- Store Management
- Inventory Control
- Distribution Strategies
- Rational Drug Use
- Drug Supply Management Information Systems
- Indicator-based Assessments

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We can also provide photocopies of the registration forms. Provincial ministries of health should consider their drug management officials for benifiting from this training opportunity.

The Network Seminars

We are continuously receiving requests from all over the country for organizing seminars and we are queuing up all of these. Due to reorganization going on in the office a backlog of request has built up. At times it may lead to frustration among you for not hearing back from us as promptly as you would have expected. But please bear with us and rest assured that we are using this time to plan well all the forthcoming seminars. One such preparatory item is a list of action points we have prepared to be shared with our collaborators in these seminars. This is a list of ideas for follow-up by the participants at local level.

We would be getting in touch with all of you who have written us in this connection by early October 1997, so please be patient until then.

Latest on Chlormezanone

Beserol® and five other Chlormezanone containing brands can still be purchased from almost any medical store in the country. The irony is that we will never be able to know how many people suffered the lethal side effects of the drug as we do not have any pharmacovigilance system in the country.

This is a clear case of corporate irresponsibility and double standards but also it highlights the stark negligence and apathy of the Ministry of Health, which has done nothing in practical terms to safeguard the people. The drug is banned in Western European countries and in the United States for its toxicity. Not only banned, it was lifted from the market to protect potential users.

Beserol®, the leading brand in Pakistan is manufactured by Searle under license from Sanofi Winthrop. Searle has informed us that they did write a letter to Federal MoH in November 1996 about their decision to discontinue the further manufacture of the drug because of its toxicity reports from Europe. They also wrote a "Dear Doctor" letter on the same line. Reportedly, on 3 April 1997 Searle also informed MoH that "instructions have been given to the Field Force to withdraw any left over stocks of Beserol tablets from the market."

In almost one year the field force cannot withdraw it from the market. How efficient!

Likewise, MoH says that it has banned the drug though it made no effort in this matter of public safety to inform the prescribers and the public about the problem. On paper both the manufacturer and the regulators are well protected, but the fact remains that people are still exposed to the lethal potentials of the drug through its continued availability in the market.

People in Pakistan are as vulnerable to develop Epidermal Necrolysis and die as anybody in France or in the US.

We hope that instead of waiting for their last tablet to be sold, the manufacturers will call back their stocks from the shops.

The campaign continues

The Network is continuing its campaign at both ends: urging regulators to get it withdrawn from the market and to inform the public about it. We have published briefing papers (in both English and Urdu) about the issue and have strategically distributed it among the policy makers and public representatives. The issue is also being covered by the print and electronic media.

To make your contribution to the campaign, send us postage stamps worth Rs. 10. The Network will send you either:

- 10 copies of the Urdu briefing paper
  OR
- A single copy of the English briefing paper

Be sure to include your full name and mailing address and indicate which version (Urdu / English) of the briefing paper you would like to receive.

The Network's Newsletter is a member of the International Society of Drug Bulletins (ISDB), a network of independent drug bulletins which aims to promote international exchange of quality information on drugs and therapeutics.

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