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The Network's NEWSLETTER Rx
Association for Rational Use of Medication in Pakistan

Drug prices: need for strong control

Drug prices have been on the increase since the government surrendered its control in 1993 in the name of market economy and deregulation. The drugs at that time were categorized into essential and non-essential drugs. The vast majority were put in the non-essential category on which price control was lifted. The result was obvious. The prices took a quantum jump. Prices of many drugs went up by more than 300 percent.

Since then there is no respite in the rise in drug prices. Now if we compare, the situation with other countries in the region we find that the prices there are some times 10% of the prices in Pakistan. For this neither the government nor the pharma industry has any plausible explanation.

One result of this disparity is that drug smuggling has become a lucrative business and large amount of all kinds of medicines are being smuggled into the country. Another outcome of this policy is that counterfeit drugs have flooded the market playing havoc with public health.

At the time of lifting the control on the drug prices MoH claimed that the price decontrol will lead to lowering of the prices by increasing the competition in the market. Unfortunately it did not happen and drugs became dearer.

Lastly, a very serious side effect of deregulating the drug prices have been the non-availability of some of the essential drugs in market. As the industry has no interest in making cheap but essential drugs inspite of the fact that according to the Drug Act of 1976 it is the responsibility of the industry to make all registered drugs available.

In the final analysis, the policy of deregulation and decontrol of drug prices has been disastrous for the public health, and it needs an urgent review to keep essential drugs within reach of the common man.

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.

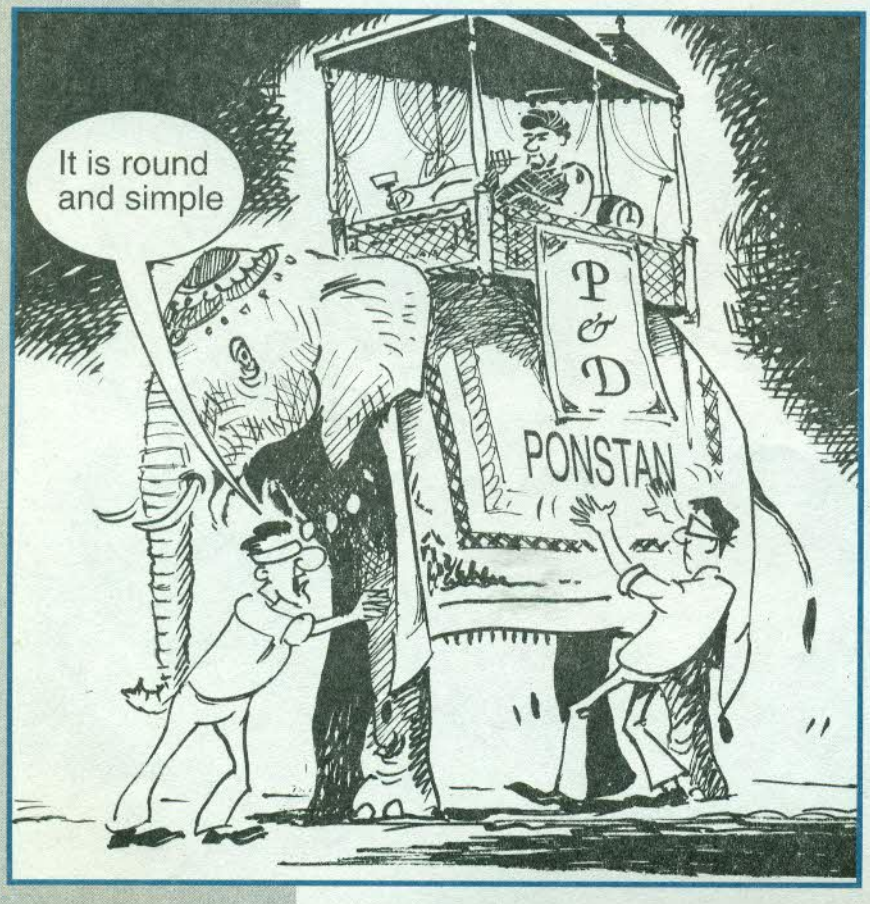
DrugNews

IFPMA's Ponstan ruling: "Unsurpassed" dishonesty

Parke Davis promotes Ponstan in Pakistan saying it "provides unsurpassed efficacy compared with acetaminophen [paracetamol] in fever control" and "better tolerance". The claim was challenged by The Network and MaLAM (Medical Lobby for Appropriate Marketing) in August last year. Parke Davis responded by promising to withdraw the "better-tolerance" claim. The company, however, continued to endorse its claim about superior efficacy to paracetamol, stating that a randomized single blind trial in 50 children showed that "At two hours and at six hours after dosing, the temperature in patients given Ponstan was significantly lower than for those given acetominophen. On the second day there was no significant difference." Parke Davis provided neither a reference to the study nor the report.

MaLAM then decided to send a complaint to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). "We had strong reservations as regards the whole effectiveness of the IFPMA Code, we wanted to test the new code and to know what level of scientific evidence is required by the IFPMA to support promotional claims," says the July/August issue of MaLAM newsletter.

In his response to MaLAM, Dr Richard Arnold, Executive Vice President of the IFPMA stated that Parke-Davis' claim about Ponstan was not judged to be a breach of its Code. He enclosed the IFPMA rulings which stated: "The company points out that the phrase "Unsurpassed efficacy compared to acetaminophen" does not mean superiority, it means equivalence (i.e. acetaminophen is not more efficacious). On the basis of the evidence cited in the advertisement, the statement is technically correct and does not constitute a formal breach of the Code. The phrase "unsurpassed efficacy" is however, normally used to indicate superior efficacy and the company has been reminded of its obligations, under section 1.22 of the Code that "every effort should be made to avoid ambiguity".



These rulings are even more unsupportable when the claim is viewed in the context of the whole advertisement. The advertisement asserts strongly that Ponstan is superior to paracetamol. The main claim "unsurpassed efficacy" is accompanied by clear statements such as "faster antipyretic action compared to acetominophen", "additional benefits to pediatrics patients", "prolonged duration of action" and two graphs showing better results for Ponstan. It is also amazing that the IFPMA accepts a single non-blind study in 50 children with inappropriate statistical analysis as conclusive evidence to support a promotional claim. Furthermore, this study was never sent to MaLAM by Parke-Davis despite several requests. This clearly breaches the IFPMA Code which requires that scientific data to support the claims should be made available on request but this breach has been ignored.

Mefenamic acid is a NSAID which is not licensed for children less than 14 years old in many countries including USA, Canada, Australia and in most European countries. The US Product Information states that "safety and effectiveness in children below the age of 14 have not been established".

'Patent-resistant' malaria vaccine

A breakthrough on several counts, the malaria vaccine developed and patented by Manuel Patarroyo of the Institute of Immunology of Bogota, Colombia is currently undergoing trials in Gambia and Thailand. The vaccine, known as SPf66, is the first against malaria, the first against any parasitic disease of humans, and the first active vaccine against any organism to be based on synthetic peptides - fragments of proteins - which mimic peptides from the malaria parasite *Plasmodium falciparum*.

But perhaps the even greater development is that the inventor has granted the World Health Organization an exclusive, worldwide, royalty-free license to his patent and know-how. An agreement to this effect was signed in May 1995. The agreement is part of wider discussions between WHO, Dr Patarroyo and the Colombian Government for the bulk manufacture of the vaccine in Colombia, at cost, by a non-profit organization. Subject to further trials and development, and the definition of a public health policy on the vaccine, SPf66 would be distributed globally, at the lowest possible cost, particularly for public sector use in developing countries.

While there is a lack of good efficacy and safety studies in children, the safety of mefenamic acid has also been questioned in adults. A review of safety data published in Meylers Side Effects of Drugs states "The reason for concern are particular effects which are unexpected for an NSAID, such as hemolytic anemia, and which may therefore take the user by surprise".[1]

The misleading promotion of Ponstan in Pakistan encourages prescribers to switch from a well-known and safe, essential drug, paracetamol, to a not well-studied potentially harmful drug, mefenamic acid. Such a promotion should have been severely condemned by the IFPMA . In response to the IFPMA's rulings, MaLAM has called all its subscribers and supporters worldwide to send a protest letter to the IFPMA.

The organization has also launched a letter writing campaign to convince the companies that misleading promotion in Third World countries is not worth the damage to their international reputation.

Persons interested in participating in the MaLAM's campaigns are requested to write to The Network, Coordinator.

Reference: 1. Biscarini L. anti-inflammatory analgesics and drugs used in gout. In: Dukes MNG, ed. Meyler's side effects of drugs 12th ed. Amsterdam: Elsevier, 1992:213.

FDA warns Pfizer

The Food & Drug Administration (FDA) of USA requires all pharmaceutical companies to report to it within 15 days any serious unexpected adverse drug experience (ADE) as a part of the post-marketing surveillance. These reports are used by the FDA to affect a labeling change or even a recall according to the ADE's severity. According to Lancet (June 1, 1996) FDA's investigation found the American multinational company Pfizer to have failed to submit the ADE's of eight of their drugs with in the time.

These reports were overdue by 70 to 500 days. One of the undisclosed ADEs involved death of a patient after taking Feldene (piroxicam). Similar problems with Pfizer's reporting of ADEs has occurred previously as well and the FDA is critical of their recurrence even after the company promised to take corrective action.

In Pakistan, there is no effective system for post-marketing surveillance of ADEs. The newly raised Clinical Pharmacology Dept. at the College of Physicians and Surgeons did announce their intention to start ADE collection but it appears to be in doldrums.

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Note

Due to shortage of space we cannot print details of references with each article. However, interested readers can get these by sending a request to The Network. Please, mention the title of the article for which you need references and your complete postal address with the request. — Editor

Dr Inam-ul-Haq calls for regulating the traditional medicine sector and pleads for a more scientific approach towards this invaluable source of therapeutic agents

The Network photo

Herbal medicines: need for regulation

Mankind has used plants as therapeutic agents for thousands of years and continues to rely on them for health care. According to a WHO estimate, around 80 per cent of the world's 5.76 billion inhabitants depend on traditional medicines for their primary health care needs, majority of which use plants or their active principles. An inventory of medicinal plants compiled a few years back by the WHO on the basis of literature from 91 countries, including the classical text on Ayurvedic and Unani medicine, lists 21,000 species of medicinal plant. The Napralert database of University of Illinois documents ethnomedical uses for about 9,200 of 33,000 species of higher plants and lichens[1]. In China alone 5,000 of 35,000 species of plants are used as drugs by traditional practitioners. 25 per cent of all prescriptions dispensed from pharmacies from 1959 to 1980 in the USA contained plant extracts or active principles from plants.

There has been a revival of interest in traditional medicines and non-conventional therapies, specially herbal drugs, all over the world in recent years. The WHO gave official recognition to these medicines in a resolution adopted by the 30th World Health Assembly in 1977[2]. Later in September 1978, the Alma Ata conference on Primary Health Care recommended governments to give priority to the promotion and development of traditional medicines as part of their programs to achieve the objective of "Health for All by 2000".

The recognition of traditional medicines by the international bodies spurred development and scientific enquiry into these medicines all over the world. The developed countries which were initially reluctant to accept these medicines due to the great supremacy and scientific merit of modern medicines, in the form of synthetic drugs, have lately shown a lot of interest in herbal drugs due to their therapeutic potential.

In June 1993, the British Medical Association published a report entitled "Contemporary medicine - new approaches to good practice" which acknowledged that some non-conventional therapies like acupuncture, osteopathy and herbalism may be a good thing used in consultation with general practitioners. A successful move in this direction was made in the evaluation of use

of a Chinese herbal preparation to treat dermatitis. The National Eczema Society sponsored two clinical trials of the preparation, zemophyte, through two leading dermatologists of the UK in collaboration with Chinese herbal practitioners. They found that the herbal preparation offers substantial clinical benefit to the patients whose atopic dermatitis had been responding to conventional modern therapies.

A lot of modern medicines have been 'discovered' as a result of the scientific follow-up of the traditional herbal preparations. A classic example is the latest development of a anti-malarial drug Quinhausu from the herb Artemisia annua which has been used in China against malaria for 2,000 years. The drug, Paluther, marketed by the multinational Rhone Poulenc Rorrer and registered in many countries[3] including Pakistan has under gone 21 clinical trials in 18 countries and is reported to have potential to treat resistant strains of malaria.

The flora of Pakistan is very rich due to the diverse climatic and soil conditions of the different regions of the country. Around 5,000 species of plants are estimated to be growing wild in the country. According to a survey of the National Institute of Health about 400 of these are presently being used in the traditional system of medicines, half of these are used extensively and daily by the traditional healers.

These healers numbering around 50,000, including homeopaths, are estimated to be catering to about 60 per cent of the population, specially those living in rural areas.

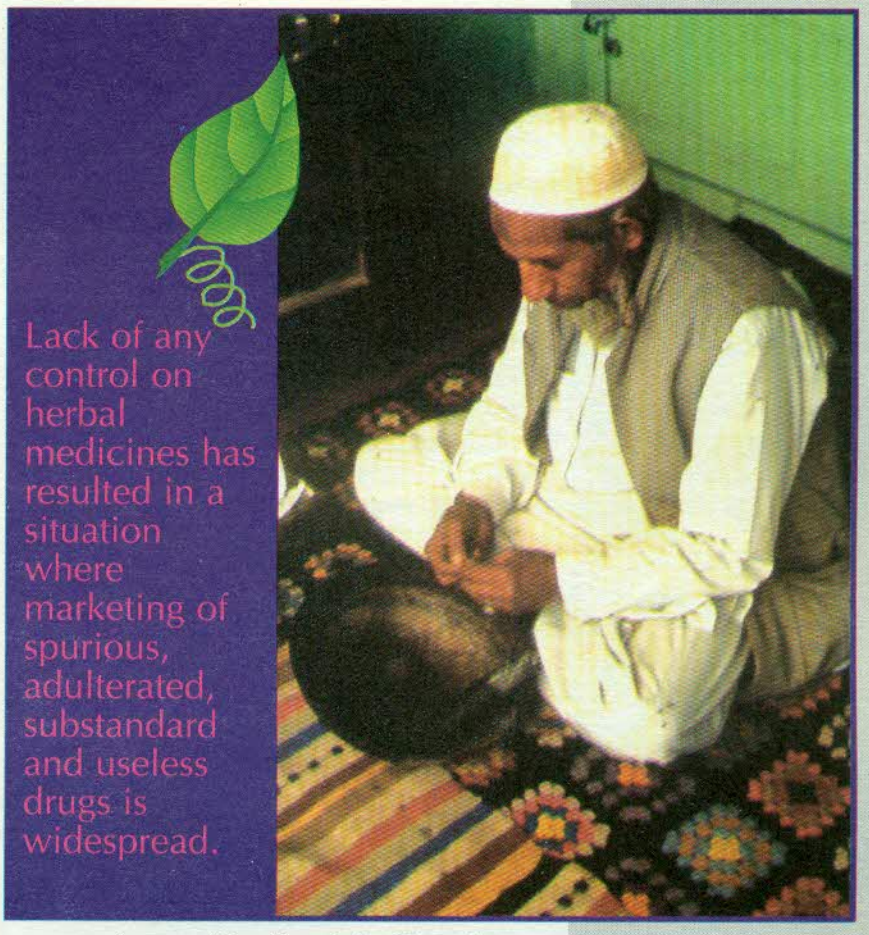
The manufacturing of traditional medicines, however, is not organized. Though the number of manufacturers would run into hundreds, there are about 27 manufacturing houses which produce Unani medicines on commercial scale. The annual turn over of some of these may be comparable to even that of multinational companies operating in Pakistan.

The Tibbi Pharmacopoeia (Pharmacopoeia of Traditional Drugs compiled by the Tibbi Board) has mentioned around 900 single drugs and about 550 compound preparations made out of these, giving their usage and even side-effects[4]. Another pharmacopoeia, Hamdard Pharmacopoeia of Eastern Medicines, published by the Hamdard National Foundation Pakistan, is more comprehensive and scientific. It describes 128 single herbs and 250 compounds besides offering five appendices giving useful information about preservation, storage, identification, storage period and age of herbal drugs. This pharmacopoeia also lists 186 vegetable drugs used exclusively in Unani system and 304 vegetable drugs found in Pakistan in addition to therapeutic classification of the drugs according to their use in Unani system of medicines.

The Homeopathic Pharmacopoeia includes around 2,388 drugs of vegetable, animal, chemical and mineral origin giving their description, preparation and dilutions.

As to the scientific enquiry into these medicines, some useful work, specially on the screening of biological activity of herbal drugs, is being done at the HEJ Institute of Chemistry, Karachi; NIH, Islamabad; PCSIR Laboratories and various universities of

The Network photo



Lack of any control on herbal medicines has resulted in a situation where marketing of spurious, adulterated, substandard and useless drugs is widespread.

Standardization and quality control of traditional medicines is essential to utilize their therapeutic potential fully

Pakistan. Following are a few illustrations of the kind of work being carried out.

Results of the preliminary screening at the NIH of antimicrobial activity of over 100 plants of the Northern Areas were reported in an international journal, Fitoterapia[5]. Another significant work undertaken and published by the PCSIR Labs, Peshawar was the screening of some 343 medicinal plants for anticancer activity[6]. A report published by the University of Agriculture, Faisalabad has described the results of pharmacological screening of some indigenous medicinal plants for antidiabetic activity.

The practice of tibb and homeopathy in Pakistan is regulated through the Unani, Ayurvedic and Homeopathic Practitioners Act of 1965, but the manufacture, sale, distribution and quality of these medicines is not regulated by any statutory or administrative measure.

Lack of any control on these medicines has resulted in a situation where marketing of spurious, adulterated, substandard and useless drugs is widespread. The quality control laboratories in the country invariably report the adulteration of Unani and homeopathic medicines with allopathic drugs specially steroids.

Standardization and quality control of these drugs is essential specially as the older day dosage forms like decoction and infusions used by the traditional healers are being replaced by more concentrated and potent preparations like extracts, tablets etc. Similarly safety assurance for these drugs is becoming more and more important in view of latest reports about their adverse effects.

Bangladesh, India and few other countries are already exercising such controls on traditional medicines through legislation. New regulations have been introduced in China to ensure the quality of crude drugs which combine traditional ways of production with modern methods of quality control. The control of non-conventional therapies varies in Europe. The Netherlands, UK and Scandinavia have fairly liberal approaches towards non-conventional therapies while there is more restrictive legislation in Belgium, France and Italy. The Commission on Herbal Medicines of the Federal Health Office of Germany had published criteria that it will use in reviewing preparations containing plant materials[7].

The WHO published The Herbal Medicines Act[8] in 1989 for guiding the member states in formulating herbal drug policies and laws. It provides for the registration of herbal remedies, licensing system for importation, distribution, sales and export of these medicines, system of quality control, labeling requirements, control of promotion/advertising besides many other things.

The need for national policies and legislation on herbal or traditional medicines was emphasized at the Fifth International Conference of Drug Regulatory Authorities in its meeting in Paris in 1989. The WHO's Chinese expert in his assignment report in November 1991 on the appropriate use of medicinal plants also emphasized the need of legislation to regulate manufacture, sale, distribution and quality control of drugs used in traditional medicine. The WHO working group on the safety and efficacy of

Allopathic medicines of herbal origin

A majority of allopathic drugs are either directly derived from plants or are synthetic manipulations of a substance of herbal origin. It is interesting to note that a number of Essential Drugs are also derived from plants used in traditional medicines. Some are: Atropine, Codeine, Colchicine, Digioxin, L-dopa, Ephedrine, Hyoscine, Morphine, Quinine and Reserpin. Following is the detail of some of these medicines with their traditional and modern uses.

Drug	Clinical use	Plant source	Traditional use
Atropine	Anticholinergic	Atropa belladonna	Dilate pupil of eye
Codeine	Analgesic, antitussive	Papaver somniferum	Analgesic, sedative
Colchicine	Anti-tumour, gout	Colchicum autumnate	Gout
Digoxin	Cardiotonic	Digitalis purpurea	Cardiotonic
Epherdine	Sympathomimetic	Ephedra sinica Stapf.	Chronic brochitis
Monocrotaline	Antitumour agent	Crotalaria sessiliflora	Skin cancer
Noscapine	Antitussive	Papaver somniferum	Analgesic, sedative
Physostigmine	Chlolinesterase inhibitor	Physostigma venenosum	Ordeal poison
Quinine	Antimalarial, antipyretic	Cinchona ledgeriana	Malaria
Reserpine	Antihypertensive, tranq.	Rauwolfia serpentina	Tranquillizer
Theophylline	Diuretic, bronchodilator	Camellia sinensis	Diuretic, stimulant
Vincristine	Antitumour agent	Catharanthus roseus	Diabetes mellitus

herbal medicines in its meeting in Manila in 1992 made a specific recommendation that all member states should develop national policies to foster rational use of these medicines.

Both the 6th and 7th Five Year Plans of Pakistan also made specific recommendations for rationalization of traditional system of medicine and control on their manufacture, sale, distribution and quality but to no avail.

Standardization, quality control and a system of ascertaining safety of medicinal plants is necessary to make full use of their invaluable therapeutic potential on the one hand and to save this treasure trove from the exploits of quacks on the other hand. Some notable work in this direction is reported to have been done in China and India but little attention has been paid to it in Pakistan. The first attempt towards quality control of herbal products in Pakistan was, however, made by the PCSIR, Peshawar laboratories and a paper "Standardization of herbal drugs" was published[9].

One reason for this lack of interest and initiative may be that herbal drugs are often considered innocent and harmless and are mostly advertised as having no adverse side-effects. But now new examples of these products containing potentially toxic substances are coming to light with the advancement of technology.

A herbal slimming product available in UK containing Sparteine obtained from Broom (Cytus scoparius) used as diuretic and for induction of labor has been associated with many serious adverse reactions when used in excessive doses[10].

Correspondence in the Lancet has brought to light at least 20 cases of aconitine poisoning in Hong Kong from 1989 to 1991. The roots of two species of aconitum, a Chinese herb, are used in traditional medicines for their analgesic and anti-inflammatory effects. Fifty medicinal plants included in the Sri Lankan traditional pharmacopoeia when screened for presence of pyrrolizide alkaloids gave positive results in three species one of which in animal experiments produced river lesions compatible with the action of pyrrolizidine alkaloids[11]. In an another study in Sri Lanka 75 medicinal plants were screened for the presence of toxic alkaloids. A number of plants produced hepatic lesions while some caused marked renal lesions[12].

The WHO emphasizes that safety should be the over-riding criteria in the selection of herbal medicines for use in the health care system. It has also provided guidelines for toxicology studies in the Herbal Remedies Act 16 and in other documents on the Safety and Efficacy of Herbal Medicines[13]. Neither the regulatory authorities nor the doctors are sufficiently aware of the potential toxicity of herbal medicines. This makes it more important and urgent to hold scientific enquiry into the subject and enact laws to regulate this sector.

References available on request.

Sri Lanka: Back to the future

After nearly four centuries of neglect, Sri Lanka is waking up to the magic of its traditional system of medicines. The resurgence began shortly after the independence in 1948, when the ayurveda medical colleges were placed under government sponsorship and a number of ayurvedic hospitals were established by the state. This process received a boost in 1956, when a separate department was created by Prime Minister SWRD Bandranaike to support and improve all aspects of ayurveda. The creation of a separate ministry of indigenous medicine in 1980 was the culmination of a series of measures taken by successive governments.

The Bandranaike Memorial Ayurveda Research Institute (BMARI) has emerged as the country's prime research and development organization. The BMARI has under taken a huge exercise to identify and document scientific names of commonly used herbs. Based on extensive interviews with traditional practitioners and written records the BMARI scientists authenticated 1,483 plants by their modern botanical names. The results of this survey have been developed as a computerized data base, which stores local names, the corresponding botanical names, known uses and citations in literature. On the other hand the BMARI is promoting the cultivation of medicinal plants as a community based small agro-industry. From a list of 200 most widely used medicinal plants. BMARI has identified 25 species for cultivation in home gardens, while 50 have been selected for use in reforestation programmes and school based activities.

Today BMARI is receiving increased recognition and funds. The UNDP has helped establish three herbal gardens and supported the training of farmers and school children in the cultivation of medicinal plants.

Courtesy: Down to Earth

Dr Inam-u l-Haq, a former Drug Controller, Ministry of Health ,has wide experience and knowledge of herbal medicines. He has a PhD in pharmacy and is a member of The Network's Council.

The Network takes a look into how the continuous rise in drug prices is hurting people's access to medicines

Should medicine prices rise again?

There cannot be two opinions about the fact that people's access to medicines in Pakistan is fast reducing. A study conducted by The Network shows that average Pakistani family of seven persons spent in 1995 double the amount on medicines than it did in 1990 and that too for a 6 per cent less quantity of drugs.

These figures are generalized - entire population divided into families of seven without taking into consideration the economic class factor (due to lack of specific information about drug use by different income groups). However, it is evident that the situation is worst for the low income groups. According to the World Development Report 1995, published by World Bank three fifth of the population in Pakistan (83 million) earns less than the per capita average income for Pakistan - $420. It could be well imagined that this segment of population will be the worst victim of drug price rise.

A host of factors are responsible for this with one common element that the pharmaceutical industry has the expertise and the clout to tilt every situation to its benefits. The regulatory authorities, it seems, have foregone their prime role in protecting the rights of the consumer. This receding of the authorities started in 1993.

During the politically turbulent period of 1993, the Government of Pakistan over ruling the Drug Act 1976 deregulated price control and awarded the industry across the board raise in drug prices. The medicines were divided into two - controlled list and decontrolled list. Legally, the industry is free to price drugs in the decontrolled list alone. But practically, the Ministry of Health has no will or mechanism of controlling prices in the controlled list as well. It only relies on the 'gentlemen's promise' by the industry not to raise prices without its consent. The gentlemen in the industry, however, do not give this promise a damn.

On June 1, 1996, Hoechst raised prices of Avil tablets, 25 mg, 50 mg, Retard and Avil injection 5 ml by around 20%. These drugs are on the controlled list (SRO 471 (I)/93 Controlled Drug Serial numbers 53 to 57). Similarly prices of Daonil tablets, Incidal suspension, Resochen tablets, Sistaigin ampules, Buscopan Plus tablets and Ciproxin infusion were raised by 16 to 20 per cent despite the fact that all these drugs are on the control list. Besides these frequent increases by the individual companies, the pharmaceutical industry has been successful in winning many across the board raises for the controlled list drugs.

During the 1990-1995 period, the joint turn over of all the pharmaceutical companies grew by 151 per cent (from Rs 11.01 billion to Rs 27.93 billion). But during the same period the volume of total pharmaceutical production rose merely by 17 per cent. The difference in value and volume growth of the market clearly shows that the industry is not relying on increasing sales (and thereby raising people's access to medicines) for keeping their profits afloat. They are depending instead on exorbitant price raises to keep their figures moving up.

The situation took a turn for the worse when in 1995, the companies' turn over grew by an unprecedented 29.4 per cent over 1994 but the sales volume were down by one per cent. If the companies earned Rs 100 by selling 100 units of drugs in 1994, they made Rs 129.4 by selling 99 units in 1995!

There was some cohesion between the growth rates in value sales and volume sales till 1993. The gulf has widened after the 1993

Might is right price!

How does a company really fix the price of any of its product? One might expect that the pricing formulas used by the companies will be based on a cost plus profit margin rationale or a return on companies' investments might be the deciding factor in fixing prices. In fact there is no formula or rule applied by companies for the purpose but one — take the maximum that the authorities of a country can allow and consumer can bear.

There could be no better illustration of this fact than a comparison of prices of same medicines manufactured by the same companies in India and Pakistan. See table.

But India and Pakistan are not a unique example. The disparity in drug prices is a global phenomenon. Take for example Glaxo's prized product - Zantac. The company sells 100 tablets of Zantac for $3 in India, for $39 in Pakistan, $20 in Australia, $95 in Phillipines, $150 in Indonesia, $73 in UK, $169 in USA and $284 in Switzerland.

This belies all arguments forwarded by the pharmaceutical industry and makes it clear that it is only a government's will to make drugs available to all its people that decides the price of a drug and nothing else.

Medicine	Company	Price in Pakistan	Price in India	Difference percentage
Brufen 200 mg 10 tablets	Boots	6.57	3.67	180
Daonil 5mg 10 tablets	Hoechst	12.48	3.54	350
Tenormin 50mg 14 tablets	ICI	124.16	29.70	420
Fefol 15 capsules	SK&F	24.15	9.20	260
Piriton 500 tablets	Glaxo	125.00	22.46	560
Voltaren 50mg 10 tablets	Ciba Geigy	62.20	7.30	850
Clafron 1gm 1 vial	Hochest	246.15	99.00	250
Surbex-T 20 tablets	Abbott	26.40	15.59	170
Valium 5mg 10 tablets	Roche	8.32	6.85	120
Flagyl 200mg 10 tablets	RPR	8.92	3.94	230

All prices are current. Indian prices are quoted from Current Index of Medical Specialities (CIMS) May-August 1996 issue and Pakistani prices are gathered from the market.
Indian prices are in Indian rupee and Pakistani in Pak rupee as official exchange rates value both the currencies as almost equal.

deregulation. Through the policy of deregulation, the government has made it possible for the companies to sell less drugs and make more money.

Officials advocate the policy of deregulation as an essential ingredient of the free market economy and a prerequisite for joining the process of globalization. But a majority of the developed countries themselves strictly control drug prices through different mechanisms. Experiences of many other countries suggest that pricing regulations do not hamper market growth.

Introduction of price controls through a National Drug Policy in Bangladesh in 1982 resulted in a sharp reduction in drug prices. Ten years later Dr Zafarullah Chowdhury, the father of Bangladesh's National Drug Policy analyzed the impact of pricing controls and wrote, "Drug manufacturers' total profits have gone up, because of the increased volume of production, while the unit profit has gone down, to the benefit of consumers."

The current policy of our government is, however, exactly the opposite. As the companies find it easier to raise profit margins, they are tailoring their marketing strategies to only concentrate on 'haves' among the consumers. This is squeezing a majority of the needy 'have-nots' while the people at the periphery are being pushed out.

The rise in drug prices cannot be justified on the routine pretext of inflation. The Consumer Price Index which takes into account the prices of a large number of daily use items grew by around 69 per cent during the period 1990-95. While the prices of medicines during the same period grew by 113 per cent. Important to note is the fact that the rise in drug prices was in harmony with the rise in prices of other consumer items till 1993. After the deregulation of price control in 1993, the drug prices rose at double the rate of other consumer goods.

The pharmaceutical industry is once again lobbying for an across the board raise in prices. Pharma Bureau, representing 31 multinational corporations is on the forefront in all these public and private lobbying efforts. The Network with the help of its supporters has launched a campaign against any further raises and is working to win a roll-back of prices.

The Network has published a detailed 6-page version of this study in English and Urdu. If you want copies of this, see Order card inserted in this Newsletter.

Study conducted by Tahir Mehdi, Campaign Officer, The Network.

All market related basic figures are quoted from the book "The Pakistan Pharmaceutical Industry" by Pharma Bureau, Overseas Investors' Chamber of Commerce and Industry. Others have been picked up from publications of Federal Bureau of Statistics, Unicef, UNFPA .

Correspondence

Readers are invited to contribute to this page. The writings should consist of specific examples and experiences about irrational use of drugs or any other unethical practices that promote irrational use.
—Editor

Dubious references

Dr S Manan Bangash,
MCPS, Hangu, Kohat

Your approach to take the product information provided by pharmaceutical manufacturers with a pinch of salt is very realistic. I have some examples to illustrate the situation.

1: In a recent detailing literature of Sandoz's product Dynacirc I found a reference to a study done in Lady Reading Hospital, Peshawar. Finding the results and the design of the study a bit suspect I asked the detailing man to provide me the complete article. I also asked the author for the article. None responded.

Such expensive antihypertensives sold with such dubious references is highly objectionable.

2: Methylcobol is being promoted very unethically. It is just a very expensive vitaminB$_{12}$ being promoted for all sorts of illogical indications.

I wrote to the company Hilton Pharma asking them a number of questions about their promotion of the product but for the last one year there has been no response. Their medical representative has also stopped visiting me.

Disturbing irrationality

Mr Ikram ur Rehman
Pharmacist, Swat

I am much disturbed at the irrational use of drugs taking place in our country. I would like to offer all help to you in your crusade against this irrationality. I have started collecting data on victims of self medication and iatrogenic disease in my area.

As Joint Secretary of Pakistan Pharmacist Association, NWFP Chapter, I am trying to hold a seminar on hazards of medicinal drug abuse in Swat in collaboration with the Social Welfare Dept. You are kindly requested to be the resource person for this workshop.

Note: The Network is willing to help all such efforts on part of our supporters and friends to provide information about rational drug use to medical fraternity as well as communities whether written or interactive (seminars and workshops) and would like to explore the possibility with you.

Growing branches

Dr Imtiaz Taj
Pasroor Road, Gujranwala

We are a group of like minded citizens from all walks of life in Gujranwala who are interested in promoting the idea of rational drug use and its application in this unlucky part of the world.

We would like to work here as a branch of The Network if you could consider opening such a branch office. Your experience in promotion of rational drug use will be of guidance for us.

Note: We would be very glad to collaborate with groups of medical professionals and citizens in order to help each other in the promotion of rational drug use. To start with we can share some resource material with you, plan a talk or discussion on some subject that interests both of us. It is not necessary to open a 'brahch office' of The Network as such because we ready to help any group in this regard.

Unholy alliance

Dr Zaheer ul Islam
WAPDA Hospital, Sahiwal

Unfortunately, a large number of doctors in Pakistan are taking sides with the profit hungry pharmaceutical industry in working against rights of the patients. They are practically abetting the crime through negligence, carelessness, unawareness or simple greed.

I appreciate the crusade started by The Network against this unholy alliance. As Chapter President of Pakistan Society of Family Physicians, Sahiwal, I would like to invite you to hold seminars/lectures etc on the subject of Rational Use of Drugs from our platform in Sahiwal.

South African National Drug Policy

Where there is a will ...

Tahir Mehdi of The Network analyzes the newly announced NDP of South Africa and finds it a bold and blunt attempt at putting things right in the pharmaceutical sector of the country

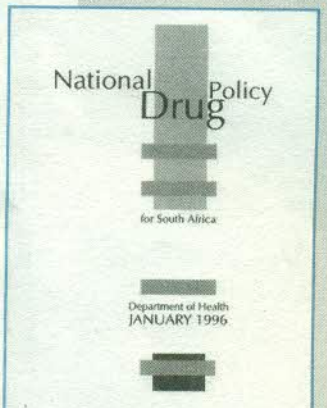
The first democratically-elected government in South Africa has boldly embarked on a path to restructure the health care system of the country which was till 1994 condemned for its inhumane system of government blatantly discriminating against its black majority. The South African Department of Health has put together and published a National Drug Policy document in January 1996 after one and a half year of exhaustive consultations with the different stake holders in the health sector.

The South African policy stands out in many respects as besides laying foundations for a non-discriminatory Primary Health Care system, it sets as its foremost goals availability of Essential Drugs to all the people of the country and a pricing plan for drugs used in both public and private sectors. It lays out in unequivocal terms its preference to Essential Drugs, its liking for generics and willingness to fight back resistance.

According to the policy a committee will prepare the National Essential Drugs List following the WHO guidelines and all the public sector institutions will be restricted to procure only from the list. A public sector coordinating body for procurement will negotiate prices of drugs and other supplies with the suppliers through national and international tender. After contracts have been awarded provincial authorities will purchase drugs directly from the suppliers. Tenders will be called for by generic names only. The policy says that national tender prices will be monitored and compared with international prices. Preference will be given to national manufacturers. Notwithstanding this preference, procurement will aim at securing the lowest available price. In an interview to the magazine Health Horizons, Health Minister of South Africa Dr Nkosazana Dlamini Zuma said, "Products on an Essential Drugs List would be available nationally for those in public and private sectors and should help to bring down the country's drugs bill. It would include some 120 to 125 drugs and should cater for at least 90 to 95 per cent of the country's health problems."

To make sure that the Essential Drugs are available at very competitive rates, the policy says: The government reserves the right to consider procurement on the international market, which includes the options of parallel importation and purchasing on the international generic market. Moreover the policy document under heading Drug Pricing says: Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well being of any sector of population, the State will make them available to the private sector (through purchasing from the international market) at acquisition cost plus the transaction costs involved.

This hidden threat to the medicine suppliers in South Africa has irked the International Federation of Pharmaceutical Manufacturers Associations, representative of transnational companies. The IFPMA in its mouth organ Health Horizons while 'offering support to the policy has voiced concern over some features'. An article in the magazine says: Application of the Essential Drugs principle to the private sector can only cut off investment in the country by the research-based industry in the years to come. However, responding to a question by the magazine Dr Zuma made it clear, "... we do not think that any government should be held to ransom (by the private sector). We believe that delivery of health care is the responsibility of the government and that the government must be in a position to do so. At the same time, we believe that the private sector and most particularly the drug manufacturers, should shoulder their responsibilities and provide us with affordable prices. If they cannot, the government should feel free to import nec-



An expression of commitment to the betterment of people.

"The commitment must go beyond lip service ... ensure that the people of South Africa receive the drugs they need at a cost that they and the system as a whole can afford"

Concluding remarks of the South African NDP document

essary drugs from any other country."

Another 'area of concern' in the South African NDP for the transnational companies is the policy's emphasis on use of generic names. It says: (For public sector procurement) preference will be given to products labeled solely by generic name; in all other cases the generic name must be printed immediately above or under the trade name, in a letter type at least as large as that of the trade name. Taking further bold step the policy says: Prescriptions in both private and the public sectors will be written using the generic name. Until this aim is achieved, generic substitution will be allowed through legislation, in the public and and the private sector. Moreover, the policy aims at encouraging the availability of generic and Essential Drugs through implementation of incentives that favor generic drugs and their production in the country. The policy says these steps will not only reduce drug costs and expenditure but will also contribute to a sound system of procurement and distribution, drug information and rational use at every level of the health care system.

The policy is also very clear about its approach towards the pricing issue. It minces no words and has set its first economic objective as "to *lower* the cost of drugs in both the private and the public sector". It plans to set up a Pricing Committee which would include besides technical and professional persons, representatives of consumers.

The policy lays out an elaborate system of monitoring and evaluating its implementation through Medicines Control Council. The council will have monetary autonomy and be allowed to retain revenue but will be accountable to the Minister. Funds for the council will be generated from registration and retention fees and licensing renewals, supplemented by the government grant.

Courtesy Health Horizon

Dr Zuma, Health Minister of new South Africa: No government should be held to ransom by the private sector.

But the real assurance that the policy will materialize comes from Health Minister Dr Zuma, "Whether a policy is implemented or not depends largely on the will of the minister involved ... First and foremost, you must know that there is a political will in the country to implement a new PHC system."

Non-emergence of Pakistan's NDP

The process of policy making in health, like in other sectors, in developing countries is increasingly slipping through the fingers of the national policy-makers. "Too painful" structural adjustment programmes and the growing influence of policies of economic liberalization on health care are constraining the ministries of health to plan and pursue their objectives. A disturbing recent illustration of this phenomenon is the National Drug Policy (NDP) here in Pakistan.

Early last year, for the first time in the history of the country, a comprehensive NDP was drafted in line with WHO recommendations. It represented the Ministry of

This article written by The Network's coordinator **Dr Zafar Mirza** was published in The Lancet, Vol 348, July13,1996

Health's over due response to pharmaceutical chaos in the country "characterized by inadequacies, irrationalities, imbalances and a lack of direction". With more than half of 120 million people having no reliable access to required medicines, about 80% of health care already located in the private sector and 90% of spending of the average household on health going on the purchase of pharmaceuticals (almost all non-essentials), the draft NDP was seen as a much belated but appropriate step in the right direction. The essential drug concept was the central feature in the policy and due consideration was given to help create the conditions that can sustain such a policy in both the short and long term.

The policy promised universal access to essential drugs, increasing self-sufficiency in the manufacture of drugs through transfer of technology, import of only those drugs by transnational companies (TNCs) that are allowed free sale in their home countries, and establishment of an autonomous Federal Drug Authority for better and effective regulation. Pharmaceutical companies were required to produce a small fixed percentage of their output in the form of essential drugs. This was to overcome the chronic non-availability and short supply of many important essential drugs in the country. These were those few important areas in the policy that directly or indirectly concerned the manufacturers of drugs.

The Ministry's efforts to seek policy consensus were shattered when Pharma Bureau, an organization representing transnational pharmaceutical manufacturers, showed their strong opposition (TNCs hold 80% of the market share in Pakistan). A supraministerial committee was set up immediately by the government with high-profile people from finance and economic backgrounds as its members. After formally hearing the points of view of important stakeholders, most importantly Pharma Bureau, local manufacturers and a professional and consumer interest group Network for Rational Use of Medication in Pakistan, the committee revised the draft policy, which no longer included any of the above mentioned sections.

The reason for these drastic and quick alterations by the committee was that the dropped sections were in conflict with the economic policy, the current ethos of which is increased liberalization and deregulation. Since the policy was opposed by Pharma Bureau as regulatory in nature, the government immediately caved in by changing it. Though the media and the Network are still challenging these changes by highlighting the controversies, it already looks like a lost cause, because the Ministry itself has lost interest in establishing a NDP. Thus, it seems that a historical opportunity is being lost to rationalize Pakistan's pharmaceutical sector.

For how long will health remain a low priority issue in relation to economic policy? Does economic liberalization mean no regulation in health? and how will the state protect health if drug policy is determined by economists who do not understand the health issues and are influenced by industry? This has been one of the persistent problems that has obstructed the national drug policies in other developing countries. In the long run what impact this policy hijack will have on people's health?

Roundup

Healthy justice

Though public interest litigation is a well established practice for consumer groups in India, recent years have witnessed a lot of health issues related cases being filed in courts.

Association for Consumer Action on Safety and Health (ACASH) is engaged in a concerted legal battle with Nestlé India. The company was found violating The Infant Milk Substitutes, Feeding Bottles and Infant Foods Act 1992 of India by the Acash. It filed criminal prosecution against the company in 1994 and is vigorously pursuing the case since then. As the court summoned the Managing Director of the company saying "there is sufficient matter on the record to summon the accused", Nestlé filed a writ petition in Delhi High Court challenging the constitutional validity of the Act. The last hearing of the case was on 6 August, 1996.

Following another case filed by Acash against Johnson and Johnson, the company recently decided to stop marketing feeding bottles in India from November 1996.

The Federation of Consumer Organizations of Tamil Nadu (FEDCOT) filed a petition last April in the Madras High Court charging the state government's World Bank funded program, the Tamil Nadu Integrated Nutrition Project, of swindling funds in procurement of drugs. The Fedcot case shows that Rs 20 million were swindled in the Rs 50 million drug procurement as the real value of drugs procured was only Rs 30 million. The drug procurement is only a small part of the 850 million project.

Based on complaints and its own investigations, the World Bank has written an official letter to the state government regretting it cannot grant Rs 50 million for drug purchases.

Three Indian organizations - All India Drug Action Network, Drug Action Forum; Karnataka and National Campaign Committee on Drug Policy - had sought in 1993 the Indian Supreme Court's intervention to ensure that the authorities weed out hazardous drugs from the market. The All India Drug Action Network in collaboration with the Voluntary Health Association of India has recently released a publication "Banned and Bannable Drugs".

The case is still being pursued. The last hearing of the case was on July 26, 1996.

Medicines for people: Ampule unit of the Gonoshasthaya (People's) Pharmaceuticals, Bangladesh

The Network photo

Paramedics battle maternal mortality

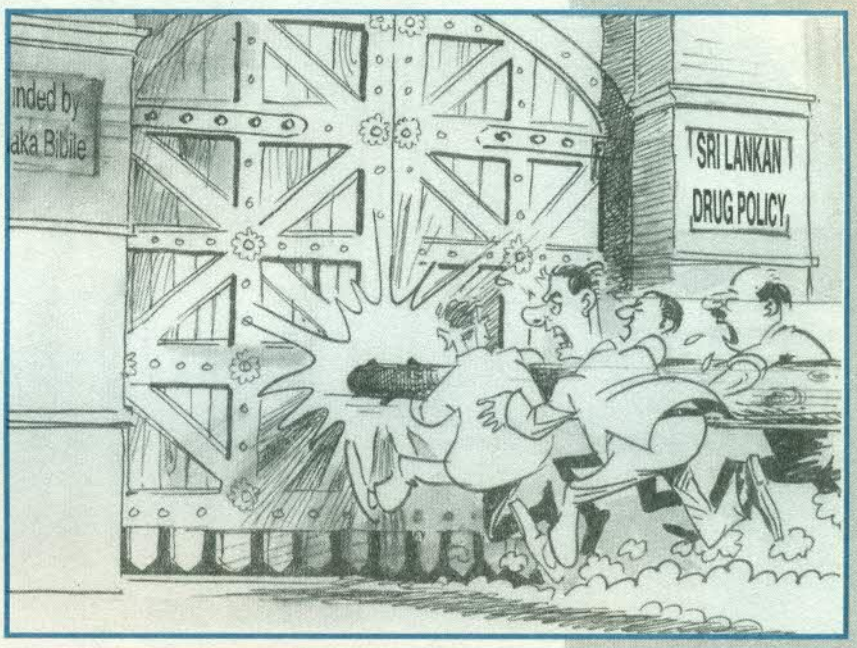
According to a recent global report of the United Nations Children's Fund, nearly 35,000 Bangladesh women died last year during pregnancy or childbirth, which UNICEF called the most neglected tragedy of our times. Yet with little outside funding and a budget of only $6 a patient annually, Gonoshasthaya Kendra (GK) or People's Health Centre, has struck a serious blow against maternal mortality in the 10 districts where it works. With dozens of well-trained village paramedics at work, maternal mortality rates in Savar in central Bangladesh are about one third the national average and at par with those of Thailand. Savar's infant mortality rate is nearly half the national average. In the village of Gopinapur, no maternal death has been recorded in five years.

"What the government and WHO want to achieve by the year 2000, we achieved before 1990," says Dr Zafarullah Chowdhury, the force behind the GK. While the United Nations and other international organizations want to build district hospitals to fight maternal mortality, Dr Chowdhury prefers to rely on a highly motivated and mobile work force, clear mission, little overhead expense and enthusiastic co-operation in the local villages.

"Our suggestion is to recruit local people, mainly women, train them and convince doctors to work with paramedics," said Dr Chowdhury. With a strong force of paramedics in the field, Dr Chowdhury now wants to take emergency obstetric care closer to villages. He wants to build scores of small health centers - field hospitals of sorts - that can handle caesarean sections, obstructed deliveries and blood transfusions.

Despite GK's low income clientele, most of its health care is financed locally: About 40 per cent comes from village patients, who must join a GK health-insurance scheme before a health worker will visit them. Most families must contribute the equivalent of $1 a year to the fund, plus 25 cents per visit by a paramedic and one quarter of the cost of medicines. Even destitute families have to pay 10 cents to join. The rest of the money comes from fees charged by GK's district hospitals and from sales from a pharmaceutical factory that Dr Chowdhury launched in Savar to avoid the high prices charged in Bangladesh by foreign-owned drug firms.

Courtesy: Network News, HAI News, August 1996.



Lankan registration policy under threat

Sri Lanka has one of the world's oldest and best drug registration systems. The small island's experience has shown a number of countries the way to maximize usefulness of medicines through a policy initiative. Since 1962, the National Formulary Committee holds sway over which drug will be allowed to be sold in the market. The committee later named Drug Evaluation Sub Committee (DESC), is based in the Department of Pharmacology in Colombo University's Faculty of Medicine. The professor of pharmacology at the department serves as the secretary of the DESC. The Ministry of Health solely depends on the committee in matters of drug registration and has virtually rubber stamped all of its decisions since its inception. The heads of the committee like Professor Senaka Bibile and Professor NDW Lionel have led many global initiatives like WHO's recommendation for formation of National Essential Drugs List, National Drug Policy.

The dedication and commitment of these great persons to rationalize the pharmaceutical sector has besides other things kept the number of registered drugs in Sri Lanka very low. This efficient committee has all along been resisting the pressure from the pharmaceutical industry to allow sale of "me-too" drugs in the market. Though Sri Lanka unlike Scandinavian countries does not have a Need Clause*, the evaluation committee has been effectively denying entry to all the drugs which are not needed by the society. The number of registered drugs in Sri Lanka stands at 3,960. (The number of drugs registered in Pakistan is now around 20,000:)

The pro-people drug policy of Sri Lanka has sailed through 34 turbulent years. It is now once again in rough waters. Some attempts were made mid last year to undermine the registration procedure which were countered by the vigilant defenders of the policy. There is a new proposal for a Second Drug Registration Committee which will work parallel to the DESC but health activists are resisting the move. "It is a joke to have two committees to perform an identical work. It can be compared to having two Supreme Courts ... two presidents for the country. (Although we presume that it would be better to have two health ministers, two secretaries as at least one might act sensibly if the industry starts controlling the other)," says an article published in Nirodha of the Organization to Safeguard Life and Environment.

The Network offers its best wishes to all who are fighting to save the legendary drug policy of Sri Lanka.

* The Need Clause requires the manufacturer to prove the real social need for the proposed drug besides providing scientific evidence of its efficacy and safety for permission to enter the market.

Using reliable evidence

The Cochrane Collaboration

By Paul Garner

If you itch ill - whether it is with malaria or a heart attack or gallstones - you trust health professionals have worked out the best treatment for you. However, tread carefully: assessing what works is not simple, and in the past many interventions have been introduced based on beliefs that they do good without adequate testing. This is particularly true with new drugs and new technologies that doctors may consider are "better" - but with very little evidence that they are actually an improvement over existing simpler remedies. The medical profession then risks providing care which may do more harm than good, or giving treatments where more effective alternatives exist. Good science and reliable research is needed to sort out effective therapies and interventions.

Reliable research: The randomized controlled trial, which allocates at random individuals or communities into comparison groups to minimize bias, is the most reliable way of examining effectiveness in clinical and public health interventions. Not all interventions or tests of safety and effectiveness will be amenable to such a study design, but many are.

Better reviews: Yet clinicians, policy makers, and users face a problem if they have a question about effectiveness in a particular area. There are an estimated three quarters of a million randomized controlled trials in existence, and they cannot be expected to unearth all studies relevant to their question and summarize all the available evidence. They depend on reviews, including text books, editorials and traditional reviews in journals. Unfortunately, there is now good empirical evidence that such reviews are usually based on opinion, and are frequently out of date and unreliable. There is now increasing acceptance that reviews must be conducted in a scientific manner, with objectives and a methods section. These systematic reviews seek to obtain the reliable evidence available and take a lot more time and effort than traditional reviews. The results, however, are important; there are now good systematic reviews that document a lack of hard evidence for effectiveness of a number of interventions many of us assume help prevent illness and death. On the other hand, reviews exist that show a single dose of steroids early in preterm labor reduces neonatal deaths, an intervention that is often not provided despite having almost no cost implications.

One initiative which is addressing the dearth of reliable, up-to-date systematic reviews is the Cochrane Collaboration. This is a growing international network of health professionals, users and researchers from a variety of back grounds, united by a common purpose: to prepare, maintain and disseminate systematic reviews of research assessing the effects of health care. Reviewers come from all over the world, and work within Collaborative Review Groups that focus on a particular problem, and depend on individual's enthusiasm and commitment to get the work done. The groups include Pregnancy and Childbirth, Parasitic Diseases, Acute Respiratory Tract Infection, Schizophrenia, and one group working on Effective Professional Practice. Dissemination of the systematic reviews is through an electronic publication called the Cochrane Library published by the British Medical Journal Publishing Group, but also through paper publications, through reviewers influence on their own peers, and some new initiatives with consumer groups to provide users with accessible information about the effects of health care.

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