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NDP on its first birthday

year has passed since the announcement of the National Drug Policy (NDP). We were critical of the hush-hush way in which the NDP was announced by the caretaker health minister in December 1996. Disregarding the history of the development of the draft up to that point, the minister put a Quranic verse at the top of the policy draft and announced it nevertheless, just to score another point for the caretakers.

The result is anybody's guess, but in just a year's time the Ministry of Health (MoH) seems to have forgotten all about the NDP. The federal health bureaucracy neither considers itself accountable to anyone nor does it like to be reminded of its responsibility in this connection. Lack of accountability and amnesia suit it well.

The two most important constituents of any well-meaning policy are commitment to goals and the provision of guidelines. But if the whole objective of policy making is to only score points and offset the criticism for not having a policy, then the process becomes self-defeating and an absolute waste of time. This looks like what has happened with the National Drug Policy.

The NDP, its high-set objectives and its commitment to essential drug concepts now lies gathering dust on some inaccessible shelf of the MoH. It is unfortunate how the officials involved in the making of the policy have conveniently let the present political decision makers forget all about the NDP.

We urge the health authorities to come up with the muchneeded resolve to overcome the chaotic pharmaceutical situation in the country. We still hold that a
well thought-out NDP with back-up support is
the solution. One of the biggest weaknesses of
the NDP is that it does not provide any system
to monitor and evaluate its implementation.
Without such accountability one can never
judge the achievements or failures of any policy. The government needs to look at all these
issues if it is serious in introducing health reforms.

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The Network's

mission is to promote the rational use of medication and essential drugs concept in Pakistan in order to optimise the usefulness of drugs and help bring equity in their access.

Products containing terfenadine banned

refenadine, the breakthrough non-sedating allergy drug implicated in heart problems when used improperly, is being pulled from the US market, drug maker Hoechst Marion Roussel announced last month.

Introduced in 1985, terfenadine was the first prescription antihistamine that did not cause drowsiness. It once held 80 per cent of the huge market for allergy drugs taken by tens of millions of sneezing, sniffling hay fever sufferers in the US. Last January, the US Food and Drug Administration recommended that terfenadine products be removed from the market due to the risk of cardiac complications when used in combination with certain antibiotics and antifungal medications.

The drug has also been taken off the shelves in France, Greece and Luxembourg. In September 1997 the UK Committee on the Safety of Medicines decided to change the status of the drug from over-the-counter to prescription-only.

Terfenadine is available in Pakistan in at least 11 brands manufactured or imported by national and international pharmaceutical concerns. The following table provides information about the availability of the drug in Pakistan for con-

Brands containing terfenadine available in Pakistan **Dosage / Formulation** Ingredients Manufacturer No. Trade name Galenika / Akhai International Bronal Terfenadine 60 mg/tab 5ml/30 mg/Susp Sami Pharmaceuticals Fenade Terfenadine 60 mg/120 mg tab Terfenadine 5ml/30mg/Susp Highnoon Laboratories Fendina 60 mg/120 mg/tab Histacam Terfenadine 5 ml/30 mg/Susp Mendoza 5ml/30 mg/Susp 5 Hypofen Terfenadine **Epla Laboratories** 60mg/tab 5ml/30 mg/Susp Pacific Pharma Meldane Terfenadine 60 mg/tab 60 mg/tab Siza International Terfenadine Nebral 5ml/30 mg/Susp Wilson's Pharmaceuticals Talérgin Terfenadine 60 mg/tab 5ml/30 mg/Susp Teldane Merrel Dow/ Terfenadine 60 mg/tab Pacific Pharmaceuticals 5ml/30 mg/Susp Ferozsons Laboratories Terfenadine Terfen 60 mg/tab **Opal Laboratories** Terfenal Terfenadine 60 mg/tab

sumers to beware and for the Ministry of Health to take appropriate regulatory action.

The toxic plague

oxic chemicals are to us now what viruses were a century ago: the hidden enemy and the source of much illness. In our everyday life we are now so immersed in chemicals — at last count there were 70,000 of them out there — that most of the latest syndromes are being named after them. There is now sick building syndrome, wood preservative syndrome, solvent intolerance, chemically associated immune dysfunction, Gulf War syndrome, not to mention the more obtuse appellations like ecological disease, clinical ecology syndrome, chronic fatigue syndrome, fibromyalgia, and, our latest, multiple chemical sensitivity (MCS) all hinting at an environmental cause.

Despite increasing evidence that chemicals are making many people ill, the medical establishment stubbornly hangs on to microbes as the one and only source of illness. This was the conclusion of the 1996 Royal College's Report on chronic fatigue syndrome and on MCS problems. Nevertheless, the editor of *The Lancet*, Dr. Richard Horton, took a brave step forward by arguing: "Somehow I cannot accept that pesticides, sprays and gases are the harmless accouterments of today's life. But how do we prove it one way or the other?"

Although several reliable scientific studies have already proved that some people are hypersensitive to chemicals, the crux of the problem is really finding out exactly how these chemicals damage us. There is no way to determine, for instance, if a single chemical disrupts hormones, say, simply by examining its molecular makeup. It has to be subjected to a battery of tests, which, incidentally, have yet to be devised.

Consumers must demand that far fewer chemicals be used; that pesticides be employed only for emergencies; and that manufacturers have the burden of proof. Perhaps most important, we must no longer allow the deadly triad of the medical, pharmaceutical and chemical giants to pretend that the beginnings of an environmental plague are all in our heads, a pretence that allows them to get away with murder.

Consumer Currents, No 199, Nov-Dec 1997

Counterfeit fluothane on sale in Peshawar

Chloroform being used as anesthetic

A counterfeit version of fluothane, a widely-used general anesthetic agent manufactured by UKbased Zeneca, is being marketed in The Peshawar. provincial Drug Testing Laboratory (DTL) has confirmed

that "it is fatal for human consumption, and contains chloroform instead of halothane." Chloroform is no longer used as anesthetic anywhere in the world due to its potential to cause liver and kidney damage, respiratory depression and cardiac arrest.

The manufacturers have replaced the genuine ingredient (halothane) with commercial chloroform, which was sporadically used till the late fifties and sixties but which is now known to be a hazardous drug.

The counterfeit drug effectively mimics the genuine and was recovered by Hayat Shaheed Teaching Hospital's (HSTH) administration from a patient who had purchased it in the local market. The culprit manufacturers, marketing managers and sales representatives of the drug are yet to be caught.

The most dangerous aspect is that the product is being supplied to a number of private and public hospitals. An anesthesia technician has alleged that "it was also used for a few cases in the 1,200 bed HSTH in July and August."

The counterfeit drug's trade has been flourishing in the secondary care centres and private hospitals in most districts of the province. This is mainly because there is often little or no government control on pharmaceutical laboratories.

The health department recently directed administrators of all hospitals in the NWFP to purchase the anaesthetic from authorised distributors.

Dr. Khabir Ahmad The Frontier Post (December 4), Peshawar

Senate passes Patents and Designs (Amendment) Bill

The Senate passed three bills on Wednesday in a matter of minutes in the absence of opposition and without any discussion on the merit of the three laws with one of the bills being the Patents and Designs (Amendment) Bill, 1997.

Minister for Parliamentary Affairs Muhammad Yasin Wattoo had introduced the bill to amend the Patents and Designs Act, 1911. Under the bill, Pakistan seeks to achieve the objectives of Article 27 of the World Trade Organisation (WTO) Agreement. At present, patents are granted by the Patents Office under the Patents and Designs Act, 1911, which does not admit patents for pharmaceutical and agro-chemical products.

Article 27 of the WTOs, on the other hand, provides for admitting the application for protection of such product with effect from January 1995, the date of coming into force of the WTO. According to the bill passed Pakistan is a signatory to the Marakash Agreement, which concluded the Uruguay Round of talks and provided for the establishment of the WTO. It also provided for the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to reduce impediments to international trade, and promote adequate protection of TRIPs.

To meet its obligations under TRIPs, Pakistan is required to amend its existing laws, particularly to avoid any penal clauses of the TRIPs Agreement. It is also necessary to urgently give effect to the provisions of Articles 70.8 and 70.9 thereof.

Mohammad Yasin Dawn (November 13)

Drug registration issues - I

In a two-part article
Dr. Zafar Mirza
dwells deep
into the mist
surrounding the
registration of
pharmaceuticals.
Part-I is an
overview of the
issues while part-II
will deal specifically with the state of
these issues with
particular reference to Pakistan.

harmaceutical products are not ordinary commodities. They are special chemical entities with remarkable therapeutic properties. But at the same time all drugs have potentially harmful side-effects. Both these properties make drugs of immense public health importance and raise concerns about the safety of its users.

To be confident about the therapeutic potential of the drugs and to ensure safety, rigorous methods are followed during their development and production.

Governments require drug manufacturers to strictly follow Good

Manufacturing

Good Laboratory
Practices (GLP) at all
levels of their business to ensure the
safety, efficacy and
quality of their products. But before allowing
the company to take its
new pharmaceutical product
to the market governments have

Practices (GMP) and

yet another system to critically check the credentials of a drug: the drug registration system.

Thalidomide disaster

Over the centuries the concept of drug regulation evolved due to a number of factors: con-

cern with commercial production of drugs, their advertising, marketing of useless or even harmful "remedies", unethical methods of drug promotion, high cost of drugs, etc.

In the 19th century a movement began to take shape to control narcotic drugs; for example, in Britain the Pharmacy Act was passed in 1868¹. Most of the modern drug legislation, however, has been enacted during this century, a major wave of which came in the sixties after the thalidomide tragedy.

In 1938 the US Food and Drug Administration was born after a drug tragedy. At the time sulfonamides were very popular as the first treatment for infections. Sulphanilamide was particularly widely prescribed. But as the drug tasted very bad, it was mixed with sweet-tasting diethylene glycol and the elixir marketed for children. The solvent was highly poisonous

and killed at least 107 people. It was withdrawn from the market and soon after the US Congress passed the Food, Drug and Cosmetic Act².

thalidomide disaster that led to a number of regulatory initiatives. Thalidomide, a sedative and antiemetic drug marketed in West Germany in 1957, was found by an Australian obstetrician Dr. William McBride to be responsible for causing congenital defects in babies. The drug caused a rare congenital disorder, phonographic ('seal limbs') in babies whose mothers can the drug mostly for morning sick-

In Europe it was the

comelia ('seal limbs') in babies whose mothers had taken the drug mostly for morning sickness. It was estimated that the drug caused more than 10,000 cases of birth malformations in West Germany alone, while it was marketed in 46 countries³ under no less than 50 brand names.

The tragedy had a profound impact on drug regulators and many legislative initiatives were taken. For example, in the UK, the Committee on the Safety of Medicines was established and a law enacted for independent evaluation of drugs for their safety before being marketed. This has been called a "turning point" which provided the "greatest single impulse" to the development of new drug legislation in Europe and elsewhere.

In the backdrop of these tragedies governments in a number of countries devised



a system of drug registration. This is now considered one of the basic systems which regulates drugs. It is a process through which pharmaceuticals are permitted in the health-care system by the authorities after appropriately evaluating them against set criteria, most importantly of safety, efficacy and quality.

Procedure

The process involves an application on a prescribed form by the manufacturer or the importer to the drug control authority, (usually the Ministry of Health), which then processes the application according to the stipulated criteria and conditions.

If the application meets all the conditions set out in the law and satisfies the members of the Drug Registration Authority, the applicant is provided with a certificate. This is usually for a limited period of time after which the registration status of the drug is reviewed. The WHO in 1983 laid down the process of Establishment of Statutory Drug Regulation in Developing Countries in which drug registration is also dealt with⁵.

The application for registration requires two kinds of information: administrative and technical. Administrative details include name of the product, details about the manufacturer, if imported the drug's status in the country of origin and in other countries, the appropriateness of the content of labeling and advertising, etc.

The technical details include pharmaceutical (stability, bioavailability, etc.), pharmacological (pharmacokinetic and pharmacodynamic) and clinical trial studies. Detailed information about these studies comes as attachments to the application. The entire documentation can be extremely voluminous.

A few countries require some additional details7:

- price of the drug;
- comparative therapeutic and/or safety advantages, local manufacture of a similar product;
- the availability on the market of several products with the same active ingredient;
- combinations not offering an advantage

over individual products;

- therapeutic justification and medical needs;
- GMP certificate in case of imported drugs;
- free sale certificate in the country of origin in case of imported drug.

The period for which the drug is registered also varies among countries.

This process of drug registration is of utmost importance to potential consumers. Any incorrect decision at this stage can lead to physical injury to the user. The extent of harm can even amount to death due to toxic potential of the drug.

Research in drug registration

Drug registration is generally a poorly researched area. Most research work has been done in industrialised countries and involves various aspects of drug regulation. Bulk of the studies has been undertaken by industry to prove how regulations have hampered its research and development activities. However, WHO European Studies of Drug Regulation have also looked into registration procedures through comparative studies of two or more regulatory systems by using different approaches.

Developing countries have lagged behind in efforts to assess their drug regulation systems. Recently though, researchers have started paying some attention to these aspects^{10,11}. This interest has evolved primarily due to three factors: several incidences of adverse drug injuries¹², gradual strengthening of consumer organisations, and international organisations' interest in rational drug use research in developing countries, which indirectly stimulates interest in drug regulation research.

Drug regulation

Drugs in Pakistan are regulated centrally through the Drugs Act, 1976, (Manual of Drug Laws, 1995). This legislation was enacted four years after unsuccessful experience with the Drug (Generic Names) Act, 1972, which banned the use of trade names and was

later repealed. According to Reekie & Weber (1979), this failing of the Generic Act in fact strengthened the multinationals¹³. The Drugs Act, 1976, superseded the Drugs Act, 1940, but is not in derogation of the Dangerous Drugs Act, 1930.

The Drugs Act, 1976, aims "to regulate the import, export, manufacture, storage, distribution and sale of drugs". It has an impressive mechanism of distribution of powers, duties and responsibilities between the Centre and the Provinces¹⁴. It is a comprehensive legislation with 45 sections dealing with various aspects of drug regulation.

The Act makes it mandatory for all drug manufacturers to obtain a licence from the Central Licensing Board. All drugs must be registered with a Drug Registration Board. A list of all registered drugs is required to be compiled, published and reviewed from time to time.

A system of hearing appeals of the aggrieved is also required by law. For the purpose there is the Appellate Board, which consists of representatives of the federal government and the provincial governments. The federal government can also constitute committees of experts when necessary.

The Act, however, covers only allopathic drugs and excludes drugs of Unani, ayurvedic and homoeopathic systems.

The federal government is required to establish a Federal Drug Laboratory and Appellate Laboratory; each provincial government is required to establish a Provincial Drug Testing Laboratory and appoint government analysts in each laboratory, and to set up a Quality Control Board to assure the quality of drugs. Governments are also allowed to appoint government analysts.

The Drugs Act provides for inspection services comprising federal and provincial drug inspectors with defined powers and set procedures to follow. It empowers the federal government to fix the maximum price for drugs. It prohibits the import, export, manufacture and sale of spurious and sub-standard drugs. Strict control on drug advertisements, sampling and printing of labeling is emphasised; any offence entails strict penalties ranging from 3-7 years imprisonment and/or fine of Rs. 100,000.

The law also provides for the setting up of special drug courts to hear drug-related cases. A system of checks covers drug imports by authorising customs officials or drug inspectors to control the type and quality of drugs imported in the country.

However, all is not well with the drug law. The Senate's Special Committee on Medicine Sector in 1991 recommended several amendments in its report and suggested that these be made in the Drugs Act before the start of the next fiscal year. They were never carried out.

References

- Berridge V. (1977), 'Opium and the Historical Perspective', The Lancet, July 9, 1977, 78-79
- Youngson R. & Schott I. (1996), Medical Blunders, Robinson Publishing Ltd., London
- Braithwaite J. (1984), 'Corporate Crime in the Pharmaceutical Industry', Routledge and Kegan Paul, London
- Dukes M.N.G. (1985), 'Effects of Drug Regulation', WHO, Butler & Tanner Limited, Frome and London
- WHO (1983), Establishment of Statuary Drug Regulation in Developing Countries; unpublished report of WHO Inter-Country Consultation of Drug Legislation, Khatmandu, April 25-29, 1983
- Eddy David M. (1990), 'Should we Change the Rules for Evaluating Medical Technologies?', in Gelijins AC (ed.), Modern methods of clinical investigation, National Academy Press, Washington DC
- Jayasuriya D. C. (1985), Regulation of Pharmaceuticals in Developing Countries; Legal issues and approaches, WHO, Geneva
- 8. Dukes M.N.G. (1985), 'Effects of Drug Regulation', WHO, Butler & Tanner Limited, Frome and London
- Dukes M.N.G. (1984), The Registration History of Cromolyn Sodium; A five country analysis (to be published) as quoted in 'Effects of Drug Regulation' by M.N.G. Dukes (1985), WHO, Butler & Tanner Limited, Frome and London
- Bhutta T. I. & Balchin C. (1996), 'Assessing the Impact of a Regulatory Intervention in Pakistan', Social Science Medicine, Vol. 42, No.8, pp. 1195-1202
- Hilbrand Haak & Mariam E. Claeson (1996), 'Regulatory Actions to Enhance Appropriate Drug Use: The Case of Antidiarrhoeal Drugs', Social Science Medicine, Vol. 42, No. 7, pp. 1011-1019
- 12. Bhutta T.I. (1990), 'Loperamide Poisoning in Children',
 The Lancet, 335, 263
- 13. Reekie W.D. & Weber M.H. (1979), Profits, Politics and Drugs, Macmillan, London
- Jayasuriya D. C. (1985), Regulation of Pharmaceuticals in Developing Countries; legal issues and approaches, WHO, Geneva

Eradicating polio



PAKISTAN'S DUBIOUS RECORD IN public health is underlined by the high incidence of polio in the country. An infectious disease which attacks the central nervous system, polio can be fatal or crippling. The pity is that the affliction still affects a large number of children in

Pakistan in spite of the fact that the disease is preventable and has been eradicated from most other countries of the world. In fact, in 1996 150 countries reported no case of polio. In this context it reflects dismally on our health care programme that 25 per cent of all polio cases in the world — and 75 per cent in the eastern Mediterranean region — should occur in Pakistan....

It is time the health authorities in this country took the polio eradication programme more seriously than they have. The strategy adopted by WHO in 1988 when the polio eradication target was set was to organise national immunisation days (NIDs) when all children under the age of five are to be administered the polio vaccine drops. Other countries such as China and India have managed their NIDs very successfully.... It is not clear why Pakistan has not been able to achieve the same kind of success, especially when polio days are being organised in this country every year since 1993. Every time an NID for polio is organised the number of children covered is said to be increasing. Thus, the polio day in December 1996 is claimed to have achieved 99 per cent of the coverage target. If that is actually so, there is no reason why there should not be a drastic drop in polio cases as happened in China after it had organised its first NID.

It is, therefore, important that the campaign is organised efficiently, correct targets are set and the process and its impact are monitored properly. The importance of this should be understood because in the absence of a meaningful response from the people, the temptation would be there for the health authorities to exaggerate the figures of the children immunised. There is also the need to store the vaccine in prescribed conditions in so far as temperature is concerned if it is not to lose its potency.

In 1995 Pakistan reported 421 polio cases (counting in the unreported ones the incidence would be higher). This speaks of apathy and callousness in dealing with a disease which generally affects children, often killing or maiming them for life. Surely, Pakistan would not want to be the country to have the dubious distinction of being the last sanctuary of polio in the world when all other countries have been declared polio-free. But that is what we seem to be heading for.

Dawn, Editorial (November 23)

LHC verdict on dealers selling banned drugs

MR JUSTICE FAQIR MOHAMMAD KHOKHAR OF Lahore High Court, Rawalpindi Bench, on a writ petition directed the government to take action against those drug dealers selling banned drugs in the country.

The court took action on a writ petition filed by advocate Mohammad Kowkab Iqbal, who brought to the notice of the court that a health hazardous drug, chlormezanone, was being sold in the market. In his petition Iqbal stated that the drug is banned in Europe and the US for its fatal effects on patients.

The lawyer said that the use of the medicine can cause a number of skin diseases. In some cases it can also lead to the death of users.

The standing counsel appeared on behalf of the government and submitted before the court that the drug had already been banned in the country by the Ministry of Health.

Challenging the counsel's argument Iqbal showed a number of receipts to the court bearing recent dates when the drugs were purchased from medical stores.

The court directed the Ministry of Health to take strict action against those drug dealers who were violating the ban on the sale of drugs containing chlormezanone.

Abrar Saeed, The Nation (October 28)



Here are salient features of the new **National Health** Policy. These are being presented to inform our readers of the government's plans to bring about changes in Pakistan's health sector. We will present an in-depth critique of the health policy in the April 1998 issue of our newsletter in light of the responses we receive from readers. You can send/fax us comments at the address/number on the back page or email them to us.

Salient features of the new health policy

Beginnings

Pakistan started with a very weak base in the health sector in 1947. At the time of Independence, the country inherited very poor medical facilities comprising one medical college, 78 doctors, widespread malnutrition, unsanitary environmental conditions and a high prevalence of communicable diseases. In spite of a steady expansion in health facilities and manpower, the present health system has not adequately met the requirements of the population. Pakistan's health indicators present a very dismal picture as compared to countries at the same level of economic development. The health status of the nation after 50 years of independence is characterised by a population growth rate of around 2.8 per cent, infant mortality rate of 86 per cent thousand live-births and maternal mortality rate of 350 per 100,000 live births which is one of the highest in the world. In the context of health-care needs, the major concerns in respect of various population segments are:

Children: Diarrhoea and pneumonia
Women of child-bearing age: Pregnancy complications
Adults: Accidents and cardiovascular diseases
Elderly: Cancer

Drug abuse has emerged as a public health problem while malaria and tuberculosis continue to be potential threats. Poor maternal nutrition status results in the high incidence (about 25 per cent) of low birth-weight babies.

Shortcomings

The last National Health Policy was developed in 1990 to form the basis for health sector development in the country. The implementation of the policy has led to a certain degree of improvement in the health-care system. However, progress has not been uniform or across the board and many deficiencies and weaknesses persist. Most of the health indicators are still poor and need significant improvement. The health-care system suffers from poor management at all levels. Health sector is not well regulated, especially with regard to the private sector. Good quality essential health-care is still out of reach of the poor. These deficiencies are due to the fact that the policy does not adequately cover all areas of essential care, especially in view of the

renewed Health For All strategy. There is a lack of focus on the district health system which is the foundation for health-care delivery in the country. Many priority health areas have not been given proper emphasis. The same is true for new and re-emerging health areas like chronic and non-communicable diseases.

Proposals

This situation calls for active remedial measures and a need to revise the health policy. There is also a need for a more action-oriented approach in policy guidelines. Practical approaches for community and private sector participation and inter-sectoral collaboration need to be highlighted. Furthermore, the newly government has promised some basic reform

need to be highlighted. Furthermore, the newly elected government has promised some basic reforms in the health sector in its manifesto that need to be incorporated in the policy. Therefore, under a directive of the Prime Minister, the Ministry of Health has prepared a new health policy for consideration by the Cabinet.

Objectives

The major objectives of the policy are to:

- i) consider health as a developmental issue;
- ii) address fundamental issues like poverty and population growth, which inhibit a lasting change in health status;
- iii) develop sound strategies for investment by the private sector to enhance the capacity of the system to deliver health care to all:
- iv) introduce alternative approaches to financing health-care through the involvement of the private sector and the national health-care scheme;
- address the health problems in the community by providing promotive, preventive, curative and rehabilitative services to which the entire population has effective access;
- vi) bring about community participation through creation of awareness, change of attitudes, organisation and mobilisation of support;
- vii)improve the utilisation of health facilities by bridging the gap between the community and health services:
- viii)expand the delivery of reproductive health services including family planning both in urban and rural areas of Pakistan;
- ix) gradually integrate existing health-care delivery programs like EPI, malaria control, nutrition and MCH within the Primary Health Care (PHC);
- x) improve the nutrition status of mothers and children and reduce the prevalence of malnutrition;

- xi) promote proper inter-sectoral action and coordination at all levels;
- xii) develop innovative control strategies for prevailing communicable diseases such as tuberculosis, viral hepatitis, acute respiratory infections (ARI) diarrhoeal diseases, and major prevalent non-communicable diseases.

Expected outcomes

The new health policy has been designed to bring about a faster, consistent and more sustainable improvement in the health situation in Pakistan through some fundamental and radical policy shifts. This change in policy will be a major step in the country's reform process that will bring about a progressive change in attitudes, structure of organisations, governance and definition of roles and responsibilities. It is aimed that through the implementation of this policy, the health indicators of Pakistan will improve significantly in the next five years, with a decrease in infant mortality from 86/1,000 live births to 40/1,000 live births, maternal mortality from 350/100,000 live births to 200/100,000 live births, and low birth-weight babies

from 25 per cent to 10 per cent. The life expectancy will increase from 62 to 65 years and the percentage of children below seven years (who are fully immunised) from 65 per cent to 90 per cent while polio



is expected to be eradicated by the year 2000.

Major components

- i) Health sector reforms
- ii) New initiatives to fulfill government commitments
- iii) Review and consolidation of ongoing projects under SAPP-II
- iv) Strengthening of the pharmaceutical sector
- v) Health legislation

Health sector reforms

The salient strategies for reforms in the health sector include:

- a) promotion of good governance, through proper training and supervision;
- b) improvement of gender staffing mechanisms and a reduction in gender disparity;
- c) delegation of more administrative and financial authority to grass-root levels;
- d) incentives to doctors, teaching faculty, and health workers serving in rural and backward areas;
- e) developing a comprehensive career structure for all cadres, with provision for training and incentives

- for upward movement;
- f) offering a service package for qualified professionals including overseas Pakistanis to serve in the country;
- g) integration of priority health programs under PHC to reduce cost, avoid duplication of services, and improve quality of care;
- h) availability of emergency care for all patients regardless of their ability to pay;
- i) setting up of monitoring and Evaluation Cells at provincial and district levels;
- strengthening of accountability through establishment of a Health Institutions Database, quality assessment and assurance, supervisory checklists and modern record keeping and audit systems;
- k) better regulation of private sector health care including the pharmaceutical industry;
- mobilisation of the private sector to take up more responsibilities in areas of preventive services, family planning, drugs, rural health services, etc.;
- m) authorisation to DFIs to lend to the health sector facilities including viable non-profit institutions.
- n) lead role for the Pakistan Medical and Dental Council (PMDC) in developing health legislation to ensure quality of services and restrict unauthorised practice to medicine in the public and private sector;
- o) preparation of a National Epidemic/Disaster Preparedness Plan, based on early warning system and close surveillance;
- p) upgradation and regulation of traditional medicine, for maximum effectiveness and reliability.

Government commitments

- A. New initiatives in PHC:
- a) Provision of reproductive health services at all levels of service delivery
- b) Launching the National Programme for TB Control
- c) Inclusion of Hepatitis-B vaccination under EPI to prevent widespread risk of infections
- d) Introduction of home health care to take health to the houses and mothers
- e) School Health Programme for elevating the health of children
- f) Environmental health for clean water, air and sanitation
- g) Community-Oriented Medical Education (COME) to train medical graduates in line with the needs of the community
- h) Enhancement of vaccine-production capability to attain self-sufficiency
- B. Poverty alleviation through WHO recommended approach to Basic Minimum Needs The Basic Minimum Needs (BMN) programme will

be implemented throughout the country in a phased manner. Through this multi-sectoral programme, interest-free loans will be provided to communities for:

- i) income-generating projects;
- ii) provision of health and social services;
- iii) training and capacity building.

C. National Health Care Scheme (NHCS):

It will be an alternative health-care financing and management mechanism based on public-private partnership that aims to:

- i) improve the quality and utilisation of services;
- ii) decrease the cost of care to the public and the government;
- iii) extend essential health care to all.

Main components of the NHCS are:

- i) district Health Authorities (DHAs) with representation from government departments and the community, to supervise the management of district health systems;
- autonomy to selected hospitals run by Hospital Management Boards, under the supervision of DHAS, with authorisation to levy user charges;
- iii) privatisation/leasing of selected Basic Health Units (BHUs)/Rural Health Centres (RHCs) contracted out to private physicians, NGOs or existing staff, to deliver a standard package of services at fixed user charges, under the supervision of Community-Based Organisations (CBOs).
- iv) National Health Cards for families in rural and

New National Health Policy financial requirements	(1998-2003)
	Rs. in billion
Preventive programme (Including FP)	27.0
Non-communicable diseases	5.0
Health manpower development	5.5
Health infrastructure	6.5
Specialised care	5.5
Nutrition	3.0
Drugs and logistic supplies	9.0
Vaccine production	0.6
BMN programme	17.0
National Health Care Scheme	20.0
Health Foundation/NGO Collaboration	1.6
Health System Research	0.7
Traditional medicine	1.0
Health Management Information System (HMIS)	1.0
Environmental health	0.6
Prevention and control of drug abuse	1.0
TOTAL	105.0

under-served urban areas, to provide essential health services at nominal charge (and free for poor families) through privatised health facilities.

Review and consolidation of ongoing projects

The following priority health programmes will be strengthened and implemented under the integrated PHC system:

- a) National EPI Programme
- b) National AIDS Control Programme
- c) Family Planning and Primary Health Care Programme
- d) Maternal and Child Health Programme
- e) National ARI Control Programme
- f) Malaria Control Programme
- g) Health Education and Health Promotion Programme

Pharma sector reforms

A comprehensive drug policy will be implemented throughout the country. The important measures proposed are as follows:

- a) provision of essential drugs free of charge in emergencies and to the poor;
- b) promotion of rational use of drugs;
- c) imposing restriction on the sale of drugs without prescription;
- d) involvement of the private sector in procurement and distribution of drugs to government facilities;
- e) appointment of qualified pharmacists at all levels;
- f) establishment of a system for drug surveillance and information;
- g) enforcement of good manufacturing practices;
- h) rationalisation and stabilisation of prices of drugs.

Health legislation

The following legislation will be enacted/amended to implement the Government's commitments to convention on the rights of the Child (CRC), Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), Health for All (HFA) etc:

- a) Universal iodisation of salt
- b) Marketing of Breast Milk Substitutes
- c) Food fortification (e.g. iron supplement)
- d) Pure Food Ordinance (to be amended)
- e) Maternity benefits
- f) Child rights to survival and development
- g) Prohibiting juvenile smoking
- h) Mental Health Act
- i) Regulation of the private sector
-) Traditional Medicine Act

Network Resource Centre expansion picking up



Over the past few months, *The Network* has been working to expand its Resource Centre. The acquisition of two new CD-ROM databases has strengthened *The Network*'s

ability to provide timely responses to information requests from both medical professionals and consumers of health services.

The Medical Information CD contains the full text of 12 important medical reference works, including the latest editions of Current Medical Diagnosis and Treatment, Current Emergency Diagnosis and Treatment, Current Ob/Gyn Diagnosis and Treatment, Current Pediatric Diagnosis and Treatment, Current Surgical Diagnosis and Treatment, William's Obstetrics, Smith's Urology, Basic and Clinical Immunology, Basic and Clinical Pharmacology, Review of General Psychiatry, Handbook of Adverse Drug Interactions, and Medical Letter on Drugs and Therapeutics (1988-1996).

The Health Source Plus CD contains citations to articles from over 500 medical and health-related journals, magazines, etc. The database also features full-text articles from over 200 publications, including such prestigious medical journals as BMJ: British Medical Journal (US edition), The Lancet, New England Journal of Medicine, Medical Letter on Drugs and Therapeutics, and Pediatrics, as well as magazines and newsletters with a consumer health focus.

In addition, the CD contains the full text of *USP DI: Volume 2 Advice for the Lay Patient* and of nearly 1,000 health-related pamphlets. The database will be updated monthly through 1998. Full-text articles generally appear in the database 2-3 months after they have been published.

The Network staff will search for information on specific topics, and, in accordance with international copyright protocols, provide single copies of articles, or portions of medical reference works of up to 20 pages, on request. A minimal fee of Rs. 100 per search and Re. 1 per printout page will be charged. Please phone *The Network* for further information. A detailed brochure about the resource centre is under preparation.

A gearing-up seminar

A one-day preliminary seminar meeting on Role of Medical Professionals in the Rational Use of Drugs was arranged in the Pharmacology Department, Liaquat Medical College (LMC), Jamshoro, on December 23. The seminar took place in response to Head of Pharmacology Department, LMC, Prof. Abdul Rahim Memon's request for one.

Thirty-five participants from departments of pharmacology, community medicine and medicine attended the seminar. In the first session Dr. Zafar Mirza spoke on the pharmaceutical situation in the country, and Dr. Inam ul Haq, ex-drug controller, on Issues in Drug Regulation in Pakistan. The talks were followed by open discussion by participants and speakers.

In the second session Principal, LMC, Prof. Jan Mohammad Memon was kind enough to attend the proceedings. In this session Member, The Network Council, Dr. Azra Talat Sayeed spoke on Essential Drug Concepts, and Dr. Zafar Mirza on Rational Drug Use (Intervention Strategies) followed by open discussion by participants and speakers.

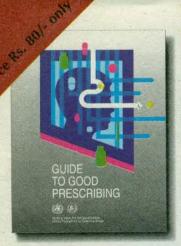
The following action points were discussed to promote rational drug use at the local level:

- i) forming a local group for rational drug use;
- ii) monitoring WHO Ethical Criteria for Medicinal Drug Promotion;
- iii) investigation of drug use in health facilities and communities;
- iv) investigating prescription patterns of non-registered/registered medical practi-
- v) developing an ethical code of medical practice;
- vi) continued medical education programmes;

vii)patient education programs.

The participants agreed to start work in accordance with the action points.





GUIDE TO GOOD PRESCRIBING

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Pharmacology training for most medical students concentrates more on theory than on practice. The material is often drug centred and focuses on indications and side-effects of different drugs. But in clinical practice the reverse approach has to be taken: from the diagnosis to the drug. Moreover, patients vary in age, gender, size and socio-cultural characteristics, all of which may affect treatment choices. Patients also have their own perception of appropriate treatment and should be fully informed partners in therapy. All this is not always taught in medical schools, where the number of hours spent on therapeutics may be low compared to traditional pharmacology teaching. As a result although pharmacological knowledge is acquired, practical skills remain weak.

This training manual meets that need. It provides step-by-step guidance to rational prescribing and teaches skills that are not time limited but which remain valid throughout a clinical career. It demonstrates that prescribing a drug is part of a

process that includes many other components. The manual explains the principles of drug selection and how to develop and become familiar with a set of drugs for regular use in practice, called P(personal)-drug. Practical examples illustrate how to select, prescribe and monitor treatment, and how to communicate effectively with patients. The advantages and disadvantages of different sources of drug information are also described.

The manual can be used for self-study or as part of a formal training programme. Although intended primarily for undergraduate medical students who are about to enter the clinical phase of their studies, postgraduate students and practising doctors may also find it a source of new ideas and, perhaps, an incentive for change.



The Network's Newsletter

A set of all the issues of *The Network*'s Newsletter since 1993 (English).



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Guide to Good Prescribing, a WHO publication reproduced by *The Network*.

Rs. 80 (as contribution to our revolving fund for the publication of low-cost books).

Understanding Rational Therapeutics

This manual can be used for self-study or as part of a formal training programme. By Dr. Mehrul Hasnain Rs. 200

Bitter Facts About Drugs

A guide to nearly 2,000 ineffective, unsafe or limiteduse drugs widely sold in Pakistan.
By Dr. Syed Rizwanuddin Ahmad
Rs. 150

Clinical Trials

Reprint article by Dr. Andrew Herxheimer from the August issue of *The Network's* Newsletter. Rs. 20

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