THENETWORK PUBLICATIONS

National Medicine Policy of Pakistan

a critical review from Consumers' Perspective

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Preface

Pharmaceutical sector in a country is a prime determinant of its modern health care system. In Pakistan pharmaceutical sector is one of the strongest performers in the economy. Paradoxically, however, consumers are facing low access, high prices, wide spread availability and trade in substandard, counterfeit, spurious and dangerous medicines. The public policy in this sector, therefore, has to contend with four key issues as follows:

1. Pharmaceuticals are not *affordable* to a vast majority of people. Some estimates put the number of people who have no access as half of the population while others count even greater numbers. Much of the population cannot even afford to approach this health care system in the first place and thus pharmaceuticals remain out of their lives, while another large section of patients who consult the modern health care system cannot afford to pay for what is prescribed.

2. Poor consumers are further disadvantaged since the treatments for the diseases of the poor majority remain *unavailable* in the market while the rich minority is overwhelmed by treatment options for their ailments, real or perceived. Time-tested treatments fall out of favor of companies as soon as they outlive their patent periods and the subsequent competition forces down their prices. Making available the time-tested and much-needed cheap medicines, Essential Drugs, is a formidable challenge for economies developing under neo-liberal paradigm.

3. Corporations are throwing products in global market at a great speed. They have secured the right to enter national markets through global financial institutions and trade agreements. But the nation states are not capable of checking all corporate moves and protecting the interests of their population. This is why pharmaceutical products banned in countries of origin are available in other countries like Pakistan. Products can be available in different countries for different indications and uses as well. Guarding people against the *dangers of unsafe drugs* is another challenge.

4. Pakistan has one of the *largest number of registered drugs*, and among the absolute highest rates in the world for unnecessary prescriptions of antibiotics, injections and numbers of medicines per prescription. Irrational use of safe and essential drugs can make them harmful and even dangerous products. It not only burdens health budgets, it also causes drug resistance, which is responsible for increasing mortality caused by TB, malaria and other such diseases. Irrationality can be ignorance but it can also be a deliberate attempt to get quick and handsome returns on a prescriber's investment.

5. The complicity between many medical professionals and most of the industry, is complicated further by the

weak, and occasionally dishonest, *role of the regulator*, primarily the federal Ministry of Health. Responsible health service systems, ethical marketing practices and aware consumers are the basic ingredients of rational use of pharmaceuticals.

In this publication we have undertaken a critical review of the national medicine policy which was launched by the federal Ministry of Health in 1997. This review comes at a time when the MoH has initiated a process of review of the policy and has asked for comments and suggestions from different stakeholders to. We have made a set of recommendations from consumers' perspective which we believe should be the prime focus of a Government.

These moves by the Ministry of Health to review the medicine policy should be seen as a positive step forward. One expects that the revised version will address the problems faced by the populace of this country. Also, the attitude of lethargy with which the bureaucracy has dealt with the policy in the past will somehow change for the better.

Introduction

Public policy making is a political process and quality of governance and national politics heavily influences it. Instable, corrupt and myopic national politics, as we have seen made during the last many decades, resulted in chaotic policies and plans. The resourceful stakeholders always take benefits from this scenario to tilt the balance of policies in their favor. The consumers are one of the most deprived, resource less, unorganized and poorly represented in the policy process and hence remain loser and bears the brunt. A national level public policy mostly involves a complex process of development, implementation and monitoring. Hence, the National Medicine Policy (NMP) of 1997 is no exception in this sense. We have discussed here briefly some aspects of the NMP by looking at international standards and norms and then correlating with the NMP process adopted in Pakistan.

The 1997 policy had a number of weaknesses leading to problems of coordination and implementation. It did not provide a framework to coordinate activities of the pharmaceutical sector with other public sector players like industry and trade, consumer groups, civil society, donors and other interested parties. In its objectives the NMP limits itself to coordinate the already existing medicine legislation, a quality control system, and certain other elements. Some of the effective NMPs we know of (e.g. South Africa, Philippines) were developed with input from the public. This input can come directly from concerned individuals or from representatives such as consumer organizations and other NGOs working toward public health goals. When the public - the consumers of medicines and health care - is left out, the policy usually end up

serving the interests of the health bureaucracies and the pharmaceutical industry meant to be regulated by government.[1] 'Healthy Consumers' should be central to the

[1] Moving in from the Margin: Increasing Consumer Involvement in the Formulation and Implementation of National Drug Policies Report of the HAI Regional Workshop on Networking for Rational Drug Use in Southern Africa. 31 May - 5 June 1998, Johannesburg, South Africa.

medicine policy objectives, but it was not the case in NMP of Pakistan, neither was it integrated with other policies like trade, industry, finance etc. Ideally a NMP should have all the consumer protection elements such as shown in the diagram.

The NMP of Pakistan contains eight objects and important consumer perspective objectives have been overlooked. Low consumer access to medicines due to high prices is arguably the most prominent issue of medicine sector in the country but the NMP does not talk about it. Other conspicuously missing objectives include implementation of the essential drug concept, ensuring good prescribing, appropriate use by the consumers, dispensing practices, independent drug information, pharmacovigilance and adverse drug reaction monitoring, reorientation of medical and pharmacy education, financing options.

Guiding Principles for Medicine Policy

The United Nations Guidelines for Consumer Protection (UNGCP), to which Pakistan is a signatory, constituted a landmark step in the international recognition of consumer rights as human rights. Although not binding, it is the first and most important international document formally including consumer rights on an international scale. The UNGCP were unanimously approved by the United Nations General Assembly on April 9, 1985. These guidelines were later developed into eight globally recognized consumer rights by the Consumer International-the global umbrella body of over 250 consumer organizations from 115 countries.

UN Guidelines on Consumer Protection[2]

RIGHT TO SAFETY

1) Measures and standards to ensure safety and quality of goods and services.
2) Facilities for testing and certification of essential goods and services.
3) Policies to ensure that manufacturers compensate for defective or hazardous products.

RIGHT TO REPRESENTATION

1) Governments to facilitate development of independent consumer groups.
2) Opportunities for consumer groups to present views in decision making processes affecting them.

RIGHT TO REDRESS

1) Governments to set up expeditious, fair, inexpensive and accessible avenues for redress.
2) Companies to resolve disputes in a fair, expeditious and informal manner and to set up voluntary mechanisms such as advisory services and informal complaint procedures for consumers.

RIGHT TO INFORMATION

1) Information for consumers on proper use and risks associated with consumer products.
2) Free flow of accurate information relating to consumer products.
3) Governments to develop consumer information programmes in mass media

[2] United Nations Conference on Trade and Development, (2001). United nations guidelines for consumer protection. Retrieved September 12, 2005, from http://www.unctad.org/en/docs/poditcclpm21.en.pdf.

aimed at rural and illiterate consumers.

RIGHT TO A HEALTHY ENVIRONMENT

1) Adopting measures relating to use, production and storage of pesticides and chemicals.
2) Including health and environmental information in labeling of pesticides and chemicals.

RIGHT TO CHOICE

1) Control of abusive and restrictive business practices.
2) Goods that meet durability, utility, reliability and fit their purpose and availability of reliable after sales service and spare parts.
3) Protection of consumers from unfair contracts and regulation of promotional markets and sales.
4) Review of the legislation and enforcement on weights and measures.

RIGHT TO BASIC NEEDS

1) Adopt food safety measures, including safety criteria, food standards and dietary requirements, effective monitoring, inspection and evaluation mechanisms.
2) Adopt food standards of FAO, WHO CODEX Alimentarius or generally accepted international food standards.
3) Improve the quality and appropriate use of pharmaceuticals through integrated national drug policies.
4) Develop national drug policies that could address procurement, distribution, production, licensing arrangements, registration systems and availability of reliable information on pharmaceuticals taking into consideration the work and recommendations of WHO in these areas.
5) Develop, maintain and strengthen national policies to improve the supply, distribution and quality of drinking water.

RIGHT TO CONSUMER EDUCATION

1) Introducing consumer education in the basic curricula of the education system.
2) Education programmes particularly for benefit of low income consumers in rural and urban areas.
3) Governments to organize training programmes for education, mass media professionals etc.
4) Business to undertake/participate in factual and relevant consumer education programmes.

The eight objectives of the UNGCP are delineated in section 1 of the Guidelines. In the preamble, it has been emphasized that "*consumers should have the right of access to non-hazardous products, as well as the importance of promoting just, equitable and sustainable economic and social development.*" The UNGCP presents general principles and governments are called upon to develop their consumer protection policies in line with these principles. Each government must set its own priorities according to the economic and social circumstances of its country and population. The case for the Guidelines is that they set out and codify the main elements of consumer protection, and create an international framework within which national consumer protection policies including the NMP can be worked out.

They give drug policy a clear set of objectives and provide a checklist to policy makers to give importance to issue which impact consumers at large.

The most important consumer right in the UNGCP is the 'Right to Basic Needs' including health. The subtext of this consumer right provides governments a clear guideline to "*develop national drug policies that could address procurement, distribution, production, licensing arrangements, registration systems and availability of reliable information on pharmaceuticals taking into consideration the work and recommendations of WHO in these areas*".

Over the years, the Guidelines have been recognized as a valuable set of principles for consumer protection. Indeed, a number of countries have enacted these consumer protection elements in their NMP. Unfortunately being a signatory to these Guidelines, the policy makers in Pakistan never gave importance to these consumer protection elements in the NMP, this reflects a non-compliance of this multilateral commitment.

Analysis of NMP Formulation

In the case of public policy it is understood that the final product is as important as the process involved to achieve it. The formulation of a NMP requires complex negotiations with interests involved: the pharmaceutical industry, the medical profession, drug sellers, consumer groups, academia, the government bureaucracy (different ministries like education, trade, industry etc.), and international donors. It is also important to consult with provincial and district governments. The formulation process involves the organization of the policy process; identifying and analyzing problem; situation analysis, setting goals and objectives; drafting the policy; circulating and revising the policy; formal enforcement of the policy; and at the end launching and promoting the policy.

In the case of NMP formulation in Pakistan, all stakeholders were not involved in the negotiations process. The care-taker Government of 1996 approved the NMP prepared by the Federal Ministry of Health. The hush-hush and haste with which the government approved the draft NMP disregarded the participatory democratic process of policy formulation. In this way the NMP got influenced by pharmaceutical industry in Pakistan. For chronology of NMP formulation see box below.

Chronology of NMP Formulation in Pakistan

- In February 1995 the first time in the history of Pakistan a comprehensive NMP was drafted by MOH in line with the recommendations of the Drug Action Program of World Health Organization
- Following this MOH initiated a process of consultations with stakeholders but its efforts to seek policy consensus were shattered when Pharma Bureau, an organization representing transnational pharmaceutical manufacturers in Pakistan, strongly opposed some important sections of the drafted policy. Immediately a supra-ministerial committee was setup by the government with high profile people from the Finance and Economics background as its members. This committee later consulted with most of the stakeholders like Parma Bureau, local manufactures and a consumer interest group (Network for Rational Use of Medication in Pakistan, The Network). After consultations, committee revised the draft policy.
- The revised draft policy drastically made alternations to policy sections which were in conflict with the economic policy of the country (liberalization, privatization and deregulation) as it was opposed by the Pharma Bureau.
- MoH decided to shelve the draft document for a while and wait for

appropriate environment to bring back consumer friendly clauses in the draft. But then caretaker government came and in order to score a point re-shelved the old draft and without any formal process of discussion all of a sudden formally announced the NMP. The draft was not shared with the stakeholders and a historical opportunity to rationalize the pharmaceutical sector in the country was lost.

The Philippines National Drug Policy (PNMP) outlined in 1987, was aimed at improved drug safety, vigorous promotion of rational drug use, self-reliance in drug production, and improved procurement. It had two distinct phases: development and implementation. During the development phase, six key strategies were used to overcome the main problems and create a consensus among the partners.

South Africa: A National Document

The National Drug Policy of South Africa was developed by the Department of Health over a two-year period through a large number of consultative meetings involving political parties, other ministries, academia, provincial and district representatives, professional bodies, the pharmaceutical industry and consumer representatives. The final document was adopted by Cabinet and presented to Parliament in June 1996; this formed the basis for a comprehensive five year Implementation Plan. Part of its success was due to the political "window of opportunity" immediately after the end of apartheid in 1994.

The Philippines: A Carefully Designed Formulation Process

Strategy I: Use Democratic Broad Consultation and Participation. The intent was to generate broad involvement so that the positions of the major affected sectors would be understood. Although consensus building was sought and a democratic process was followed, the government took a leadership role in policy formulation and tried to solve any bottle- necks expeditiously. The process of consultation involved three main groups: the top management of the Department of Health (the secretary and the two undersecretaries, who initiated the activities); the Task Force on Pharmaceuticals (including representatives from the drug industry, academia, private medical practice, professional societies, other government agencies, and NGOs), which had to produce a framework for the policy; and a third group composed of organizations, associations, companies, and individuals who felt that they had a stake in the policy. In the course of a one-year development process, two national workshops were held, twenty-five position papers were submitted, and ninety-nine individuals representing sixty-one organizations were involved. This first strategy created a sense of "ownership" of the proposed reforms among those involved and increased their willingness to defend the policy.

Strategy 2: Institutionalize the Policy through Laws and Regulations. The most important legislation was the Generics Act of 1988, passed unanimously in congress and signed into law by the president eighteen months after the PNMP was declared. The act contained straightforward guidelines (on generics, informed consumers, supply, national drug formulary, and so forth) and gave the PNMP a legal basis that ensured its long-term sustainability.

Strategy 3: Formulate as Comprehensive and Practical a Policy as Possible. The group assigned to formulate the PNMP relied on experiences of other countries and developed a comprehensive framework to cover both the supply and demand sides of the pharmaceutical system. The goal was simple: the provision of essential drugs. To achieve this, the PNMP depended on four "pillars" to be built simultaneously: quality assurance, rational use, self-reliance, and tailored procurement.

Strategy 4: Involve the Best-Qualified People. The policy needed to be promoted by high-level officials convinced of its worth, including the secretary, some of the undersecretaries, the assistant secretary responsible for the NMP; and members of the task force selected for their competence and dedication.

Strategy 5: Gather Adequate and Scientifically Sound Data. Data gathered by the task force on pharmaceutical systems and NMP guidelines provided

support in the debates on the scientific soundness and social relevance of the PNMP.

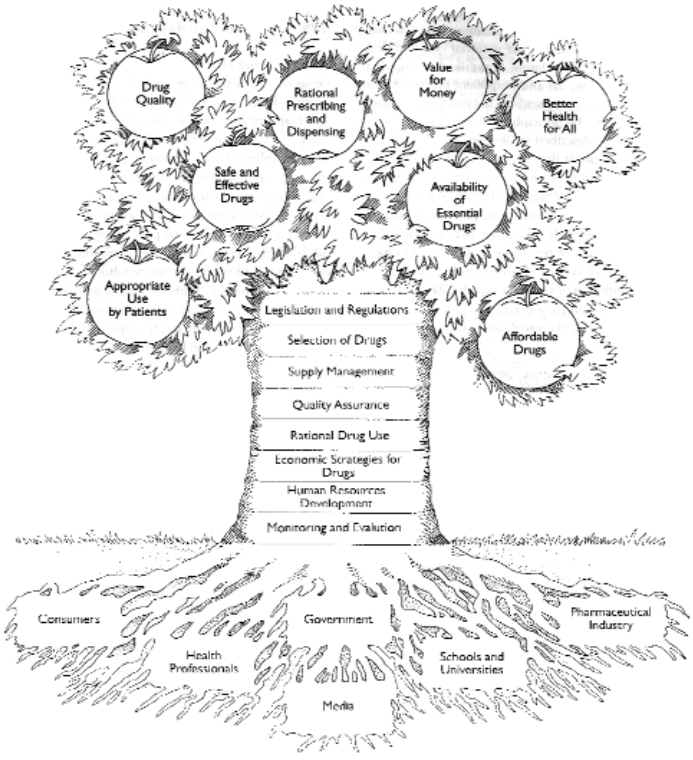
Strategy 6: Harness and Mobilize International Support. From the beginning, international support was sought from WHO, members of the Association of Southeast Asian Nations (ASEAN), Japan, and Australia. This support was important when the policy was under strong attack both within and outside the country.

Careful and comprehensive development was absolutely necessary, since the policy aimed to transform the pharmaceutical sector. Such changes require political will and public involvement of the main initiators, with the widest possible consultation and participation of all sectors affected by the policy.

Source: Philippine Centre for Investigative journalism 1992.

Components

A national medicine policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy. The Pakistani NMP did not balance the various objectives to create a complete and consistent entity. For example, access to essential medicines can only be achieved through rational selection, affordable prices, sustainable financing and reliable health and supply systems. Each of the four components of the "access framework" is essential but not sufficient in itself to ensure access. Similarly, rational use of medicines depends on many factors, such as rational selection, regulatory measures, educational strategies and financial incentives.[3] Diagram below lists the key components of a national drug policy and shows how they relate to the main objectives of the policy and that most components cannot be linked to one objective only.



NMP - A Tree That Bears Fruit[4]

[3] World Health Organization 2002. How to develop and implement a national drug policy. Geneva
[4] Management Science for Health (1997). Managing Drug Supply, Kumarian Press, USA

Components of NMP[5]

Legislative and Regulatory Framework
- Legislation and regulations
- Drug regulatory authority
- Drug registration and licensing
- Pharmaceutical quality assurance
- Post marketing of surveillance
- Regulation of prescription and description

Choice of Drugs
- Principles of drug selection
- Selection process
- Selection criteria
- Use of essential drugs lists
- Traditional medicines

Supply
- Local production
- Supply system strategies and alternatives
- Procurement mechanisms
- Distribution and storage

Rational Use of Drugs
- Objective drug information
- Rational use of drugs by health personnel
- Rational use of drugs by consumers
- Promotional and storage

Economic Strategies for Drugs
- Role of government in the pharmaceutical market
- Measures to encourage competition
- Public drug financing mechanism (public financing, user charges, health insurance, external assistance)
- Measures to improve efficiency and cost effectiveness

[5] Adapted from Report of the WHO Expert Committee on National Drug Policies (WHO/DAP/95.9), 1995.

Human Resource Development
- Role of health professionals
- Human resource development plan
- Education, training, and courses
- National; collaborating networks
- Motivation and continuing educaton

Monitoring and Evaluation
- Responsibility
- Indicators for monitoring
- Periodic evaluation

Research
- Operational research
- Drug research and development

Technical Cooperation among countries

Critical Analysis of Pakistan NMP

The NMP of Pakistan has overlooked many of the above key components. The following table presents a summery of NMP with a critical analysis on each component:

#	Component	Summary	Comments
1	Objective	This section contains eight objectives of the NMP, like promoting the concept of essential drugs; rational use of drugs; availability and accessibility of drugs; self sufficiency in formulation of finished drugs; hazards of substandard, counterfeit and unsafe drugs; trained manpower; research base; and development of the pharmaceutical industry in Pakistan. The rest sections of the NMP are designed and formulated to achieve these eight objectives.	None of the eight objectives of the NMP speaks of ensuring the availability and accessibility of the essential drugs to the people of Pakistan. The first and second objectives are just incomprehensible. Third objective mentions the drug prices in passing whereas the drug prices in the country are the most prominent issue in the pharmaceutical sector at present. It does not talk of lowering the drug prices but reads as "to ensure the supply of unadulterated, pure and genuine drug at reasonable prices to the people in all parts of the country". Fourth objective talks of developing and promoting the concept of essential drugs and interestingly it does not mention the implementation of the essential drug concept. Rest of the four objectives of the policy are about rational drug use, self-sufficiency, spurious drugs and the promotion of the pharmaceutical industry. The policy document does not set for itself the objectives of ensuring good prescribing and dispensing practices, independent drug information, reorientation of medical and pharmacy education towards the principles underlying the NMP, support of local industry to produce essential drugs.
2	Legislation	The section contains information on the Drugs Act, 1976, which has been framed on various aspects of drug control like a system of licensing and registration, quality control	The three subsections under legislation deals with an ineffective commitment in the first, modification of these laws as and when required and need to regulate the traditional systems of medicine. There is not a word about the impediments in its implementation and how to overcome these. Having a "fairly modern" law in place seems to be an end by the policy formulators.No areas have been identified in the Act

		through inspection and laboratory services, and compliance of Good Manufacturing Practices. Under this Act, the manufacturing, registering and import/export are regulated by the Federal Government where as the sale is regulated by the Provincial Governments.	to be absent, weaker and/or requiring amendments. Likewise when need for regulation in traditional medicines is mentioned no frame-work for the formulation of law is mentioned. At best it is a very non-committal stance. One would have like to see the following areas taken-up by the policy; 1. Legislative measures for reorienting the Drug Registration Board in terms of making it autonomous, professional, transparent and revenue generating. Renewal of fee structure to undertake drug evaluations, drug testing and computerization of its administrative procedures; 3. Drug registration data exchange system with regulatory bodies in other countries; 4. Provision of legal cover to the essential drug concept i.e. production, registration and procurement of essential drugs; and 5. Clear distinction between OTC and prescription-only drugs and strengthening and implementation of the law in this regard.
3	National Essential Drugs List (NEDL)	This is one of the detailed section of the Policy which deals with almost all the important aspects of the essential drug concept: preparation of National Essential Drug List (NEDL), bulk purchases of essential drugs by health institutions, promotion of essential drug concept, prescriptions based on NEDL, system of audit and	There are two impressions while going through this elaborated section of the policy. Firstly that although there is mention of all the necessary ingredients but as one carefully read about these one gets a feeling that no solid measures are provided to institutionalize the concept into the system. For example very appreciably it is mentioned that the essential drug concept will also be promoted in the private sector but there is no mention about how to go about it, likewise there is mention about increasing the share of essential drugs in local production but again there is no mention about what minimum percentage of essential drugs will be required by the manufacturers. Same way although periodic review of NEDL is provided but there is no mention about the formation of National Formulary Committee as suggested by the WHO.

		accountability, periodic review of NEDL, criteria for selection of essential drugs, availability of essential drugs, constitution of hospital pharmacy and therapeutics committees and use of generic names for essential drugs.	Secondly, one gets an impression of too ambitious, incoherent and non-committal plans. For example while discussing "criteria for selection of E.Ds." it is given that "For the selection of essential drugs and for establishing a national program for the use of essential drugs, the guidelines and criteria recommended by the WHO shall be followed" !
4	Drug Production	This section highlights the drug production vision by encouraging manufacture of drugs within the country. The section provides the situational analysis and vision for self-reliance in drug manufacture. Some of the incentives for drug production has been highlighted like concessional rates of import duty and sales tax on the import of plant, machinery equipment, all raw materials; tariff protection against imports; loans for the establishment of basic / semi-basic manufacturing plants; adequate and timely supply of raw materials at international standards; preferred treatment in	This is the most elaborated section of the policy with clear description of measures for enhancing the local production of drugs through easing the existing tax regime especially the sales tax and by providing the tariff protection. Although it is against the current economic policy of the country one hopes that MoH had inter-ministerial consultation before committing these measures. An emphasis has been on encouraging basic manufacture and then semi-basic manufacture which is correct from the point of view of creating self-sufficiency in the pharmaceuticals. One would have like to see the focusing of local production on essential drugs but unfortunately this is not the case. Comparing the lucidity and specificity of arguments which directly deal with the consumers and those which relate to industry one clearly come out with an impression that policy has a clear tilt and emphasis toward the industry. National Industry and Export In the February 1995 draft NMP on the question of self-sufficiency and transfer of technology to the domestic producers the section read like this "To upgrade and develop national units, new foreign companies shall be allowed joint ventures only with

		tariff rates and in drug prices to manufactures of drugs included in the National Essential Drug List. This section also highlights the linkages of national industry and exports aiming to encourage exports of drugs.	the national units" where as a very weaker prescription is provided in the current policy, " where a multinational company and a national collaborator partnership splits up, the former shall be permitted either to set-up an independent unit or to enter into a joint venture project only with another national company".
5	Registration of Drugs	This section explains the registration of finished drugs under the Drug Act, 1976 (Drugs Registration Board) against a prescribed criteria. The section also highlight the de-registered of drugs which are irrational, unsafe and obsolete formulations and combinations. Banning of drugs, which are already banned in some advanced countries. Computerize data and publication by the Ministry of Health. The section also elaborates the country of origin and labeling of drugs using the generic names. The import of drugs will be allowed to ensure availability and fair pricing through competition and at the same time anti-dumping	There is a contradiction in the first statement under this head when it says that "presently some 13,000 products are registered ...". According to our report until 20 March 1996 meeting of the Drug Registration Board (DRB) some 19,157 drugs had been registered. There had been DRB meetings after that so one can easily say that the current number of registered products under Drug Act 1976 would be easily around 20,000. This section of the Policy claims that "all irrational, unsafe and obsolete formulations and combinations shall be de-registered". In this regard it would have been much pertinent to link this sub-section to Pakistan Medical Research Council's commendable work of review of all drugs in early 1980s. This work is available with MoH in a 10 Volume study. In February 1995 draft policy it was explicitly mentioned that "the foreign companies shall be allowed to manufacture only those products which are registered and allowed free sale in the country of origin" but in the present policy this issue has taken a step back. The current policy reads that "drugs or any indication of a drug which are banned for safety reasons either in USA, Canada, European Union, Japan, Australia, China, Switzerland or in the country of origin shall not be allowed sale in Pakistan".

		laws shall be enforced in order to prevent dumping when necessary.	Computerization of drug registrations is a welcome step similarly the use of generic names with at least same prominence as brand names is also a much desired measure to be followed by the manufacturers. Provision for establishment of adverse drug reactions is also a welcome measure though an already taken initiative by College of Physicians & Surgeons in this direction needs to be strengthened and a reference to that was in order.
6	Drug Pricing	This section covers the drug pricing issues, starting with a government's commitment to make efforts to make availability of much needed drugs at reasonable prices. The grant of patent protection for drugs shall be only of process and not for the product up till a certain period of time for this to happen the patent law shall be amended accordingly. There is a commitment to revise the pricing formula on the basis of international competitive prices of raw materials, cost of production and reasonable margin of profit. There is also commitment towards development of a system for monitoring and evaluation of drug.	There is a lot of rhetoric in the policy on drug prices but no reference is made to the existing partial deregulation pricing policy which has given rise to phenomenal price increases. Lofty promises are made but no implementation framework is provided. For example revision of pricing formula, annual drug price review and system of monitoring and evaluation of drug prices. Second section reads "the grant of patent protection for drugs shall be only for process and not for product". One can only wish that this could happen because as member of World Trade Organization (WTO) it has become rather difficult, if not impossible, to go for only process patents. This section also mentions transfer pricing as it reads "Transfer pricing over and above the margin of 15% shall not be allowed after the expiration of patent of a product". It is good that policy has at least mentioned about the issue of transfer pricing which is a major instrument with the industry for syphonening the money out of the country. Policy does not tell that how the transfer pricing will be assessed, monitored and controlled on patent protected products. Interestingly the last sub-section says that "adequate powers shall be made available under the Drug Laws for fixing and revising the drug prices of both finished drugs and there active ingredients" but while discussing legislation in NMP it mentions that the law provides for fixing drug prices and there is no mention of making available of such powers under

			the law. In fact section 12 of Drug Act 1976 empowers the Federal Government to fix the maximum prices of drugs. This is an obvious contradiction in terms.
7	Drug Supply System	This section elaborates the drug supply system in both public and private sector. This section has two parts, the first part discusses the 'Hospital Pharmacy' the policy objective of the Government is to introduce the scheme scientific hospital pharmacy and appointment of hospital pharmacists to be appointed in all the hospitals of the country at the rate of one pharmacist for each fifty beds. There is a commitment to organizing the Hospital Pharmacy System on scientific lines. There is also commitment towards modernizing the Federal and Provincial drugs supply system for the hospitals and dispensaries etc. This section also highlights the procurement of drugs shall be based on reliable quantification of drug needs in the public sector and all drugs supplied to the health institutions shall be monitored for quality at the time of purchases. The second part discussed the Community Pharmacy (Retail Pharmacy) in the Private Sector, with government's commitment to introduce a system of scientific retail pharmacy in a gradual manner.	The role of the pharmacist has rightly been highlighted in the area of drug supply system. Their dearth and importance is mentioned and one hospital pharmacist per fifty beds is set as a policy objective. There is no mention of this objective in details of objectives in the beginning of the policy. Setting up of Model Hospital Pharmacies, procurements based on quantification of needs and quality checks of drug supplies are the basic requirements of any rational drug supply system. There are good points about the retail pharmacies e.g. appointment of a graduate pharmacist in the retail pharmacies, future issuance of drug sale licenses in view of the size of the community and the catchments' areas so as to avoid their concentration around hospitals in order to increase the geographical access of the people to the retail pharmacies and restriction to sell all the drugs over-the-counter (although the law needs to be strengthened in this case).

8	**Quality Assurance**	This section covers the quality assurance aspects of drugs and forms the main objectives of the NMP. This section has been divided into two parts as inspection services and laboratory services. The first part highlights the mechanisms of the inspection services; Good Manufacturing Practices (GMP): Good Storage and Distribution Practices; inspection and sampling; market surveillance and spurious drugs. The second part on laboratory services highlights the resource mobilization for the Central Drugs Laboratory, Appellate Laboratory. There is a commitment to develop Good Laboratory Practices, systematically use of WHO Certification Scheme; WHO Good Clinical Practices, establishment of full time drug courts and self monitoring by the Industry.	Policy promises recruitment of new quality assurance inspectors both at federal and provincial level and for improvement in their reporting system so that they can ensure compliance to GMP and Good Storage and Distribution Practices. This is something which requires urgent action but again like rest of the policy it does not tell that how and when this will be done. Likewise is the question of quality assurance laboratories. The policy provides realistic situation analysis about the state of quality assurance laboratories in the country and need for improvement both in hard and soft-ware. While describing the WHO certification scheme it is said that "in order to ensure quality of drugs in the international commerce, the WHO certification scheme shall be used systematically", one fails to understand the meaning of word systematically. It does not augur well for a national policy document to leave important issues vague ended, it just indicates the emptiness of the promises and lack of any will for implementation.
9	Measures to Support Rational Use	This section addresses to promote rational drug use by measures like Drug Information Bulletin; Ethical Criteria for Medical Drug Promotion: publication of a National Formulary in a new context so as to serve as reliable prescribing and dispensing guide to all doctors and pharmacists of the country and as an effective teaching aid; similarly Standard Treatment Guidelines	A narrow approach has been taken for measures to promote rational use of medication. Apart from provision of drug information and regulating the drug promotion there seems to be no other measures for rational drug use promotion. One would like to see other measures for changing the drug use behavior in addition to those provided in the policy for example training for appropriate prescribing, influencing opinion leaders, banning

		in important areas shall be prepared and published and made available for wider circulation; and establishment pf computerized Drug Information Centre and a Adverse Drug Reaction Monitoring Centre.	undesirable drugs and other managerial and regulatory strategies.
10	Human Resource Development	This section provides commitments toward human resource development for an efficient drug supply system and to encourage rational use of Drugs. The commitment has been made to support facilities and curricula in Medical and Pharmacy Schools. Strengthening and revision of curricula for formal training of ancillary health workers and nurses. In-service training courses for pharmacists, medical officer, graduate nurses and ancillary health workers to improve skills in their respective areas of activity related to drugs. Refresher and continuous education courses, seminars and lecturers to promote the concept of essential drugs and rational drug use. As recommended by WHO, pharmacists shall be made to play their recognized role in all activities relating to drug control, management, supply and distribution.	All the measures proposed in the policy for human resource development are important; however the objective of HRD in this context should be to support the successful implementation of the policy and to promote the concepts of the rational drug use and essential drug concept.
11	Research and Development	This section covers the research and development issues, mainly the requirements of Drugs Act, 1976 that requires the manufacturers to contribute a certain percentage of their profit (1 %) towards a Drug Research Fund. There is a commitment towards establishment of a comprehensive national drug research program, where preference shall be given to operational and applied research along with incentives in the fol	The stipulated contribution by manufacturers towards Drug Research Fund is restated and another lofty promise is made to launch a National Drug Research Program. One is compelled to ask that if this research fund is not used in last 20 years then how this will be used now and what has led to make this promise?

		lowing areas in particulars. ■ Exploitation of local resources for basic manufacture of drugs. ■ Development of new drugs from local resources. ■ Studies in rational drugs use. ■ Drug utilization studies. ■ Traditional Medicines.	
12	Drug Control Organization	This section gives the descriptions of commitments to strengthen the Drug and Quality Control Organization at the Federal Level and similarly the Provincial Drug Control Organization. The policy recognizes the e existing facilities of manpower in the drugs control administration and for drug registration are presently inadequate even for day to day work and recommends providing the additional expert technical staff.	Establishment of an autonomous Federal Drug Authority (FDA), and necessary amendments to the 1976 Drugs Act for it, was provided for in the February 1995 draft NMP but this provision is now weakened in the present Policy and instead of autonomous FDA it talks only about strengthening of the existing structure for drug and quality control within MoH which at present is not adequate for the gigantic task of drug regulation in the country. An autonomous authority is the need of the hour and many even developing countries have already established such authorities.
13	Master Plans	The last section provides implementation commitments in the forms of developing Masters Plans. A Master Plan shall be prepared every five years on the basis of current situation analysis. The plan should identify the basic problems and the measures to be taken; identify the targets to be achieved in quantitative terms in a specified time; and prepare an estimate of the resources needed to implement the Plan and identify the sources for funding and support.	What one should understand with this "plan"? Who will develop the plan and when, which is the first five year period, haven't the policy already identified the basic problems?

Implementation

Policy implementation is mainly about management and coordination of actions. Implementation of a policy becomes easier if the responsibilities and roles are well defined and assigned in the action plans. The execution approach of a NMP is included in the policy through specific plans and programs. Implementation is a critical step especially in Pakistan, where the research-policy-implementation nexus mostly fails at implementation stage. It is important to note that the gap between official policy and its implementation in practice has always also been major concerns in Pakistan. In principle and given the multi-sectoral nature of pharmaceutical issues in Pakistan, the MoH should have developed, as early as possible, a consensus with other government ministries/agencies and stakeholders on action plans. The NMP of Pakistan mentions the development of 'Master Plans' after every five years, still after announcing the NMP there is no such Master Plan in action to implement the Policy on grounds.

On the implementation issues, some countries have used innovative and different approaches to link NMP formulation and implementation areas, one of the interesting country case is of Australia. The National Medicines Policy of Australia has four arms - quality, safety and efficacy of medicines; equity of access; a viable and responsible pharmaceutical industry; and quality use of medicines. The four arms of the Policy are interlinked and interdependent for optimal functioning as given in the box below.

NMP Formulation and Implementation in Australia

By 1992, Australia had three elements of a drug policy in place:

1. A system for regulating the marketing of high-quality, safe, and efficacious products;
2. An equitable system of drug access that ensures supply and controls price;
3. An industry development program.

What was missing, however, was a rational drug use component that would firmly link these three activities to health outcomes.

The minister of health was committed to the issue, and the government began to fund educational programs. After two years, however, it became clear that an overall strategy was needed. Attempts to introduce policy or action that did not adequately involve doctors and pharmacists were likely to fail. Consumers had

not traditionally been involved in the decision- making process. Lessons from the past suggested that communication with and involvement of all interested parties were crucial.

In 1990, the minister formed two advisory groups. The first was a council of representatives from the major organizations involved, which would raise issues and make recommendations across the gamut of drug policy. The second was the Pharmaceutical Health and Rational Use of Medicines (PHARM) working party, to advise the ministry on a policy for the use of medicines and a strategy for its implementation. PHARM drew on the best available knowledge and relevant concepts to establish a coherent framework for tackling the complex set of problems involved in the way medicines are used. The group also drew on research in behavioral change and health education; espoused principles of community ownership, participation, and consultation; and acknowledged the importance of media advocacy.

In 1992, this collaborative approach led to the adoption of an NMP. The approach was to

. use consumer and professional education as a primary tool;
. stimulate partnerships among the major players;
. identify
  - what will empower consumers to use drugs well and encourage health professionals to help them do this?
  - what constitutes effective education?
  - what combination of information, skills, and motivation will be effective for different groups?
  - what will work in practice?
  - what standards should apply, and who should set them?

Through various mechanisms of encouragement-including proactive consultation, targeted grants, and support for further development of existing programs-actions were stimulated, and new ideas from various groups were identified, including:

Objective information: The preparation of national prescribing guidelines, a national formulary, consumer information, and independent monitoring of drug advertising have been sup- ported.

Education and training: A school kit for young children was funded.

Consumer services: Medication record cards and innovative consumer education programs have been provided to encourage consumers to ask their health professionals more questions about medicines and to support them in

running local campaigns on drug use.

Provider services: Several types of academic detailing programs were developed.

Education campaigns: National education campaigns took place in 1992, including one aimed at educating health professionals and the community about the safety of using non- steroidal anti-inflammatory drugs.

The "Be wise with medicines" campaign: This major national community awareness campaign used the principles of community development and involved all players. Three hundred fifty local community groups were given small grants to design activities aimed at stimulating discussion and educating their members about medicines. Groups came up with a wide range of activities, including health fairs, discussion groups, talks by local doctors or pharmacists, and shopping center displays. A range of ages, many multicultural groups, and aboriginal groups in metropolitan, rural, and remote settings were represented.

A strong principle underlying the approach to optimizing the use of medicines is to stimulate new programs and ideas whenever possible while supporting existing effective initiatives within local communities or professional and consumer groups. A sustainable infrastructure is needed to facilitate, coordinate, and support initiatives at the state, regional, and local levels in a way that honors this principle.

So far, the partnership developed among groups is fragile. There are signs, however, that continued dialog and experience working jointly on projects are significantly improving the understanding of others' responsibilities and constraints.

Source: Adapted from Hodge 1993.

Monitoring and Evaluation

Monitoring and evaluation are essential components of a national drug policy and provisions for monitoring and evaluation need to be included in the policy itself. It is unfortunate that key indicators for each component of the policy are not well defined in the NMP of Pakistan. As the there is Master Plan to implement the NMP, so no adequate staff and an operating budget was set aside to monitor and evaluate. As there are not well define indicators, so it is were difficult to measure and assess the progress.

Ideally key aspects to monitor and evaluate a NMP should include:

- explicit government commitment to the principles of monitoring and evaluation;
- baseline survey of the whole country carried out early in the implementation of the policy;
- monitoring of the pharmaceutical sector through regular indicator-based surveys; and
- independent external evaluation of the impact of the policy on all sectors of the community and the economy preferably every 2 to 3 years.

A consumer perspective to monitoring and evaluation of a NMP is primarily based on the Participatory Monitoring and Evaluation (PM&E) that promotes the involvement of a wide range of stakeholders, employing methods that allow a more equal opportunity for the expression of views and sharing of lessons and experiences, leading to greater accountability and transparency, i.e. for signs of progress towards goals. This should be reflected both in improved monitoring (e.g. report writing), as well as in evaluation (reflection and learning) of the NMP.[6]

[6]http://www.eldis.org/participation/pme/pme1_1.htm

RECOMMENDATIONS

The first and foremost important step to be taken is to open a debate for revamping the NMP in the country with a participatory approach involving all the stakeholders. Also, attention must be paid to create sustainable resources, systems and mechanisms that ensure implementation of the policy.

The following recommendations provide a basis to amend the NMP from a consumer perspective.

1. The revised policy document should set the objectives and implementation mechanisms of ensuring good prescribing, storage and dispensing practices, independent drug information, pharmacovigilance and ADR monitoring, removal of all counterfeit, spurious and substandard as well as dangerous medicines, ensuring through out the year availability of all essential drugs across the country and mandating industry to produce and market essential drugs, reorientation of medical and pharmacy education towards the principles underlying the NMP.
2. Lowering of drug prices should also be one of the main objective of the NMP and the Ministry should use the powers conferred on it by the Drug Act. Interestingly, Drug Pricing chapter's last sub-section of the NMP says that "adequate powers shall be made available under the Drug Laws for fixing and revising the drug prices of both finished drugs and there active ingredients" but while discussing legislation in NMP it mentions that the law provides for fixing drug prices and there is no mention of making available of such powers under the law. In fact section 12 of Drug Act 1976 empowers the Federal Government to fix the maximum prices of drugs. This is an obvious contradiction in terms.
3. A narrow approach has been taken in the NMP for measures to promote rational use of medication. Apart from provision of drug information and regulating the drug promotion there seems to be no other measures for rational drug use promotion. The revised policy must have rational drug use promotion, both at the providers as well as users (community) level, as its core objective and ways and means should be laid out to ensure that the objectives are achieved.
4. The section on "Masters Plans" is very vague in nature and shows weak commitment to implement the plans. There must be clear targets, responsibilities, time frame and allocation of resources earmarked for the purpose of implementation. Also a clearly laid out monitoring and evaluation mechanism should be part of the policy.
5. Although periodic review of NEDL is provided in the NMP but there is

need to establish and fully activate a National Formulary Committee on an agreed mandate and resources as suggested by the WHO.

6. The NMP mentions the tariff protection for pharmaceutical industries. Drug Pricing Section: "the grant of patent protection for drugs shall be only for process and not for product", this is some what to rethink as member of World Trade Organization (WTO) it has become rather difficult, if not impossible, to go for only process patents. MoH should have an inter-ministerial consultation before committing these measures in the NMP, as it is contrary to WTO obligations.
7. In the February 1995 draft NMP on the question of self-sufficiency and transfer of technology to the domestic producers the section read like this "To upgrade and develop national units, new foreign companies shall be allowed joint ventures only with the national units" where as a very weaker prescription is provided in the current NMP, "where a multinational company and a national collaborator partnership splits up, the former shall be permitted either to set-up an independent unit or to enter into a joint venture project only with another national company". The text of draft NMP (1995) should be followed in this regard.
8. There is a contradiction in the first statement under (Registration of Drugs Section) when it says that "presently some 13,000 products are registered ...". According to TheNetwork's report until 20 March 1996 meeting of the Drug Registration Board (DRB) some 19,157 drugs had been registered. There has been many DRB meetings after that and the current number of registered products under Drug Act 1976 is estimated to be around 45,000. This unnecessarily high number of pharmaceutical products puts unbearable burden the weak quality assurance system in the country and as a result the quality of the products available in the market suffers from horrifying results including counterfeiting, spurious and substandard medicines playing havoc with the lives of the consumers. There must be a stringent check on the existing as well as new registrations and the quality assurance system made modern and up to date with the challenges faced by the sector. The role and performance of the Drug Registration Board must also be reviewed and appropriate amendments brought in its terms of reference.
9. In February 1995 draft NMP it was explicitly mentioned that "the foreign companies shall be allowed to manufacture only those products which are registered and allowed free sale in the country of origin" but in the present policy this issue has taken a step back. The current policy reads that "drugs or any indication of a drug which are banned for safety

reasons either in USA, Canada, European Union, Japan, Australia, China, and Switzerland or in the country of origin shall not be allowed sale in Pakistan". The text of draft NMP (1995) should be included in the revised NMP.

10. While describing the WHO certification scheme it is mentioned that "in order to ensure quality of drugs in the international commerce, the WHO certification scheme shall be used systematically", here it is very difficult to understand the meaning of word systematically. It does not augur well for a national policy document to leave important issues vague ended, it just indicates the emptiness of the promises and lack of any will for implementation.
11. Central Research Fund: If the research fund is not used in last 25 years then how this will be used now, even there is no mentioning of the processes of implementing this commitment. The revised policy must be clearly operationalise the research fund on priority research needs of the sector.
12. Establishment of an autonomous Federal Drug Authority (FDA), and necessary amendments to the 1976 Drugs Act for it, was provided for in the February 1995 draft NMP but this provision is now weakened in the present NMP and instead of autonomous FDA it talks only about strengthening of the existing structure for drug and quality control within MoH. The text of draft NMP (1995) should be followed in this regard.