

August 2011

# Access to essential medicines: in Pakistan identifying policy research and concerns

Shehla Zaidi
*Aga Khan University*, shehla.zaidi@aku.edu

Noureen Nishtar
*Aga Khan University*

# ACCESS TO ESSENTIAL MEDICINES: IDENTIFYING POLICY RESEARCH AND CONCERNS

**August 2011**

آغا خان یونیورسٹی
THE AGA KHAN UNIVERSITY

**Shehla Zaidi & Noureen Nishtar**
Department of Community Health Sciences
Aga Khan University, Karachi

Funded by Alliance for Health Policy and Research,
World Health Organization, Geneva

# ACCESS TO ESSENTIAL MEDICINES: IN PAKISTAN IDENTIFYING POLICY RESEARCH AND CONCERNS

## ACKNOWLEDGEMENT

This report would not have been possible without the participation provided by a range of stakeholders. Their time commitment, candid sharing of information and thoughtful perspectives are gratefully acknowledged.

In particular we would like to thank the Federal Ministry of Health, National Health System & Policy Unit, Department of Health Sindh, Department of Health Punjab, President's Primary Health Care Initiative, Pakistan Medical Association, Pakistan Pharmacists Association, Pakistan Pharmacy Council, Pakistan Pharmaceutical Manufacturer's Association, Bio-Equivalence Centre Lahore, Experts and NGOs.

The study was a result of close collaborative work with Eastern Mediterranean Regional partners, Dr. Arash Rashidian at Tehran University of Medical Sciences and Dr.Samer Jabbour at American University Beirut. Valuable facilitation and feedback was provided during data collection and synthesis by Khalid Bukhari Coordinator Essential Medicines WHO Pakistan and Dr. Guido Sabatinelli WHO Representative Pakistan. Technical guidance was provided by Maryam Bigdeli at the Alliance for Health Policy System Research, Geneva.

Funding support was granted by Alliance for Health Policy & Systems Research- World Health Organization, Geneva and is gratefully acknowledged. The study was conducted by the Department of Community Health Sciences of Aga Khan University, Karachi.



## *Authors:*

Dr Shehla Zaidi - Country Investigator, Pakistan
Noureen Nishtar - Research Coordinator



## *The correct citation for this report is:*

Zaidi S, Nishtar NA (2011). Access to Medicines: Identifying Policy Concerns and Policy Research Questions, Research Report, Aga Khan University Karachi and the Alliance for Health Policy & Systems Research – WHO Geneva.

# TABLE OF CONTENTS

## ACRONYMS

| | |
|---|---|
| AHPSR | Alliance for Health Policy & System Research Geneva |
| ATM | Access to Medicine |
| AUB | American University Beirut |
| BHUs | Basic Health Units |
| CSOs | Community Service Organizations |
| DFID | Department for International Development UK |
| DHQ | District Headquarters |
| DOH | Department of Health |
| EDL | Essential Drug List |
| EMRO | Eastern Mediterranean Regional Office |
| GMP | Good Manufacturing Practices |
| GPs | General Physicians |
| HAI | Health Action International |
| HIV | Human Immunodeficiency Virus |
| LMICs | Low and Middle income Countries |
| MDG | Millennium Development Goal |
| MOH | Ministry of Health |
| MPR | Median Price Ratio |
| NHA | National Health Accounts |
| NPPI | Norwegian Pakistan Partnership Initiative |
| OECD | Organization for Economic Cooperation and Development |
| PDHS | Pakistan Demographic and Health Survey |
| PMDC | Pakistan Medical and Dental Council |
| PPHI | Presidents Primary Health Care Initiative |
| PSLM | Pakistan Social and Living Standards Measurement Survey |
| RHCs | Rural Health centers |
| THQ | Tehsil Headquarter |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| TUMS | Tehran University of Medical Sciences |
| WHO | World Health Organization |

## ABSTRACT

The fundamental importance of ensuring access to medicines, particularly for the poor, is reflected in MDG 8 however remains poor in many low and middle income countries (LMICs). Country specific evidence on access to medicines is weak in LMICs and research has rarely been from an integrated health systems perspective. This study used an evidence based approach to identify key priority concerns and emerging research questions related to access to medicines in Pakistan. WHO's Access to Medicine Framework was used as the conceptual basis for data collection on rational usage, affordability, financing and health systems. Methods involved a systematic desk review, in-depth stakeholder interviews and a consensus building Roundtable exercise.

In Pakistan there has been considerable work in terms of medicines related policy acts and operative guidelines. However considerable gaps exist between policy and practice and between medicine policies and health systems strategies. Average number of medications prescribed is higher than other LMICs and prescription practices frequently do not follow standard recommended therapies from specialists down to general practitioners. There is a widely entrenched private informal sector and shadow pharmacies which remains largely unregulated. Spending on drugs is mainly borne by households, accounts for 63% of total spending on drugs in Pakistan as compared to only 18% in OECD countries and can lead to catastrophic household expenditure. Medicine therapy for chronic care is particularly unaffordable even with use of low cost generics.

Within the public sector, availability of essential generics is extremely low at 3.3% as compared to 29-54% in LMICs. Public sector spending on drugs is far below the minimum $2 per capita indicated for LMICs and existing spending faces issues of questionable adherence to EDL, low quality drugs and outdated logistics management systems. Contracting out the management of BHUs has resulted in better medicine availability. There is serious shortage of trained manpower pharmacists across private and public sector with 0.9 pharmacist / 100000 population in Pakistan far below recommended ratio of 1 pharmacist per 2000 population. Drug regulation also requires with registration of excessive number of drugs, wide quality variation in quality and pricing, and frequent instances of spurious drugs and black marketing. Chronic shortage of low prices essential medicines is a long standing issue linked to disincentive to production due to low pricing and flat price control.

The above policy concerns raise need for research in key areas. First, there is need for surveys on continuous surveillance of policy impact on availability, price and affordability of medicines; mapping of private informal sector and shadow pharmacies; and consumer health seeking preferences. Second, collation is required of best practice lessons on registration, pricing, market vigilance and enhancement of rational drug use. Third, operation research pilots in key areas such as alternative health financing mechanisms involving commodity voucher, GP contracting, pre-payment schemes, equity funds for increasing drug availability and affordability; scientific improvement of logistics management system in public sector; and introducing community participation in accountability mechanisms.

Pharmaceutical policy and research needs to be centrally placed within larger health systems related initiatives. It needs to be accompanied by sustained dialogue and interaction between multiple stakeholders including private sector. Adequate steps also need to be taken to ensure a continuous culture of research feeding into evidence based policies.

# EXECUTIVE SUMMARY

**Background:** The fundamental importance of ensuring access to medicines, particularly for the poor, is reflected in MDG 8 however access and appropriate use of medicines remains poor in many low and middle income countries (LMICs). WHO estimates that the average availability of essential drugs in LMICs is only 35% in public sector facilities and 66% in the private sector, and that medicines account for a high proportion and between 20% – 60%, of health spending in LMICs as compared to 18% spending in developed countries with substantial costs often borne by households Even where medicines are available, there are concerns of drug quality and inappropriate prescription.

Research on improving access to medicines has not been an integral part of health systems research. Data on access to and use of medicines is often weak and country specific context on medicine policies and practices is often missing. In an attempt to increase use of evidence in policies so as to make them more responsive to local country needs, a policy exploratory study on "Identification of Policy Concerns and Research Questions related to Access to Medicines" was conducted in Pakistan, Iran and Lebanon in the Eastern Mediterranean Region as well as 16 other countries in different WHO regional clusters. These priority setting studies are part of a larger global research initiative on Access to Medicines (ATM) being implemented by Alliance for Health Policy and Systems Research WHO Geneva and funded by the UK Department for International Development (DFID).

**The Study:** The Pakistan Priority Setting project, which is the subject of this report, had two fold objectives: i) to identify Pakistan specific policy concerns related to access to and use of medicines, as perceived by policy makers, civil society organizations and patients and communities; and ii) based on evidence generated to identify emerging research questions. The study was implemented over a six month period and involved a systematic desk review, in-depth stakeholder interviews as a consensus building Roundtable exercise for prirotization of emerging issues and research concerns.

The Pakistan report provides an agenda for country level action –policy concerns for a range of government and non-government stakeholders as well as researchable areas for researchers, Alliance HPSR, other research funding entities and policy makers. It also attempts to bridge the gap between pharmaceutical sector and health systems by integrating responses with health financing, human resource planning, service delivery, information and governance systems.

**Salient Findings:** In Pakistan there has been considerable work in terms of Policy Acts, legislations, detailed regulatory and operative guidelines for the pharmaceutical sector. It is one of the first countries in which the Essential Medicine Program of WHO was initiated in the 1970's and has a National EDL comprising of 335 medicines. The industry has grown from hardly any production unit at the time of Independence to 414 local and 30 multinational drug production companies in Pakistan. Drugs are exempt from sales tax and a flat price control is in place for the last decade in an attempt to increase access of the poor to medicines. However considerable gaps exist between policy and practice leading to high expenditure on drugs by the poor, widespread quality concerns on drugs, widespread inappropriate prescription practices and low drug availability in the public sector facilities.

There is dire need for update of policies in line with on ground evidence and infusion of an innovative mix of policy measures.

**Policy Concerns:** Medical practitioners, including both GPs and specialists, often prescribe unnecessary number of medications with average for Pakistan being >3 medicines per prescription as compared to 2-3 in LMICs and injection usage rate one of the highest in the world. Additionally, population in Pakistan frequently utilizes quacks and informal providers and there is also considerable self medication with indicative figures are of 30-55%. As a result of irrational drug use, drug expenditure borne by households is one of the highest in LMICs, drug resistance

to first line antibiotics has been documented at least in urban Pakistan, and frequent injection usage has been linked to the high prevalence of Hepatitis B and C in the population.

There are several contributing reasons for irrational drug use requiring integrated action at multiple tiers of the health systems. These include poor training and enforcement of standard therapies in the medical sector, unrestricted interaction of industry with practitioners, loose regulation of private informal sector and shadow pharmacies, and registration of unnecessary number of drugs. Successful examples of GP training and franchising for appropriate treatment have long been in place by CSOs but have not been replicated by government.

63% of total drug expenditure is borne by households, one of the highest in developing countries, as opposed to only 18% in OECD countries and leads to non-compliance with chronic care treatment and risk of catastrophic expenditure. Low spending by public sector forces patients utilizing 'free' public sector facilities to private retail outlets.

Medicine therapy for chronic care is clearly unaffordable even with use of low cost generics (MPR of 1.7-7.7) while it can be dangerously expensive with originator brands (MPR of 1.9-36.4). In affordability of medicines has been documented as one of the primary reasons for loose compliance with chronic care therapy.

Availability of essential generics is extremely low in public sector 3.3% in public sector compared to 29-54% in LMICs. Reasons for frequent drug stock-outs have not been properly investigated but are attributed to a combination of low budget, lack of rational procurement and delayed release of funds. Contracting out management of BHUs has resulted in better medicine availability in public sector.

There has been limited attention to management of drugs supply in the public sector with issues of low quality and logistics management. Low quality threshold in purchase of drugs, lack of scientific forecasting, budgeting and procurement, traditional logistic management systems and poor storage facilities need attention.

Private retail outlets are the predominant means to supply to both private and public sector patients however the existence of close to 80,000 drug stores, one of the highest in developing countries, defeats attempts at regulation. Only a fifth of all retail outlets meet licensing requirements and are mostly manned by untrained persons rather than pharmacists.

There is shortage of trained human resource across public and private sector for drug procurement, management and dispensation. As opposed to WHO's recommended ratio of 1:2000 pharmacists per population, Pakistan has only 0.9 pharmacists per 100000 population, of which 70% are engaged in industry with a very small core serving in health service delivery.

Pakistan produces 70% of consumed medicines however close to 50% of the market belongs to multinationals and is far from achieving self-sufficiency in production. Self-sufficiency in tem of raw material production is yet to be achieved with dependence essentially on imports and assistance needs to be provided to local companies for making use of patents available through TRIPS.

Pakistan has 76000-88000 registered drugs, one of the highest numbers in LMICs, with many being unnecessary drugs having marginal therapeutic effect over each other or multiple variations of the same drug available at different prices and quality. There are wide discrepancies in terms of quality of registered products with little incentive for more sophisticated production units to invest in quality control. An autonomous Drug Registration Authority to counter poor drug quality has been endorsed but still needs to be put into practice.

Market vigilance needs strengthening as counterfeit medicines and black-marketing with creation of artificial shortages is common in Pakistan. New modalities of control are needed with move to more participatory and incentive based policies to overcome existing nexus of corruption in the existing hierarchal control system.

Flat price control is in practice and although well intentioned is also counterproductive resulting in disappearance of low cost essential medicines, even life saving drugs, from the market, little impact on high priced items, and a general disincentive to producers. Targeted action is instead needed on identification and tight control of standard treatment for chronic care drugs, life saving drugs and those drugs that are excessively priced. A clearer pricing formula is also needed to reduce opportunity for collusion and inefficient market spending on products.

Greater participation of implementers is needed in regulation however move to totally devolve drug registration to provinces as part of ongoing devolution of Ministry of Health may have serious repercussions due to uneven regulatory capacity of provinces and potential creation of inequities across provinces with differential drug availability and prices. Institutional realignments need to be directed towards creation of an autonomous drug regulation authority but built along more participatory lines.

**Research needs for addressing policy concerns:** There is high need for evidence generation to assist action on prioritized policy concerns. So far research in the pharmaceutical area in Pakistan has been occasional, mostly confined to rational prescription while areas such as policy, supply side and financing have largely been under-examined. Key research priorities were identified through the consensus building exercise and salient features are given as follows:

Continuous surveillance is needed into effect of national policies on medicine availability, prices and affordability covering both the market and the public sector. It is internationally recommended that such surveys should be repeated periodically every two years however there has been no updating of information since the last WHO global survey in 2004.

Quality monitoring and pharmaco-vigilance of market products is required accompanied by compilation of best practice lessons from other countries on new strategies.

Pricing policies require examination to improve access to essential generics particularly for standard chronic care therapy and contain prices of excessively priced originator brands.

Bottlenecks faced by the Essential Medicines Programme in Pakistan need to be examined to reduce the gap between policy and practise with targeted interventions for promotion of generics at policy level, supply side level, individual provider levels and consumer level.

Examination of alternative financing mechanisms is required to reduce medicine expenditure borne by households particularly on chronic care therapy, and supplement public sector provision. Possible mechanisms include franchising with GPs, contracting with NGOs, commodity vouchers, health equity funds and pre-payment schemes, to supplement public sector provision.

Standardised mapping and assessment surveys of private sector are required including of qualified providers, informal providers, shadow pharmacies, and traditional healers.

Formative research is needed into consumer demand, health-seeking preferences, willingness to pay, and enhancing patient role in accountability.

Finally operation research is also needed into improving logistics and human resource management in the public sector for improving drug access. Successful examples from INGOs and donor funded projects can be tested into the public sector.

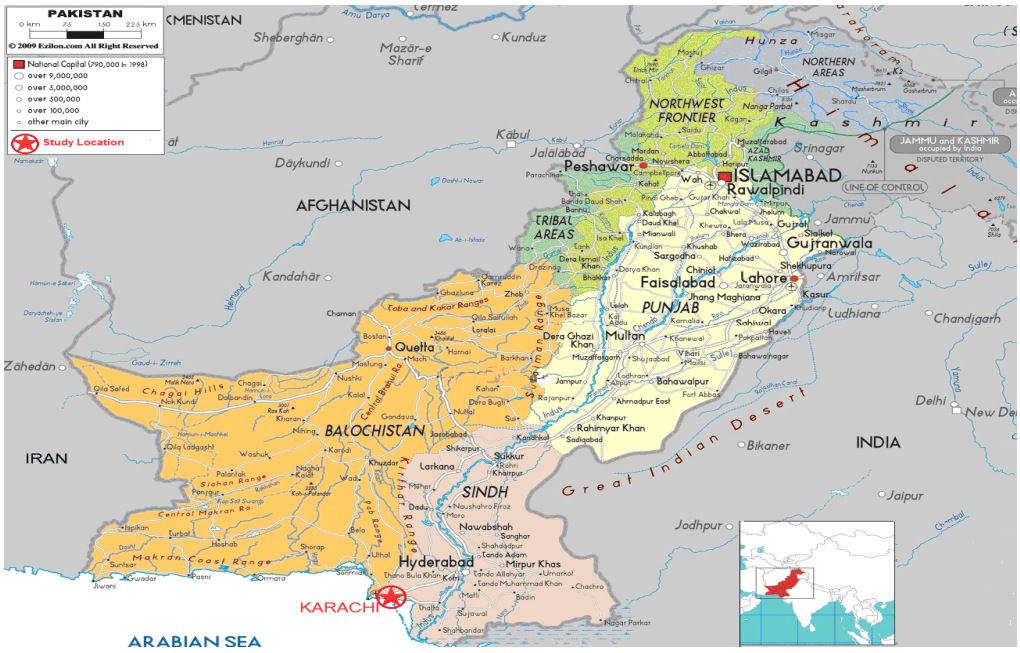
**Way Forward:** Pharmaceutical policy and research need to be centrally placed within larger health systems related initiatives, reviews and policy updates. Action is particularly needed on following priority areas:

- *Continuous surveillance of impact of policies on availability, price and affordability*
- *Identification, regulation and monitoring of standard chronic care therapies that would particularly benefit from reduced pricing and wider availability.*
- *Optimal mix of pricing regulations to reduce expenditure burden on households.*
- *Tighter regulatory control to cut down on unnecessary medicines having marginal therapeutic effect over each other.*
- *Market vigilance for spurious drugs and participatory strategies to counter spurious drugs*
- *Multi-tiered health system measures for promotion of generics*
- *Operation pilots on alternative financing mechanisms to supplement public sector through a range of commodity voucher, GP contracting, pre-payment schemes, equity funds for increasing drug availability and affordability*
- *Mapping of private sector and exploring support needs for rational use*
- *Consumer health seeking preferences and participation in accountability mechanisms*
- *Improvement of logistics and human resource management in public sector for drug access*

This needs to be accompanied by sustained dialogue and interaction between entities including public health sector, pharmacists association, medical doctors association, local governments, industry, researchers and development partners. Adequate steps also need to be taken to ensure access to research, feedback on research and a continuous culture of research feeding into evidence based policies.

# COUNTRY PROFILE

Pakistan is situated in the North-Western part of South Asia, with about 185 million people and annual population growth rate is 1.9% .It is bordered by China on the northeast side, India on the eastern side, Iran and Afghanistan on the western side and the Arabian Sea on its south. The GNP per capita is $1200 and 1% is spent on health.




Life expectancy in Pakistan is 63 for males and 65 for females. Maternal mortality ratio is 276, infant mortality rate is 74 and under five mortality rate is 98 (PDHS 2006-07). Total fertility rate in Pakistan is 4.1, 3.3 in urban and 4.5% in rural areas and CPR is 30%, whereas unmet need of contraception is 25%. (PDHS 2006-7). At the same time Non Communicable Disease burden in Pakistan is also high and accounts for 59% of the forgone DALYs while the remaining 41% disease burden is due to communicable diseases and maternal, child care and nutritional issues (World Bank 2011).

In recent years natural disasters have also had a detrimental effect on health status. 75,000 people died in the 2005 earthquake and 1,810 in the 2010 floods but asides from fatality these disasters resulted in widespread communicable diseases and destroyed the health care infrastructure and peoples' livelihoods in affected areas.

Health care provision in Pakistan comprises private and public services. Although the public sector has a well developed infrastructure of primary, secondary and tertiary facilities as well as an outreach Lady Health Worker Program, public sector is under-utilized and serves 21% of the population (WHO-EMRO 2011). The private sector serving nearly 79% of the population is primarily a fee for service system and covers the range of health care provision from commercial private sector, CSOs, philanthropic institutions and traditional faith healers.

Under Pakistan's constitution, health is primarily the responsibility of the provincial government, except in the federally administrated areas. Ministry of Health (MOH) at the Federal level has played the major role in developing national policies and strategies, hosts 11 vertical programs and also the Drug Control Organization. Under a recent constitutional amendment the Federal MOH along with a number of other ministries is to be devolved to the provinces in 2011 with retaining of a minimalist MOH under the Cabinet Division. Areas and functions to be devolved to provinces are as yet unclear.

# SECTION 1: BACKGROUND

**Introduction:** The provision of reliable access to affordable, appropriate and high-quality medicines is a key component of a functioning health system (WHO 2007). Access to medicines needs to be fully integrated with health financing, human resource planning, service delivery, information and governance systems.

Access to and appropriate use of medicines is often poor in low and middle income countries (LMICs). WHO estimates that the average availability of essential drugs in LMICs is 35% in public sector facilities and 66% in the private sector (MDG 2008). Medicines account for a high proportion, between 20% – 60%, of health spending in LMICs as compared to 18% spending in developed countries (Cameron 2009). Moreover, between 50% - 90% of expenditure on medicines in LMICs is out-of-pocket (WHO 2004a). This inequitable mode of financing creates significant access barriers for the poor and/or may lead to catastrophic household expenditures. The poor as well as other population groups often rely on the private informal sector for medicines, particularly in rural areas. Over and inappropriate prescription and dispensing of medicines are prevalent (WHO 2008).

Despite some progress in some areas - such as price and availability - **,** data on access to and use of medicines is often weak (WHO 2004a). Even where data are available, there is limited contextual evidence and analysis to assist in interpretation or in the development of policy options to improve access to medicines in different health systems and country settings, especially for LMICs. Health Systems Research (HSR) is essential to understanding, planning, monitoring and evaluating access to medicines and importance of HSR was confirmed by the High Level Forum task team report at the Global Ministerial Forum on Research for Health in Bamako in 2008 (WHO 2009).

**The Study:** The Access to Medicines (ATM) Policy research is a new program of work, implemented by the Alliance for Health Policy and Systems Research (AHPSR), WHO Geneva and funded by the UK Department for International Development (DFID). The program aims at improving the availability and use of evidence on access to medicines in Low and Middle Income countries, particularly for the poor (MDG 8) by increasing the use of evidence in policies to improve access to and use of medicines. The Prioritization Study is one of the studies being conducted under the broader ATM project, and is being simultaneously implemented in 19 countries.

Its objectives are two fold, to

- Identify and rank, to the extent possible, country level (PAKISTAN) policy concerns related to access to and use of medicines, as perceived by policy makers, civil society organizations and patients and communities
- Identify and rank, to the extent possible, related policy research questions in the field of access to and use of medicines in PAKISTAN.

The findings are intended to forge an evidence based link to medicines policy and health policy in Pakistan and the EMR region.

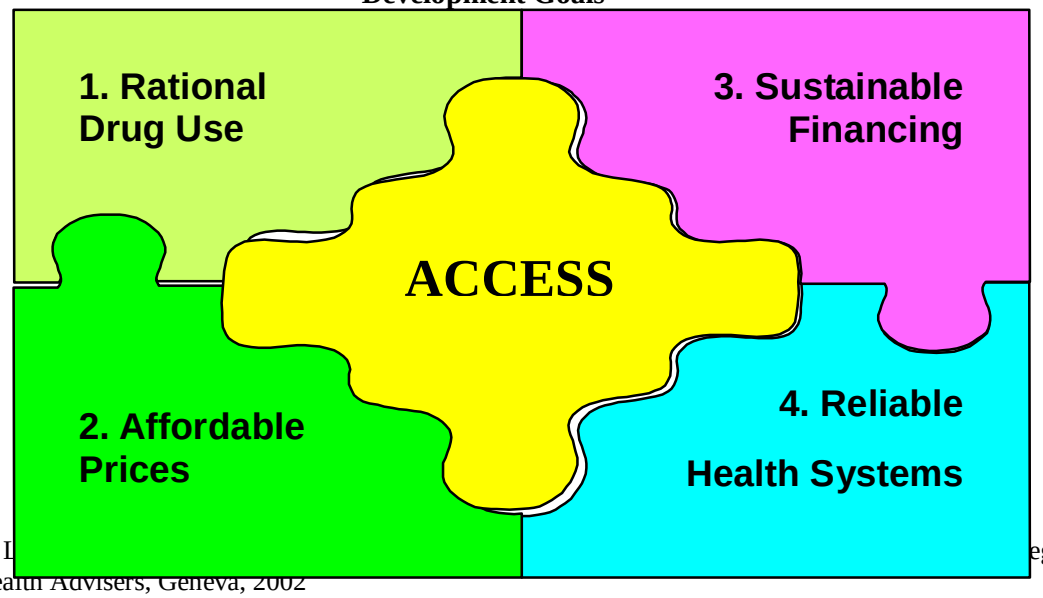
Other planned activities under the larger ATM project include research grants for multi-site studies on access to medicines; systematic reviews, syntheses and overviews; policy briefs; evidence to policy activities, and dissemination activities.

**Partners:** The Pakistan priority setting study is part of a larger EMR project involving three country specifics studies for Iran, Pakistan and Lebanon and a review of Eastern Mediteranean Region. Aga Khan University Karachi is the institute responsible for the Pakistan study in collaboration with the Tehran University of Medical Sciences (TUMS) the lead partner for the EMR region and for the Iran country study, University Beirut (AUB) partner institute for Lebanon, and Alliance HSPR-WHO for funding and overall technical direction.

## SECTION 2: METHODOLOGY

The WHO Framework for Access to Medicine (WHO 2002) was used as the basis for data collection and synthesis. Under this framework accessibility has been defined as having four parameters: that the available medicines are effective and of consistently good quality, that there is no financial obstacle to a patient receiving it, and that required knowledge and guidance are available for proper use of these medicines Any isolated effort to improve one part may be effective for that part but it would not improve the overall situation.

**Improving Access to Essential Medicines: A Framework for Collective Action in Line with Millennium Development Goals**




**Source:** Richard L egional and Country Child Health Advisers, Geneva, 2002

The methods involved desk review, stakeholder interviews and consultative prioritization through Roundtable.

**Desk Review:** This involved published studies, unpublished studies and grey literature such as commissioned reports and surveys. A total of 11706 titles were yielded using the electronic search and reference from bibliographies. These were sifted by 2 researchers for identification of relevant studies. A total of 184 studies were shortlisted. Abstracts and report summaries of 184 studies were reviewed and a total of 96 studies were further short-listed. The full text of all these 96 studies, including articles, reports, presentations and books was then reviewed and 92 studies were selected and uploaded into EndNote

In addition 19 policy documents were also included through a system involving online search as well as opinion taken from experts. Identification and access to other policy documents that are not in public domain were sought during stakeholder interviews. Data from each reviewed study and policy documents was systematically extracted and analyzed using grids based on the WHO Access to Medicines Framework under the four domains of rational use, affordability, financing, and reliable health systems. Details of search strategy and analysis of desk review is presented in Annex.

**Stakeholder Interviews:** 21 in-depth interviews were conducted involving a diverse range of stakeholders. Purposive sampling was done and the list of stakeholders was developed in a 2 step consultative process. In a meeting of regional partners at Tehran University a matrix was developed mapping major *organizational backgrounds* for stakeholder selection across all the three participating EMRO countries. These included MOH

and its entities, CSOs (as patients' representatives), medical associations (as clinician representatives), pharmacists associations (as pharmacists representatives), industry, research institutions, development partners etc (see attached stakeholder matrix). These would be consistent for all 3 countries but identification of specific names and exact numbers would be done by country team. Subsequently a meeting was held of Pakistan team with WHO Pakistan for identification of specific interviewees under each organizational category.

Ethical approval was obtained prior to interviews. Written informed consent was obtained from each interviewee and written project information and contact details of investigators were provided. Written assurance was also given of confidentiality of interviewee identity in making reference to interview results. Interviews were conducted in Islamabad, Karachi and Lahore. Interviews notes were taken by a two member team and transcribed and compared between note takers on same day. Interview analysis was done manually and the WHO 2002 Access to Medicine Framework was taken as the conceptual framework for analysis**.**

**Mapping of Key Stakeholders**

| Ministry of Health | Department of Health | Other Providers |
|---|---|---|
| • Director General Health<br>• Officials Licensing & Registration Board | • Additional Secretary Technical, DHO<br>• Executive District Health Officer<br>• Additional Medical Superintendent, Tertiary hospital<br>• Chief Pharmacist, Tertiary Hospital<br>• Drug Inspector | • President Primary Healthcare Initiative, Sindh |
| **Development Partners** | **Pharmaceuticals** | **Pharmacies / Other Provider** |
| • WHO<br>• GAVI | • Pakistan pharmaceutical Manufacturing Association | • Pakistan Pharmacists Association<br>• Director Pharmacies, AKU |
| **Research Institution** | **CSOs** | **Clinicians** |
| • Bio-Equivalence Centre, Lahore | • Merlin<br>• Consumer Protection Network | • Pakistan Medical Association |

**Consensus Building:** A consultative process was taken for identification of policy and research concerns. A Roundtable with stakeholders was held on 12th May at AKU Karachi involving 25 stakeholders from different entities attended the meeting including country Investigators from Iran and Lebanon as well as focal person for ATM project from Alliance HPSR, WHO Geneva. The Roundtable was chaired by Secretary Health, Sindh, Pakistan. The roundtable took a consultative process to identify emerging policy concerns and research questions. It involved presentation of scope and objectives of ATM prioritization project being carries out globally, brief overviews of findings from Iran and Lebanon and detailed presentation on Pakistan findings. Following the presentation, policy concerns were collectively identified and a list of research questions generated for further action. Written comments were further invited posts Roundtable through an email listing for improvement of data and incorporation of needed research areas.

# SECTION 3: RESULTS OF DESK REVIEW

## I. RATIONAL USE OF MEDICINES IN PAKISTAN

Irrational drug prescribing, dispensing and self-medication continue to be a major problem in Pakistan. Although a national essential drug list exists it is poorly enforced across the health sector. Irrational prescription is due to high level of prescription by non-qualified practitioners and self medication, frequently inappropriate prescription particularly by qualified providers, particularly high use of injectables, and resulting issues of polypharmacy, unnecessary expenditure, drug resistance, and contributing to high prevalence of Hepatitis B and C in the country.

**National Essential Drug List:** Essential medicines as defined by WHO are those that satisfy the health care needs of majority of the population. Through 1970s and 1980s the Essential Medicines Program of WHO Pakistan promoted this concept to redress imbalance in selection of drugs. The National Essential Drug List (EDL) of Pakistan was first prepared in 1994 in consultation with relevant experts and using WHO's model list of Essential Medicines as a template. The list was subsequently reviewed in 1995, 2000 and 2003 and the present list is the fourth revision containing 335 medicines (MOH 2007).

Development of EDL is a function of the Federal Ministry of Health (MOH) while compliance and adherence rests with the provincial Departments of Health (DOH). Procurement of drugs in DOHs is based on EDL although non-EDL purchasing has been reported (details in supply side issues). Compliance and adherence to EDL varies from poor to good in different parts of Pakistan (DFID 2002; Najmi et al 1998; Das 2001). In a baseline survey in three provinces of Pakistan, it was found out that EDL is only available in one out of five public sector facilities (DFID 2002). Compliance with EDL in terms of prescriptions was found to be 50% at public sector facilities in one survey (Das 2001) and 80% in a survey of three public sector teaching hospitals (Najmi et al 1998).

**Frequent prescription by non-qualified prescribers:** Prescription by non-qualified practitioners as well as self-medication is common in Pakistan; however there are few studies that capture the magnitude of self-medication and hardly any literature on quacks. In a survey of 500 households examining health seeking behavior for childhood illnesses, self-medication for childhood illnesses was seen in 51.3% children (Haider &Thaver, 1995). These mostly comprised of analgesics/antipyretics (25%), anti-diarrheals/ anti-emetics (11%) and antibiotics (11%) while 34% were unidentified drugs (34%). Infants were self medicated particularly during diarrheal episodes, which is a dangerous trend as improper management has resulted in childhood diarrhea being the number two cause of death in children under five (Haider & Thaver 1995). A study on youth reported frequent prescription and consumption by college students on medical student's advice or self prescription (Zafar et al 2008a). 55.3% of medical students prescribe medicines independently and most are likely to belong to 1st and 3rd year of medical college while a third of non-medical students report self prescription (Zafar et al 2008a&b). Another study pointed out that most potent drugs like antibiotics, psychotropic, narcotics, anti-cancers and hormones are being misused by un-trained doctors or by quacks or through self medication due to lack of co-ordination among the relevant professionals (Das, 2001).

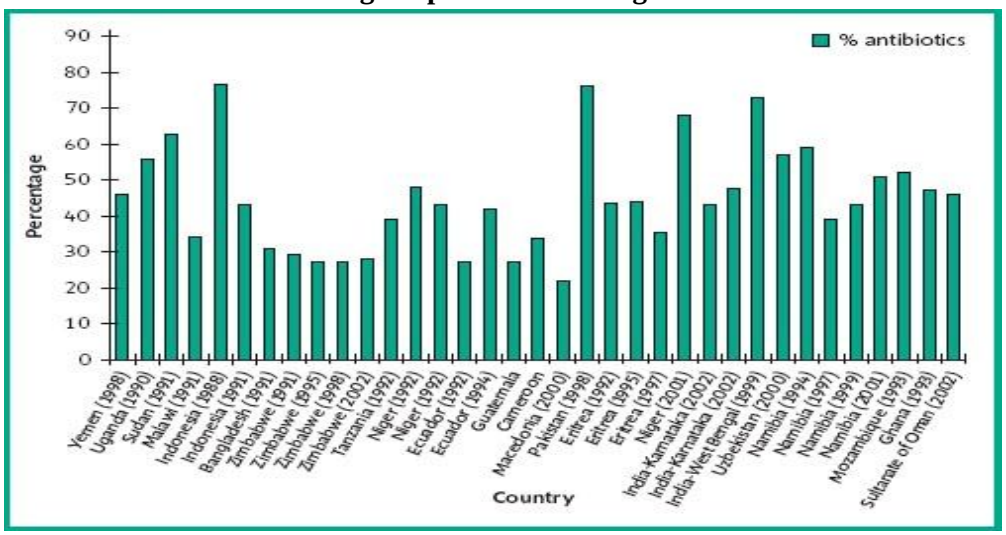
**High level of inappropriate prescription by qualified providers for non communicable diseases:** Drug Prescriptions amongst general practitioners (GPs) for chronic diseases also need significant rationalization. Similarly, a survey of 1000 GPs in Karachi reports that appropriate therapy for hypertension in elderly was initiated by only 35% of GPs while thiazide diuretics, internationally recommended as first line regimen, were rarely prescribed (4.2%) (Jafar et al 2005). Alarmingly, sedatives were commonly used either as first-line medication for lowering BP (23.8%) or in combination with antihypertensive agents (45%). A facility based study was conducted on eight fifty six patients to assess pharmacotherapy-based problems in the management of diabetes mellitus (Ali N et al, 2010). It was found out that there was a poor correlation between the advised insulin therapy and patients' fasting blood glucose levels (12%, n=103) was observed. To most of the patients (41.66%, n= 357), insulin therapy was advised in combination with glucocorticoides, thiazides diuretics, and

propranolol, which are contraindicated due to drug interactions (Ali N et al, 2010). In facility based study on 186 patients in Karachi to assess the general practitioners (GP) knowledge regarding the diagnosis and initial drug therapy for acute myocardial infarction (AMI), the GPs were not giving initial drug therapy and were less likely to carry management for acute myocardial infarction(Ali M et al 2009). In another study on mental health, the treatment for psychiatric and paediatric illnesses did not correlate to diagnosis in 25% of cases and doses of drugs were inappropriate in 31% prescriptions (Najmi et al 1998).

**High level of inappropriate prescription by qualified providers for communicable diseases:** A longitudinal cohort study was conducted on 200 patients at Camp Hospital Batagram to ascertain the effect of Zinc utilization in tablet and suspension formulations on the frequency and recovery rates of diarrhoea among young children (Bhuttta ZA 2010). It was found out that significant p-values were established among Zinc use and reduction in frequency of stools on Day 2 and 3, with better outcome in the group using Zinc in suspension form (Bhuttta ZA 2010). Although tuberculosis is an endemic disease and Pakistan has a national TB control program there is frequent variation from the recommended treatment. A survey of 88 GPs in Kyber Pukhtoonkhwa and Northern Areas of Pakistan showed that only 3.4% GPs knew all the components of DOTS, only 35% were able to write a prescription with correct drugs, dose and duration for initial phase and 30% for continuation phase of the therapy (Shehzadi et al 2005). In major urban centers, of the 120 private general practitioners surveyed, only half of respondents could prescribe ethambutol or pyrazinamide in the correct doses or for the correct duration (Khan et al 2003).

In a survey on 245 medical practitioners on knowledge and practice regarding Tuberculosis diagnosis and treatment in Rawalpindi, only 1 of the 245 physicians was aware that cough > 3 weeks alone is the main symptom suggesting pulmonary TB. None of the practitioners were following National TB Control guidelines for prescribing drugs and none ensured compliance with anti-TB treatment under supervision of a doctor/health worker (Shah S 2001). Likewise in a cross sectional study on 151 GPs in private and public clinics of Karachi regarding practices among the general practitioners (GPs) of Karachi regarding dog bite management only 19.4% GPs had appropriate knowledge about the first line treatment. Almost all GPs (98%) had no knowledge about the types of anti-rabies vaccine and only 19.2% knew about anti-rabies serum (Faraz S 2009). A multi-center study was carried out to assess the treatment pattern in upper respiratory tract infections mostly of viral nature, revealed an alarming 88.9% rate of antibiotic prescription for these self-limiting infections (Ahmed Z 2005). While GP prescriptions are frequently inappropriate those of specialists have also been reported to be questionable. Little difference was seen in practices of GPs and specialists in treatment of childhood diarrhea. It was observed that only 17.7% of GPs and 14.3% of pediatricians prescribed ORS in all of their encounters while instructions for preparing ORS were given in only 6% of encounters by GPs and 8.4% of encounters by pediatricians (Nizami et al 1996). A significant difference was observed only in higher prescription of anti-diarrhoeals by GPs over pediatricians ($P < 0.01$) while there was no significant difference in antibacterial amongst GPs and pediatricians ($P < 0.16$).

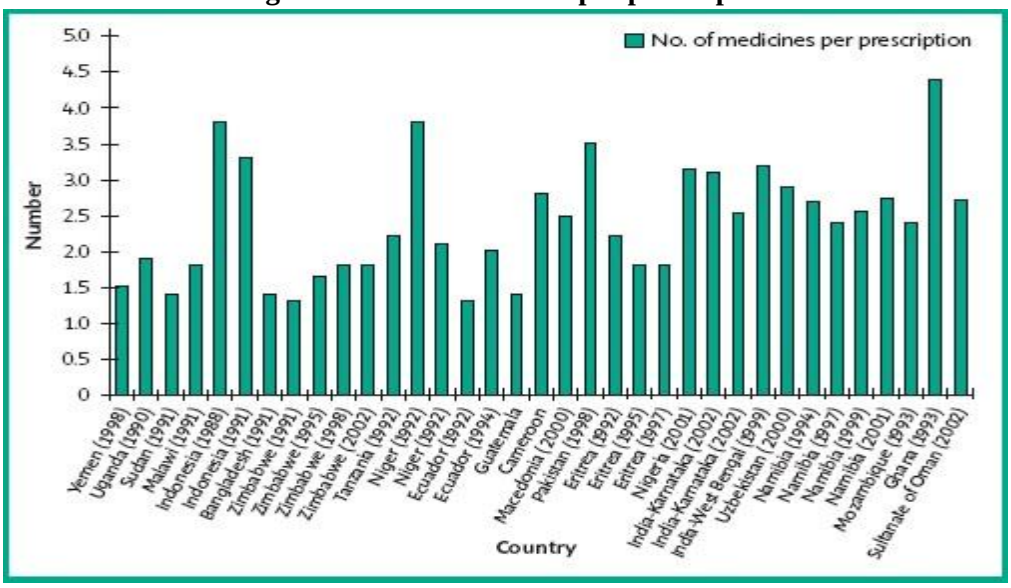
**Percentage of patients receiving antibiotics**




Source: The World Medicines Situation, WHO 2004

**High number of drugs per prescription:** The average number of drugs prescribed per patient is 3 or more in Pakistan as compared to an average of 2-3 in LMICs, and over 70% of patients are prescribed antibiotics (WHO 2004 ). A survey of 10 health care facilities from each province were selected keeping appropriate representation from first level health facilities, district health facilities and tertiary care hospitals, found out that average prescribed number of drugs per patient was 2.77 (Range: 0-7) and would be higher if drugs per prescription rather than drugs per patient were to be computed (Hafeez et al 2004). Drugs prescribed at BHUs and RHCs is high at 2.75 medicines per prescription and close to the average of 2.79 prescribed at Teaching Hospitals (DFID 2002). In a randomized survey of prescriptions of 354 (specialists), practicing in private facilities, there was an average of 4.51 medicines per prescription and over prescriptions of antimicrobials, vitamins/minerals and injections (Das 2001).

**High Number of medicines per prescription**



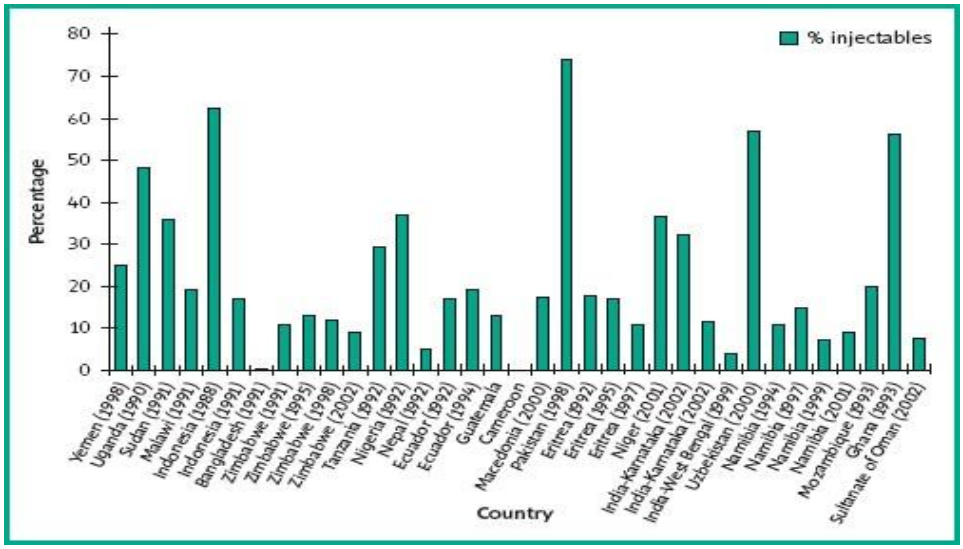

Source: The World Medicines Situation, WHO 2004.

**High use of injections:** Overuse of drugs also translates into a high rate of injection usage. Pakistan is globally one of countries with the highest rate of injection usage with over 60% of patient encounter involving an injection (WHO 2004). This translates into 13 injections per person per year (DAWN 2009). Studies in Pakistan show that up to 90% of injections are estimated to be unnecessary (WHO 2004 a). A cross-sectional survey of general practitioners in urban and rural areas of Murree showed that 80% of the general practitioners give injections to every patient (Janjua 2003). 53% of GPs in rural areas and 28% in urban areas preferred injection as an essential component of treatment (Janjua, 2003). When comparing public and private healthcare providers, in Attock district, over 48% of GP prescriptions had at least one injectable drug compared with 22.0% by public providers ( $p < 0.0001$) (Siddiqi et al 2002).

In a case control study facility based study in a teaching hospital in Karachi on 1050 patients suffering from chronic HBV or HCV related liver disease, history of therapeutic injection use for various ailments including intravenous drips was present in over 90% patients as compared to 76% seen in controls, the difference was statistically significant (P < 0.001), and in majority of the cases injections were given by general practitioners by their own syringe (Querashi et al 2009). In a case control facility based study to find the association of risk factors with hepatitis C virus infection on pregnant women in Karachi on 119 cases and 238 controls, it was found out that among cases an average number of injections in any month was 40%, with (OR = 2.33; 95% CI =1.38-3.91), showing that in cases injection usage is 2.33 times more than controls (Khan R U, 2008). Overuse of injections is of particular concern as patients are not aware of the risks associated with reuse of injection equipment (Altaf, 2005). To find out the determinants of therapeutic injection overuse among communities, a qualitative study was conducted in rural Sindh, peri-urban and urban Karachi during January-February 2001. It was found out that Injections were overused in Sindh, Pakistan, because patients prefer them (Altaf 2005).

Asides from polypharmacy issues, high injection use raises grave risks of spread of blood borne diseases such as Heptatis B, C and HIV. GPs largely make use of unsafe practices with most surveyed GPs using multi dose vials for medications and none of the practitioners used separate syringes for drawing and injecting. There was also seen to be insufficient numbers of sharp material disposal boxes, which were not available in 86% of the facilities. Moreover, 79% of the injection providers were never vaccinated for Hepatitis B (Samad 2001).

**Percentage of patients receiving injections**




Source: The World Medicines Situation, WHO 2004.

**Higher rate of irrational use amongst GPs over public sector:** In a survey in 114 health facilities, including 62 public sector and 52 private sector facilities, it was found that the mean number of drugs per prescription was 4.1 (SE: +/- 0.06) for general practitioners and 2.7 (SE:+/- 0.04) for public providers ($p < 0.0001$) (Siddiqui et al 2007). Prescription rate was particularly higher for antibiotics (62%) and injections (48%) amongst GPs as compared to public sector with rates of 54% and 22% respectively ($p < 0.0001$). Similarly more than 11% of GP prescriptions had an intravenous infusion compared with 1% for public providers ($p < 0.001$). General practitioners were also found to prescribe anti-diarrheals more frequently than doctors working in the public sector ($p < 0.01$) (Siddiqi et al 2002). However, many public sector physicians also practice as general practitioners during evening hours and it is uncertain whether the relative edge of prescriptions within public sector facilities is maintained during switch to general practice.

**Drug resistance:** Antimicrobial resistance and containment often results from irrational drug use (WHO-EMRO, 2000). The emergence of antimicrobial resistant bacteria and an increased number of patients experiencing adverse drug events have been documented by the irrational usage of antibiotics (Khan et al, 2010). A study conducted in tertiary hospitals of Peshawar on 519 patients from July 2006 to June 2007 to determine the trend of use of antibiotics showed that the leading type of antibiotic prescribed was third generation antibiotic used by 28.3 percent patients in all the three units followed by 1st generation 24.47 percent and penicillin 19.08 percent, while Macrolides are the least (Khan et al 2010). In a facility based cross sectional study on 890 pulmonary tuberculosis (PTB) patients in Sindh, the MDR-TB isolates were detected in 42.10 percent cases (Khoharo 2010). High level of resistance has been found to ampicillin, cotrimoxazole, chloramphenicol and erythromycin in a large study of 9209 individuals in Karachi (Sturm et al 1997). The results are alarming as these are the frontline antibiotics for control of infections. The study also found that these drugs had been frequently used by the individuals in the four weeks preceding the resistance survey. It is expected that resistance to front line anti-malarials, anti-tuberculous therapy and HIV retroviral therapy is also present in Pakistan however surveillance of resistance is a major challenge and there is need for robust information in this area.

**Irrational prescription linked to drug companies' advertisement:** Attending sponsored CME events and accepting funding for travel or lodging for educational symposia is associated with increased prescription rates of the sponsor's medication as about 88% medications are prescribed by their brand names in Pakistan (Shiwani, 2006). In a descriptive study, Critical analysis of the claims from drug brochures was made and for appraisal of drug promotional brochures was made. It was found out that eighteen percent of 345 advertisements were adjudged to be unjustifiable, which were again classified as, exaggerated thirty two percent, ambiguous twenty one percent, false twenty six percent and controversial twenty one percent. Therefore it can be anticipated that inappropriate advertisement claims would lead to irrational prescribing and physicians had no any other information to follow (Rohra 2005).

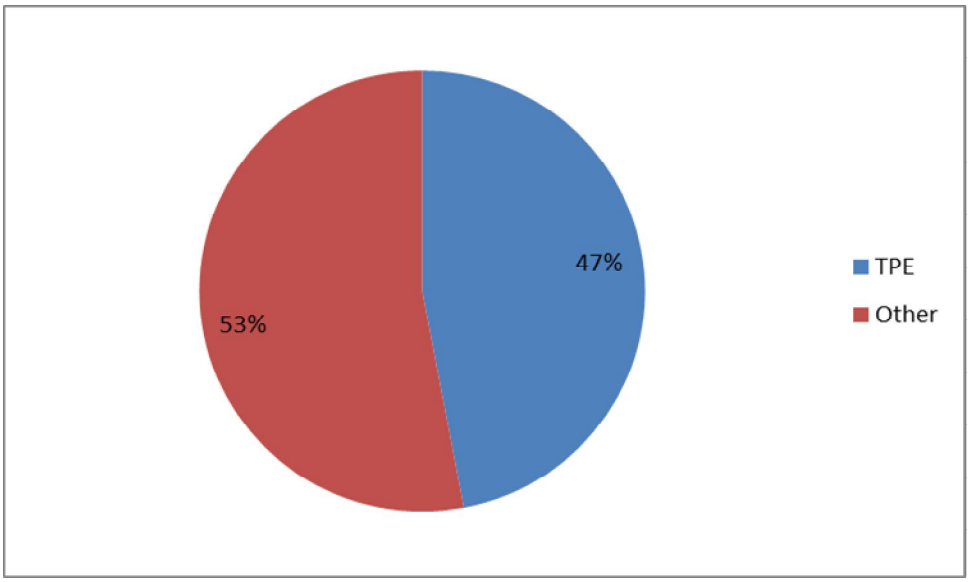
## II. AFFORDABILITY & FINANCING

**Total financing to health sector is inadequate:** In Pakistan 2.4% of GDP is spent on health with total health expenditure being extremely low at $15/capita/ year. National Health Accounts analyzing 2005-06 data shows that of the total health expenditure, that only 32% is spent by public sector including the Ministry of Health, para-statal organizations and facilities of Armed Forces Federal Bureau of Statistics (NHA, 2009). Private health expenditure is responsible for the major share 64% of total health expenditure of which 97.5% comes from out of pocket spending by households with very few covered by pre-payment schemes (NHA 2009). International development partners have a marginal contribution of 1.9% of total health expenditures.

**Medicine expenditure is low and responsible for shortages:** Overall, an estimated 47% of the total health expenditure in Pakistan is spent on medicines (MOH 2010). The public sector is responsible for only 27% of medicine expenditure while private health expenditure on medicine comprises nearly three-fourth with the burden borne by households through out of pocket payments (WHO 2004). 43% of private sector users pay for medicines within the facility while 60% pay for medicines at outside pharmacies/ drug stores.

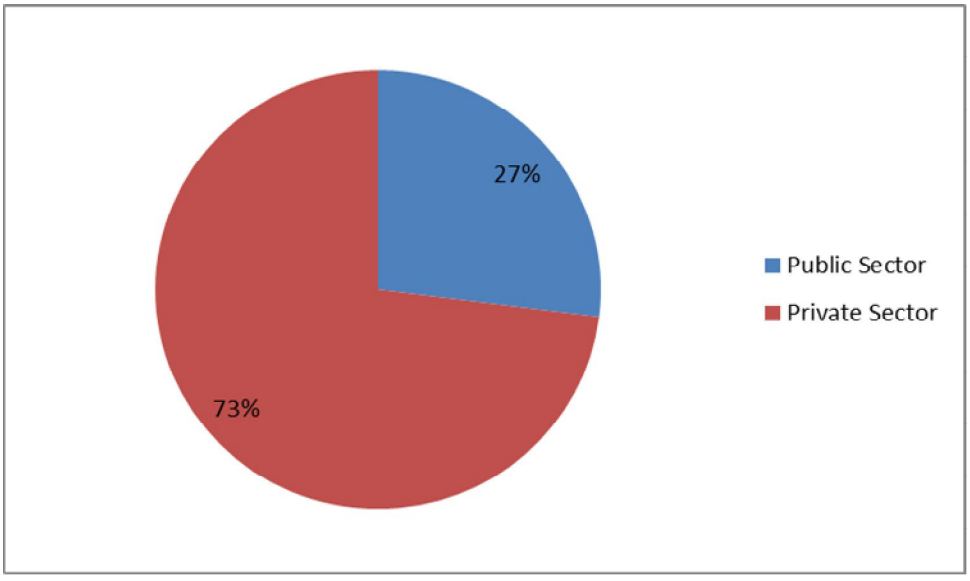
Spending in the public sector on medicines is clearly inadequate and a major contributor to drug shortages as shown in later sections. WHO predicts that governments spending less than US$2 per person per year on essential drugs are likely to face shortages in the public sector forcing patients and their families to purchase from the private sector (Laing, 2002). The MOH in Pakistan spends $3 per capita on health (NHA 2009) and available evidence shows that the Ministry of Health's operational budget is mainly taken up by salaries with a 30-20% spent on non-salary expenditures including medicines (World Bank 2008, 2007, 2005).

**Share of Total Pharmaceutical Expenditure in Total Health Expenditure**




Source: NHA 2007

**Share of Public and Private Sectors in Total Pharmaceutical Expenditure**




Source: World Medicines Report 2004

**Out of pocket medicine expenditure at public and private sector facilities:** A synthesis of national evidence shows that out of pocket expenditure at public sector facilities consists largely of payments for medicines bought outside the facility by nearly two-thirds of users. Mean cost of medicines outside is Rs. 252 in private and Rs. 198

in public facilities (World Bank, 2010). With lack of specific financing schemes such as prepayment schemes for risk-pooling or commodity vouchers, the poor and sick are vulnerable to prescription practices of health staff and the pharmaceutical market (WHO-EMRO 2007).

A study reported that low income users of obstetric care at a government hospital in Karachi spent 44% of the direct medical expenses on drugs (Kadir et al, 2000). Expenditure estimation for out-patient diabetes care at three facilities including a NGO, private sector and government health facility in Karachi found that 46% of the total out of pocket expenditure is on drugs (Khowaja et al 2007). A population based study on 2675 households in Karachi reported that 54% of patient expenditure on hypertension control at outpatient cares across is spent on purchase of medicines (Zaidi et al 2008). The high share of expenditure consumed by medicines is one of the major reasons underlying patient non-compliance with chronic care therapy. Available studies examining non-compliance report that in at least 33.5% of psychiatric patients and 41% of tuberculosis patients unaffordability of drugs was the primary reason for non-compliance (Rizwan 2005; Ahmed 2009). The above findings highlight that sufficient financial access to even generic equivalents needs to be guaranteed for the poor while use of originator brands needs to be substantially rationalized.

**Medicine prices of public sector procurement:** The Median Price Ratio (MPR) gives an indication of country price to international reference price with a ratio of 1 or below considered to be efficient. The public sector procurement of generics medicines is at an acceptable Median Price Ratio of 0.6 however that for originator brands is substantially high with a MPR of 7.0 as compared to international average of 3.0 (Cameron 2009). This shows that generics in the public sector are purchased at acceptable prices however it does not give an indication of quality of medicines. At the same time the gap between generics and originator brands is extremely high and needs to be reduced through both price regulation and rational selection.

**Medicine prices in private sector:** In the private retail sector, Median Price Ratios of drugs are substantially higher in private retail outlets than those observed in public sector procurement both in Pakistan and most LMICs with the exception being countries such as Kuwait where because of pricing regulations there is little price differential between originator brands and generics. In Pakistan basic generic medicines in private retail outlets have a MPR range of 1.2-7.3 and originator brands for basic therapy have a range between 0.8-15.8 (WHO-EMRO 2007). Specific medicines suffer from excessive prices and need to be targeted for regulatory action and cautious prescription.

**Affordability Indexes and Studies:** A price and availability survey by the World Health Organization and Health Action International studied the affordability of 29 important medicines in 36 countries including Pakistan (WHO/ HAI 2008 ). The affordability of treatment was estimated as the number of days' wages the lowest paid government worker would be required to pay to purchase a standard one-month medicine therapy for a chronic illness or for one episode of acute illness. A treatment requiring more than one day's wage is considered unaffordable. In the public sector in Pakistan, like most of other countries, medicines are generally provided free of charge however given frequent non-availability of medicines, patients were commonly forced to seek supply from private retail pharmacies. Medicine therapy for acute respiratory infection was affordable given a range of 0.3-1 days wage, therapy for chronic illness such as hypertension, depression, diabetes, epilepsy, arthritis and peptic ulcer was unaffordable even with use of low priced generics (WHO-EMRO 2007). Affordability of chronic conditions with low priced generics was 1.7-7.7 while with originator brand was the range was much higher from 1.9-36.4 (WHO-EMRO 2007).

## III. RELIABLE HEALTH SYSTEMS

### 1. Public Health Care System

Public sector facilities provide medicines free of charge. There are more than 10000 health public sector facilities ranging from 5798 Basic Health Units (BHUs), 581 Rural Health Centres (RHCs), 947 Tehsil HeadQuarter and

District HeadQuarter Hospitals (THQH/ DHQH), and 29 Teaching Hospitals (WHO-EMRO, 2011). Supply of medicines to primary and secondary facilities is based on essential drug list for each tier of health facility and inlcude approximately 70-80 drugs for BHUs, 100-120 for RHCs and 300 for District Hospitals. Tertiary facilities, including Teaching Hospitals, procure medicines independently based both on the National EDL as well as recommendations of the hospital drug procurement committee.

**Low utilization of public sector facilities:** Overall utilization of public sector is low with 21% of the population utilizing public sector while the rest utilize a primarily fee based private (PSLM 2006-07). Low utilization is consistent across both rural and urban areas with respectively 36% and 22% of households utilizing the public sector (WHO-EMRO, 2011). There is particularly low utilization of primary care tiers of the health systems, with 1 visit/capita/ year to a PHC facility, while there is heavy utilization of tertiary hopsitals. Amongst users of public sector facilities, 40% are dissatisfied with services provided with lack of medicine availability being the most frequent reason for dissatisfaction (PSLM, 2004-05 ).

**Level of Dissatisfaction with Public Sector and Underlying Reasons**

| Percentage dissatisfied with service | 40 |
|---|---|
| Reason for dissatisfaction | |
| No doctor | 12 |
| No trained staff | 20 |
| No medicine available | 23 |
| Long waiting | 13 |
| Staff not helpful | 14 |
| Treatment unsuccessful | 11 |

Source: PSLM 2004/05

**Availability of medicines in public sector facilities:** Availability of even essential recommended generics is extremely low in public sector facilities with a 3.3.% median availability and is much lower than the range of 29-54% found in LMICs while originator brand medicines are generally not available in public sector facilities in Pakistan as well as other LMICs (WHO-EMRO 2007). Availability in public sector is lower than that in private sector as discussed in a following section. Availability of medicines for acute care range between 30-67% while availability of essential chronic care drugs for management of cardiovascular disease, diabetes, chronic respiratory disease, glaucoma and palliative cancer therapy ranges between 3-57% (WHO-EMRO 2007; Mendis et al., 2007).

**Medicine Availability at Public Facilities and Private Pharmacies**

| 0% | beclomethasone inhaler, Carbamazepine, Hydrochlorothiazide, Indinavir, Losartan, Lovastatin, nevirapine, Nifedipine retard, phenytoin, zidovudine |
|---|---|
| **1-10%** | Acyclovir, fluconazole, fluoxetine, fluphenazineinj, ranitidine, salbutamol inhaler, Sulfadoxine/Pyrimethamine |
| **11-40%** | Amitriptyline , ceftriaxone inj , Co-trimoxazole, susp, Diclofenac , Glibenclamide, Omeprazole |
| **41-50%** | Ciprofloxacin |
| **51-60%** | Captopril, diazepam |
| **61-80%** | Amoxicillin, atenolol, metformin |
| **>80%** | None |

Source: WHO/HAI Report 2008

There is lack of comprehensive assessments of drug availability across the country giving details by drug type and by primary and secondary tiers. Available information from one province, the province of Sindh, shows that there was not a single BHUS or RHC maintaining a full stock of mandated drugs (World Bank, 2008.). Stock outs were comparatively higher in BHUs as compared to RHCs. BHUs had 10-25% availability of antibiotics in

BHUs, followed by 25-50% availability of iron tablets, anti-malarials and anti-tuberculosis drugs and 50-80% availability of anti-pyretics while in RHCs there was comparatively better availability of anti-tuberculosis and anti-malarials with more acute shortage of antibiotics and oxytocin (World Bank 2008)

**Availability of Medicines in Percentage of BHUs and RHCs**

| Medicines | Availability of Medicines in %age BHUs | Availability of Medicines in %age RHCs |
|---|---|---|
| **Antibiotics** | <25% | <25% |
| **Analgesics** | | |
| **Paracetamol** | 70% | |
| **Antituberculosis** | | |
| **Streptomicin, Isoniazid Pyrazinamide, Ethambutol** | <50% | >80% |
| **Rifampicin** | <50% | 50-80% |
| **Antimalarials** | | |
| **Fansidar** | | <50% |
| **Chloroquin** | <50% | 50-80% |
| **Obsterics** | | |
| **Oxytocin** | | <25% |

Source: NPPI Baseline Survey 2009

Medicine availability in THQs and DHQs, particularly of emergency medicines, is also sub-optimal. Asides from dexamethasone, the availability of emergency medicines ranges between 30-50%, and is even lower for certain basic drugs such as Calcium Gluconate and Magnesium Sulphate (NPPI 2009). Availability of basic obstetric care medicines was also very poor with 45-60% availability of ergometrine and oxytocin and 0% of mesoprostol. Availability of antibiotics was comparatively better however only 1 antibiotic had 100% availability with availability of others ranging between 25-80%.

**Availability of Different Medicines in THQHs and DHQHs**

| | Availability in % THQs | Availability in % DHQs |
|---|---|---|
| **Emergency Medicines** | | |
| **Diazepam and Frusemide** | 50% | 50% |
| **Dexamethasone** | 80% | 86% |
| **Cagluconate and Magnesium Sulphare** | 20% | 3% |
| **Insulin and Adrenaline** | 30-40% | 30-40% |
| **Antibiotics** | | |
| **Cloxacillin** | 80% | 25% |
| **Amoxacillin** | 56% | 100% |
| **Metronidazole** | 100% | 73.3% |
| **Ciprofloxacillin** | 40% | 60% |
| **Obstetric Medicines** | | |
| **Ergometrine** | 60% | 46% |
| **Oxytocin** | 60% | 56% |
| **Misoprostol** | 0% | 0% |

Source: NPPI Baseline Survey 2009

Shortage of medicines for, at least for obstetric care, has also been reported by other studies. Essential low cost drugs such as iron tablets, folate tablets, broad spectrum antibiotics and oxytocin were largely unavailable at primary and secondary health facilities (Fikree et al., 2006). while Magnesium Sulfate needed for basic emergency obstetric care services was only sporadically available or completely unavailable (Meyer, 2004.)

**Procurement and Supply of Drugs:** Procurement of drugs is based on an essential list of medicines specific for each facility tier; however procurement in practice has also frequently involved purchasing of other drugs not on the list. Although a computerized Health Management Information System (HMIS) exists there is little link between case volume and morbidity generated by HMIS reports and the process of forecasting and budgeting. Purchasing is done on the basis of cheapest tender submitted by any licensed drug production company. This has often been criticized as resulting in a low quality threshold as company registration is used as the only quality criteria and with presence of 500-650 licensed production companies in Pakistan, it does not serve to discriminate on quality aspects. The onwards supply chain essentially relies on manual record keeping and although a computerized drug logistics management systems is in place for the GFATM it is yet to be applied to the public sector.

Existing public sector procurement practice has resulted in curtailing drug expenditure. A median price ratio (MPR) compares local price to international price and a MPR of greater than 2.5 indicates excessive medicine prices. Generics purchased by public sector are either below or equal to the international price index however branded drugs have been bought up to 3.5 times the international reference prices (WHO-EMRO 2007). The price index of public sector, for both generics and branded drugs, is more efficient than that of the private sector in Pakistan. Whether efficiency has been achieved as a result of quality compromise, needs serious exploration. Anecdotal evidence highlights institutionalized malpractices in procurements where standard mark-ups are charged as a result of collusion between public entities and production companies (Nishtar 2010).

**Median MPRs for innovator brands and lowest priced generics in the public (procurement only) and private sector (patient price only)**

| | | | Median Price Ration (MPR) to Reference Price (MSH, 2003) | | |
|---|---|---|---|---|---|
| **Reference Price** | **Sector** | **Type and No. of Medicines** | **Median MPR (25% - 75% IQR)** | **Minimum MPR** | **Maximum MPR** |
| **MSH, 2003** | Public | Brand (n=2) | 2.24 (1.60-2.87) | 0.96 | 3.51 |
| | | Lowest Priced Generic (n=14) | 0.57 (0.38-0.74) | 0.24 | 1.04 |
| | Private | Brand (n=23) | 3.36 (2.20-5.88) | 0.72 | 26.20 |
| | | Lowest Priced Generic (n=21) | 2.26 (1.15-3.60) | 0.20 | 7.02 |

Source: Medicine Price Surveys undertaken in Selected Countries, WHO-EMRO 2008.

Procurement has traditionally been done at the provincial level with supply onwards to different districts however as a result of devolution to district level under the Local Governance Ordinance of 2001 drug budgeting, procurement and management took place at the district level for a stretch of nearly ten years. With lapse of the ordinance in 2010, it is uncertain whether there will be a shift back to centralized procurement and supply. As yet there has been no study to assess the relative performance of district versus provincial based drug management.

**Issues related to drug storage & dispensation:** A survey of first level care facilities, district hospitals and tertiary hospitals conducted as part of Emergency Drug Supply Project in NWFP, Punjab and Balochistan, highlighted issues related to drug storage and dispensation (DFID 2002; Imran et al 2009). Dispensing time on average is merely half a minute which is inadequate for good dispensing while communication with patients was poor and is a cause for concern given low awareness level of patients. Preparation of prescriptions by dispensers is often unhygienic, prone to mistakes and every one in five prescription is dispensed without validation. Preparation of drugs, labeling of drugs and record keeping were also inadequate.

Storage issues were also examined at public sector facilities. It was found that while stock auditing was satisfactory at majority of sites, presence of essential drug list was seen in only 1 facility, storage conditions

including temperature maintenance, hygiene and pest control was unsatisfactory at majority of places, and actual store capacity was not known by 97% of storekeepers. Store keepers lacked both pre-service and in-service training on proper stock handling. Another study reports labeling and storage of anesthetic medications across 58 operation rooms. Only 15% of operating rooms were compliant with proper drug labeling (Imran et al 2009).

## 2. New Modalities of Health Care Provision – Contracting out of Health Facilities

The Government of Pakistan launched a country wide program known as the People's Primary Healthcare Initiative (PPHI) involving contracting the management of BHUs for improved service delivery. Out-sourcing of BHUs has been done to the National Rural Support Program (NRSP) and the initiative is administratively housed under and financially assisted by the Federal Ministry of Industries. It is an example of contracting-in through management contracts and involves outsourcing the operation budget of BHUs by the department of health to the contractor accompanied with financial and administrative powers for flexible usage of budget and staffing to improve BHU utilization. Overall, 2391 BHUs and 701 other health facilities including dispensaries and MCH centers have been contracted out over 127 districts including 36 in Punjab, 23 Sindh, 30 in Balochistan, 31 in NWFP and 7 in Gilgit-Baltistan.

Further experiments with alternative financing models are underway with performance based contacting out, contacting in and competitive voucher schemes being rolled out in the province of Sindh with Norwegian government and One UN Program assistance.

**Availability of medicines at contracted BHUs:** A study to evaluate the pilot of BHU contracting in Rahim Yar district of Pakistan was conducted using intervention and control districts. Although it found mixed result with improvements in curative care and under performance in preventive and promotive care, drug availability was improved in contracted BHUs. Users reported 30% availability of medicines in contracted BHUs as compared to only 7% in non-contracted (Loevinsohn et al, 2009).

A national third party evaluation has been recently conducted which confirms that there have been improvements in essential drugs availability. Overall 22.5% of contracted BHUs were in the highly satisfactory category for drug availability as compared to only 8.3% of non contracted BHUs, while close to 87% of non-contracted BHUs fell in the unsatisfactory or highly unsatisfactory category compared to 57% of contracted BHUs (TRF 2010). Greatest improvement with contracting was seen in Sindh and least in Khyber Pukhtunkhwa. A breakdown of results by essential drugs shows that highest improvement was in availability of amoxicillin, oral pills and chloroquin, with little change seen in availability of iron/ folic acid and IV infusions.

**Availability of Essential Drugs and Vaccines: Comparison between Contracted and Non-Contracted BHUs**

| Availability of essential drugs and vaccines: percentage composite score January-March 2010 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Balochistan | | Sindh | | KP | | GB | Total | |
| | Old | New | PPHI | DDOH | PPHI | DDOH | PPHI | PPHI | DDOH |
| | 12 | 12 | 12 | 12 | 12 | 12 | 4 | 40 | 36 |
| 10 essential drugs | | | | | | | | | |
| Highly Satisfactory | 8.3 | 0.0 | 58.3 | 25.0 | 0.0 | 0.0 | 25.0 | 22.5 | 8.3 |
| Satisfactory | 50.0 | 16.7 | 16.7 | 0.0 | 0.0 | 0.0 | 0.0 | 20.0 | 5.6 |
| Unsatisfactory | 25.0 | 75.0 | 25.0 | 25.0 | 8.3 | 16.7 | 50.0 | 22.5 | 38.9 |
| Highly Unsatisfactory | 16.7 | 8.3 | 0.0 | 50.0 | 91.7 | 83.3 | 25.0 | 35.0 | 47.2 |
| 5 Vaccines | | | | | | | | | |
| Highly Satisfactory | 50.0 | 33.3 | 66.7 | 50.0 | 33.3 | 41.7 | 50.0 | 50.0 | 41.7 |
| Satisfactory | 0.0 | 25.0 | 0.0 | 33.3 | 25.0 | 16.7 | 25.0 | 10.0 | 25.0 |
| Unsatisfactory | 0.0 | 0.0 | 0.0 | 0.0 | 25.0 | 8.3 | 0.0 | 7.5 | 2.8 |
| Highly Unsatisfactory | 50.0 | 41.7 | 33.3 | 16.7 | 16.7 | 33.3 | 25.0 | 32.5 | 30.6 |

Source: PPHI Third-Party Evaluation 2010

**Number of sample BHUs with essential drugs available on day of visit**

| | Balochistan | | Sindh | | KP | | GB | Total | |
|---|---|---|---|---|---|---|---|---|---|
| | Old | New | PPHI | DDOH | PPHI | DDOH | PPHI | PPHI | DDOH |
| | 12 | 12 | 12 | 12 | 12 | 12 | 4 | 40 | 36 |
| Amoxicillin capsule / syrup | 12 | 12 | 12 | 8 | 10 | 5 | 4 | 38 | 25 |
| Contrimaxazole Tab/syrup | 12 | 11 | 12 | 12 | 7 | 6 | 3 | 34 | 29 |
| Metronidazole Tab / syrup | 12 | 12 | 11 | 12 | 12 | 10 | 3 | 38 | 34 |
| Inj. Ampicillin | 1 | 8 | 9 | 11 | 1 | 1 | 3 | 14 | 20 |
| Tablet Diclofenic | 11 | 11 | 12 | 10 | 10 | 7 | 3 | 36 | 28 |
| Chloroquin tablet / syrup | 12 | 11 | 12 | 11 | 11 | 8 | 3 | 38 | 30 |
| Oral pills | 10 | 7 | 9 | 6 | 5 | 1 | 4 | 28 | 14 |
| Intravenous infusions | 12 | 12 | 12 | 12 | 10 | 10 | 4 | 38 | 34 |
| Inj. Dexametazone | 3 | 12 | 12 | 11 | 12 | 6 | 3 | 30 | 29 |
| Tablet Iron-folic acid | 12 | 12 | 11 | 9 | 9 | 9 | 3 | 35 | 30 |
| **% of sample BHUs with essential drugs available on day of visit** | | | | | | | | | |
| Amoxicillin capsule / syrup | 100.0 | 100.0 | 100.0 | 66.7 | 83.3 | 41.7 | 100.0 | 95.0 | 69.4 |
| Contrimaxazole Tab/syrup | 100.0 | 91.7 | 100.0 | 100.0 | 58.3 | 50.0 | 75.0 | 85.0 | 80.6 |
| Metronidazole Tab / syrup | 100.0 | 100.0 | 91.7 | 100.0 | 100.0 | 83.3 | 75.0 | 95.0 | 94.4 |
| Inj. Ampicillin | 8.3 | 66.7 | 75.0 | 91.7 | 8.3 | 8.3 | 75.0 | 35.0 | 55.6 |
| Tablet Diclofenic | 91.7 | 91.7 | 100.0 | 83.3 | 83.3 | 58.3 | 75.0 | 90.0 | 77.8 |
| Chloroquin tablet / syrup | 100.0 | 91.7 | 100.0 | 91.7 | 91.7 | 66.7 | 75.0 | 95.0 | 83.3 |
| Oral pills | 83.3 | 58.3 | 75.0 | 50.0 | 41.7 | 8.3 | 100.0 | 70.0 | 38.9 |
| Intravenous infusions | 100.0 | 100.0 | 100.0 | 100.0 | 83.3 | 83.3 | 100.0 | 95.0 | 94.4 |
| Inj. Dexametazone | 25.0 | 100.0 | 100.0 | 91.7 | 100.0 | 50.0 | 75.0 | 75.0 | 80.6 |
| Tablet Iron-folic acid | 100.0 | 100.0 | 91.7 | 75.0 | 75.0 | 75.0 | 75.0 | 87.5 | 83.3 |

Footnote: 'old' Balochistan counted as PPHI and 'new' counted as DDOH equivalents as they have had less time to change to PPHI management practice

Source: PPHI Third-Party Evaluation 2010

**Procurement and Supply in Contracted BHUs:** The contracted BHUs have a more expanded list of approved drugs - 117 drugs as compared to 70-80 drugs at non-contracted BHUs – with some drugs falling outside the national EDL. Procurement and supply of drugs in the case of contracted BHUs is centralized at the provincial level. Some adaptation of public sector purchasing rules has been done for procurement and purchase not necessarily bound by cheapest tender in an attempt to improve drug quality. Although availability has been proven to be higher, there are concerns over presence of inappropriate drugs at BHUs not required for first level primary care. Standardized and clear selection and procurement systems are needed across all provinces.

### 3. Essential Medicine Management during Emergencies:

In Pakistan, areas affected by the earthquake in 2005 and floods in 2010 are being supported for drug supply through the WHO and international NGOs. Assessment of essential medicines management in disaster hit areas in Pakistan showed that a steady supply of medicines without stock-outs was seen in 56 first-level care government facilities of calamity hit area (Bukhari, 2010). WHO has been assisting in the procurement and supply of drugs to in disaster areas and has outlined modalities for acceptance of donated medicines, assisted in speedy procurement, developed tools for forecasting, designed customized kits and implemented a computerized logistic support system for assisting in sustained supply and inventory control. Due to lack of WHO certified production units in Pakistan, drugs are procured internationally. A computerized Disease Early Warning System provides alert on diseases meeting in disaster areas for timely provision of essential and life saving drugs. Large international NGOs have also been directly procuring and dispensing drugs through their health delivery network. The most

notable amongst the INGOs is Merlin which is providing services to a population of 2 million though 100 government health facilities.

### 4. Private Sector Market

**Composition of private sector:** In Pakistan, 79% of the population utilizes the private health sector (World Bank, 2010). Private providers largely rely on private pharmacies and medical stores for provision and dispensing of medicines to patients with few large hospitals maintaining own chain of selection and supply of medicines. Of the total expenditure on medicines, private health expenditure on medicine comprises nearly three-fourth with the burden borne by households through out of pocket payments (Cameron 2009).

The private sector comprises a wide mix of providers including at least 20,000 registered general practice clinics, 340 dispensaries, 300 MCH centers and 450 laboratories/ diagnostic centres, however actual numbers are probably much higher as all cadres of government health staff also maintain private practice (WHO-EMRO, 2011). There are also 500 small to medium sized hospitals and although large regular hospitals are much fewer in number (WHO-EMRO 2011) they include some of the longest established philanthropic hospitals that continue to be heavily utilized (World Bank 2008b). In addition there are 1800 local NGOs providing health care services including few large national NGOs and several small-medium scaled NGOs. Beside the allopathic sector, there are at least 52,600 registered unani medical practitioners providing non-allopathic remedies.

**Private pharmacies/ medical stores:** Pharmacies and medical stores are an important source of care as there is little restriction on drug sales and patients frequently resort to self medication. Although there are no national figures for self medication, available studies indicate 6-51% depending on the contextual setting (Thaver & Haider 1995; Sturm 1997), and figures are nearly two decades old and require updating. There are 45000-50000 pharmacies and medical stores in Pakistan (Butt et al 2005), one of the highest numbers in LMICs.

Many drug sellers have minimal formal education and little or no professional training; of those with training, most were absent from pharmacies (Rabbani et al 2001) a practice also observed in other developing countries. While there are regulatory checks on drug quality at retail outlets there is little regulation of quality of retail outlet. A cross-sectional survey of 311 pharmacies /medical stores in Rawalpindi showed that the proportion of pharmacies meeting licensing requirements was only 19.3% [95% C.I: 15.1, 24.2] (Butt et al 2005). Qualified staff was present in only 22% of pharmacies. Only 10% had a temperature monitoring device and only 4% had an alternative power supply for refrigerators as a back-up for frequent power outages.

**Availability of medicines in private sector:** In private retail pharmacies medicine availability is higher than public sector both for generics and originator brands. Availability of originator brands exceeds that of low cost generics with respective figures of 59% for originator brands and under 30% for low priced generics. There is excess availability of originator brands in the private sector, exceeding the 23-47% range found in LMICs while low priced generics needs to be increased as it falls much below the 50-75% availability figures for LMICs. The originator brand versus generic imbalance is influenced by local regulations on production of medicines as well as demand, marketing by industry and demand of health care providers and patients.

**Marketing of Drugs to Health Providers:** Malpractices in the distribution chain are evident in the area of marketing, where members of the industry collude with health providers in order to promote the use of medicines, products, and technologies without regard for cost, quality or appropriateness of use (Nishtar 2010). Health care facilities whether in the public and private sector, with extremely few exceptions, do not place any restriction on industry representatives to health providers. Pakistan Medical and Dental Council's ordinance on relationship between the industry and registered doctors and dentists is vague at best. It does not prohibit the receiving of gifts, inducements, or promotional aids by registered practitioners from pharmaceutical industry provided it does not compromise professional integrity (PMDC, 2011)

Visit by industry representative for many general practitioners is alarmingly often the only source of treatment information, underscoring the lack of in-service training, however information provided is questionable. A study found that 18% of sales advertisements had unjustified or misleading claims (Rohra et al., 2006). Another study involved promotional brochures claiming that full prescribing information was available on request. When doctors requested information from a mix of 45 multinational and local companies 26% letters received a response and only 15% of responses met the WHO criteria for optimal drug information (Hafeez & Mirza, 1999).

### 5. Trained Human Resource:

**Inadequate supply and use of pharmacists:** Pharmacists in developing countries are still underutilized and their role as health care professionals is not deemed important by either the community or other health care providers (Azhar et al 2009). There is inadequate supply of pharmacists with a total of 28 pharmacy institutions but only 8102 pharmacists in the country as compared to 110,000 doctors. This provides a ratio of 0.9 pharmacists: 10000 population as opposed to a recommended ratio of 1 pharmacist: 2000 population (WHO-EMRO 2009). Among the total number of pharmacists in Pakistan, approximately 55% are engaged in the production of pharmaceuticals – 15% of them working at the federal and provincial drug control authority and hospital pharmacy level – with another 15% in sales and marketing of pharmaceuticals, 10% in community pharmacy, and the rest 5% in teaching and research (Azhar et al 2009). Particularly acute shortage of pharmacists is seen in the areas of drug procurement, management and dispensing across both the public and private sectors. Within the public sector, the post of pharmacist is only seen in district and teaching hospitals, however numbers are meager with for example only 1 pharmacist posted in Civil Hospital Karachi a large teaching hospital with an OPD of 800 patients/ day and 1500 beds. Although elsewhere in the world the role of pharmacists is recognized in community pharmacies, hospital and drug regulatory authorities, the health care system of Pakistan has yet to recognize this role.

**Regulation of pharmacy practice:** There are legal provision requiring pharmacists to be registered and requiring private pharmacies to be licensed however National Good Pharmacy Practice Guidelines have not been made public by the government (Bukhari 2010). A Pharmacy Council has been recently formed under the Pharmacy Council Act 2009 to regulate the practice of pharmacy. Specific functions include developing and overseeing standards for conduct of pharmacists and allied staff, standard of teaching and accreditation of pharmacy degrees, maintaining registers of qualified pharmacists and pharmacy technicians, and training programs, and organization of continuing training courses. The Pharmacy Council is currently functional however its functions are limited to the relatively low numbers of pharmacists in the country and has no control over the vast number of medical stores in the country manned by those holding no training or qualification in pharmacy.

### Regulation: Licensing, Registration, Pricing, and Quality Control

**Drug Policy & Acts:** Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the national constitution. Regulation of the pharmaceutical sector had traditionally been by the Drug Act 1940 and the Pharmacy Act 1967. In 1972 the Generic Drug Act was introduced but had to be revoked in the wake of strong opposition by the commercial sector and the medical community (Nishtar 2010). The Drug Act 1976 currently regulates the pharmaceutical sector and is a comprehensive document setting out extensive stipulations for industry licensing, drug registration, quality control etc. However implementation of the act is loosely monitored and creates space for abuse. Furthermore, it has not been updated since the declaration of the World Trade Organization's (WTO) statutes and Pakistan's Patent Ordinance 2000.

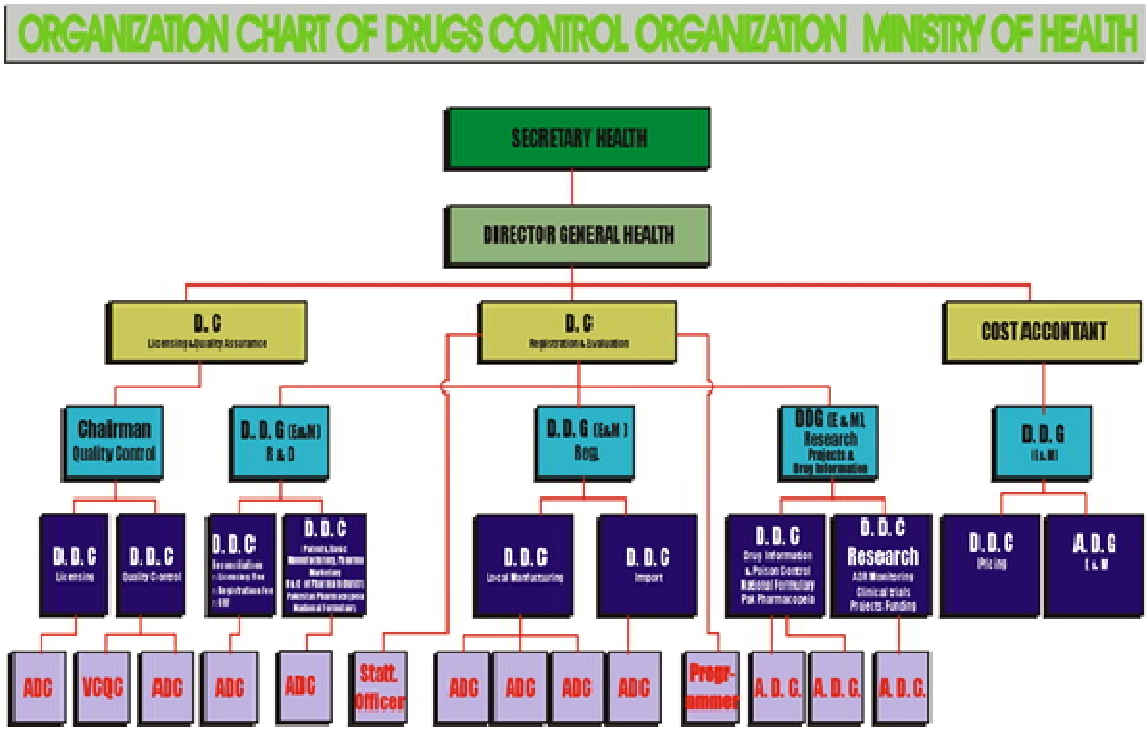
A National Medicines Policy was also formed in 1993, updated in 1997 and is currently again in the process of update. At present there is no strategic plan for implementation of National Medicine Policy. Issuance of Statutory Regulatory Orders further creates confusion and unevenness in the application of policies. In response to quality concerns over drugs in the market, the Federal Cabinet has approved the establishment of an independent Drug Regulatory Authority (DRA), however its constitution has not taken place so far.

**Areas Covered by National Medicines Policy**

| Selection of essential medicines | Yes |
|---|---|
| **Medicines financing** | NO |
| **Medicines Pricing** | Yes |
| **Procurement** | Yes |
| **Distribution** | Yes |
| **Regulation** | Yes |
| **Pharmacovigilance** | Yes |
| **Rational use of medicines** | Yes |
| **Human resource development** | Yes |
| **Research** | Yes |
| **Monitoring and evaluation** | Yes |
| **Traditional Medicine** | Yes |

Source: Pharmaceutical Country Profile, MOH 2010

**Regulatory Functions & Organizational Structure:** The federally based Ministry of Health (MOH) is responsible for licensing of drug production companies, registration of drugs and pricing while the function of quality control lies with the provincial Departments of Health (DOH). Each function has detailed and well developed guidelines given by the Drug Act 1976.




Source: Ministry of Health Pakistan

**Drug Production:** Pakistan meets 70% of its domestic demand of medicines from local production and 30% through imports (MOH 2011). Although at the time of independence in 1947, there was hardly any pharmaceutical industry in the country there are currently 30 multinational and 411 local units involved in pharmaceutical manufacturing (MOH 2011). However, share of market both in terms of number of medicines manufactured and revenues, is almost evenly divided between the few multinationals and large number of local companies. The local market for pharmaceuticals in Pakistan has been expanding at a rate of around 10-15% over the last few years. The value of pharmaceuticals sold in Pakistan exceeded US$1.4 billion, which equates to per

capita consumption of less than US$ 10 per year while it is expected to exceed US$2.3 billion by 2012 (PPMA, 2007). The Pakistan pharmaceutical industry has a small share of the international market with an export turnover of US$ 400 Million and accounts for 1% of the exports (PPMA, 2007).

However there is wide variation in quality of drugs manufactured with existence of both sophisticated manufacturing units having well developed quality monitoring mechanisms as well as low cost units having non-existent quality assurance systems (Nishtar, 2010). There is lack of local production of WHO certified drugs which are mandated for usage in donor funded programs such as GFATM and also required for use by international NGOs serving mainstream and refugee populations. So far industry has not shown interest in investing in quality assurance for WHO or FDA certification, and quality measures are up to interest and motivation of individual production units.

**Drug Licensing:** In Pakistan, there are legal provisions requiring manufacturers to be licensed and requiring manufacturers to comply with Good Manufacturing Practices (MOH, 2010). Drug Act 1976 provides a system for licensing of each manufacturing unit. The Licensing Board at the MOH examines and approveslayout plans of new manufacturing units, inspects units through panel of experts and processes applications for renewal of licenses. However there is wide variation in terms of quality of registered production units. At present there is no WHO certified nor FDA approved manufacturing facility in the country. In the process of manufacturing, very few manufacturers in Pakistan comply at best, only with minimal quality standards and the barest minimum current Goods Manufacturing Practices (GMP) stipulated criteria raising quality concerns. These entities find compliance with regulations costly and try to influence regulators to get their products registered, speed up approval processes, get favorable prices or to have their drugs included in the formularies of various hospitals and institutions (Nishtar, 2010).

**Drug Registration:** The Drug Registration Board processes application for registration of any new pharmaceutical item including new molecules, new dosages of approved molecules as well as different brands of approved molecules under the Drug Act 1976, the de-registration process is also a function of the board. Registration can be made on basis of proven efficacy in any country and does not require bio-equivalency results from Pakistan. Cost effectiveness studies are also not required for registration of products. At present there are 1100-1200 registered molecules and approximately 76000-88000 registered products which is one of the highest across LMICs. This is due to a high number of drug registrations for example there are 7 different forms of Acetaminophen in the market being sold under different brands, dosages and prices.

**Drug Pricing:** In Pakistan, there are regulatory provisions affecting pricing of medicines targeted at manufacturers, wholesalers and retailers. Pricing is fixed at the MOH with the standard practice of pricing based on reported price of raw material, other input and overhead costs. This also creates opportunity for collusion to obtain high prices (Nishtar 2010). As yet there has been no move towards a clear pricing formula. By law, wholesalers can markup goods by maximum 2% of the final price and retail markup for locally produced medicines is 15% of the final price. Regulations exist mandating that retail medicine price information should be publicly accessible and the information is made publically available through the Official Gazette Notification and printed on each medicine box. The capacity of inspectors to comprehensively monitor prices and ensure adherence to officially set prices is limited and there is no official data on levels of adherence (WHO/HAI, 2008).
The MOH has consistently provided measures for low pricing tax breaks as well as price control. There is tax exemption on import of raw material and equipment for basic manufacturing of drugs and is of considerable importance given that there is little production of raw material with most being imported in large quantities from different countries. In addition, medicines are exempted from the general sales tax on commodities. Moreover, full import tariff exemptions are provided for UN partners and for HIV/AIDS medicines when procured by a donor funded program (WHO/HAI., 2008). Asides from tax breaks, there is flat price control is in place since the last 10 years in which prices of all pharmaceutical products have been frozen. The only attempt at partial price de-regulation attempt led to several fold increase in price of drugs and had to be rescinded.

**Issue of Orphan Drugs:** While price control is well intentioned it has also contributed to the issue of 'Orphan Drugs' by which essential low cost drugs have disappeared from the market due to lack of profit margins. The list is alarming and includes basic essentials such as phenytoin, thiazide, adrenaline, thyroxine, primaquin, folic acid to name a few. Action by the MOH to enforce production of 'orphan drugs' has usually been counter productive leading to sub-standard production Reliance is often on import of 'orphan drugs' to plug in chronic shortages. The MOH has not yet explored the potential of various approaches of differential pricing to control prices of drugs on the National EDL. Differential pricing is expected in the new National Drug Policy currently under development

**Quality Control:** The quality of drugs on the market is an important public health concern in many countries. In Pakistan the quality monitoring of products on the market is done by the provincial governments while registration authority, as earlier mentioned, rests with the federal government. Quality control in Pakistan follows the traditional approach of being a government dominated function relying on monitoring and punitive action. There has been little attempt for more participatory regulation of drug quality that could result in more buying in from industry, distributors ns retailers.

The basic functions for quality monitoring include sampling and testing of drugs being sold at retail outlets, inspection of drug storage and inspection of drug transportation. Investigation reports for sub-standard drugs, misbranded or adulterated drugs are sent to Federal Licensing and registration Boards and through them to all the provincial governments for ensuring effective recall of drugs. 7 laboratories exist in Pakistan for Quality Control testing and include the federal Drugs Testing Laboratory located at Karachi; an Appellate Laboratory for re-testing is in Islamabad and drug testing laboratories of the Provincial Governments at Peshawar, Quetta, Lahore and Karachi. In the past 2 years, 60,000 samples were taken for quality control testing of which 1,194 failed to meet the quality standards, however results are not publicly made available (MOH 2010)

**Issues of counterfeit medicines:** According to WHO, 25% of all medicines in developing countries are counterfeit with prevalence far higher in certain countries Counterfeit medicines constitute between 40-50% of total supply in Nigeria and Pakistan (Morris & Stevens, 2006).Counterfeit medicines result in either under-dosage or even active harm causing injury or death. It also undermines the incentives of registered pharmaceutical producers to invest in quality control. Report from pharmaceutical manufacturers of the European Union and another from US Trade Office have alleged that the Pakistani market has almost 50% spurious drugs (Nishtar, 2006). Similarly, official channels of trade can involve trade of counterfeit medicine inadvertently or intentionally and it is reported that 6-10% of cross border trade in medicines in developing countries comprises of counterfeit medicines (Nishtar 2010).

**Research fund tax:** A Central Research Fund is maintained by the MOH for investigation, evaluation or development of a drugs and its use is governed by detailed guidelines given by the Drug Research rules 1978. Every pharmaceutical manufacturer is supposed to contribute 1% of gross profit, before deduction of income tax, towards the Central Research Fund (WHO/ HAI., 2008.) An Expert Committee is responsible for fund allocation to individuals and/ or Institutions, which are engaged in research in the field of pharmacy and medicine however to date there has been little utilization of research funds.

# SECTION 4: RESULTS OF STAKEHOLDER INTERVIEWS

### Is Access an Issue?

All stakeholders were unanimously of the opinion that access to medicines was a major issue in Pakistan. There was divided opinion on extent of work done in this area with close to half of the opinion that some work had been done on this area but major work needed to be done while others opinion that substantially little work had been done so far. Only 3 respondents identified access as involving elements of quality, affordable prices and availability at nearest access while others mainly tended to identify with one aspect either physical availability, quality or affordability.

### Main Barrier to Access:

Weak regulation, supply side issues and irrational prescription of drugs were identified as the main barriers to access. Although open end in-depth interviews precludes computing of quantitative frequency, broadly most stakeholders identified weak regulation is the main barrier, followed closely by irrational prescription while a variety of supply side issues was the third common response. Weak regulation covered a range of issues including low quality threshold for registration, weak enforcement of existing regulations, flat price control leading to drug disappearances from the market, and corruption nexus at the level of licensing, registration and quality control. Supply side issues cited included inappropriate procurement of drugs, lack of pharmacists rile in supply management, and poor management of drug availability at public sector facilities. Irrational use responses involved inappropriate prescription by providers, undue influence of medical specialists in procurement and nexus between providers and industry.

### Irrationality of Drug Use:

*"Essential generics don't have star status like new brand drugs..." (Intw: 21)*

Stakeholder responses showed that this was a multi-dimensional issue requiring action from policy level down to patient level. There was wide felt concern that prescribing practices needed improvement from specialists to GPs and moreover that there was unabated non-authorized prescription by paramedics and dispensers. It was felt that since essential drugs have been around for a long time and they don't have the same prestige as new brand products leading to irrational prescription even amongst well meaning practitioners. This was felt to be aggravated by lack of in-service training and enforcement of standard treatment protocols. Moreover the open access of doctors to industry representatives and lack of bar on receiving incentives from industry for drug promotion had promoted entrenched nexus between industry and practitioners. Another frequently cited factor was the lack of tight controls in drug registration leading to domination of well promoted originator brands in the private market. Similarly, little restriction over medicine purchase by patients and low levels of patient awareness were felt to further enforce irrational use. Weak presence of pharmacists in drug selection at health care facilities and drug dispensation at facilities and outlets was also identified as a contributing factor. Stakeholders called for a multi-pronged strategy to control irrational drug use.

### Weaknesses in Drug Registration:

*"There is an 'open access policy' in Pakistan for drug registration..." (Intw: 4)*

All stakeholders felt that an excessive number of products are registered however there were somewhat differing perceptions over underlying reasons. Respondents reported that there were only estimates available of number of registered products, that exact number was not available even with MOH and that there is continued absence of national formulary.

Some stakeholders cited weak technical management and planning by Ministry of Health. Registration does not look into cost effectiveness, comparative cost analysis over other products, local bio-equivalency is not required and scrutiny of submitted bio-equivalence is variable. Registration system is still manual making it difficult to manage the data and provide a systematic system of de-registration of old and superfluous products. As a result there are few occasional attempts at de-registration but lack of a systematic system. Staff managing registration has not received targeted training for registration nor been exposed to drug registration best practices in other countries.

Other stakeholders were wont to blame this on a nexus between industry and technical registration staff and that lack of a tight registration system leaves open opportunities for collusion. Opinion was divided about generic policy however many stakeholders expressed strong need for aggressive policy and implementation measures for generic encouragement.

### Issues with Quality Assurance:

It was generally felt that there is a wide variation in quality of registered drugs and quality surveillance needs to be strengthened by all stakeholders. The local market ranged from high quality products to those with of sub-standard quality and additionally there is frequent inundation with counterfeit drugs. Multiple reasons were put forth.

Within the industry, the low threshold for drug registration was cited as a disincentive for manufacturers investing in quality. Those manufacturers with high quality products were driven by internal quality checks rather than regulatory pressures and relied on private market and exports for sales. Quality producers also tended to stay away from public sector procurement due to low priced tenders as well as concerns over government being a reliable payer. While there is little interest within industry in WHO certification there is comparative interest in FDA certification amongst the more equipped units as that expands access to foreign markets

Capacity for quality assurance and nexus with inferior providers were other key issues raised by stakeholders. Only 3 of 7 testing laboratories were deemed to have required capacity while staff for licensing of units and market inspection were felt to be poorly paid and trained giving rise to avenues for collusion. Lack of an independent drug regulatory board was felt to enhance undue political influence over quality checks with swings of high and low corruption taking place according to the leadership in place. Presence of counterfeit drugs was another area and of similar concern to registered industrial unit as well as policy makers and end users. Counterfeit medicines get access into the medicines chain through manufacturing of spurious drugs by unlicensed manufacturers and smuggling. It was felt that new policy measures need to be explored to not only tighten action from government but also include other stakeholders as partners in market surveillance,

### Orphan Drugs – Is There A Way Out?

The issue of critical shortages of essential drugs was felt to be of high concern across all stake holder with basic drugs missing from the market such as phenytoin, phenobarbitone, thyroxine, thiazide, and folic acid. Low prices of these essential drugs led to low production making physicians substitute with new drug on the market thus perpetuating the cycle of orphan drugs. Flat price control in place over drugs was felt to be a contributing factor resulting in major disincentive to industry for production of low cost drugs. However fear of public outcry led to reluctance within MOH to experiment with pricing measures while forced production by Industry on MOH's directives tended to result in production of sub-standard drugs and cross border trafficking to regional counties offering better prices. At the same time little discrimination on introduction of new medicines products encouraged prescribers to move away from standard drugs. Respondents called for more innovative market management by introducing a mix of pricing measures, tightening streamlining registration of unnecessary drug and sharper surveillance of orphan drugs. There was also demand that pricing deliberation should be made more

participatory with greater inclusion of provincial implementers. A suggestion was put forward to move to regional basket of drugs to avoid drug shortages.

### Overlooked Areas of Procurement and Stock Management:

*"We have always focused on macro-economic policies but attention to service delivery level; has been lacking …there lies the gap"(Interview 5).*

Respondents felt that supply chain was an area that does not get sufficiently highlighted with spotlight usually being on registration and pricing, but needs practical attention and may be more amendable to quick wins rather than larger contentious issues.

Public sector has a generic procurement policy with provincially pre-approved tenders at an annual rate contract. However quality of drugs at public sector facilities was generally felt to be suspect due to low quality threshold at the time of procurement. The procurement practice of going for the cheapest tender was felt to allow companies with low quality drugs to be eligible for tenders. So far only one province has moved forward in raising the threshold for drug tenders. Many of the better quality producers tended to stay away from public sector tenders and can be drawn in only if the system is made more transparent and competitive. There was also concern that shifting of procurement function to district level under the Local Government Ordinance was contributing to purchases of drugs other than those on the national EDL.

Forecasting was another area highlighted for improvement and several gaps were identified. The current practice relied on incremental increase in inventory rather than a scientific forecasting based on morbidity data and patient volume statistics. In case of hospitals, procurement was also excessively dominated by specialists resulting in deviation from EDL and inefficient purchasing. Some stakeholders pointed to marginal involvement of pharmacists in procurement- some of the larger teaching hospitals having only 1 pharmacist for 1000 beds - while others felt that drug selection was an area that could be taken care off by medical doctors. Another area of concern was frequent shortage of drugs, with stakeholders divided over whether this was an issue of inadequate funds or lack of proper stock management. Large national and international NGOs were in comparison felt to be more scientific in procurement due to tying of stocks reports to morbidity reports, a stronger check on drug quality and avoidance of stock-outs through bumper stocks.

Stock outs were a commonly reported problem and felt to be more a problem of management of funds rather than non-availability of funds. Logistics management systems were not in place and where developed were being applied only to donor funded programs with little roll out to the mainstream public health care sector. Enforcement of standards for drug storage and dispensing was also felt to be poor and there was concern of lack of professional staff for handling drug distribution and storage as well as absence of staff training and capacity building.

### Post Devolution Prospects:

While respondents saw partial devolution as an opportunity for increased implementer feedback on drug regulation there was concern by nearly all stakeholders on total devolution of drug regulation to provinces. The latter was viewed as creating inequities in terms of physical availability, quality and pricing within country population. Respondents expressed concern that if medicine is registered in one province but not another then, patients in another province will be deprived of the drug. This can create legal implications by compromising right of patient access to drugs. Furthermore not all provinces have even capacity to register and test drugs putting in question their regulatory role. Similarly the same drug will be registered cross-province movement of drugs with low availability in provinces with higher prices. Respondents cited example of OECD countries where drug regulation is a centralized function but autonomous function and current situation in Pakistan can be improved by an autonomous regulatory body with adequate stakeholder representation.

### Key Areas for Research:

Stakeholders identified the following key areas for research feeding into practice:

- how to increase compliance with standard therapy amongst providers and patients;
- how can awareness of patients and end users be increased for rational drug use;
- what are the underlying factors behind poor availability of medicines at public sector facilities;
- what measures are needed to improve quality control of drugs;
- what best practice lessons can be taken from other countries to strengthen registration and pricing
- What measures are needed to address issue of orphan drugs.

## SECTION 5: RESULTS OF ROUNDTABLE

**Policy Concerns:** The following were the policy concerns prioritized through the Roundtable discussion.

Rational Use

- Unnecessary, and often inappropriate prescriptions, by medical practitioners
- Large and unregulated private sector with reportedly high utilization levels of informal providers and quacks
- Underutilized role of pharmacists in health service delivery
- Little presence of therapeutic protocols & formularies
- No restriction of type of prescriptions by level of health care
- Open access of industry to health care providers

Financing & Affordability

- Burden of medicine payment mainly on households
- Chronic care therapy unaffordable with both generics and originator bands
- Inadequate operational budget for medicine in public sector
- Existing budget in public sector need to be more efficiently managed
- Contracting out of BHUs has resulted in better availability of drugs
- Need to explore new financing mechanisms for health service delivery that can improve access to drugs

Supply Side Issues

- Low availability of medicines in public sector at all tiers of health system
- Low quality threshold for procurement in public sector
- Information on pricing fixed by MOH is not readily available for procurement
- Lack of bumper stocks & advance forecasting based on morbidity pattern
- Outdated logistics management systems
- Drug storage and dispensing poor across public and private sector
- Lack of sufficient number of pharmacists across public and private sector
- Too many drug stores o proper regulation
- Black-marketing practices in private retail market due to collusion

Registration

- Too many registered products
- Low quality threshold for registration
- No WHO or FDA certified production unit in the country
- Need for regular review of EDL
- Little utilization of Central Research Funds despite need for evidence

Pricing

- Clear cut pricing formula needed
- Flat price control is counter productive
- Low priced essential drugs, even life saving ones, are chronically short in the market
- Wide gap between prices of generics and originator brands
- Uneven regional pricing contributes to cross border supply resulting in stock-outs

Quality Assurance

- Lack of incentives to produce quality drugs
- Continuous capacity building of for quality surveillance
- Government dominance and punitive measures not enough for quality improvement

Decentralization

- Need for independent drug regulation authority with greater representation of provinces
- Total devolution of drug regulation can potentially have negative consequences on drug availability and cost across provinces

**Research Concerns:** The following were the research priorities identified collectively through the Roundtable discussion

- Impact of decentralization on
  - Prices
  - Availability
  - Overall access
- Regulations exist in Pakistan but need to be implemented : research into implementation gap for existing medicines policies (determinants, reasons)
- Investigating the success and failures (and reasons) of the essential medicines programme in the past 20+ years in Pakistan

- Human resources:
  - The role of pharmacists at decision making level on medicines policies
  - Credibility of health professionals and the issue of trust
- Pricing policies
  - Deregulation or price regulation? Which regulation mechanism
  - How to improve access to orphan medicines
  - Monitor price in the actual market to inform pricing regulations
- - Lack of medicine unit cost estimation
- Role of private sector
  - Informal / shadow pharmacies: prominent role that need to be investigated
  - Regulated private sectors
  - Traditional healers
- Documentation of quality – post-marketing surveillance system
- Transparency of information, availability in public domain:
  - Research into a health /medicines information system
    - Registered medicines (and unregistered)
    - Human resources
    - Prices
  - Routine monitoring of relevant indicators on medicines access
  - Integrated HMIS

- Medicines policies part of an overall health policy – Research needs to feed national health policy
- Harmonization and Alignment –
- Access to research – feedback on research made – Need for a wider research network, continuous culture of research
- Consumer perspective
  - Health seeking preferences
  - Other

# SECTION 6: DISCUSSION

In Pakistan there has been considerable work in terms of Policy Acts, legislations, and detailed regulatory and operative guidelines for the pharmaceutical sector. From 1960s onwards to date Pakistan has introduced at least 16 documented regulations for enhancement of access to medicines, including an abortive attempt to bring into place the Generic Drug Policy Act, however gaps exist between policy and practice. This is due to weak implementation, absence of monitoring framework, as well as a traditional tilt of policies towards punitive action by government rather than co-option of other stakeholders towards more participatory regulation.
There is dire need for update of policies in line with on ground evidence and infusion of new strategies involving an innovative mix of measures.

## PRIORITY POLICY CONCERNS FOR INCREASING ACCESS TO MEDICINES:

Using the WHO's Access to Essential Medicines Framework (Laing 2002) we came up with the following policy concerns.

*Rational Use:* **Medical practitioners, including both GPs and specialists, often prescribe unnecessary number of medications with average for Pakistan being >3 medicines per prescription as compared to 2-3 in LMICs and injection usage rate one of the highest in the world.** Pakistan was one of the first countries in which the Essential Medicine Program of WHO was started back in the 1970s and a National EDL comprising of 335 medicines is in place, however rational drug use continues to be a major issue. There is unnecessary prescription of antibiotics, vitamins and painkillers, preference for higher line therapy over standard therapy, sub-optimal knowledge of standard therapy for endemic diseases even amongst licensed practitioners. Apart from medical practitioners, population in Pakistan frequently utilizes quacks and informal providers who are not only unqualified to prescribe but alarmingly also dispense their own medication mixtures. Rate of injection usage in Pakistan is one the highest in the world at 13 injections/person/ capita and is driven by quacks as well as qualified medical practitioners. With largely unrestricted access to drugs in pharmacies and medical stores, there is also considerable self medication and although its prevalence has not been comprehensively assess, indicative figures are of 30-55%. Drug resistance to first line antibiotics has been established at least in urban Pakistan while there is also high prevalence of Hepatitis B and C diseases as a result of injection usage across Pakistan.

**There are several contributing reasons for irrational drug use requiring integrated action at multiple tiers of the health systems**. Standard therapies are poorly enforced in the medical sector with prescribing practices influenced by peer modeling on specialists, patients demand for quick treatment and information by industry. Industry representatives have unrestricted access to medical practitioners and reported nexus of industry and practitioners has been a long-standing concern in Pakistan. Moreover over 79% of the population utilizes the private sector which also comprises of licensed providers as well as quacks and informal providers, and continues to be loosely regulated. Although there are successful examples of large CSOs franchising with GPs for appropriate treatment these have yet to be replicated on a large scale. There is also unrestricted access to drugs in retail outlets and an unnecessarily high number of drug stores most of which do not meet appropriate dispensing requirements.

*Financing & Affordability:* **63% of total drug expenditure is borne by households, one of the highest in developing countries, as opposed to only 18% in OECD countries and leads to non-compliance with chronic care treatment and risk of catastrophic expenditure.** The public sector in Pakistan spends merely $5 per capita when compared with other countries with similar income levels. Spending by public sector is only 34% of total health expenditure and of that less than 25% is spent on non-salary items including medicines. Patients incur costs for medicines at both public and private sector facilities with drug shortages in public sector forcing patients to private retail pharmacies. Patient spending on medicines at public sector facilities is considerable at Rs198 on medicines / visit versus Rs258 per visit at private sector facilities. At present there are no pre paid schemes and

commodity vouchers to ensure patient compliance with therapy and protect households against catastrophic expenditure

There is wide gap between prices of generics and originator brands in Pakistan. Certain medicines have very high prices several fold those of international reference prices. Unaffordability of medicines has been documented as one of the primary reasons for loose compliance with chronic care therapy. **Medicine therapy for chronic care is clearly unaffordable even with use of low cost generics (MPR of 1.7-7.7) while it can be dangerously expensive with originator brands (MPR of 1.9-36.4).**

*Reliable Health Systems:* Policy concerns within this area are further sub-divided into:

*Supply Side Issues:* **In Pakistan availability of essential generics is extremely low in public sector 3.3% in public sector compared to 29-54% in LMICs.** Only 21% of the population utilizes the public sector facilities, despite provision of free services, with medicine non-availability reported by users as one of the primary reasons for dissatisfaction with public sector services. Amongst medicines, there is relatively better availability of acute illness drugs 30-60%), much lower for chronic care (1-57%), while that of emergency life medicines is alarmingly low (30-50%). Reasons for frequent drug stock-outs have not been properly investigated but are attributed to a combination of low budget, lack of rational procurement and delayed release of funds.

**There has been limited attention to management of drugs supply in the public sector with issues of low quality and logistics management.** Generic procurement and cheapest tender practice in the public sector has managed to secure efficient prices for drugs however lack of a quality threshold raises widespread concerns over quality of drugs. Companies better known for quality are hesitant to apply for public sector tenders due to fears of delayed payments, rent seeking and government preference for favored suppliers. Lack of scientific forecasting, budgeting and procurement results in areas of inefficiency and inappropriate drug selection. Over the last decade, drug management has been devolved to districts however there is little assessment of its impact on drug quality and availability. Additionally manual logistic management systems and poor storage facilities are key issues needing attention and while new systems are in place for GFATM supported TB and malaria programs these need to be rolled out to the mainstream public sector.

**Improvement in drug availability has been seen in contracted Basic Health Units with need for attention to alternative financing mechanisms for improving drug availability.** Only 8.3% falling in unsatisfactory category as compared to 87% of those directly managed by the Department of Health, however quality, appropriateness of drugs and storage have not been assessed. New financing mechanisms can potentially improve drug access for the poor and need to be aggressively explored.

**Private retail outlets are the predominant means to supply to both private and public sector patients however the existence of close to 80,000 drug stores, one of the highest in developing countries, defeats attempts at regulation.** Most of these are drug stores rather than pharmacies, are manned by untrained persons rather than pharmacists, and only a fifth of all retail outlets meet licensing requirements. Disappearance of certain drugs from the market drugs is common and is due to withholding by and black-marketing by wholesalers and distributors.

**There is shortage of trained human resource across public and private sector for drug procurement, management and dispensa**tion. As opposed to WHO's recommended ratio of 1:2000 pharmacists per population, Pakistan has only 0.9 pharmacists per 100000 population, of which 70% are engaged in industry with a very small core serving in health service delivery. Role of pharmacists is also not institutionalized with selection and procurement dominated by medical doctors while dispensing is done by junior untrained staff.

*Regulation & Production*: **Pakistan produces 70% of consumed medicines however close to 50% of the market belongs to multinationals and is far from achieving self-sufficiency in production.** Local production

units number up to 414 but vary widely from well equipped units to those with questionable quality of drugs putting into question licensing and quality assurance practices. Self-sufficiency in tem of raw material production is yet to be achieved with dependence essentially on imports. Although TRIPS has afforded certain new opportunities there has been little use of patents and local companies need assistance in deciphering legalities of patents on offer.

**Pakistan has 76000-88000 registered drugs, one of the highest numbers in LMICs, with many being unnecessary drugs having marginal therapeutic effect over each other or multiple variations of the same drug available at different prices and quality.** Although Pakistan has detailed guidelines on licensing of drug production units and registration of drugs however implementation has been questionable with existing practice encouraging a market monopoly with loose control. This results in irrational prescription, unnecessary drug expenditure and weakens monitoring of quality assurance. Reliance on a traditional manual registrations system makes it difficult to strategically plan and review drug registrations while there has also been little utilization of the Central Research Fund in bioequivalence and comparative cost analysis. There are wide discrepancies in terms of quality of registered products with little incentive for more sophisticated production units to invest in quality control. The Supreme Court and Cabinet have recommended Creation of an autonomous Drug Registration Authority to counter poor drug quality but still needs to be put into practice.

**Counterfeit medicines are common in Pakistan and need new modalities of control.** Traditional market monitoring systems is government dominated, punitive and there are widespread concerns of nexus between laboratories, inspectors, suppliers and industry. More participatory and incentive based policies need to be implemented.

**Price of standard chronic care therapy is unaffordable across generics and originator brands and excessive prices are in place for certain medicines in general.** Pricing is based on input costs but lack of a clear pricing formula creates opportunity for collusion and inefficient market spending on products. A flat price control is in practice and although well intentioned has resulted in disappearance of low cost essential medicines, even life saving drugs, from the market, little impact on high priced items, and a general disincentive to producers.

**Greater participation of implementers is needed in regulation however move to totally devolve drug registration to provinces as part of ongoing devolution of Ministry of Health may have serious repercussions.** Regulatory capacity of provinces is very uneven at present. Moreover total devolvement can result in creation of potential inequities across the country with differential drug availability and prices across provinces as well as cross provincial trafficking in drugs. Institutional realignments need to be directed towards creation of an autonomous drug regulation authority but built along more participatory lines.

## RESEARCH NEEDS FOR ADDRESSING POLICY CONCERNS:

There is high need for evidence generation to assist action on prioritized policy concerns. So far research in the pharmaceutical area in Pakistan has not been from a comprehensive health systems perspective with the result that existing research is small scale, mostly confined to rational prescription while areas such as policy, supply side and financing have largely been overlooked. There is need for collation of best practice from other countries, routine monitoring surveys to assess policy impact, operational pilots for testing out new financing and supply side strategies, formative research on health seeking and affordability, and increased pharmaco-vigilance studies. For achieving this, an expanded range of researchers needs to be involved including policy analysts, financing specialists, health systems specialists in addition to pharma experts.

Key research priorities were identified through the consensus building exercise and salient features are given as follows:

**Continuous surveillance is needed into effect of national policies on medicine availability, prices and affordability covering both the market and the public sector.** It is internationally recommended that such surveys should be repeated periodically every two years however there has been no updating of information since the last WHO global survey in 2004. District level information is also need to assess impact of Local government Ordinance as well as Devolution of federal Ministry of Health on access to medicines. Accompanying this there is also high need for policy analysis research as to explore reasons underlying gap between policy regulations and actual practice.

**Pricing policies require examination to improve access to essential generics particularly for standard chronic care therapy and contain prices of excessively priced originator brands.** There is need to move away from flat price control to exploring optimal mix of pricing regulations based on lessons learnt from other countries. There is also need to monitor price in the actual market to inform pricing regulations and production of disaggregated information by prices fixed by MOH, prices at retail pharmacies, and prices for public sector procurement.

**Bottlenecks faced by the Essential Medicines Programme in Pakistan need to be examined to reduce the gap between policy and practise.** This would required identification of constraints and opportunities at different health systems level. Compilation of lessons learnt from other LMICs is needed for promotion of generics at policy level, supply side level, individual provider levels and consumer level.

**Examination of alternative financing mechanisms is required to reduce medicine expenditure borne by households particularly on chronic care therapy, and supplement public sector provision.** Possible mechanisms include franchising with GPs, contracting with NGOs, commodity vouchers, health equity funds and pre-payment schemes, to supplement public sector provision. As a first step operational research pilots and compilation of best practise lessons are needed to inform decision-making on best-suited financing mechanisms for Pakistan's context. Unit cost estimation of standard therapies will also be needed to roll out financing support platforms for drugs.

**Standardised mapping and assessment surveys of private sector are required including of qualified providers, informal providers, shadow pharmacies, and traditional healers.** Information is needed on adequate licensing, prescription practises, dispensation practises, medicine charges, and patient satisfaction. Qualitative information is also needed on sources of information, openness to regulation, and expressed information needs of private sector.

**Formative research is needed into consumer demand, health-seeking preferences, willingness to pay, and enhancing patient role in accountability.** Credibility of health professionals and the issue of trust is also an area that needs to be explored.

**Finally operation research is also needed into improving logistics and human resource management in the public sector for improving drug access.** Areas t be looked into include scientific budgeting, forecasting and procurement, integrated HMIS for drugs, institutionalization of pharmacists and increasing supply, monitoring of quality storage, and routine monitoring of access to health facilities.

## CONCLUSION

Pakistan has relatively well documented policy and operative guidelines however there is gap between policy and actual practice. There is tremendous need for both standard assessment surveys to assess policy impacts as well exploratory research to identify major constraints.

**Priority areas** as identified through this exploratory study and consensus building exercise include

- *Continuous surveillance of impact of policies on availability, price and affordability*
- *Identification, regulation and monitoring of standard chronic care therapies that would particularly benefit from reduced pricing and wider availability.*
- *Optimal mix of pricing regulations to reduce expenditure burden on households.*
- *Tighter regulatory control to cut down on unnecessary medicines having marginal therapeutic effect over each other.*
- *Market vigilance for spurious drugs and participatory strategies to counter spurious drugs*
- *Multi-tiered health system measures for promotion of generics*
- *Operation pilots on alternative financing mechanisms to supplement public sector through a range of commodity voucher, GP contracting, pre-payment schemes, equity funds for increasing drug availability and affordability*
- *Mapping of private sector and exploring support needs for rational use*
- *Consumer health seeking preferences and participation in accountability mechanisms*
- *Improvement of logistics and human resource management in public sector for drug access*

Pharmaceutical policy and research need to be centrally placed within larger health systems related initiatives, reviews and policy updates. This needs to be accompanied by sustained dialogue and interaction between entities including public health sector, pharmacists association, medical doctors association, local governments, industry, researchers and development partners. Adequate steps also need to be taken to ensure access to research, feedback on research and a continuous culture of research feeding into evidence based policies.

## References


- Aaserud, M., *et al*. 2005. Translating research into policy and practice in developing countries: a case study of magnesium sulphate for pre-eclampsia. *BMC Health Serv Res,*. 5: p. 68.
- Alam, M.T., 1997. Therapeutics: a state of the art. *Pak J Pharm Sci*. 10(1): p. 69-78.
- Azhar, S., *et al.*2009. The role of pharmacists in developing countries: the current scenario in Pakistan. *Hum Resour Health,*. 7: p. 54.
- Babar, Z.U. and S. Jamshed, 2008. Social pharmacy strengthening clinical pharmacy: why pharmaceutical policy research is needed in Pakistan? *Pharm World Sci,*. 30(5): p. 617-9.
- Bhutta, T.I. and C. Balchin, 1996. Assessing the impact of a regulatory intervention in Pakistan. *Soc Sci Med,*. 42(8): p. 1195-202.
- Bloom, G., H. Standing, and R. Lloyd, 2008. Markets, information asymmetry and health care: towards new social contracts. *Soc Sci Med,* 66(10): p. 2076-87.
- Butt, Z.A., *et al*. 2005. Quality of pharmacies in Pakistan: a cross-sectional survey. *Int J Qual Health Care,* 17(4): p. 307-13.
- Cameron, A., *et al*. 2009. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet*, 373(9659): p. 240-9.
- Das, N. 2001.Prescribing Practices of Consultants at Karachi Pakistan. . *JPMA*.
- DFID. 2002. *Prescription, dispensing and storage practices in the provinces of NWFP, Baluchistan and Punjab in collaboration with Network for Consumer Protection*. EDSP Baseline Survey Report. 2002
- Drugs Control Organization; Ministry of Health of Pakistan. Accessed on 21-06-2011
- EDSP. 2002. *Standard operating procedures for prescription, handling and dispensing*.
- EMRO, WHO. 2011. *Regional Health Systems Observatory*- EMRO. World Health Organization. 2011.
- EMRO. 2007. *Regional Health Systems Observatory- EMRO.2007.Health Systems Profile- Pakistan.*
- Farkhondeh, M., *et al*. 2009. Antiepileptic drugs in children in developing countries: research and treatment guideline needs. *Epilepsia,* 50(11): p. 2340-3.
- Fikree, F.F., A.M. Mir, and I.U. Haq, 2006. She may reach a facility but will still die! An analysis of quality of public sector maternal health services, District Multan, Pakistan. *J Pak Med Assoc*, 56(4): p. 156-63.
- World Bank. 2005. *North West Frontier Province Economic Report*.
- Haak, H. and M.E. Claeson, 1996. Regulatory actions to enhance appropriate drug use: the case of antidiarrhoeal drugs. *Soc Sci Med,* 42(7): p. 1011-9.

- Habib, F. and L. Baig, *Cost of DOTS for tuberculous patients.* J Pak Med Assoc, 2006. 56(5): p. 207-10.
- Hafeez, A., et al., *Prescription and dispensing practices in public sector health facilities in Pakistan: survey report.* J Pak Med Assoc, 2004. 54(4): p. 187-91.
- Hafeez, A. and Z. Mirza, *Responses from pharmaceutical companies to doctors' requests for more drug information in Pakistan: postal survey.* BMJ, 1999. 319(7209): p. 547.
- Haider, S. and I.H. Thaver, *Self medication or self care: implication for primary health care strategies.* J Pak Med Assoc, 1995. 45(11): p. 297-8.
- Hamid, M.H., *et a*l., 2005. Acute poisoning in children. *J Coll Physicians Surg Pak,*. 15(12): p. 805-8.
- Hashmi, S.K., *et al.* 2007. Factors associated with adherence to anti-hypertensive treatment in Pakistan. *PLoS One,* 2(3): p. e280.
- Imran, M., F.A. Khan, and S. Abbasi, *Standards for labelling and storage of anaesthetic medications--an audit.* J Pak Med Assoc, 2009. 59(12): p. 825-8.International, B.M., Pakistan Pharmaceuticals and Healthcare Report Q2 2011.
- Israr, S.M., *Is Ministry of Health fully prepared to implement an effective DOTS program in Pakistan? An operations research on TB control program in the public health sector in Sindh.* J Pak Med Assoc, 2003. 53(8): p. 324-7.
- Jafar, T.H., et al., *General practitioners' approach to hypertension in urban Pakistan: disturbing trends in practice.* Circulation, 2005. 111(10): p. 1278-83.
- Jamshed S, B.Z., *Generic Medicines as A Way to Improve Access and Affordability: A Proposed Framework for Pakistan. Journal of Clinical and Diagnostic Research.* 2009
- Janjua, N.Z., *Injection practices and sharp waste disposal by general practitioners of Murree, Pakistan.* J Pak Med Assoc, 2003. 53(3): p. 107-11.
- Janjua, N.Z., M.I. Khan, and B. Mahmood, *Sharp injuries and their determinants among health care workers at first-level care facilities in Sindh Province, Pakistan.* Trop Med Int Health. 15(10): p. 1244-51.
- Janjua, N.Z., et al., *Pattern of health care utilization and determinants of care-seeking from GPs in two districts of Pakistan.* Southeast Asian J Trop Med Public Health, 2006. 37(6): p. 1242-53.
- Kadir, M.M., et al., *Out-of-pocket expenses borne by the users of obstetric services at government hospitals in Karachi, Pakistan.* J Pak Med Assoc, 2000. 50(12): p. 412-5.
- Khan, J., et al., *Tuberculosis diagnosis and treatment practices of private physicians in Karachi, Pakistan.* East Mediterr Health J, 2003. 9(4): p. 769-75.
- Khowaja, L.A., A.K. Khuwaja, and P. Cosgrove, *Cost of diabetes care in out-patient clinics of Karachi, Pakistan.* BMC Health Serv Res, 2007. 7: p. 189.

- Laing, R., *Improving Access to Child Health Medicines Review and Discussion Paper prepared for WHO Regional and Country Child Health Advisers Geneva*. 2002.

- Leslie, T., et al., *Epidemic of Plasmodium falciparum malaria involving substandard antimalarial drugs, Pakistan, 2003.* Emerg Infect Dis, 2009. 15(11): p. 1753-9.

- Loevinsohn, B., *et al*. 2009. Contracting-in management to strengthen publicly financed primary health services--the experience of Punjab, *Pakistan. Health Policy,*. 91(1): p. 17-23.

- IPN. 2006. *Counterfeit medicines in less developed countries. Problems and solutions.*. International Policy Network London. *Accessed on 18th February 2011*.

- Mendis, S., *et al.*, 2005. WHO study on Prevention of Recurrences of Myocardial Infarction and Stroke (WHO-PREMISE). *Bull World Health Organ*, 83(11): p. 820-9.

- Mendis, S., *et al.*, 2007. The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. *Bull World Health Organ,* 85(4): p. 279-88.

- Meyer, J. 2004. *Emergency Obstetric Care: Critical Need among Populations Affected by Conflict.* Reproductive Health Response in Conflict Consortium.

- *http://womensrefugeecommission.org/docs/emoc.pdf Accessed on 19th February 2011*. 2004.

- MOH. 2009 *National Health Policy, Final Draft,*. Ministry of Health. Government of Pakistan, *2http://bravo.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---ilo_aids/documents/legaldocument/wcms_117438.pdf, Access date: 18th February, 2011*, in 2009.

- MOH. 2010. The Drugs (Bio-Study) Rules, *Government of Pakistan,* Ministry of Health, Government of Pakistan, Islamabad. Accessed online at http://202.83.164.27/wps/portal/Moh/!ut/p/c1/04. Accessed on 12th Feb 2011.

- MOH. 2010. Pakistan Medical and Dental Council *(Physician-Pharmaceutical Industry Relationship Ethical Standards), Regulations 2010.* Ministry of Health, Government of Pakistan http://202.83.164.27/wps/portal/Moh/!ut/p/c0/04_SB8K8xLLM9MSSzPy8xBz9CP0os_hQN68AZ3dnIwN_Qz8DAyPXQGczU08jA29nM_2CbEdFAHXcy38!/?WCM_GLOBAL_CONTEXT=/wps/wcm/connect/MohCL/ministry/news/pharma+physician+relation+guidlines, Accessed on 18th Feb 2011.

- MOH. 2010. *Draft Vitamin Policy 2010.* Ministry of Health, Government of Pakistan, Islamabad, http://202.83.164.27/wps/portal/Moh/!ut/p/c0/04_SB8K8xLLM9MSSzPy8xBz9CP0os_hQN68AZ3dnIwN_Qz8DAyPXQGczU08jA29nM_2CbEdFAHXcy38!/?WCM_GLOBAL_CONTEXT=/wps/wcm/connect/MohCL/ministry/news/draft+vitamin+policy+2010+123. Accessed on 18th Feb 2011.

- MOH. 2003. *National Drug Policy.* Ministry of Heath, Government of Pakistan, Islamabad. http://www.health.gov.pk/, Accessed on 18th February 2011.

- MOH.2007. *National Essential Medicine List of Pakistan.* Ministry of Health. Government of Pakistan. 2007. http://apps.who.int/medicinedocs/documents/s17119e/s17119e.pdf. Accessed on 18th February, 2011.

- MOH. 2009. *Pakistan Pharmacy Council Act, 2009.* Ministry of Health. Government of Pakistan. http://www.na.gov.pk/private_bills/pvt_bill2009/pakistan_pharmacy_council_act2009_300609.pdf. Accesssed on: 18th February 2010.

- MOH. 1967. *Pharmacy Act 1967*. Ministry of Health. Government of Pakistan, http://www.dcomoh.gov.pk/regulations/pharmacyact1967.php. Accessed on 18th February 2011.

- .MOH. 1986. *The Drugs (Labeling and Packing) Rules, 1986.* Ministry of Health, Government of Pakistan. http://www.dcomoh.gov.pk/regulations/drugrules1.php. Accessed on: 18th February 2011.

- MOH. 1976. *Drugs (Licensing, Registering and Advertising) Rules,1976.* Ministry of Health, Government of Pakistan. http://www.dcomoh.gov.pk/regulations/drugrules2.php. Accessed on: 18th February 2011.

- MOH. 1976. *The Drugs (Appellate Board) Rules, 1976,* Ministry of Health, Government of Pakistan. http://www.dcomoh.gov.pk/regulations/drugrules3.php. Accessed on 18th February 2010.

- MOH. 1978. *The Drugs (Research) Rules, 1978.* Ministry of Health. Government of Pakistan...http://www.dcomoh.gov.pk/regulations/drugrules4.php. Accessed on: 18th February 2011. .

- MOH. 1978. *Drugs (Specifications) Rules, 1978.* Ministry of Health, Government of Pakistan. http://www.dcomoh.gov.pk/regulations/drugrules7.php. Accessed on 18th February. 2011.

- The Drugs (Federal Inspectors, Federal Drug Laboratory & Federal Government Analysts) Rules, 1976. *Ministry of Health, Government of Pakistan.* http://www.dcomoh.gov.pk/regulations/drugrules5.php. Accessed on: 18th February 2011.

- MOH. 1976. *The Drugs (Imports & Exports) Rules. 1976.* Ministry of Health, Government of Pakistan. http://www.dcomoh.gov.pk/regulations/drugrules6.php. Accesssed on 18th February 2011.

- MOF. 2008. *Pakistan Economic Survey 2007-08*. Ministry of Finance, Government of Pakistan. 2008.

- MOH. 2004. *Forging Alliance for Health with Legislators. "Promoting people's access to health through improved access to Primary Healthcare.* Ministry of Health, Government of Pakistan.

- Najmi, M.H., *et al.*, 1998. Prescribing practices: an overview of three teaching hospitals in Pakistan. *J Pak Med Assoc*, 48(3): p. 73-7.

- WHO. 2003. *An Analysis of Essential Drugs, Contraceptives and Vaccines at Government Health Facilities.* World Health Organization Islamabad

- Nishtar, S., 2006. Pharmaceuticals--strategic considerations in health reforms in Pakistan. *J Pak Med Assoc*, 56(12 Suppl 4): p. S100-11.

- Nishtar, S., 2006.The Gateway Paper--health service delivery outside of the public sector in Pakistan. *J Pak Med Assoc*, 56(12 Suppl 4): p. S66-77.

- Nizami, S.Q., I.A. Khan, and Z.A. Bhutta, 1996 Drug prescribing practices of general practitioners and paediatricians for childhood diarrhoea in Karachi, Pakistan. *Soc Sci Med*,. 42(8): p. 1133-9.

- NPPI. 2009. *NPPI Baseline survey of key indicators in Sindh Norway-Pakistan Partnership Initiative,* Government of Sindh, 2009
- Obaid, A., 2009. Quality of ceftriaxone in Pakistan: reality and resonance. *Pak J Pharm Sci,* 22(2): p. 220-9.
- NHA. 2008. *National health accounts: country information Pakistan. , 2008.*
- Nishtar S. 2010. *Choked pipes* Oxford University Press. 2010.
- PRB. 2010. *World Population Report.* Population Reference Bureau. 2010. Washington DC
- PSLM. 2005. *Pakistan social and living standards mearurement survey 2004-05* **Federal Bureau** of **Statistics**, Islamabad
- PSML. 2007. Pakistan social and living standards measurement survey. ***Federal Bureau** of **Statistics 2006-2007***
- NHA 2005-2009. *NHA, Pakistan: Altering household cost-benefit decisions about immunisation, 2005-2009.*
- NHA. 2009. *National Health Accounts for Pakistan, Islamabad. 2009.*
- MOH. 2011. *Ministry of Health of Pakistan, Islamabad. Accessed on 20 th June 2011.*http://202.83.164.26/wps/portal/Moh. 2011 [cited; Available from: http://202.83.164.26/wps/portal/Moh.
- MOH. 2010. *Pharmaceutical Country Profile. Pakistan.* Ministry of Health, Government of Pakistan 2010.
- Patel, M.J., *et al.* 2008.Drug overdose: a wake up call! Experience at a tertiary care centre in Karachi, Pakistan. *J Pak Med Assoc,* 58(6): p. 298-301.
- PMDC. *PMDC Ordinance 1962. Available at http://www.pmdc.org.pk/AboutUs/tabid/72/Default.aspx. Accessed on 20th June 2011.*
- PPMA. 2007. Available at *http://www.ppma.org.pk/PPMAIndustry.aspx*.
- Network for Consumer Protection. 2006. *Prices, availability and affordability of medicines in Pakistan.*
- Qazi, S.A., G.N. Rehman, and M.A. Khan, 1996. Standard management of acute respiratory infections in a children's hospital in Pakistan: impact on antibiotic use and case fatality. *Bull World Health Organ,* 74(5): p. 501-7.
- Qidwai, W., *et al.* 2006. Private drug sellers' education in improving prescribing practices. *J Coll Physicians Surg Pak,*. 16(12): p. 743-6.
- Qureshi, N.N., *et al.* 2007.Effect of general practitioner education on adherence to antihypertensive drugs: cluster randomised controlled trial. *BMJ,* 335(7628): p. 1030.
- Rohra, D.K., *et al.* 2008 Drug-prescribing patterns during pregnancy in the tertiary care hospitals of Pakistan: a cross sectional study. *BMC Pregnancy Childbirth,*. 8: p. 24.

- Rohra, D.K., *et al*. 2006.Critical evaluation of the claims made by pharmaceutical companies in drug promotional material in Pakistan. *J Pharm Pharm Sci*, 9(1): p. 50-9.
- Bukhari SKH, J.A.R.H.Q. 2010.Jooma 1 R., Bile K.M, *et al*, Essential medicines management during emergencies in Pakistan. *EMHJ*, Vol. 16.
- Samad, L. 2001. *SIGN Rapid Assessment Survey Northern Areas, Pakistan*
- Shah, S.A., *et al*. 2005.Antiretroviral drugs obtained without prescription for treatment of HIV/AIDS in Pakistan: patient mismanagement as a serious threat for drug resistance. *J Coll Physicians Surg Pak*, 15(6): p. 378.
- Shah, S.K., *et al*. 2003. Do private doctors follow national guidelines for managing pulmonary tuberculosis in Pakistan? *East Mediterr Health J,*. 9(4): p. 776-88.
- Shaikh, B.T. and J. Hatcher, 2005.Complementary and Alternative Medicine in Pakistan: Prospects and Limitations. *Evid Based Complement Alternat Med*, 2(2): p. 139-142.
- Shehzadi, R., *et al*. 2005.Knowledge regarding management of tuberculosis among general practitioners in northern areas of Pakistan. *J Pak Med Assoc*, 55(4): p. 174-6.
- Siddiqi, S., *et al*., 2002. Prescription practices of public and private health care providers in Attock District of Pakistan. *Int J Health Plann Manage*, 17(1): p. 23-40.
- Siddiqui, S., *et al.*, 2007. Impact of antibiotic restriction on broad spectrum antibiotic usage in the ICU of a developing country. *J Pak Med Assoc*, 57(10): p. 484-7.
- Sturm, A.W., *et al.*, 1997 Over-the-counter availability of antimicrobial agents, self-medication and patterns of resistance in Karachi, Pakistan. *J Antimicrob Chemother,*. 39(4): p. 543-7.
- Thaver, I.H., *et al*. 1998. Private practitioners in the slums of Karachi: what quality of care do they offer? *Soc Sci Med*, 46(11): p. 1441-9.
- Times, D. 2005. *Quacks spreading AIDS and hepatitis: experts* in *Daily Times*. 2005.
- WHO, *Desk Guide for Doctors. National TB Control Programme Pakistan*
- WHO. 2007. .*Regional Office for Eastern Mediterranean Technical discussion on Medicine prices and access to medicines in the Eastern Mediterranean Region.* World Health Organization. Regional Office for the Eastern Mediterranean. Accessed on 17th February 2010.
- WHO, H.A.I. 2008. *Medicine prices, availability, affordability and price components, A synthesis report of medicine. Price surveys undertaken in selected countries of the WHO Eastern Mediterranean Region.* World Health Organization. 2008.
- WHO. 2004. *National Action Plan for Prevention and Control of Non-Communicable Diseases and Health Promotion in Pakistan. A Public private partnership in health.* 2004. World Health Organization,
- WHO. 2004. *The World Medicines Situation.* World Health Organization,

- WHO-EMRO. 2000. *The Work of WHO in the Eastern Mediterranean Region, Annual Report of the Regional Director, 1 January - 31 December 2000.* World Health Organization,
- World Bank. 2008. *Evaluation of quality of care in public sector in Sindh, Pakistan / Islamabad Report, 2008.*
- World Bank. 2005. *Sindh: Health Policy Note*. World Bank. Islamabad.
- World Bank. 2007. *Health and Population Policy Note for Pakistan*. World Bank South Asia Region.
- World Bank. 2008. *Health Policy Note, Northern Areas*. World Bank South Asia Region.
- World Bank. *2008. Country data, Pakistan.* World Bank Washington.
- World Bank. 2010. *Delivering Better Health Services to Pakistan's poor.*
- Zafar, S.N., *et al.* 2008. Prescription of medicines by medical students of Karachi, Pakistan: a cross-sectional study. *BMC Public Health,* 8: p. 162.
- Zafar, S.N., *et al.* 2008. Self-medication amongst university students of Karachi: prevalence, knowledge and attitudes. *J Pak Med Assoc,* 58(4): p. 214-7.

## Search Strategy

The scope of the search includes identification of relevant research, policy and programmatic documents. A systematic wide scoped search was conducted looking into published and unpublished documents. This primarily involved a desk review but was assisted by key informant interviews.

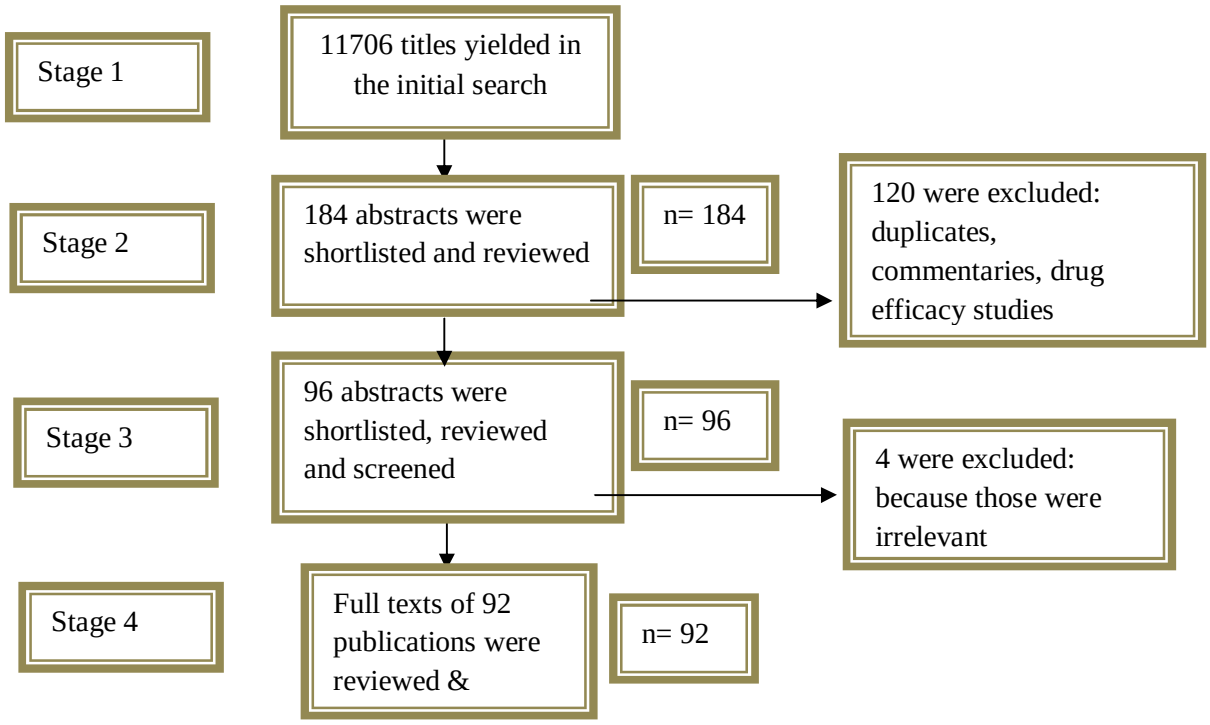
*Research Studies:* Sources included a range of both peer reviewed electronic databases such as Pubmed, Cochrane, Cinahal as well other unpublished databases such as WHOLIS, ELDIS and Google Scholar. We also reviewed bibliographies of all selected articles. A combination of search terms was applied to yield a sufficiently large number of studies for detailed analysis. Search terms were carefully selected, keeping in mind the objective of the study. Five sets of search terms were used Drugs Pakistan; Drugs Pakistan Affordability; Drugs Pakistan Rational Use; Drugs Pakistan Financing; and Drugs Pakistan Health System.

The following inclusion criteria were applied:

1. Studies reporting on Pakistan, whether Pakistan only studies or multiple country studies inclusive of Pakistan.
2. Studies published 1990 onwards.
3. Studies on bio-efficacy of drugs were excluded.
4. Commentary articles were excluded with inclusion restricted to primary research, systemic reviews and reviews supported by research data.

A total of 11706 titles were yielded using the electronic search and reference from bibliographies. These were sifted by 2 researchers for identification of relevant studies. A total of 184 studies were shortlisted. Abstracts and report summaries of 184 studies were reviewed and a total of 96 studies were further short-listed. The full text of all these 96 studies, including articles, reports and books was then reviewed, of which 4 were found to be irrelevant and a total of 92 studies were selected and uploaded into EndNote. Diagram 1 shows the study identification process and yielded results.

**Research Study Selection Diagram**




**Policy and Programmatic Documents:** For policy and programmatic documents an online search was conducted as well as opinion taken from experts. Online search was conducted of websites of the Ministry of health, provincial Departments of Health, WHO Pakistan, WHO-EMRO and Pakistan Consumer Protection Network on Rational Use of Drugs and Google Scholar. These yielded a total of 15 documents. Identification and access to other policy documents that are not in public domain were sought during stakeholder interviews and yielded another 4 policy documents. Presently we have a total of 19 policy documents

*Data Extraction Strategy:* Data from each reviewed study and policy documents was systematically extracted and analyzed. The WHO access to medicines framework identifying type and level of barrier to access to medicines (WHO 2004) [i] was used as a guideline for extraction of data. Findings from were categorized under four grids as under:

1. Rationale Use of Drugs in Pakistan
2. Reliable Health System in Pakistan
3. Sustainable Financing of Drugs in Pakistan
4. Affordability of Drugs in Pakistan

Each grid in turn slotted information on:

- study title,
- author,
- study year,
- source,
- type of publication,
- level of barrier,
- methodology,

- key findings,
- Identified issues & challenges (See attached).

During review of study, notable findings were highlighted. Findings from each study were categorized into the relevant grid/s and within each grid into the relevant sections. A narrative synthesis is also provided on barriers to access based on the systematic organization of retrieved information.

All the above mentioned documents were analyzed systematically using different grids employing World Health Organization Access to Medicines Framework for Essential Medicines for this purpose[1]

[1] WHO Policy Perspectives on Medicines, March 2004. Equitable access to essential medicines: a framework for collective action