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RESEARCH PAPER ON

DRUGS ADDICTION IN PAKISTAN AND THE ROLE OF MINISTRY OF HEALTH, GOVERNMENT OF PAKISTAN

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DEDICATION

We dedicate our project to our respected Prof. Ms. Priscilla Lall who delivered us her best knowledge and expertise and we also recognize the efforts of Mr. Mehboob Alam, associate dean, University of Lahore on significant guidance.

EXECUTIVE SUMMARY

The Ministry of Health is responsible for matters concerning National Planning and coordination in the field of health. International liaison legislation pertaining to the drugs and medicines, administration of drugs Act 1976.

The core area of research is to find the route causes of drugs in Pakistan, how people are to be addicted? What are the reasons of drugs use? What are the behavioural and psychological signs and what are the factors involved in drugs use?

A survey study of 150 drugs abuser is conducted all over the Pakistan that shows the percentage of initial use of drugs in different age group of people. Most common age of first starting drug use 11-20 years is burning issue for our society as it is the age when career making initiates.

Keeping in the view of above mentioned facts, some healthy steps are initiated to reduce the drugs addiction in Pakistan.

1. Stoppage of smuggling of Opium from Afghanistan to Pakistan and arrest the persons who involved in it with the coordination of government of Afghanistan.
2. Levy the high taxes on the tobacco and other illicit drugs.
3. Reduce the unemployment to establish new industries in Pakistan.
4. Conduct seminars for awareness about drugs addiction.
5. Ban all those medicines those are being used in addiction.
6. Strict licensing conditions have been established.
7. Monitoring and inspection of drug units has been strengthened.
8. Establishment of Drugs Control Organization.

In the light of above mentioned steps, the research finds the positive results to apply these effective steps.

ABBREVIATIONS

AI	AVIAN INFLUENZA
AIDS	ACQUIRED IMMUNE DEFICIENCY SYNDROME
BHU	BASIC HEALTH UNIT
BISP	BENAZIR INCOME SUPPORT PROGRAMME
BOD	BURDEN OF DISEASE
CCB	COMMUNITY CITIZEN BOARD
CMW	COMMUNITY MIDWIFE
CPR	CONTRACEPTIVE PREVALENCE RATE
DALYS	DISABILITY ADJUSTED LIFE YEARS
DHDC	DISTRICT HEALTH DEVELOPMENT CENTER
DHIS	DISTRICT HEALTH INFORMATION SYSTEM
DHQ	DISTRICT HEAD QUARTER
DOH	DEPARTMENT OF HEALTH
DOTS	DIRECTLY OBSERVED TREATMENT – SHORT COURSE
EMONC	EMERGENCY OBSTETRIC AND NEONATAL CARE
EPI	EXPANDED PROGRAMME ON IMMUNIZATION
ESDP	ESSENTIAL SERVICE DELIVERY PACKAGE
FATA	FEDERALLY ADMINISTERED TRIBAL AREAS
FBS	FEDERAL BUREAU OF STATISTICS
FLCF	FIRST LEVEL CARE FACILITY
FP	FAMILY PLANNING
GOP	GOVERNMENT OF PAKISTAN
GDP	GROSS DOMESTIC PRODUCT
HIV	HUMAN IMMUNODEFICIENCY VIRUS
HMIS	HEALTH MANAGEMENT INFORMATION SYSTEM
HR	HUMAN RESOURCE
IDUS	INJECTING DRUG USERS
IMNCI	INTEGRATED MANAGEMENT OF NEWBORN AND CHILDHOOD ILLNESS
IMR	INFANT MORTALITY RATIO
ITNS	IMPREGNATED TREATED NETS
LHV	LADY HEALTH VISITOR
LHW	LADY HEALTH WORKER
M&E	MONITORING AND EVALUATION
MCH	MATERNAL AND CHILD HEALTH
MDGS	MILLENNIUM DEVELOPMENT GOALS
MMR	MATERNAL MORTALITY RATIO
MNCH	MATERNAL, NEWBORN AND CHILD HEALTH
MOH	MINISTRY OF HEALTH
MTBF	MEDIUM TERM BUDGETARY FRAMEWORK
MTDF	MEDIUM TERM DEVELOPMENT FRAMEWORK
NCD	NON-COMMUNICABLE DISEASES
NEML	NATIONAL ESSENTIAL MEDICINE LIST
NGO	NON GOVERNMENTAL ORGANIZATION
NWFP	NORTH WEST FRONTIER PROVINCE

OOP	OUT OF POCKET
PHC	PRIMARY HEALTH CARE
PHDC	PROVINCIAL HEALTH DEVELOPMENT CENTER
PMDC	PAKISTAN MEDICAL AND DENTAL COUNCIL
PMRC	PAKISTAN MEDICAL AND RESEARCH COUNCIL
PNC	PAKISTAN NURSING COUNCIL
PPP	PUBLIC PRIVATE PARTNERSHIP
PPRA	PUBLIC PROCUREMENT REGULATORY AUTHORITY
PRSP	POVERTY REDUCTION STRATEGY PAPER
PSLM	PAKISTAN SOCIAL AND LIVING STANDARD MEASUREMENT SURVEY
RHC	RURAL HEALTH CENTRE
SARS	SEVERE ACUTE RESPIRATORY INFECTION
SBA	SKILLED BIRTH ATTENDANCE
STI	SEXUALLY TRANSMITTED INFECTIONS
TB	TUBERCULOSIS
THE	TOTAL HEALTH EXPENDITURE (BOTH PUBLIC AND PRIVATE)
THQ	TEHSIL HEAD QUARTER
U5MR	UNDER FIVE MORTALITY RATE
UN	UNITED NATIONS
WHO	WORLD HEALTH ORGANIZATION
WTO	WORLD TRADE ORGANIZATION

FACTS AND FIGURE OF MINISTRY OF HEALTH

Federal Government Expenditure on Health (2007-08)

Development Expenditure	Rs. 14.272 billion
Current Expenditure	Rs. 3.791 billion

Health Indicators

Infant Mortality Rate (IMR) (per 1000 persons)	76.7
Maternal Mortality Rate (MMR) (per 100,000 live births)	350
Under -5mortality rate (per 1000 persons)	101
Parasite Incidence of Malaria (per 1000 persons)	0.75
Incidence of TB (per 100,000 persons)	181
Fertility Rate (percentage)	4.1 (source: NIPS)
Contraceptive prévalence rate %	30 (source: NIPS)
Births attended by skilled persons %	19
Population growth rate	1.9
Total Population	159.06: million (source NIPS)

Health Services Delivery (2006-07)

Total Health Facilities	13,937
Hospitals	965

Dispensaries	4,916
Basic Health Units	4,872
Rural Health Centers	595
MCH Centers	1,138
TB Centers	371
First Aid Points:	1,080
Beds in hospitals & dispensaries	105,005
Population per bed	1,515
Population to health facility ratio	11,413

Human Resources (Registered, 2007)

Doctors	107,835
Doctors registered as specialists	19,623
Dentists	7446
Dental specialists	433
Nurses	43,646
Midwives	2,788
Lady Health Visitors	3,864
Lady Health Workers	95,000
Lady Health Supervisors	3,385
Population per doctor	1,475
Population per dentist	21,362
Population per nurse	3,644

Academic Institutions (2007)

Public sector: Medical colleges	23
Dental colleges	9
Private sector Medical colleges:	24
Dental colleges:	12

Federally Administered Medical Facilities

Total health facilities includes 7 hospitals, 39 dispensaries, 1 TB clinic, 4 MCH Centers, 3 RHCs, 14 BHUs Reported data for 09 hospitals and dispensaries (2006-07)

Patients treated in OPD	4,637,970
Patients operated	74,444
Patients attended in emergency	922,037

Drugs Registered during Last 5 years

Human Locally Manufactured Drugs

Year	**Drugs Registered**
1999	731
2000	699
2001	865
2002	3395
2003	2762
Jan, 2004 to July 2004	2373
Total	10807

Human Imported Human Drugs

Year	Drugs Registered
1999	255
2000	50
2001	33
2002	90
2003	103
Jan, 2004 to Sep 2004	124
Total	655

Veterinary Drugs

Year	Drugs Registered
1999	203
2000	322
2001	102
2002	193
2003	210
Jan, 2004 to Sep2004	92
Total	1122

International Health Days 2008

World Leprosy Day	Tuesday	31st Jan
World Cancer Day	Monday	4th Feb
International Women's Day	Saturday	8th Mar
World TB Day	Monday	24th Mar
World Health Day	Monday	7th April
World Haemophilia Day	Thursday	17th April
International Nurses Day	Monday	12th May
International Day of Action for Women's Health	Wednesday	28th May

World No Tobacco Day	Saturday	31st May
World Environmental Day	Thursday	5th June
International Day against Drug Abuse and illicit Drug Trafficking	Thursday	26th June
World Population Day	Friday	11th July
World Breastfeeding week	Friday to Thursday	1st to 7th Aug
International Alzheimer's Day	Sunday	21st Sep
World Heart Day	Tuesday	30th Sep
International Day for Older Persons	Wednesday	1st Oct
International Day for Nature Disaster Reductions	Wednesday	8th Oct
World Mental Health Day	Friday	10th Oct
World Arthritis Day	Sunday	12th Oct
World Food Day	Thursday	16th Oct
World Trauma Day	Friday	17th Oct
International Day for the Eradication of Poverty	Friday	17th Oct
World Osteoporosis Day	Monday	20th Oct
World Polio Day	Friday	24th Oct
World Diabetes Day	Friday	14th Nov
World AIDS Day	Monday	1st Dec
International Day of Disable Persons	Wednesday	3rd Dec
International Volunteers Day	Friday	5th Dec

MINISTRY PROFILE

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Minister for Health

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INTRODUCTION

The Ministry of Health is responsible for matters concerning National Planning and Coordination in the field of Health. International Liaison, legislation pertaining to the drugs and medicines, administration of drugs Act 1976. Among major nursing, dental, pharmaceutical, Para-medical and allied subject such as maintenance of educational standard, education abroad, educational facilities for backward areas and for foreign nationals except the nomination of candidates from the FATA for admission to Medical Colleges. Ministry of Health consists of one division; Health Division.

VISION

The vision of the Health Department is to improve the health and quality of life of all Pakistanis, particularly women and children, through access to essential health services

GOAL

The goal of the Health Department is to remove barriers to access to affordable, essential health services for every Pakistani

OBJECTIVES

To achieve the above stated goal of removal of barriers to essential health services, the Government of Pakistan adopts the following six Objectives to reform and strengthen critical aspects of its health systems to enable it to:

1. Provide and Deliver a basic package of quality Essential Health Care Services
2. Develop and manage competent and committed health care providers
3. Generate reliable health information to manage and evaluate health services
4. Adopt appropriate health technology to deliver quality services
5. Finance the costs of providing basic health care to all Pakistanis
6. Reform the Health Administration to make it accountable to the public

The Ministry of Health recognizes that provinces have varied needs and expectations regarding health and that each Department of Health is fully capable of identifying as well as delivering appropriate health care to their populations. It is in this spirit that the federal ministry will support and facilitate the provinces in implementation of their strategies by providing relevant financial and technical resources to ensure that essential health service package is accessible to all the citizens. The national health policy has been formulated with the primary objective of resonating with the expectations of Provinces. It is designed to contribute to advancing and strengthening the **provincial health strategies**.

DEPARTMENTS:

There are three types of departments as follows:

- Subordinate
- Attached
- Autonomous

SUBORDINATE DEPARTMENTS

> Appellate Laboratory, Islamabad

> Central Drugs Laboratory

> Drugs Control Administration

> National Control Laboratory

> National Institute of Rehabilitative Medicine (NIRM)

> T.B. Centre Rawalpindi

ATTACHED DEPARTMENTS

> Central Health Establishment

> Directorate of Malaria Control, Islamabad

> Federal Government Services Hospital, Islamabad

> Jinnah Postgraduate Medical Center, Karachi

> National Institute of Child Health, Karachi

> Pakistan Institute of Medical Sciences, Islamabad

AUTONOMOUS BODIES

> College Of Physicians & Surgeons (CPSC)

> Health Services Academy

> National Leprosy Control Board

> National Council for Homeopathy

> National Council for TIBB

> National Institute of Cardiovascular Diseases

> National Institute of Health

> Pakistan Medical and Dental Council

> Pakistan Medical and Research Council

> Pakistan Nursing Council (PNC)

> Pharmacy Council of Pakistan

The following programs and health topics of Ministry of Health for the improvement of health of Pakistanis are as;

HEALTH PROGRAMS

> Expanded Program on Immunization (EPI)

> National Programme for Family Planning & Primary Health Care(LHW Programme)

> National Maternal, Neonatal and Child Health (MNCH) Programme

> National AIDS Control Programme

> National Tuberculosis Control Programme

> National Programme for Prevention of Blindness

> National Nutrition Program

> National Wheat Flour Fortification Programme

> National Malaria Control Programme

> National Programme for Prevention and Control of Hepatitis

LIST OF PRIORITY HEALTH PROBLEMS

> Influenza (H1N1)

> Acute Watery Diarrhea / Cholera

> Cholera

> Crimean Congo Haemorrhagic Fever

> Dengue and Dengue Hemorrhagic Fever

> Diphtheria

> Hepatitis

> Hepatitis C

> Human Immunodeficiency Virus (HIV)

> Breastfeeding

> Influenza

> Leishmaniasis

> Malaria

> Swine Flu

> Tuberculosis

Our group chose the area of drugs of Ministry of Health.

ROUTE CAUSES OF DRUGS IN PAKISTAN

DRUGS IN PAKISTAN

Pakistan's geographic location next to Afghanistan, the world's largest producer of illicit opium, places the country in a vulnerable position in terms of drug trafficking as well as drug abuse. Patterns of illicit drug production, distribution and abuse change as a result of social, economic and political developments.

Year	**Cultivation of Opium poppy**
1992	9441 hectare
2001	213 hectare (Decrease)
2003 (in Balochistan)	6,703 hectare
2007 (in Balochistan)	2,306 hectare (Decline)

Pakistan's cultivation of opium poppy largely declined during the 1990's to near zero levels in 1999 and 2000. The commitment of the Government of Pakistan (GOP) to measures for eliminating opium poppy cultivation, together with alternative development projects funded by the international community, led to a decrease in poppy cultivation from approximately 9,441 ha., in 1992 to some 213 ha., in 2001. However, there was a reemergence of poppy cultivation, probably as a result of high opium prices following the Taliban's prohibition of poppy cultivation in Afghanistan in 2001. In 2003 poppy cultivation was reported at 6,703 ha., including for the first time cultivation in the Balochistan Province. The total area cultivated declined to 2,306 ha., by May 2007 as a result of concerted eradication efforts. Pakistan is one of the primary transit countries for drugs from Afghanistan and hence knowledge of new routes and evolving methods of drug trafficking is essential for successful interdiction. In 2007, law enforcement agencies seized 13,736 kg of heroin/morphine base, 101,069 kg of cannabis and 15,362 kg of opium (down from the 2006 seizures of 35,478 kg of heroin

heroin/morphine base and 115,443 kg of cannabis and up from the 2006 opium seizures of 8,907 kg). Intelligence on groups involved in drug trafficking and their links to other crime groups is also key to controlling drug trafficking.

While the area cultivated in Pakistan during 2007 was equivalent to only around 1.2 percent of the area cultivated in Afghanistan, there is a risk that cultivation in Pakistan could increase substantially unless there are sustained efforts to dissuade farmers from planting poppy and to destroy opium crops before they are harvested.

The problematic areas in terms of poppy cultivation are largely concentrated in the Federally Administered Tribal Areas (FATA). Concerns about losing community acquiescence in counter terrorism operations and a lack of available security forces due to ongoing counter terrorism operations in the Pakistan-Afghanistan border areas are factors that hamper the eradication efforts in FATA. Eradication efforts need to be improved, particularly in Khyber Agency where there is a trend towards cultivation within walled compounds to conceal the crop from the authorities.

DRUG ADDICTION IN PAKISTAN

Pakistan is today notorious for many things, but in the last 20 years, drug production and addiction has increasingly become just one of them.

The issue of drug addiction is often overshadowed by the many of the country's other human development problems, such as poverty, illiteracy and lack of basic health care. But the fact is, drug abuse is rapidly growing in Pakistan and in South Asia in general.

While Bangladesh, India, Nepal and Maldives all suffer from this, Pakistan is the worst victim of the drug trade in South Asia. Today, the country has the largest heroin consumer market in the south-west Asia region.

It wasn't always this way. Pakistan became a major exporter of heroin in the 1980s, following the influx of Afghan refugees escaping the Soviet invasion of Afghanistan in 1979.

The major consequence of this has been a significant increase in domestic consumption of heroin in Pakistan. Heroin was once upon a time a drug which was virtually unknown in the country until the late 1970s. Today, Pakistan is not only one of the main exporters of heroin, it has also become a net importer of drugs. It is estimated that about 50 tons of opium are smuggled into Pakistan for

processing heroin for domestic use. Almost 80 percent of the opium processed in Pakistan comes from neighboring countries.

Widespread drug abuse may be indicated by the fact that almost five percent of the adult population is using drugs in Pakistan. As a proportion of drug abusers, heroin users have increased from 7.5 percent in 1983 to a shocking 51 percent a decade later in 1993.

Drug production for Pakistan's domestic market is estimated at close to $1.5 billion. It appears that only three percent of the gross profits from the illegal opium industry remain within Pakistan.

Like many of the country's other human development problems, the issue of drug abuse touches the most vulnerable: the majority of drug users in South Asia belong to the poorest state of society. In addition, the presence of a large drug industry in Pakistan leads to a redistribution of income from the poor to a few rich individuals who control the drug trade. This not only makes the gap between the rich and the poor as well as income inequality even worse, it also erodes Pakistan's social cohesion and stability.

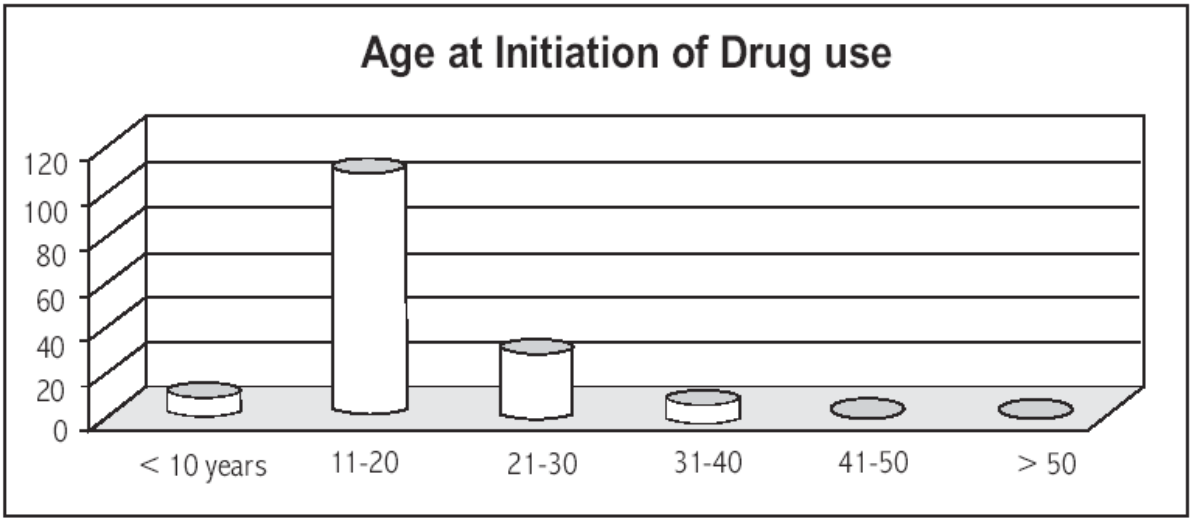
Although almost all South Asian countries have enacted strict laws for fighting drug trafficking and drug use, these measures have produced very disappointing results.

One problem is that corruption has also touched the fight against drug abuse in Pakistan and other South Asian countries, since drug traffickers often

escape punishment by giving bribes to get out of being held accountable for their actions.

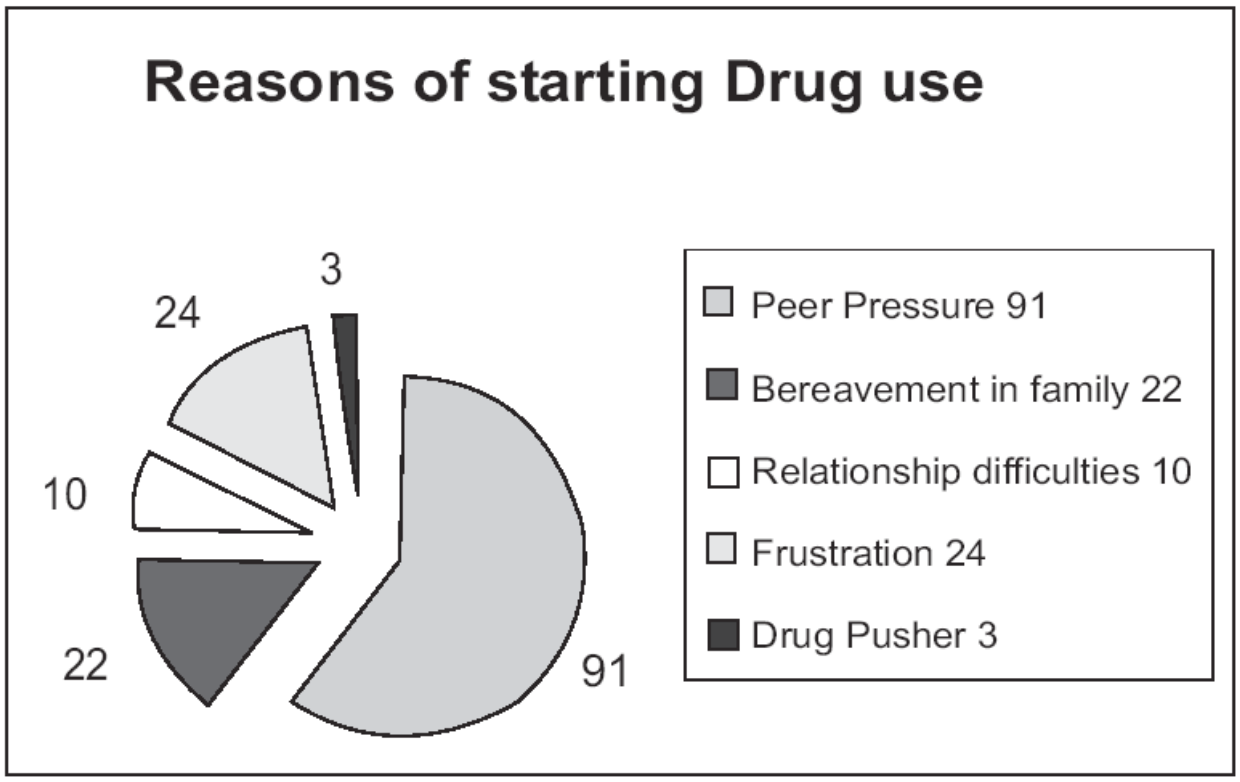
But Pakistan is not alone in fighting this disease. With the globalization of the drug abuse problem in the last two decades, the situation has gone from bad to worse, so much so that the United Nations Commission on narcotic drugs no longer discusses individual situations. It has argued that the solution does not lie in the hands of individual countries. It has to be worked out through mutual efforts by South Asian countries.

A SURVEY STUDY OF 150 DRUG ABUSERS



This is a study of 150 drug abusers, who participated in this investigation and revealed information on various internal and external factors relating to the phenomenon of drug abuse. Most common age of first starting drug use 11-20 years is burning issue for our society as it is the age when career making initiates. About 41.9% of drug abusers were less than 30 years of age. Within different age groups, the highest percentage of drug abusers in the study was found within age group of 21 to 30 years (34.6 %). Urban rural breakdown revealed very minor urban predominance (53.3 %). The same is true for marital status; 50.6% drug abusers were married. Regarding socio-economic profile, 88 % of them were employed, at the time of interview whereas 22% were unemployed. The three higher classes of drug abusers were: laborers 28.6 %, government servants 13.3% and drivers 4.6%. Amazingly the frequency of drug abuse was higher among the literate (62.6%). Main sources of introduction were friends. 62.6% told that their friends introduced drugs to them. Peer pressure was major reason causing 60.6% of indulgence in drug abuse. Heroin was most commonly used drug (80%). Next was benzodiazepine dependence (8%). Most

common route of administration was smoking (70%). Source of money in 64 % cases was self-support and age at which they first started using drugs belonged to 11-20 years age group.



Reasons for the use of drugs

- To produce positive feeling or to reduce anxiety.
- To mask caused of psychic distress such as fears, impulses and wishes to escape from responsibility.
- To neither allow the acting out of a role or behavior pattern that might not otherwise be part of the user's life style and which the user might find personally and socially unacceptable.
- To help gain attention, acceptance and affection from people the user values (as symbols of fellowship).

- To help with the expression of feelings.
- As a guide in searching for meaning and independence.
- As a way of showing rebellion and defense against authority or society creative.
- For the risk and excitement in procuring drugs as well as using them.

Behavioral signs

- Signs of physical abuse.
- Overall untidy appearance
- Falling asleep in class
- Grade swings or poor grades
- Lack of friends
- Social disengagement (shy and withdrawn)
- Extreme fear about situations involving contact with parents
- Lack of parental interest in the child's report card or academic status
- Learning difficulties
- Consistent concern about getting home promptly.
- Excessive demand for attention to compensate for lack of attention at home.
- Unexplained absences from school and morning tardiness.
- Sudden behavior changes (quiet and moody or acting out)
- Child remarks about the drinking / drug-taking at home.
- You see one of the parents intoxicated.
- Classmates ridicule the parent's drinking/drug-taking

- Parental authoritarianism and unrealistic expectations.
- Hyperactivity or difficulty concentrating.
- Compulsive behavior (overeating, overachieving, smoking, chemical dependence) and constant health problems (headache, stomachaches)

Psychological sign

- Low self esteem
- Anxiety
- Easily embarrassed
- Suppressed anger
- Perceive problems as beyond their control
- Poor coping skills
- Prone to depression
- Unreasonably fearful
- Sad and unhappy
- Difficulty adjusting to changes in routine

Factors involved in drugs addiction

- Family problems
- Poverty
- Social system
- Economic problems
- Unemployment
- Friends Company

STEPS TO REDUCE THE DRUGS ADDICTION

1. To stop the smuggling of Opium from Afghanistan to Pakistan and arrest the persons who involved in it with the coordination of government of Afghanistan.
2. To levy the high taxes on the tobacco and other illicit drugs.
3. To reduce the unemployment to establish new industries in Pakistan.
4. To conduct seminars for awareness about drugs addiction.
5. To establish the Medical Centres for drugs addicted persons in all provinces.
6. To ban all those medicines those are being used in addiction.
7. Strict licensing conditions have been established.
8. Monitoring and inspection of drug units has been strengthened.
9. Role of federal /provincial drug inspectors has been defined.
10. Stress has been laid down on local manufacture of drugs
11. Medical stores and pharmacies must be registered through Drugs Control Organization.
12. To start the Income Support Scheme for poor people to reduce the poverty.
13. To motivate the parents that they must observe the activities of their children.

14. To control the quality assurance of medicines.

15. Strict policy for import the drugs from abroad.

16. To encourage the young generation appropriately in their ideas.

17. Media like TV Channels, Newspapers, Magazines, Brochures, Banners and Educational institutes can motivate the people effectively through dramas, tele films, advertisement, articles and books that uses of illicit drugs like opium, heroine, cocaine, charas etc is not only bad for our life but our society also.

DRUG CONTROL ORGANIZATION

Introduction:

The Drugs Control Organization is a wing of the Ministry of Health. It executes its work under the Drugs Act, 1976 and rules made there-under. Drugs Controller is the technical head of this Organization and the Director General is the department head.

The Drugs Control Organization also has its field offices in the Provincial Headquarters. All the imports of pharmaceuticals are conducted through these offices. They also monitor the compliance to conditions of Drug Manufacturing Licenses, including Good Manufacturing Practices.

The provincial Governments have their own Inspectors for post marketing surveillance. The Provincial Quality Control Boards have jurisdictions in Quality Control cases in the respective provinces.

OBJECTIVES:

- To develop and promote the concept of essential drugs and to ensure regular, uninterrupted and adequate availability of such drugs of acceptable quality and at reasonable prices.
- To inculcate in all related sectors and personnel the concept of rational use of drugs with a view to safeguarding public health from over-use, mis-use or inappropriate use of drugs.
- To encourage the availability and accessibility of drugs in all parts of the country with emphasis on those which are included in the National Essential Drugs List.

- To attain self sufficiency in formulation of finished drugs and to encourage production of pharmaceutical raw materials by way of basic manufacture of active ingredients.
- To protect the public from hazards of substandard, counterfeit and unsafe drugs.
- To develop adequately trained manpower in all fields related to drugs management.
- To develop a research base particularly for operational and applied research with a view to achieving the above mentioned objectives.
- To develop the pharmaceutical industry in Pakistan with a view to meeting the requirement of drugs within the country and with a view to promoting their exports to other countries.

LEGISLATION:

In order to ensure availability of safe, effective and quality products at reasonable prices. Pakistan has a fairly modern legislation namely the Drugs Act, 1976. Under this law comprehensive rule have also been framed on various aspects of drug control. The law provides a system of licensing of each manufacturing house and registration of all finished drugs with a view to ensuring efficacy, safety ad quality of the drugs sold in the market. For licensing and registration Central Licensing and Registration Board comprising of experts from the field of medicines and pharmacy are established. Quality Control is ensured through inspection and laboratory services. The law also provides for compliance of Good Manufacturing Practice by the manufacturers, for fixing drug prices and for regulation of imports, export, and sale of drugs. Under this Act, the manufacturing, registering and import/export are regulated by the Federal Government where as the sale is regulated by the Provincial Governments.

These laws have been considered to be fairly modern with correct philosophy for public safety. These laws shall be modified as and when necessary to keep them up-to-date as well as to provide legal basis for the support and implementation of the National Drug Policy.

The manufacture and trade of medicine of traditional systems of medicines are not being properly regulated resulting in problems of public health. These shall therefore be regulated by law with a view to their rationalization, to improve their standards and for the protection of the public from any the health hazard.

NATIONAL ESSENTIAL DRUGS LIST (NEDK):

Preparation of NEDL. The Federal Government and each provincial government until 1993 had their on lists of drugs for purchases for the government institutions and thus there was lack of uniformity in these lists. The concept if graded system if these lists for various levels of Health Institutions was also not distinctly defined. There was, therefore, an urgent need to prepare a National list of Essential Drugs of Pakistan with graded lists for various levels to be implemented uniformly both at the Federal and Provincial levels. A National Essential Drugs List of Pakistan was thus prepared in 1994 in view of the health needs of the country with the help of specialists organizations in the field of medicines and pharmacy from all over the country. This has already been published and circulated widely throughout the country.

Bulk purchases for Health Institutions. Future bulk purchases of drugs for all government and semi-government health institutions shall be made in

accordance with this list. The NEDL has specified the health care levels at which each essential drug is to be used. Effective and well organized operating systems shall be developed for procurement and distribution of such drugs for the population. This shall envisage quantification of the actual needs for drugs and effective logistics for supply.

Promotion of Essential Drugs Concept. The Essential Drug Concept and the National Essential Drug List will be promoted in the public and private sector. Policy will be geared to increase share of essential drugs in local production and to make such drugs available at affordable prices where-ever needed. Efforts will also be made to promote rationality in essential drug prescribing and use. To encourage this, Drug Information Sheets in line with those of WHO model providing concise, accurate and comprehensive information shall be prepared and widely circulated.

A comprehensive public information shall be launched to enhance understanding and acceptance of the Essential Drugs Concept by the patient and the health care personnel.

In order to promote the concept of Essential Drugs, the doctors in the public sector shall be persuaded to prescribe rationally cost-effective drugs from the Essential Drugs List. In order to encourage such practices, unbiased information about drugs shall be published and widely circulated to the Federal and Provincial Health Institutions.

A system of audit and accountability shall also be introduced for monitoring the prescribing practices. Procurement of drugs in the public sector shall also be subject to similar audit and accountability.

Review of NEDL: The National Essential Drugs List will be periodically reviewed and revised every year and made more pragmatic by a committee that includes competent specialists in clinical medicine, pharmacology and pharmacy and from other related fields and published.

Criteria for selection of E Ds. For the selection of essential drugs and for establishing a national program for the use of essential drugs, the guidelines and criteria recommended by the WHO shall be followed.

Availability of E Ds The availability of essential drugs which could be in short supply shall be ensured through the establishment of hospital pharmacy for manufacture of such drugs and also by providing incentives to the local industry"'

Constitution of Hospital Pharmacy and Therapeutic Committee; All teaching divisional and district hospitals shall constitute "Pharmacy and Therapeutic Committees" to monitor and promote rational use of drugs in the hospitals.

Generic names for E Ds: Only generic names will be used for drugs in the NEDL all public sector drug lists, inventory sheets and tender documents.

DRUG PRODUCTION

Pakistan has always been following the policy of encouraging manufacture of drugs within the country. Consequently whereas there was virtually no pharmaceutical manufacturing in Pakistan at the time of its independence in 1947, today about 80% of the drugs market is from local production by some 285 companies including 25 multinationals. However the industry still depends largely on imported raw materials and that there is no assessment

of the actual requirement of drugs according to the health needs of the country.

Situational Analysis; In order to have realistic assessment of the real demand of essential drugs corresponding to our health needs with quantification of requirements as far as possible, the Government shall arrange for an in-depth technical, economic, marketing study and critical analysis of the existing situation in this behalf with a view to find ways and means to meet this demand.

Measures shall be taken to enhance the formulations, of pharmaceutical products to facilitate the availability of quality drugs at reasonable prices and to bring a high level of self sufficiency in the country, coupled with a gradual up-stream integration in the manufacture of active ingredients thorough exploitation of local flora and fauna, fermentation, synthesis, semisynthesis, and application of modern method of bio-technology and genetic engineering. These measures will include incentives for transfer of technology and import substitution.

In view of the existing system for creating and stimulating the demand for medicines and their consumption, options shall be exercised to ensure effective quality control, to encourage the rational use of medicines, for the human resources development, as well as for the conduct of operational and applied research studies in order to produce quality medicines of high standards meeting the actual health needs.

Pakistan shall try to be self sufficient in the basic manufacture of drugs.

Self-reliance in drug manufacture: With a view to creating self reliance in the country by encouraging manufacture of pharmaceuticals raw materials by way of basic/semibasic manufacture, the following incentives shall be given:

i. Concessional rates of import duty and sales tax on the import of plant, machinery equipment which is not produced locally and is required for basic and semi-basic manufacture of drugs.
ii. Import of all raw materials, chemicals and other consumables required for the basic/ semi-basic manufacture of drugs at Concessional rates of duty and sale tax.
iii. Tariff protection against imports as and when the production starts satisfactorily.
iv. For the establishment of basic / semi-basic manufacturing plants the loan advanced shall be with a dept equity ratio of 70:30.
v. Adequate tariff protection to the basic / semi basic manufacture shall be extended against import of finished drugs on the merits of each case. In case of general decline in import duty regime, the same level of protective duty shall be maintained as before, both in respect of import of raw materials and the finished drugs.

    a. The manufactures shall be made responsible for adequate and timely supply of raw materials to formulators at reasonable prices.
    b. The quality of the locally produced raw materials shall be of international standards.
    c. In Semi basic manufacture, there will be a gradual upstream integration towards basic manufacture.

d. In order to encourage introduction of high technology in the country as well as to bring relative self-sufficiency, the tariff regime shall be so made that it is in favour of basic manufacture compared to semi basic manufacture so that there is gradual upstream integration from the later to the former and taking into account the effect on process and factors of value addition ad foreign exchange saving.
e. Basic manufacture of drugs included in the National Essential Drug List shall be given preferred treatment in tariff rates and in drug prices as compared to semi basic manufacture or manufacture of other drugs.

NATIONAL INDUSTRY AND EXPORT.

a. To encourage exports of drugs, incentive similar to those available to other value added export industries shall be made available.
b. Where a multinational company and a national collaborator partnership splits up, the former shall be permitted either to set up an independent unit or to enter into a joint venture project only with another national company.
c. Where a pharmaceutical company has set up its own manufacturing facilities. It shall be allowed import, if necessary, of products not otherwise manufactured locally, only for a limited period after which the company shall be required to start local manufacture of that product.
d. An institutional mechanism shall be developed so that the national units are brought at par with the international standards. Transfer of technology shall be encouraged by allowing contract manufacture by a multinational with national companies.

REGISTRATION OF DRUGS:

Under the Drug Act, 1976, all finished drugs ready for use are required to be registered through the Drugs Registration Board. Presently some 13000 products are registered including some 10000 locally produced and 3000 imported products.

The registration shall be granted and reviewed on the basis of established criteria of acceptable safety, efficacy, in terms of significant therapeutic value, quality and keeping in view real health needs of the country and the public interest.

All irrational, unsafe and obsolete formulations and combinations shall be deregistered. 6.4 Fixed ratio combinations products will be registered only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has proven advantage over single compounds administered separately in therapeutic effect, safety or compliance.

Drugs or any indication of a drug which are banned for safety reasons either in USA, Canada, European Union, Japan, Australia, China, Switzerland or in the country of origin shall not be allowed sale in Pakistan.

The present identification number of drugs shall be rationalized on the basis of various basic entities.

Action has already been initiated to computerize data in respect of drug registrations. The sphere of activity in this field shall be expanded to. Efforts shall be made to compute all necessary information relating to registered

products and their procedure for quick retrieval. A more comprehensive drug information system shall be established in the Ministry of Health in each Province in respect of registered drugs with facility of retrieval in relation to medical pharmacological, pharmaceutical and economic aspects.

Information in respect of every registered drugs shall be compiled and published by the Ministry of Health.

For products of foreign companies with parent offices abroad, the indications, adverse effects, dosing information etc, that were approved in the country of origin will be accepted. Any other indications would require a separate and detailed justification. In the labellling of drugs the use of generic names with at least the same prominence as brand names and necessary information in national language shall be made as a mandatory requirement.

A system for monitoring of adverse reactions shall be established.

For the registration of a new drug the fact that the drug is registered in one of certain specified countries (USA, UK, European Union, Switzerland, Japan and China) would be necessary.

When a MNC or subsidiary of MNC wishes to manufacture a drug already registered in Pakistan it may be allowed to do this regardless the fact whether it produces the drug in question in its country of origin.

The import of drugs, be allowed to ensure availability and fair pricing through competition.

Anti-dumping laws shall be enforced in order to prevent dumping when necessary.

DRUG PRICING

Efforts will be made to make availability of much needed drugs at reasonable prices. In doing so the element of price competition between similar products shall also be introduced.

The grant of patent protection for drugs shall be only of process and not for the product. Further after the expiry of initial period provided in the law, no extension shall be granted in case of drugs. The patent law shall be amended accordingly. After the expiry of a patent, a fresh pricing exercise shall be undertaken and a maximum of 15% allowance for R&D may be allowed over the international prices for the raw materials. Thus transfer pricing over and above the margin of 15% shall not be allowed the expiry of patent of a product.

The pricing formula may be revised on the basis of international competitive prices of raw materials, taking into account the cost of production and reasonable margin of profit. Prices of existing registered drugs which are higher shall be revised on the basis of the revised formula. An annual review shall also be conducted on the basis of feed back from the provincial governments about the actual sales prices.

A system for monitoring and evaluation of drug prices shall be developed. Adequate powers shall be made available under the Drug laws for fixing and revising drug prices of both finished drugs and their active ingredient.

DRUG SUPPLY SYSTEM:

The drug supply system in both public and private sector is the legacy of the pre-independence era. Efforts shall be made to bring rationality in these systems both at the government level and in the private sector.

(a) Hospital Pharmacy.

It will be the policy objective of the Government that the scheme scientific hospital pharmacy shall be introduced in the country both under the Federal and Provincial Governments. In order to provide efficient health care service, hospital pharmacists shall be appointed in all the hospitals of the country at the rate of one pharmacist for each fifty beds. Efforts will be made to increase the availability of qualified pharmacists for this purpose. The Hospital Pharmacy System will be properly organized on scientific lines under the supervision of graduate pharmacists. They will be assigned with specific duties to provide an efficient drug supply system and where possible a limited production of pharmaceuticals. Model Hospital Pharmacies shall be set up in each Federal and Provincial Government teaching hospital in line with the system in any developed country to set an example for the others to follow.

The Federal and Provincial drugs supply system for the hospitals and dispensaries etc. will be modernized and strengthened and will be managed to ensure correct ordering, efficient procurement, proper packaging, storage, distribution and inventory control with lese waste through deterioration and loss. The system will ensure the availability of essential drugs in health facilities according to their level. Allocated drug schedules for different categories of hospitals and health units will be followed as far as possible.

In the public sector the procurement of drugs shall be based on reliable quantification of drug needs. The drugs shall generally be procured under generic names through competitive tenders and a system shall be developed for monitoring supplier performance. The average lead time form order to receipt shall be minimized. The provinces would coordinate and exchange information on costs in order to ensure reasonable purchase prices. All bulk supplies of drugs to health institutions shall be obtained in government approved special packs.

All drugs supplied to the health institutions shall be monitored for quality at the time of purchases. The provincial government shall also share the results of their drug testing with Federal Government. Companies supplying any substandard drug shall not only be required to compensate for compensate for the loss and shall be debarred for future supplies but their license for manufacture or as the case may be for sale shall be reviewed and cancelled where necessary.

(b) Community Pharmacy (Retail Pharmacy)

In the Private Sector, a system of scientific retail pharmacy service shall be introduced in a gradual manner and following specific steps shall be taken:-

(a) As recommended by the WHO, pharmacists shall be made to play their recognized in all activities relating to drugs management supply and distribution. Their services shall be effectively utilized in management of prescription drugs. To implement this, to begin with, the drug sellers / distributors having certain turn-over.

(b) Future policy for issuance of drug sales license shall be developed and in view of the size of the community to be served in the catchment area or on the basis of area instead of concentrating on one place.

(c) The sale of all potent drugs shall be restricted only on prescription of registered medical practitioner. To begin with all psychoactive drugs, hormonal and steroidal preparations and antibiotics shall be so restricted. In order to maintain uniformity throughout the country the Federal Government being so authorized shall notify such drugs or classes of drugs from time to time.

(d) Training Courses for the existing qualified persons on licences for retail and wholesale shall be conducted in collaboration with the Pharmacy Council, Pakistan Pharmaceutical Manufacturing Association, Pharmacists Association and Pakistan Chemists and Druggists Association at the district level for their orientation on the modern concepts of pharmacy services.

(e) The market intelligence shall be strengthened and import may be resorted in case

QUALITY ASSURANCE.

Quality assurance, one of the main objectives of this policy, is covered under its various heading viz: a viz LEGISLATION, REGISTEATION OF DRUGS and DRUG SUPPLY SYSTEM. However, a well defined quality control program with special reference to the inspection and laboratory services exists at both the Federal and Provincial levels of the country which shall also be strengthened as under.

Inspection Services:

At the Federal level 8 inspectors are working to monitor compliance of Good Manufacturing Practices at the manufacturing level whereas, at the Provincial level 81 regular inspectors of drugs in various grades as district, divisional and chief inspectors have been appointed but in most places without proper hierarchy. In addition, the DHOs have also been appointed as ex-officio inspectors in some provinces who are supervise the district drug inspectors. In some areas separate inspectors have been appointed for factory inspections and for inspection of sale outlets but without any chain of command. In most cases they lack facility of transport and funds for purchase of samples. Under the Federal Government additional posts of Federal Inspectors shall be created for ensuring compliance of Good Manufacturing practices and to act as adviser to the industry to improve their standards in a satisfactory manner. Under the Provincial set up, uniformity in their set up and a hierarchy shall be created with proper chain of command and clearly defined duties for each level and efficient system of management and control. Additional inspectors shall be appointed to check specifically the sale of spurious drugs.

Both at the federal and provincial levels these services shall be equipped with necessary logistics and communication facilities with a view to ensuring effective regulatory controls. The inspectors shall also be provided with regular training to keep abreast of latest quality control techniques and inspections for compliance of Good Manufacturing Practices (GMPs) and Good Sales Practices (GPs).

Good Manufacturing Practices: The Good Manufacturing Practices laid down under the law shall be up-dated from time to time keeping in view the

recommendations of WHO and recent developments in the field of Quality Control.

With a view to improving Good Manufacturing Practices at the manufacture level, the number of pharmacists to supervise production in the pharmaceutical manufacturing houses shall be required in accordance with the size of the manufacturing facilities. Similar requirements shall be laid for Quality Control Department also.

Good Storage and Distribution Practices: The existing conditions of storage both in the public sector and the private sector require a lot of improvement. For that the Good Procurement, Distribution and Storage Practices shall be developed and implemented. In case of thermolabile drugs, cold chain shall be ensure from the level of manufacturer to the enduser in order to maintain the quality and potency of the product the importers, manufacturers, distributors, wholesalers and retailers shall be required to ensure storage facilities which would maintain the quality of the drug in accordance with Good Storage Practices for each level. Facilities of all the licensees shall be reviewed carefully in accordance with the Good Storage Practices at the time of the renewal of their license.

Inspection and Sampling: An inspection and sampling policy shall be developed so that all essential potent, life saving and fast moving drugs are monitored on priority keeping in view testing facilities available in the country.

Check lists shall be prepared for self audit as well as for carrying out inspections for different types of pharmaceutical establishments by the inspection services.

Organized Market Surveillance: A programme for organized market surveillance shall be established for monitoring the quality of various products which are of common use and of and actions will be taken to remove products of doubtful efficacy from the market. Information regarding products of standard quality shall be widely disseminated to medical and pharmacy profession to build their confidence on all competitive products available in the country.

Spurious Drugs: Manufacture and trade of spurious drugs is a cognisable offence special high level teams shall be constituted to monitor the market and take action to eradicate this menace. The Drugs Act, 1976 shall be amended so that the seller of such drugs is also made equally responsible as that of the manufacturer and that the punishment for this offence shall be enhanced.

The manufacturers, sellers and importers or the distributors shall be responsible to ensure the quality and efficacy of the drugs in accordance with the requirements of law.

Laboratory Services:

Presently there are five drug testing laboratories in the country. Four are for routine analysis out of which one is under the Federal Government at Karachi as Central Drugs Laboratory (CDL) and one each under the Provincial Governments of Punjab, Sindh and NWFP at Lahore, Karachi and Peshawar respectively the law provides that any one who is not satisfied with the results of the these laboratories can appeal requesting for retesting of the sample by an Appellate Laboratory. Thus the drug Control and Traditional Medicines Division at the National Institute of Health, as the most

modern laboratory is assigned with the functions of Appellate Testing. This however lacks necessary manpower and The Central Drug Laboratory, Karachi is housed in an old dilapidated army barracks and this along with the Provincial Laboratory are also defierent in well qualified staff and equipment. The said Drug Testing Laboratory, Karachi is also not properly housed. There is no laboratory in Baluchistan and thus the CDI is performing test on behalf of that province

Central Drugs Laboratory: The Central Laboratories shall be provided with an appropriate premises. It shall also be manned with more technical staff and equipped with new instruments and other facilities. Like-wise the provincial laboratories shall be strengthened.

Appellate Laboratory: The Appellate Laboratory shall be provided with necessary staff, equipment and chemicals. Besides its existing functions, it shall be used for testing of drugs prior to registration, for organized post-marketing surveillance and for stability and bio-availability studies none of which is being done at present.

In these laboratories, the drug testing shall be entrusted to persons holding degree in pharmaceutical sciences.

Testing capacity shall be improved through provision of modern equipment and staff.

Good Laboratory Practices: Standard procedures for Good Laboratory Practices shall be developed so as to ensure effective management, meticulous operational procedures and timely reporting.

WHO Certification Scheme: In order to ensure quality of drugs in the international commerce, the WHO certification scheme shall be used systematically.

Good Clinical Practices: To ensure patient's safety, Good Clinical Practices for clinical trials as recommended by the WHO shall be followed.

Drug Courts: The Drug Courts which are presently working on part-time basis shall be established on full time basis for speedy trial and disposal of the cases.

Self Monitoring by the Industry: A new role shall be given to the industry and trade for self-monitoring for quality assurance through market surveillance product real and selfinspections and to create a sense of self-participation.

MEASURES TO PROMOTE RATIONAL DRUG USE:

Drug Information Bulletin: The Drugs Act, 1976, provides for regulation of promotional activities of the pharmaceutical industry and to allow correct information to be supplied to the medical profession. From the Government platform, a Drug information Bulletin is issued from time to time to provide unbiased information to the medical profession. This shall be published on regular basis and distributed to all doctors, pharmacists and other health professionals. Apart from providing these with accurate and timely information, the bulletin will endeavor to promote the concept to essential drug and their rational use.

Ethical Criteria for Medical Drug Promotion: The pharmaceutical industry and all other concerned shall be required to follow the Ethical Criteria for Medical Drug Promotion which has been developed on the basis of WHO guidelines will be to allow sales promotion only through the health institutions though a well defined system as in practice in some other parts of the world.

National Formulary: A National Formulary shall be published in a new context so as to serve as reliable prescribing and dispensing guide to all doctors and pharmacists of the country and as an effective teaching aid. Similarly Standard Treatment Guidelines in important areas shall be prepared and published and made available for wider circulation.

Drug Information and A.D.R Monitoring: A computerized Drug Information and poison Centre and a Adverse Drug Reaction Monitoring Centre will be established and provided with a comprehensive library and literature search facilities. On the basis of world-wide information monitoring, these Centers will also undertake post-marketing surveillance studies of newly registered drug products containing newly developed drug substance. These Centers shall also provide regular information on drug to prescribers and pharmacists.

HUMAN RESOURCE DEVELOPMENT.

There is an urgent need for development of manpower for an efficient drug supply system and to encourage rational use of Drugs.

The government will encourage and support facilities in Medical and Pharmacy Schools to strengthen their curricula in Clinical Pharmacy and Clinical pharmacology, Therapeutics, Hospitals Pharmacy and Pharmaceutical

Technology. The curricula shall be revised to include promotion of concept of essential drugs, rational drug use and related subject, e.g., supply management, communication technique and drug utilization studies.

Formal and training curricula for ancillary health workers and nurses will similarly be revised and s strengthened. Facilities of foreign training shall be provided to pharmacists working in the Drug Control Organization to keep them abreast of the latest knowledge in the field.

In-service training courses in rational use of drugs, drug supply management, communication technique etc., will be organized for pharmacists, medical officer, graduate nurses and ancillary health workers so as to improve skills in their respective areas of activity related to drugs.

Facilities for post graduate studies in pharmacy shall be strengthened including creating of facilities for the same at the Quaid-e-Azam University.

Refresher and continuous education courses, seminars and lecturers to promote the concept of essential drugs and rational drug use will be organized on a regular basis at the national and provincial levels.

As recommended by WHO, pharmacists shall be made to play their recognized role in all activities relating to drug control, management, supply and distribution. Their services shall be effectively utilized in management of prescription drugs in particular with the objective of their rational use. The teaching curricula for pharmacy student shall be revised to provide adequate training to prepare pharmacists to render efficient health care service with special emphasis on hospital pharmacy and community pharmacy service.

RESEARCH AND DEVELOPMENT

In the field of research, Drugs Act, 1976 requires the manufacturers to contribute a certain percentage of their profit (1 %) towards a Drug Research Fund. These funds will be spent for conducting researches on the development of new drugs and encouraging rational drug therapy.

A comprehensive national drug research programme will be jointly developed by the universities and research institutes active in this field according to national health priorities to ensure co ordination and collaboration in drug research.

Preference shall be given to operational and applied research in the following areas in particulars.

- Exploitation of local resources for basic manufacture of durgs.
- Development of new drugs from local resources.
- Studies in rational drugs use.
- Drug utilization studies.
- Traditional Medicines.

Incentives e.g. Prizes shall be provided for encouraging researches.

RESULTS/FINDINGS

Keeping in view the above mentioned steps, we find the following results.

1. For restriction of smuggling, a clearly reduction in illicit drugs may occur.
2. Not easy excess of drugs for everyone due to high prices of tobacco and illicit drugs.
3. Due to awareness, people will avoid to use drugs.
4. Medical Centres treated the addicted persons so it will also bring the reduction in addiction.
5. Addicted persons cannot buy the drugs those are banned.
6. When medical stores and pharmacies are registered then very few chances are to be sold the illicit drugs.
7. Reduction in poverty will definitely be in reduction in drugs addiction.
8. Behavioral signs and psychological signs tell about the children if the parents observe that then they will overcome this curse immediately.
9. Quality Assurance will definitely reduce the illicit drugs and find out the proper requirement of specific disease.
10. Mostly drugs are brought into Pakistan through import and for strict policy of import, it can be removed.

11. Awareness through media is most effective way to spread awareness that drugs addiction is a curse for our life so people will avoid it.