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THE PHARMACEUTICAL SECTOR STUDY OF PAKISTAN

DU/PAK/86/023/11-51

PAKISTAN

Technical report: Findings and recommendations*

Prepared for the Government of the Islamic Republic of Pakistan
by the United Nations Industrial Development Organization

Based on the work of Dr. Kamen Ivanov and Mr. H. Persson,
experts in production of pharmaceuticals

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* This document has not been edited.

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Introduction

When thinking about Pakistan, one should realize the dominant factors which will exercise a long term impact on the development of the country and by the same token, on the effect of recommended solutions. They are: a very high population growth, a very low literacy rate and limited financial resources.

While the economic development efforts of the country are laudable, the Pakistan economic growth did not alleviate poverty, it depleted the physical assets and is not sustainable. Without an effective population policy as an indispensable complement to any sound economic policy, the transition of the economy to a sustainable growth path will not occur.

The scenario of the health and pharmaceutical sector in Pakistan is characterized by inadequacies, irrationalities, imbalances and a lack of direction and implementation of operational guidelines.

While the market is increasing at a rate of about 20 - 25% per annum with a relatively high level of per capital consumption of pharmaceuticals, 50 - 60% of the population has no access to modern medicine, and 80 - 90% of the expenditure on drugs is spent on only 10% of the population. In the last few years the number of registered pharmaceutical preparations has shown an unprecedented increase in the market. Although there is a relatively high degree of self-sufficiency in the formulation and packaging of finished pharmaceutical forms, the manufacture of active ingredients, or basic production of pharmaceutical chemicals is negligible, with virtually total dependence on imports.

There is also a lot to be desired in the rational use of medicines, the quality control and assurance, the controls on prescription medications, the mix of the private and public spending, the procurement and distribution of medicines, the human resources development and pharmacists education, the operational and applied research, etc. However, the potential and the enthusiasm in the related sectors exist and could contribute towards an improvement of the situation:

The Minister of Health has shown keen interest in the development of a comprehensive national drug policy and the government has announced a political commitment for creating self-reliance and self sufficiency in the country.

Thus, a base is present and could be used towards achieving the long-term objectives of ensuring adequate and rational supply and use of medicines to meet the health needs of the country.

Nevertheless, significant changes in the immediate future will be rather difficult to achieve. The majority of the problems of the sector are systemic and will require concerted action on several fronts in order to solve them.

Comprehensive studies are therefore proposed to be undertaken of the entire pharmaceutical sector and of all related aspects for a correct situational analysis with a view of recommending options towards the achievement of the set objectives.

A. THE PREPARATORY MISSION

1. BACKGROUND

The necessity for a pharmaceutical sector study emerges from the realization of inadequacies, irrationalities, inefficiencies and lack of direction in the demand/supply situation of pharmaceuticals, some of them identified in separate independent studies from time to time. According to a high-level Government Committee investigating the Health Sector:

> "A major attempt to rationalize the pharmaceutical situation (has to be made) including: the promotion of essential drugs, enforcing drug schedules for differing levels of facility, revision of the method of drug price control and encouragement of local drug production."[1]

The basis for the government request to UNDP to finance a pharmaceutical sector study is a summary proposal by the Ministry of Health in March 1990, preceded by a World Bank Mission report in 1989, a World Bank "Draft Project Formulation Framework" in November 1988 and an Health Finance and Expenditure study in April 1988 (under the second technical assistance credit finance by IDA); a separate draft project document, focusing on the industrial aspects, was prepared by UNIDO in November 1990.

In view of the magnitude and complexity of the projected pharmaceutical sector study undertaken for the first time by UNDP and/or specialized agencies in this field, as well as "the long-term implications of any decision that may result", a balanced approach giving adequate attention and weight to all aspects of the study, is to be adopted.

In order to prepare the necessary ground work for a proper and smooth execution of the study, two senior consultants form UNDP and UNIDO were fielded on a preparatory mission.

2. OBJECTIVES

2.1 To review the scope and contents of the study

2.2 To discuss ways and means to ensure optimum compliance with its recommendations for action and policy adjustments

2.3 To review the best ways to execute it

2.4 To prepare a draft project document for consideration by the government of Pakistan and UNDP.

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[1] Terms of reference, 15.12.1991

In close cooperation with the Ministry of Health and more specifically with the government assigned senior counterpart Dr. F.R. Yussuf Fazli, Chairman of the Quality Control Authority, the UNDP/UNIDO consultants have undertaken and executed the various specific tasks pertaining to each of the above mentioned objectives, as presented in this report.

They have also provided the authorities with a detailed list of data to be prepared for the team of experts, (attached to an unedited rough outline of the mission activities presented to UNDP before departure).

3. CONSTRAINTS

3.1 Period of Assignment

The allocated time of three weeks was inadequate to reach the assigned objectives. Due to the wealth of data, the diversity of its sources, the variety of issues to be discussed, the complexity of the Pakistani situation in general and the pharmaceutical sector in particular, the national counterpart and the experts were often compelled to work very late at night. From personal experience gained with a multitude of consultants and their reports, the Pakistani authorities estimate that a minimum assignment period of eight weeks is required in the country, coupled with two weeks of preparation at home, to accomplish a mission and to present a meaningful report with realistic recommendations.

3.2 Availability of Data

As in several development countries, the single most salient constraint was the difficulty in obtaining complete and reliable data, a fact inhibiting the extent and the quality of the studies, as well as prolonging their duration. Not only data from various sources were different, but often information obtained from the same source, at different times, showed wide variations. The experts were compelled to use as many sources as possible in order to cross-check the figures, their reliability and validity, sometimes arbitrarily deciding the most logical numbers to be taken into account.

3.3 The Pharmaceutical Industry

The conviction that the pharmaceutical industry should necessarily encompass also the manufacture of pharmaceutical chemicals was a point for clarification. In fact, the pharmaceutical industry normally consists of formulation, often misconstrued as single mixing of ingredients, and packaging of the finished dosage forms. Strictly speaking, the manufacture of active substances or pharmaceutical chemicals, belongs to the chemical industry. In this sense, reputable domestic and foreign Pakistani pharmaceutical manufactures, are doing exactly what their colleagues in the pharmaceutical industries of industrialized countries do.

The prevailing belief of an almost immediate cost reduction of the pharmaceutical products after the establishment of a domestic basic pharmaceutical manufacture (pharmaceutical chemicals) was another factor of concern. In reality, particularly in the first years of operation, costs of locally produced fine chemicals are substantially higher, due to the cost of purchased technology, the training of experienced technical and managerial staff, as well as of skilled labor, the adoption of good working habits and discipline, the reaching of the "cruising manufacturing rhythm", etc.

Finally, it should be noted that the expert did not provide an exhaustive situational analysis (the complexity of the subject and the time would not to have permitted it anyhow), but have emphasized some major issues of particular concern to the study, suggesting specific points of interest to be taken into consideration. For instance, when speaking about quality control and assurance - the analysis of the number of personnel and their qualifications, the assessment of the laboratory equipment and its utilization, were not mentioned. In the same way, when dealing with the subject of manufacture of pharmaceutical chemicals - feasibility studies or socio-economic cost-benefit analysis were not included. The above mentioned factors are obvious to any expert in this field and should be left to the discretion of the sector study team.

B. POPULATION AND SOCIETY

According to the last census in March 1981 the population of the country was of 84.3 million, making if the ninth most populous country in the world. With an estimated annual growth rate of 3.2% (well above the South Asian annual average of 2.4%),[2] the total population is estimated at about 115 million in 1991 (excluding the Afghan refugees estimated at around 3.8 million). The population density was recorded at 106 per km^2 in 1981 and is estimated to be 143 per km^2 in early 1991, with a wide variation between the provinces: - 12.5 per km^2 in Baluchistan and 230 per km^2 in Punjab, where about 60% of the total population live.

Table No. 1, shows the population by age group and the rural/urban distribution, clearly indicating that about 70% of the population is rural and that there is a high ratio of dependents to adults.[3]

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[2] 2.8% in Bangladesh, 2.3% in India and Egypt and 2.2% in Indonesia (Balanced Development, UNDP, February 1992).

[3] The Economist Intelligence Unit (EIU Country Profile Pakistan 1991/1992)

Table No. 1

Population by age group and rural/urban distribution, 1981 ('000)

	Urban	Rural	Total
0-14	10,251	27,267	37,518
15-55	11,842	27,435	39,277
55 & above	1,747	5,711	7,458
All ages	**23,480**	**60,413**	**84,253**

Source: Ministry of Finance, Economic Survey, 1990/91.

If the population explosion continues unchecked, in the year 2000 it will reach about 150 million, fact which is and will be one of the biggest challenges for the country and its Government.

1. FAMILY PLANNING

The 1992 State of World Population Report (UNFPA, April 1992) suggests that slower population growth could help development, particularly in developing countries struggling against a rising tide of poverty, hunger and illiteracy. Slower population growth helped with economic growth, too. Out of the 82 developing countries surveyed, 41 with slower population growth managed to increase incomes by an average of 1.25% per year, whereas in 41 countries with faster population growth, incomes per person fell by the same average.

What could be done is to create conditions in which people will freely choose to have fewer children. Experience shows that the fastest way is to develop human resources: to lower infant mortality, increase education (especially for women), improve women's rights to property and equally paid work, and provide an easy access to a wide choice of family planning methods.

Family planning programmes in Pakistan have been in existence for 27 years and in 1980 a 20 year perspective plan for population policy was adopted. The VIIth five-year plan (1998 - 1992) provides for an integrated programme to improve family planning acceptance. The Government has allocated RS 1.156 billion (±46 million US$) for the population programme of the VIIth five year plan, as disclosed by the Ministry of State for Population Welfare on April 20, 1992. The target

of the Ministry was to bring down the current rate of population growth of 3.1% per annum to 2.5% by the year 2000. The main trust of the programme will be towards establishing family planning services in the rural areas, with only "a 5 percent current coverage to be expanded to 20 percent by the end of the year". Hopefully, this target will be achieved and Pakistan could embark on a more efficient and successful spacing of births campaign, than in the past.

As part of the UNICEF Pakistan Master Plan of operations, a family planning/child spacing programme is included under safe motherhood.

The World Bank is presently negotiating with the authorities the implementation of a seven year US$ 130 million project, which will include also family planning.

Some other countries like China, Republic of Korea, Thailand, Indonesia, etc., have been more successful. For instance in Thailand, despite relatively low incomes, the average number of children per women come down from 6.1 in 1965-70 to only 2.2 in 1987. Infant mortality reached the levels of European countries in the 1960s. Nine out of ten women were literate. Two thirds of couples are using contraception.

Whichever the country "sound economic policies require the complement of an effective population policy to facilitate the transition of the economy to a sustainable growth path" [4].

The subject of contraception has been extensively addressed in the UNFPA study "Contraceptive requirements and logistics management needs in Pakistan" (March 1992).

The figure No. 1 on the following page presents the utilized contraceptive method mix, including traditional methods[5].

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[4] Asian Development Bank 13.04.1992

[5] Contraceptive requirements 1992 - 1990 (UNFDA, 1992 - Contraceptive requirements and logistic management needs in Pakistan: page (14)

The following Table No. 2 presents the projected contraceptive users

Table No. 2

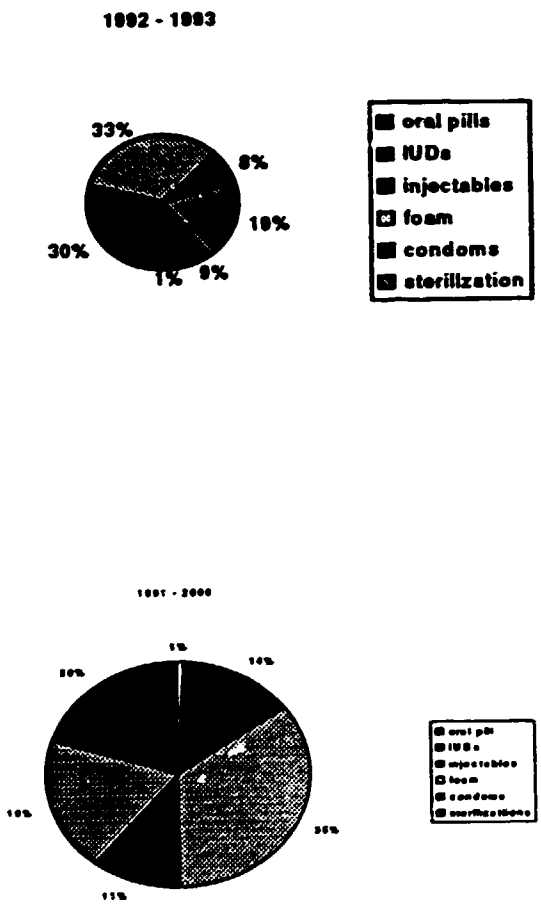
TABLE 2 : Projection 1; Contraceptive Users of Modern Methods
1992/1993 - 1999/2000
PAKISTAN
(000)

	TOTAL	CONDOM	PILL	IUD	INJ	STERIL	FOAM
92/93	2,725	818	218	518	245	899	27
93/94	3,395	941	286	645	359	1130	34
94/95	4,110	1045	364	781	499	1380	41
95/96	4,894	1133	454	930	671	1657	49
96/97	5,728	1195	556	1088	876	1956	57
97/98	6,608	1227	670	1256	1114	2275	66
98/99	7,185	1170	760	1365	1324	2494	72
99/00	7,900	1106	869	1501	1580	2765	79

Figure No. 1

METHOD MIX

'92/93 AND '99/00



"Oral contraceptives are manufactured and packaged by one local subsidiary of Wyeth, a multinational pharmaceutical company. Wyeth produces and markets two brands: Ovral, a standard dose pill with a retail price of 6.79 Rs, and Nordette, a low dose pill with a retail price of 7.95 Rs. Schering has the capability to manufacture OCs, but in 1989 decided that the commercial retail market was insufficient to warrant the continued investment in manufacturing and packaging.

Similarly, Organon has just withdrawn its premier product (Marvalon) from local manufacturing of OCs because of insufficient sales in the retail market. But both Schering and Organon have the necessary infrastructure to resume local OC manufacturing should circumstances warrant it. Overall, the private sector OC market is growing at approximately 10 to 15 percent annually.

The present production capacity for oral contraceptives in Pakistan is more than adequate to handle the existing commercial retail market as well as the oral contraceptives needed for social marketing hold this method be added."[6]

In accordance to data provided by (K) and PATH in 1990, as well as during interviews with manufacturers, the current production level of hormonal contraceptives (oral and injectable) appears to be of 815,300 cycles and 62,000 ampoules per annum, and the current capacity - of about 4 million cycles and 4 million ampoules, respectively.

Two pharmaceutical companies: Organon with Megastron and Upjohn with Depo-Provera seem to be planning to manufacture injectable contraceptives in the future. Schering is currently producing Norigest.

2. HUMAN RESOURCES DEVELOPMENT

"Development does not start with goods; it starts with people and their education, organization and discipline. Without these three, all resources remain latent, untapped, potential". [7]

Until recently, when thinking about development, people from the developing countries were speaking mainly about factories, plant machinery and equipment, solvent yards, precision instruments and other physical assets. Only "the last three years have witnessed a growing international consensus that development is more than economic growth. Development is about people. International and national policies must take human development as their ultimate goal". [8]

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[6] Contraceptive requirements and logistics management needs in Pakistan (1992 page 76)

[7] EF Schumacher "Small is beautiful", 1973

[8] HV von Sponeck, Resident Representative UNDP Pakistan (Balanced Development - An approach to social action in Pakistan 1992)

This subject was further developed by the UNDP Resident Representative in Pakistan during the Aid to Pakistan meeting held in Paris in April 1992. A statement to that effect reiterates the emphasis on the human development. It says that human development in Pakistan will only take place when the imbalance of past decades in favor of physical assets and non-sustainable use of natural resources is corrected through equal investment in people.

The progress in the human development in Pakistan has been poor, with poverty explaining only partially the reason behind it. Table No. 3 is giving the human development indicators. It shows that when adjusting the purchasing power of real GDP per capita, Pakistan comes well above India and Bangladesh close to Egypt and Indonesia, both in terms of its present income level per capita and in terms of real income growth per capita over the last thirty years. However, poorer countries like India have performed better than Pakistan in the human development area. [9]

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[9] Balanced Development (UNDP, February 1992)

Table No. 5

Human Development Indicators

	Pakistan	Low Human Development Group	All Developing Countries	Industrial Countries
Life expectancy at birth (1)				
Total	57.7	55	64	
Female as % of males	100	103	104.4	74.5
Adult Literacy rates (2)	31	47	60	110.1
Male	43	59	70	-
Female	18	34	49	-
Purchasing power of real GDP				-
per capita in $ (3)	1790	1080	2170	14350
Percent, of population with access to				
Health services (4)	55	56	63	-
Safe water (5)	45	50	62	-
Sanitation (5)	20	29	46	-
Daily calory supply as % of requirements (6)	97	99	107	132

Notes : (1) 1990; (2) 1985; (3) 1988; (4) 1985-87; (5) 1985-88; (6) 1984-86.

Sources : UNDP, Human Development Report 1991.

The progress of Pakistan in the field of education has been particularly poor. The Minister of State for Economic Affairs, addressing a conference[10] on April 19, 1992 said that "the present literacy rate of 16 percent is a disgrace". He remarked "that every eight Pakistani is barely literate."

The figures for literacy or illiteracy vary considerably, depending from the criteria used in the calculation. According to UNESCO (Europe Year Book 1991), in 1990 the average rate of adult literacy was 65.2% (males 52.7% , females 78.9%). The rate was put at 26.2 percent in 1991 compared with 21.7 percent in 1972 (when less demanding criteria were used).[11]

[10] National Institute of Historical & Cultural Research "The News" April 20,1992.

[11] The adult literacy (% 15+) in 1985 was indicated as 31 percent - UNDP Human Development profile

The distribution is uneven: the literacy rate amount women was 16 percent in 1981, amount rural population 15 percent and among rural women 55 percent. UNESCO[12] estimates that the literacy rate had increased to 35.1 percent by 1990 (rate for men 45.1 percent, rate for women - 20.9 percent).

In 1990/91 only 71.3 percent of the eligible population is estimated to have been enrolled in primary schools and 22.5 percent in secondary schools. [13]

Low public expenditure on education has been identified as a major reason for the persistently low level of literacy; as a proportion of GNP, it actually declined in the course of the fifth plan period. The figure peaked at 2.89 percent in 1987/88, but in 1990/91 expenditure on education fell 2.25 percent of GNP compared with the UNESCO recommended level of 4 percent[14]. The Government expenditure on education as a percentage of GNP is summarized on Table No. 4. The seventh plan proposes to expand the provision of primary education so as to increase the literacy rate to 40 percent in 1992/93, a rather optimistic target indeed. The number of students in higher education has increased rapidly from 242,000 in 1972-73 to 658,000 on 1990-91. The increase has been much more on the general side than on the technical and vocational side; with decreased emphasis an acquired knowledge, especially practical experience and expertise, the current Government policy is aimed at somehow rectifying this imbalance.

Table No. 4

Government expenditure on health and education
(% of gross national product)

	1972 /73	1984 /85	1985 /86	1986 /87	1987/ 88	1988 /89	1989 /90	1990/ 91*
Health	0.39	0.66	0.77	0.97	1.02	0.92	0.78	0.85
Education	1.47	1.98	2.15	2.52	2.89	2.44	2.33	2.25

*Estimates
Source : Ministry of Finance, Economic Survey, 1990/91.

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[12] EIU Country Profile Pakistan 1991-1992

[13] The Economist Intelligence Unit (EIU country profile, Pakistan 1991-1992)

[14] The primary and secondary enrollment ratio for 1987 has been shown as 29 percent of school age children (38% boys, 19% girls), (UNDP Human Development profile 1990)

As far as higher education of pharmacists is concerned, in accordance to statements of some members of the University Grant Commission (April 1992), there are about 500 pharmacists graduating each year, without uniformity in their educational curricula. Despite the urgent need of expertise in this field, the ±20,000 - 30,000 so called retail pharmacies (chemists and druggists), many hospital pharmacies and some local pharmaceutical manufactures do not use their services, leaving about 2000 unemployed pharmacists!

Unfortunately, in very broad terms, pharmacists are neither a highly respected nor a highly paid profession in Pakistan, with a rather weak and inefficient lobby in the country.

Development expenditure on science and technology, and education and training was projected at RS2,038.70 million (4.4% of the total government spending) in 1990/1991. (See Table No. 5)

In accordance to the statement of the Minister of Finance on April 26, 1992[15], the Government will launch a three year RS103 billion social action programme from the next financial year. Priority areas include primary education, nutrition, primary health, population welfare, rural water supply and sanitation. Besides a total commitment of US$ 2.3 billion, the donor countries are expected to provide an additional US$ 500 million over the next three years to support this programme.

The pattern of social expenditures is illustrated on Table No. 6

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[15] Press conference after the Paris Aid to Pakistan meeting April 1992

Table No. 5

PLANNED DEVELOPMENT EXPENDITURE*
(million rupees, year ending 30 June)

	1988/89+	1989/90	1990/91
Sectoral programme:			
Agriculture (incl. subsidy for fertilizers)	1,230.0	1,244.2	2,557.3
Water	2,966.3	3,145.0	5,386.3
Power	13,699.3	16,325.2	16,586.6
Industry	245.6	158.6	113.7
Fuels	2,821.5	2,492.5	3,212.1
Minerals	310.7	294.7	63.4
Transport and communication	6,138.1	6,645.9	8,203.6
Physical planning and housing	766.6	790.2	773.1
Science and technology and education and training	1,172.7	1,971.2	2,038.7
Social welfare, culture, tourism, sport and manpower and employment			
Health	307.8	326.7	1,158.5
Population planning	676.8	855.2	1,640.2
Rural development	433.8	445.5	597.1
Mass media	263.3	526.9	646.7
Miscellaneous	152.3	277.9	377.3
	19,353.7	22,170.7	3,059.6
Total sectoral programme	**50,538.7**	**57,679.4**	**46,414.2**

* The draft of the seventh Five-Year Plan, covering the years from 1 July 1988 to 30 June 1992, envisaged total development outlay of Rs616,000m., of which public sector investment was to be Rs350,000m and private sector investment RS266,000m.

\+ **1988/89** (revised estimate, million rupees): Development expenditure 57,845.2.

1990/91 (million rupees): Special development programmes 5,300; Annual provincial projects 14,721; Total planned development expenditure 66,435.2; Less economy cut 3,435.2; Net total planned development expenditure 63,000.

Table No. 6

PATTERN OF SOCIAL EXPENDITURES

As % of GDP (MP)	1990-92	1991-92
Total Public Spending	24.00	25.00
Total Expenditure on Social Services	3.90	4.10
Current Expenditure on Social Services	2.70	2.80
Development Expenditure on Social Services	1.20	1.30
Expenditure on Education and Training	2.10	2.30
Expenditure on Health and Nutrition	0.80	0.80

3. THE HEALTH SECTOR

Pakistan is committed to the goal of "Health for all by the year 2000", a goal which seems rather difficult to reach (See Table No. 7). Hereafter are given the country's health indicators and health care availability.

To begin with, health should be understood as " a state of complete physical, mental and social well-being, and not merely the absence of decease or infirmity",[16] as usually interpreted. Therefore, health services are often wrongly identified with the availability of medicines. While relevant pharmaceutical products should be available, the presence of a wide range of them should not necessarily be the determinant factor; health services are functioning even without medicines, when considering the preventive, primitive and other aspects. Under the pretense, that there are not enough drugs, the basic health services in the country are under-utilized with only 10% of the eligible population using them in the rural setting, when 85% of the population have physical access to health.

In addition, the majority tend to think that the health services are not theirs - they belong to the Government and as such, people who do

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[16] WHO

not even realize that this is achieved basically with their own money, do not really participate.

According to the UNDP Human Development profile (1990),[17] 54.6 million people in Pakistan are without access to health, (44.5%), 67.5 million without access to safe water (55%) and 97.6 million (79.6%) without access to sanitation, with a rural-urban disparity as follows:

		% (R/U)
Access to health (1986)	-	(35/99)
Access to Water (1987)	-	(27/83)
Access to Sanitation (1987)	-	(6/51)

3.1 Health Expenditure

The total expenditure on health is illustrated on Table No. 8.[18]

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[17] Based on an estimated population of 122.6 million in 1990, a figure considered on the high side.

[18] See VIIth year plan

Table No. 7

LIFE EXPECTANCY AND HEALTH

		Earlier year	Latest year
Life expectancy (years)	1960/1990	43.1	57.7
Fertility rate	1990		6.2
Crude birth rate	1960/1990	48.6	44.4
Crude death rate	1960/1990	22.1	11.6
Total population (million)	1960/1990	50.0	122.6
Annual growth rate	1960-90		3.0
Urban population (%)	1960/1990	22.1	32.0
Annual growth rate	1960-90		4.3
Dependency ratio	1990		94
Contraceptive prevalence rate	1985-87		11.0
Infant mortality rate	1960/1989	163	106
Maternal mortality rate	1980-87		500
Under five mortality rate	1960-1989	276	162
One year old immunized (%)	1981/1989	5	72
Access to health services (%)	1985-87		55
Access to safe water (%)	1975-80	25	45
Access to sanitation (%)	1985-88		20
Births attended by health serv(%)	1985-88		24
Population per doctor	1983-88		2,910
Population per nurse	1984		4,900
Low birth weight babies (%)	1988	76	25
Malnourished Children (%)	1980-88		52
Daily calorie supply (as % of requirements)	1965/1985	3.6	97
Food import dependency ratio	1970/1987		13.7
HEALTH CARE AVAILABILITY			
Number of registered Doctors	1987		51,020
Population per doctor	1987		2,004
Number of hospitals	1987		679
Population per hospital bed	1987		1,704
Number of retail "pharmacies" (druggists & chemists)	1990		13,973

Table No. 8

TOTAL EXPENDITURE ON HEALTH (Current Prices)
(Rs Million)

Year	Development Expenditure	Non Development Expenditure	Total Expenditure	GNP *	Total Expenditure as % of GNP
1972-73	95.55	171.90	267.45	67,955	0.39
1973-74	175.67	210.10	385.77	88,719	0.43
1974-75	363.00	278.00	641.00	112,330	0.57
1975-76	629.10	360.64	989.74	133,356	0.74
1976-77	540.00	439.20	979.20	155,288	0.63
1977-78	512.00	558.60	1070.60	188,473	0.57
1978-79	569.00	641.60	1210.60	209,448	0.58
1979-80	717.00	661.89	1378.89	252,463	0.55
1980-81	942.00	794.82	1736.82	300,888	0.58
1981-82	1037.00	993.10	2030.10	349,508	0.58
1982-83	1183.00	1207.00	2390.00	403,782	0.59
1983-84	1526.00	1564.90	3090.90	459,397	0.67
1984-85	1587.45	1785.12	3372.57	510,468	0.66
1985-86	1881.51	2393.81	4275.32	555,891	0.77
1986-87	2615.00	3270.00	5885.00	608,857	0.97
1987-88	3114.41	4064.00	7178.41	704,484	1.02
1988-89	2802.00	4519.00	7321.00	800,283	0.91
1989-90	3010.00	4761.00	7771.00	903,880	0.86
1990-91	3917.26	5012.65	8929.91	1,006,600	0.89

Source : Planning and Development Division

The comparison of aggregate Government and private health spending relative to GNP in some developing countries is shown on Table No. 9.

Table No. 9

	Total Health Expenditure % in GNP	Private Health Expenditures % in GNP	Gov't. Health Expenditure % in GNP	Insurance % in GNP	Year
Nepal	1.4	0.5	0.8	0.0	1987
Bangladesh	1.7	1.0	0.7	0.0	1987
Burma	3.2	2.0	1.1	0.0	1986
India	4.3	2.5	1.6	0.2	1987
China	4.0	1.2	0.8	2.0	1987
Pakistan	3.5	1.0	2.5	0.0	1987
Sri Lanka	2.3	0.9	1.3	0.0	1986
Philippines	2.4	1.7	0.6	0.1	1987
Thailand	3.8	2.6	1.1	0.0	1987

Source : i) Health Sector Financing in Asia, World Bank, August, 1990
ii) Health Sector Financing in Pakistan, World Bank, April, 1988

"From this information it appears that investments in the health sector in Pakistan are not bad in comparison with countries that have a similar GNP per capita; however, the performance in improving the health status indicators is not encouraging. This raises an important policy issue of public - private mix of health spending and composition of that spending. In Pakistan there are higher levels of private spending which are not commensurate with improvements in health; this could be because of limitations of the private sector in solving environmental health problems and breaching the vicious cycle of communicable, infectious and parasitic diseases"[19].

As against a common belief that the best way to express the health sector spending is to visualize the percentage of GNP, a better way might be to consider the actual expenses. According to the study of

[19] World Bank, 1989

the World Bank[20] the per capita expenditure on health in 1987 was Rs 200 or US$ 11.4 (see Table No. 10)

Table No. 10

Health Expenditure in US Dollars and Percent of Spending by Government

	US dollars per capita	Government Percent of All Health Expenditure	Year
Nepal	2.1	61	1987
Bangladesh	2.81	40	1987
Burma	6.4	36	1986
India	12.5	37	1987
China	11.0	19	1987
Pakistan	11.4	35	1987
Sri Lanka	9.2	58	1986
Philippines	14.1	27	1987
Thailand	32.8	30	1987

Source : i) Health Financing in Asia, World Bank, August, 1990
ii) Health Sector Financing in Pakistan, World Bank, April, 1988

Coming back to medicines, the timely availability of relevant ones, or essential drugs in the health service, could be theoretically ensured, since the allocations are adequate. As in many other cases, it is a question of weak management and lace of implementation of operational guidelines in the field of their utilization, procurement (non essential and irrelevant drugs are often available, essential ones are not) storage and distribution.[21]

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[20] Pakistan Health Sector Study (January 1992 - World Bank - unpublished)

[21] This was also identified by a mission of the World Bank in 1989.

In accordance to unpublished data from the Planning Division (April 1992), the expenditure on pharmaceuticals could be summarized as follows:

Government Sector -	3.2 billion Rs (±40%)	
Private Sector - (mostly curative)	12.0 billion Rs (±60%)	
Total	15.2 billion Rs	

OR

Government Sector expenditure for drugs per capita :	Rs 27.82	=	US$ 1.14
Private Sector expenditure for drugs per capita :	Rs 104.26	=	US$ 4.26
Total			US$ 5.40

The above mentioned total figure of $5.40 corresponds to the one mentioned in "Asia, Africa and Australia - WDMM 1991 (23.17)" of US$5 per capita in 1990, using an estimated population figure of 112.05 million.

3.2 Health Policy

The health policy announced on May 7th 1990, is a continuation of policy initiatives of the VIIth five year plan, which addresses the primary health care, the immunization, the nutrition, the manpower development, etc. The policy, reinforcing and developing further the areas of concern in the current plan, emphasizes decentralization, introduction of out reach services, encouragement of the private health sector, expansion of the female health workers, introduction of family planning, expansion of social security and introduction of a health insurance scheme.

The three main objectives of the health policy are:[22]

- health care to the entire population within shortest possible time
- enhancement of the health budget to meet the goal
- identification of additional revenue resources to finance the health policy

"Pakistan in spending about the same level of income on health care per

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[22] World Bank, 1989

person as in China and Sri Lanka, but female life expectancy is about 20 years less and infant mortality is more than three times as high. The Government spending of 4.0 per capita is higher than that being spent by China and slightly less than Sri Lanka. This raises a major policy question as to whether few resources available are being targeted to major public health problems besides mobilizing the private sector in pursuit of health sector goals." (World Bank, 1989)

The above mentioned data should be also considered in the light of the purchasing power of real GDP per capita ($1'90 as against $370), the relatively low prices of health services and drugs, etc.

In fact, the present situation could be improved not by pumping more money in the sector, but by a redistribution of the resources, by improving the management and the technical skills, etc. The nine largest cities[23] consume 70% of the total resources in the public and private sectors, ie. ±25 million of the population, whereas only 30% of the investments are for ±95 million of the population.

Finally, to conclude this chapter, one could cite :[24]

"The inherent inconsistency of low levels of health (as indicated by poor health indicators) on the one hand and the relatively high private and public expenditures (Rs 475 or 2.2% of average household expenditure) on health on the other hand, is evidence of the room for corrective measures.

In particular, there is believed to exist substantial scope for adjustments in :

- consumption and prescription patterns
- distribution, storage, marketing and pricing of drugs and medicines
- production and supply situation in general"

3.3 Health Insurance

Studies for the implementation of health insurance schemes are in progress. In April 1992 the Ministry of Health has prepared a draft proposal to that effect-in five chapters covering among others[25] :

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[23] Abbottabad, Faisalabad, Hyderalad, Karachi, Lahore, Multan Pershawar, Quetta and Rawalpindi

[24] Terms of Reference - UNDP, Dec. 1991

[25] See Annex I

- the situation in Pakistan (imbalances in the health sector, quackery and illiteracy)
- proposals for collecting resources and measures for affecting savings (user changes, autonomy of hospitals, essential drug list, payment for drugs, hospital pharmacies)
- health insurance levels
- Government hospital insurance principles:
  - hospitals (compulsory insurance, subsidized insurance for deserving, free treatment for destitute)
  - satellite clinics
- health insurance plans (additional, basic, comprehensive, disability, special and family health insurance plans).

4. THE PHARMACEUTICAL SECTOR

4.1 The Pharmaceutical Market

The pharmaceutical market in Pakistan, at factory sales price level, is estimated to be about 530 to 550 million US Dollars[26], excluding Government and Defense purchases, both of which are said to represent about 10% each: thus, the total market will be situated in the vicinity of 550 - 600 million US Dollars. On retail price level that will mean 630 - 690 million US$ or about US$ 5.50 per capita[27]. With only ±50% of the population with access to modern pharmaceuticals, the actual per capita expenditure will then become about US $11 per annum. Seen in the light of the real purchasing power of the US Dollar in Pakistan and the relatively low prices of medicines - the consumption of the latter could be considered relatively high.

An example illustrating that fact, is given on Table No. 11

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[26] According to the Pakistan Pharm. Manuf. Association, if the price levels in the country would be the same as in the Philippines, the pharmaceutical market will be equivalent to ± 1.5 billion US$.

[27] See also planning division forecast 1992 of ± $ 5.40 per capita.

Table No. 11

COMPARISON OF PRICES ON PHARMACEUTICALS BETWEEN PAKISTAN AND SWEDEN (RUPEES 1991)

	Pakistan	Sweden	Time more expensive in Sweden that Pakistan
Co-trimoxazol 200+ 40mg, per 1 caps.	0.80-1.20	6	6
Amoxycillin 500 mg, per 1 caps.	1-3	16	8
Doxycycline 100 mg, per 1 caps.	3-5	20	5
Ibuprofen 200 mg, per 1 tabl.	0,5	2,6	5
Paracetamol 500 mg, per 1 tabl.	0,12	1	8

Sweden, with a per capita expenditure on medicines of US$ 170 and Pakistan with US$ 5.50, seem a world apart. However, with minimum wages in Sweden about 27 times higher than in Pakistan and prices of pharmaceuticals 6 - 8 times higher, the consumption of pharmaceuticals in Pakistan appears high.

There are 226 registered pharmaceutical companies in the country. (See Annex II). According to the Chairman of the Pakistan Pharmaceutical Manufactures Association, 32 companies cover 70% of the consumption, and the remaining ones (including those producing bandages and other sanitary material) - 30%.

The same source was indicating that the market grows by roughly 20% per year, out of which: 12 - 13% in volume, 3 - 4% in price increases and the balance in new products introduction.

The fifteen leading pharmaceutical companies by volume are illustrated in Tables No. 12 and 13. They are all subsidiaries of foreign companies[28] and cover over 50% of the total market; the first five in the list (by value) cover alone more than 23% of the total market.

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[28] The term "Multinationals and/or Transnational" are strongly debated and will not be used in this text (see Christopher Lorenz and Yao-Su-Hu, "Multinational Myth explodes", 1992)

The number of pharmaceutical products registered in Pakistan is rapidly increasing from approximately 8000 in 1989 to about 13000 in 1992, according to the Ministry of Health. Out of these, about 9000 seem to be manufactured locally and the remaining 3000 - imported in finished form.

Pakistan has a list of essential medicines for use by hospitals under federal administration, since 1988, which was revised in 1991 (See Annex III) .

On the question "is there an essential drug list in Pakistan? - the answer is yes and no[29]. Yes, because of what precedes and No in the sense that procurement of drugs at the provincial level is not limited to items in the national formulary or in the established drug lists. Around 400 different items, a great many under brand names, are still purchased by the Provincial Medical Store Depots".

Significant cost reductions could be obtained by a careful selection of medicines and their forms on the basis of cost and therapeutic value, avoiding for instance items of questionable therapeutic effect, those with unfavorable risk benefit reviews and the higher priced medicines and dosage forms, with similar therapeutic value than cheaper ones[30].

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[29] Pakistan Child Survival Project (Reports August 1991 and March 1992)

[30] Pakistan Child Survival Project (Reports August 1991 and March 1992)

Table No. 12

LEADING PHARMACEUTICAL COMPANIES

(BY VALUE)

S. NO.	NAME OF COMPANY	% SHARE
1.	M/s Wellcome	5.27
2.	M/s Abbott	4.90
3.	M/s Glaxo	4.80
4.	M/s Beecham	4.79
5.	M/s Hoechst	3.78
6.	M/s Sandoz	3.63
7.	M/s Pfizer	3.00
8.	M/s Merck AG.	2.97
9.	M/s Ciba Geigy	2.76
10.	M/s Boots	2.76
11.	M/s Merck Sharp Dohme	2.69
12.	M/s Roche	2.65
13.	M/s Squibb	2.64
14.	M/s Cyanamid	2.59
15.	M/s Wyeth Labs.	2.25
		51.48

Table No. 13

LEADING PHARMACEUTICAL COMPANIES
(BY UNITS)

S. NO.	NAME OF COMPANY	% SHARE
1.	M/s Wellcome	8.57
2.	M/s Glaxo	6.67
3.	M/s Pfizer	5.07
4.	M/s Abbott	4.53
5.	M/s Beecham	3.60
6.	M/s Parke-Davis	3.45
7.	M/s Sandoz	3.42
8.	M/s Reckitt & Colman	2.79
9.	M/s Wyeth Labs.	2.78
10.	M/s Rhone-Poulenc	2.75
11.	M/s Cyanamid	2.70
12.	M/s Searle	2.60
13.	M/s Smith-Kline-French	2.52
14.	M/s Boots	2.16
15.	M/s Merck	1.64
		55.25

4.2 Consumption and prescription patterns

"A pill for every ill"[31] seems to be the main preoccupation of people seeking medical help. As briefly mentioned in the previous chapter, health services are usually identified with medicines and are considered practically not existing if they are not well stocked with the latter. Self-medication is widely spread and when physician's consultations are required, either for prescriptions or for direct dispensing, the patient's expectations are to receive several products in varicus forms; a simple prescription normally disqualifies the physician.

There is also a tendency to require newer more sophisticated drugs, preferably from foreign origin. A typical example would be the use of Amoxycillin versus Ampicillin, or instead of Cimetidine/Ranitidine, preparations much more expensive than their analogues, with almost identical therapeutic values.

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[31] "Bitter facts about drugs" Dr. Syed Rizwanudding Ahmad, September 1990

These factors together with the easy access to medicines without prescription and the ignorance of the dispensers in the chemists/druggists shops, the sales promotion activities of the pharmaceutical companies, the existence of a large number of unregistered doctors and quacks, the after-hour practice by public sector physicians, create an image of over-prescription and wrong prescription and completely distorts the picture of the real needs of pharmaceutical products (quantitatively and qualitatively), corresponding to the health needs of the country.

The irrational and dangerous use of drugs has been widely published in the press and was one of the subjects of a Senate Committee report on the pharmaceutical sector, in March 1991.

When analysing the consumption and prescription patterns in Pakistan, the following criteria, as general principles for rational use of drugs, should be borne in mind while undertaking a drug therapy in any clinical setting.[32]

- Choice of Drug Therapy

Many diseases require no drug therapy eg. self limiting viral infections, non infectious diarrhea etc. If a drug is really needed the one with scientifically proven clinical efficacy should be chosen. The market is flooded with drugs whose usefulness has not been adequately demonstrated and which are not recommended for use in scientific literature. These include rheological agents, cerebral vasodilator, deflatulating agents, mucolytics/expectorants, liver pills and appetite stimulants.

- Drug Combinations:

If a decision in favor of drug therapy is made, an attempt should be made to use monodrug therapy. If it becomes necessary to prescribe more than one drug, it must be ensured that the drugs do not interface with each other. A fair knowledge of the absorption, plasma protein binding, metabolism and excretion of drugs is necessary to avoid drug interactions.

Many fixed combinations of drugs are also available in the market, mary of which are not logical eg. absorbent with antibiotics, expectorants with cough suppressants, antibiotics with chymotrypsin and mucolytics. These should not be prescribed.

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[32] "Muslim" April 10,1992

- Cost Effectiveness:

Rigorous economic approach is needed to provide the minimum essential health facilities to the masses within the limited financial resources available in the developing countries. A large number of expensive new drugs available do not have practically any advantage over the old cheaper alternatives, which have stood the test of time. For example, the newer analgesic drugs such Froben, Dolobid, Donorest and Naprosyn, do not offer any significant advantage over aspirin, paracetamol and ibuprofen, which are much cheaper as compared to the former ones.

Therefore, the cost of the drug should be considered as one of the important factors in making a therapeutic decision, if the patient's life is not at stake.

- Dose of the Drug

Selection of the appropriate dose of the drug according to the age/body weight of the patient and severity of the disease is the mainstay of drug therapy.

This is particularly important in case of certain drugs such as anti-microbials, anti-hypertensives and anti-diabetics.

Dosage of the vitamins should be calculated according to the daily physiological needs.

- Patient's compliance:

Even the best treatment would fail if it is not correctly administered by the patient. To achieve the desired compliance by the latter, the instructions by the doctor should be comprehensive and elaborate. Patient's education about the disease and the drugs is important for compliance, particularly in chronic conditions such as tuberculosis, hypertension and diabetes mellitus. Usually, a better compliance is achieved when the number of drugs prescribed and the number of doses administered per day are less than three.

4.3 Traditional Medicine

There are few pertinent data concerning the imports, manufacture, marketing and utilization of traditional medicines, including homeopathy and medicinal herbs in various forms, not to speak about the scientific or technical aspects. What is, however, known is that many of them are often substandard, unsafe and spurious, containing sometimes allopathic drugs to enhance their therapeutic effects, such as corticosteroids, sex hormones, etc. For the time being the manufacture, sale or utilization of the traditional medicines are not

regulated, a legislation to that effect being on the unveil.

4.4 Prices and price control

The maximum retail prices of locally manufactured and imported drugs are fixed according to the following formula:

4.4.1 Locally Manufactured Drugs:

Maximum Retail Price = Prime Cost (Cost of Raw Material + Packing Material + Direct Labor) + 75%.

(a) 75% Mark up covers the following:

i)	Retailer's discounts	15%
ii)	Distribution including Wholesaler's Commission and Distribution cost	10%
iii)	Sale promotion cost	5%
iv)	Cost of goods sold	5%
v)	Administration	5%
vi)	Factory overhead including operational cost, services, maintenance and depreciation	15%
vii)	Miscellaneous including workers Welfare (Social Security, Education ceases and gratuity etc).	10%
viii)	Profit	10%

(b) For those products which are manufactured in a sterile area like injectables and ophthalmic preparations, a 90% mark up is allowed since extra and special arrangements are needed for their manufacture.

(c) For research products manufactured for the first time in Pakistan the mark up may be enhanced up to 125%.

4.4.2 Imported Drugs:

Maximum Retail Price = Cost and freight + Mark up of 40%.

The 40% mark up is permitted to cover the following costs:

i) Cost of import (license fee 4%; insurance 2%; LC. charges 1%; bank commission and interest 1%; clearing charges including forwarding, octroi, warfare, demurrage 3%) 11%

ii) Retailer's discount 15%

iii) Distribution cost including storage, transportation, local control and wholesaler's margin and profit 9%

iv) Promotion cost 5%

4.4.3 Price Control

Importers have been allowed to adjust the cost and freight price of life-saving and essential drugs according to the exchange rate prevailing as on the 5th July each year.

The Ministry is determined to keep prices at a most competitive level so that they remain within the reach of the common man. Accordingly the Ministry continues to monitor the prices and rationalize or reduce them where possible. When fixing prices in Pakistan, the prices of the same or similar drugs in other countries, especially India, Bangladesh, Sri Lanka, Indonesia and the country of origin are also considered.

"Under the present policy, drugs which are manufactured by way of formulation in the country, as well as all imported finished drugs, are subject to price control. Price fixation is done by the Drug Registration Board as one of the conditions of drug registration on the recommendation of the Cost Accountant.

Price fixation of drugs is based on the estimates of expenditure submitted by the manufacturing firms and on the basis of the following formula:

IMPORTED DRUGS: Cost and freight + Mark up of 40 percent = Maximum Retail Price.

LOCAL DRUGS: Prime Cost (Cost of raw and packaging materials + direct labor) + Mark up of 75 percent = Maximum Retail price."[33]

In April 1992, at a meeting between the Pakistan Pharmaceutical Manufactures Association and the Ministry of Health, it seems that an accord in principle was reached to decontrol the prices of all the drugs, except the essential drugs (lists of 1988 and 1991) representing an estimated number of about 1000 items, including all forms and presentations, out of a total of about 13,000 registered

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[33] Report of the Committee of ECC, 1992

pharmaceuticals. (See Annexes III and IV)

4.5 The pharmaceutical Industry

Contrary to the general belief that the Pakistani pharmaceutical industry is only limited to processing imported raw materials into various dosage forms, with hardly any effort to manufacture basic raw materials, this is exactly what all pharmaceutical manufactures in the world do - formulation and packaging of finished pharmaceutical forms: the mandate to manufacture active ingredients, or pharmaceutical chemicals belongs to the chemical industry.

While about 90 - 95% of active ingredients are imported, with an estimated volume of about 3.3 billion Rs in 1989, some 35 pharmaceutical chemicals are manufactured in the country, (See Annex V) either entirely or at a certain step of the chemical process.

Some 31 companies are licensed to conduct "basic or semi-basic manufacture", but are not very active, except for one major unit in the private sector Glaxo and two in the public sector - Antibiotics and Kurrum (latter sold to Upjohn from the USA).

It is said that about 70 - 80% of the pharmaceuticals are produced locally by the 226 pharmaceutical manufacturing units, with the 29 subsidiaries and/or joint ventures of large foreign companies getting the lion share (See Tables 12 and 13).

The large majority of companies are operating below capacity even on a one shift basis levels, with capacity utilization ratios estimated at an average of 40 - 50%.[34]

The exception is the production of sera and vaccines by the National Institute of Health in Islamabad, (Biological production Division) with a gradual built up of the manufacturing capacity during the last 20 years and a recent installation of a new unit. Today Pakistan is self sufficient in the manufacture of major sera and vaccines and is cooperating with several foreign companies and institutes. Lately, there is a question of a cooperation in the field of "Hepatitis B" vaccine.

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[34] The figures mentioned by some manufacturers, members of the PPMA were in the vicinity of 25-30% (April 1992)

The production of Vaccines/Sera for the year 1990 was:

Name of Vaccine/Sera	Quantity (in Mili Litre)
Cholera	888,735
Typhoid	1,426,850
Measles	1,152,220
Polio (live oral)	2,437,280
Typhoid-Cholera (mixed)	2,200,715
TAB and Cholera (Mixed)	688,000
Anti Rabies (Human)	2,026,520
Anti Rabies (Animal)	1,200
Anti Rabies serum	13,170
Tetanus Toxoid	148,880
Anti Diph. Serum	5,860
Anti Venom Serum	200,480
Anti Venom Serum (Polyvent)	68,860
Tuberculide, 1, 2, 5, 10, 100 TU	81,780

The Government is committed to encourage and promote the local production of pharmaceuticals both for formulation and packaging of finished forms and the manufacture of active ingredients, in view of creating self-reliance and relative self-sufficiency in the country.

The Pakistan customs tariffs are very favorable for local pharmaceutical manufacture, for example:

SRO - 349 of 1985 - all raw materials and packaging materials used for the manufacture of pharmaceutical products are exempted from duties and taxes.

SRO - 545 of 1989 - all plant machinery and equipment imported for the manufacture of pharmaceutical products are exempted from custom duties and taxes

A further position step in this direction is granting of industrial promotional incentives for foreign investors (See 4.9)

4.6 Distribution

Most of the pharmaceuticals are purchased by the public from private retail stores (chemists and druggists), specially concentrated in urban areas, preferably in clusters often located in the vicinity of large hospital facilities.

According to the Federal Bureau of Statistics, there are 10,861 registered "pharmacies", out of which 2,034 are in rural areas. The Senate Special Committee report on the pharmaceutical sector in March 1991, indicates more than 25,000 retail shops. The Ministry of Health and the Pakistan Pharmaceutical Manufacturers Association estimate that there are 30,000. The Asian Development Bank study from November 1989 reports 60,000. A large number of grocery stores sell also medicines informally.

Almost all prescription medications are freely available over the counter, as OTC drugs. This is due to self-medication habits, prescription and dispensing patterns by physicians and quacks, laxity in the implementation of Government rules & regulations, long distances, the employment of unregistered and unqualified staff, the large number of products, the low level of education, etc.

The pharmaceutical retail shops, the wholesalers and distributors, as well as most as the hospitals operate without pharmacists, employing usually under-qualified "dispensers".

Proper storage conditions are inexistant and medicines are often kept on the open air with temperatures sometimes exceeding 40°C humidity - 90% and covered with dust. The resulting deterioration and loss of activity do no seem to worry neither the outlets, nor the customers.

4.7 Quality Control and Assurance

The levels for quality assurance of pharmaceuticals are:

(a) Licensing: At the time of Licensing, while granting license it is ensured after preliminary scrutiny of plans for establishing a unit and physical inspection of the premises by a panel of experts, that the company possesses adequate facilities to manufacture drugs applied for.

(b) REGISTRATION: At the time of registration the drug is to be evaluated for efficacy, safety and quality before granting registration.

(c) POST - MARKET SURVEILLANCE: Post marketing surveillance, a system of regular inspection of manufacturers and sellers and sampling through drug inspectors is already operating. The Federal Inspectors, eight in number at various provincial

headquarters, check the manufacturing facilities while provincial inspectors appointed at the district level being 85, check primarily the sale of drugs, besides a panel of inspectors appointed from time to time for the pharmaceutical manufacturers.

For drug testing, there are four laboratories : one each in Punjab and NWFP, one at Federal level at Karachi and a most modern appellate laboratory at the National Institute of Health. The Government of Sind is in the process of establishing its own. In these laboratories a total of about 11000 samples are tested per year.

The public sector drug laboratories have not expanded since 1953 and the facilities are inadequate for monitoring the quality of the rapidly increasing number of pharmaceuticals (from 3,663 in 1979 to over 12,000 in 1991)[35].

There is a shortage of qualified manpower in the laboratories, the technical facilities at the federal QC laboratory in Karachi (where more than 60% of the Pakistan pharmaceutical trade and industry is located) are most inadequate and inappropriate[36], the QC laboratory in Peshawan has a lower standard than the one in Karachi, the Baluchistan provincial drug laboratory in Quatta is barely functional.

"The Government has failed to establish national drug testing and research laboratories with regional branches as required under the 1976 drugs act. Statistics on the magnitude of the supply of substandard and counterfeit drugs are lacking, but the problem is thought to be considerable"[37]

4.8 Institutional framework

NATIONAL DRUG POLICY OF PAKISTAN

Pakistan is committed to the goal of "Health for all by the year 2000" and to achieve this, the Government is taking various measures in the field of health services at large and drugs in particular.

It has a drug legislation, a defined quality control system, a policy to encourage local production of medicines, a plan for research and development and a strategy to introduce the essential drug concept. Similarly, a legislation to regulate traditional medicines is also on the unveil.

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[35] World Bank - Pakistan Health Sector Study, unpublished

[36] Senate Committee Report, March 1991

[37] World Bank - Pakistan Health Sector Studies, unpublished

The objectives of the National Drug Policy are as under:

(a) to ensure availability of essential drugs of good quality in adequate quantity at affordable prices to the entire population.

(b) to protect the public from health hazards of substandard, spurious, superfluous and unsafe drugs.

(c) to inculcate in all related sectors the concept of rational use of drugs with a view to safeguard public health from over-use, under-use or misuse of drugs.

(d) to encourage local production of drugs both for formulation and basic manufacture of active ingredients with a view to create self reliance and self sufficiency in the country.

(e) to develop a research base for operational, applied and basic research with a view to achieve the above mentioned objectives.

LEGISLATION

To ensure availability of safe, effective and quality products at affordable prices, Pakistan has a model legislation called the Drugs Act, 1976 with comprehensive rules on various aspects of drug control (See Annex VI). These laws provide for a system of licensing of premises to manufacture drugs and registration of finished drugs, as well as quality control. The former is done through a Central Licensing and Registration Board comprising experts from the field of medicine and pharmacy, whereas the later, through inspection and laboratory services. The law also provides for compliance of good manufacturing practice by the manufacturers in line with the W.H.O. recommendations, for fixing medicine prices and for regulation of imports, exports and sale of drugs.

DRUG PRODUCTION

Pakistan has been following the policy of encouraging local production of pharmaceuticals with a view to bring self reliance and self sufficiency in the country. Thus today some 226 manufacturing units including 29 foreign companies are meeting about 80% of the country's demand for medicines compared to almost nothing at the time of its creation in 1947. However, the industry ins still dependent largely on imported raw materials. Therefore, the Government of Pakistan shall now be considering providing of attractive incentives with a view to build up a base for local production of active ingredients in the country. In this connection the Government will arrange for an in-depth analysis of the pharmaceutical sector and for a technical, economic and marketing study for the feasibility and extent of basic production of pharmaceutical chemicals. On the basis of the results of

such a study, a clear cut Government policy on this subject will be formulated and announced.

The Government will also, in particular, encourage and support local production of essential drugs, as well as ensure rapid increase of the market share held by national pharmaceutical companies.

PROVISION OF REGISTRATION

Presently some 12000 drugs are registered under the Drugs Act, 1976. The next Five Year Plan provides for review of these drugs on the basis of established criteria of safety, efficacy, quality and the health needs of the country. Irrational, unsafe and unnecessary products, formulations and dosage forms will be de-registered as and when the evaluation so justifies.

THE DRUG SUPPLY SYSTEM

Presently the sale of pharmaceuticals is regulated in Pakistan primarily through the Provincial Governments. It is fully recognized that there is a lot to be desired to bring rationality in this system, both at the Government level and private sector.

At the Government level, a scheme of Hospital Pharmacies is being introduced gradually in the country both under the Federal and the Provincial Governments. The existing Five Year Plan provides for appointment of at least one hospital pharmacist for each one hundred beds. The Hospital Pharmacy System will thus be properly organized so as to provide an efficient drug supply, compounding and dispensing of drugs.

The Federal and Provincial drugs supply system will be modernized and strengthened and will be managed to ensure proper efficient procurement, storage, distribution and inventory control. The system will ensure the availability of essential drugs in sufficient quantities and on a regular basis 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 private sector, however, a system of scientific retail pharmacy service shall be introduced in view of the availability of adequate manpower.

DEVELOPMENT OF MANPOWER

A programme shall be chalked out with the help of the University Grants Commission to develop adequate manpower in the field of pharmacy in

view of the need of the Government, Industry and Trade. As recommended by the W.H.O. consultants, pharmacists shall be made to play their recognized role in all drug management, supply and control activities. Their services shall be effectively utilized in distribution of prescription drugs in particular with the objective of their rational use. Similarly, all categories of other drug supply personnel in different supply units and hospital stores shall be given training in relevant aspects of the drug supply management.

In order to encourage rational prescribing, the Pakistan Medical and Dental Council will be asked to provide in the curriculum of medical education, adequate training on the subject. Similarly Pharmacy Education Institutions will also be directed to provide more emphasis to rational use of drugs.

QUALITY ASSURANCE

An organized quality assurance programme exists on the Federal and Provincial levels. There are nearly 100 inspectors of drugs and five Drug Testing Laboratories including one most modern laboratory for the appellate testing. These facilities, some of them quite inadequate, shall be appropriately strengthened to ensure effective drug regulatory control and compliance with quality specifications and current legislation. The Good Manufacturing Practices as laid down under the law shall be updated, keeping in view the modern requirements of effective quality control. The W.H.O. certification scheme shall be applied to all the imported drugs. Whereas the inspectors shall be provided regular training courses to keep abreast of latest quality control techniques, new standard procedures for good laboratory practices in all drug quality control laboratories shall be introduced to improve laboratory systems.

DRUG INFORMATION

The Drugs Act, 1976 provides for regulation of sales promotional activities of the pharmaceutical industry to allow correct information to be supplied to the medical profession.

From the Government platform, a Drug Information Bulletin is issued on a regular basis to provide unbiased information to the medical profession.

The Pakistan National Formulary shall be published in a new context so as to serve as a reliable prescribing and dispensing guide to all doctors and pharmacists of the country as an effective teaching aid.

For the public a Drug Education Programme shall be introduced through various media and channels to promote proper use of medicines, compliance in drug-use according to the instructions and to educate

about the hazards of misuse, under-use or overuse of drugs.

RESEARCH AND DEVELOPMENT

In the field of research, the Drugs Act, 1976 requires the manufactures to contribute a certain percentage of their profit towards a Drug Research Fund which will be spent for conducting research on the development of new pharmaceutical formulations. Further policy guidelines to encourage research and development in the field will be formulated. To begin with, research of operational and applied nature may include the following :

- Drug utilization studies
- Stability studies
- Resistance
- Evaluation Survey
- Traditional Medicines, etc.

These studies will be aimed at achieving the main objectives of the National Drug Policy as outlined above.

4.9 Concessions for Foreign Investment[38]

A foreign investor enjoys the following privileges :

* Could own up to 100% equity.

* Negotiate terms and conditions of foreign currency loans independently.

* Capital invested, appreciation thereof and profit on it is freely repatriable.

* Decide the mode and level of transfer for technology.

Foreign investment is fully protected :

* Capital invested, appreciation thereof and profit on it is freely repartriable.

* Upper ceiling previously fixed for payment of royalty and technical fee has been removed.

* Requirement for work permit for expatriate managerial and technical staff stands abolished.

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[38] Pakistan Investment Opportunities (Ministry of Industries 1991)

* Access to domestic borrowing has been enlarged.

A foreign controlled company, exporting 50% or more of its production can borrow working capital from the domestic capital market and the companies which do not export and fulfill the demand of the domestic market can borrow rupees loan equal to their equity.

* Foreign investors can invest in the share capital of companies through the stock exchanges by paying in foreign exchange.

* A foreigner can now bring any amount of foreign currency, posses and take it out abroad freely.

Protection to foreign investment

Foreign investment is protected under the Foreign Private Investment (Promotion and Protection) Act, 1976. The Act provides for security against expropriation and adequate compensation in case of acquisitions. The Act also guarantees the following :

i) Remittances of Profit and Capital;

ii) Remittances of appreciation of Capital Investment;

iii) Foreign Private Investment shall not be subjected to more burden of taxes on income than those applicable to investment made in similar circumstances of citizens of Pakistan; and

(iv) Relief from double taxation in cases of those countries with which Pakistan has agreement for avoidance of double taxation.

Pakistan has a well developed financial system. The banking system comprises the State Bank of Pakistan which exercises control and regulates the activities of scheduled banks in pursuance of the responsibility assigned to it under its charter. The commercial banks constitute the most important source of institutional credit in the country. Development Finance Institutions also play their role in providing sole term loans to the industrial sector. The institutional credit is also supplemented by a host of foreign banks working in the country. Presently, eighteen foreign banks are operating in Pakistan.

Presence of foreign Companies

To give an idea of the foreign companies already working in the country, an abridged list is given thereunder:

1. Lever Brothers (Pakistan) Limited
2. Brooke Bond (Pakistan) Limited

3. I.C.I (Pakistan) Limited
4. Pakistan Tobacco Company
5. Glaxo laboratories (Pakistan) Limited
6. Beecham (Pakistan) Limited
7. BASF (Pakistan) Limited
8. A.E.G. Telefunken (Pakistan) Limited
9. Siemens Pakistan Engineering Company Limited
10. Philips Electronics Industries (Pakistan) Limited
11. Johnson and Johnson (Pakistan) Limited
12. National Petroleum, Crescent Petroleum Limited
13. Pakistan Petroleum Limited
14. Attock Cement Limited
15. Pakistan Refinery Limited
16. Indus Motors Limited
17. Sandoz Pakistan Limited
18. General Tires Limited
19. Wah Nobel (Private) Limited
20. Industrial Promotion Services Limited

While the above mentioned industrial promotion privileges have helped to attract foreign capital, the investment incentives in the ASEAN countries cover a much broader area, particularly in the field of tax exemptions, deductions from taxable corporate income, tax credits, etc. (See Annex VII), which have proved to be very successful.

4.10 Development of the pharmaceutical industry

A plan for the long-term development of the pharmaceutical industry could be a logical extension of the pharmaceutical sector study of the country.

The potential benefits derived from developing a domestic pharmaceutical industry, could be summarized as follows:

- reduction of foreign exposure and savings in foreign exchange
- stimulation of auxiliary industries development with a catalytic effect on the industrial development in general
- creation of jobs in the pharmaceutical and auxiliary industries
- development of manpower, qualifications and expertise in the production, organization and management of industrial enterprises and providing of educational opportunities in new disciplines
- promotion of applied research and development and strengthening of the national scientific basis
- improvement of industrial information and standardization
- amelioration of international and regional cooperation.

The above mentioned advantages and the eventually resulting effects, such as, more regular and timely supply and distribution of pharmaceuticals avoiding excess or shortage of stock, a better and more efficient quality control, lower costs, etc. are only potential ones and are certainly not guaranteed. Very often, especially during the initial stages of the development process, manufacturing costs of domestically produced drugs are higher than the imported ones and their quality and presentation - inferior. These facts are accepted by many developing countries, as a price to be paid for progress and in some cases pharmaceutical policies and legislation provide for the differences.

Finally, besides the economic and social reasons for launching a domestic pharmaceutical industry, other reasons such as the strong desire for national development and some political pressures should not be ignored.

By and large, the creation and expansion of the pharmaceutical industry in the developing world did not follow a systematic planning pattern, but came and grew sporadically in an unbalanced way, responding to the needs and conditions of the moment and/or as a remnant of the past.

The main constrains in adopting a methodical approach and in the elaboration of a rational and coherent plan for the development of an integrated pharmaceutical industry, is the inherent weakness of the statistical apparatus in the developing countries, often with incomplete or misleading data, the inadequate communication and insufficient coordination between the responsible organs in the private and public sectors, the confidentiality of the information, the educational level and the weak expertise of some of the planners or the appointed members of the counterpart, the budgetary limitations and a lack of sensibility on the complexity of this issue, in general.

Some questions have been raised as to the compatibility of plans for the development of an industry, with the unavailability or the lower development stage of appropriate infrastructures in the developing countries, essential for a successful implementation of such as plan. In other words, a "built-in contradiction of preparing a Development Plan requiring an established infrastructure in a developing country, where it does not exist."

The Plan for the development of an integrated pharmaceutical industry is a long-term objective, encompassing periods of fifteen to twenty years, presupposing a parallel build-up and continuous improvement of the basic infrastructures and support services, on which the productive activity must rely. The infrastructural development, for example, in the field of urban and rural public transport, industrial water and energy supplies, port facilities, telecommunication services, etc., are incorporated in the national economic development plans together with the industrial development and might include measures to boost the efficiency of public infrastructure services quantitatively and

qualitatively to support the national production and trade sectors, measures to increase the financial efficiency of public investment expenditures, measures to improve the machinery of investment planning and programming, institutional arrangements for developing the sectorial and intersectorial coordination, etc. Finally, the present state of the industries in the developing world has not been reached suddenly waiting for the necessary infrastructure to be first established, but both have followed similar development patterns.

The plan for the development of an integrated pharmaceutical industry is a working tool in the hands of technical experts, financial specialists, as well as Government policy-planners and decision makers, containing pertinent data and information, and recommendations for the rehabilitation, rationalization and development of a national pharmaceutical industry. The Plan makes transparent to all concerned the basic conditions and requirements, the interdependence of auxiliary industries, the necessary infrastructure, the appropriate institutional framework and the corresponding legal provisions and procedures. The Plan clarifies the short-term goals and plans, identifying specific projects as well as feasibility and investment studies, essential for reaching the long-term objectives.

While following some general principles and considerations, the plan will be specifically adapted in the light of Pakistan's socio-economic structure and degree of development, with a corresponding degree of sophistication as a function of the latter and of its priority steps. The plan could encompass for instance, several phases of a horizontal and vertical integration, with all accompanying measures, parallel structures and institutions in the field of education, R&D, maintenance, etc.

The chronological development and implementation takes also into account, as previously mentioned, the Government priorities in their economic development plans. In various cases, for instance, strong emphasis, in the immediate future, is put on the natural resources distribution and use, the land and environment management, and the agricultural development, leaving the industrial development, as a second priority.

The multidisplinary nature of the pharmaceutical manufacture, the interdependent character of this industry, its dynamic growth and its close relation to the health status of the country, makes it a particularly responsible, complex and difficult task, to elaborate and implement a plan for its development.

C. ECONOMY AND GROWTH

"Economic policy in Pakistan has centered on a series of five year plans. The first three of these plans, which operated during the 1950s and 1960s, mainly emphasized growth and the transformation of the

economy from the backward and relatively stagnant state in which it was at the time of independence. Industrialization was the key aim in the 1950s with agriculture being relatively neglected. More attention was paid to agriculture in the 1960s, but strong emphasis was also placed on industrial investment and investment incentives. The strategy pursued owed much to current thinking among Western economists. During this period the economy grew rapidly, but the benefits of growth were seen to go unproportional to a small section of the population.

By the end of the third plan period in 1970 it was felt that the ideal of growth had been overstressed at the expenses of equitable distribution of the benefits. The investment incentives allowed were considered wasteful and an encouragement to profligate spending. The fourth plan, 1970/71 - 1974/75, was therefore prepared with the emphasis on social justice, and a system of industrial sanctions and permits was formulated. During this period the economy was also hit by the effects of the first "oil shock" and world recession, as well as increased bureaucratization. Many sectors of the economy were nationalized, and there was virtually no private sector industrial investment.

After the change of regime in 1977, five year planning was restored. The main aims of the fifth plan (1978/79 - 1982/83) were: to stabilize the economy; to restore rapid but balanced growth; to develop the more backward regions and improve health, education and water supply facilities; and to improve the situation of the poorest sections of the community. Real GDP was targeted to grow by 7 percent on average with 6 percent growth in real agricultural output and 12 percent growth in real manufacturing output. Private sector industrial investment was to be revived and smaller sector units denationalized.

The implementation of the fifth plan is generally considered to have been successful, especially considering the effect on Pakistan of the second oil shock and the fall in commodity prices of the early 1980s. Real GDP grew by an annual average of 6.4 percent although agricultural output growth, despite a series of good monsoons, averaged only 4.4 percent. Manufacturing output grew by 9 percent, below the 12 percent target. Inflation, after surging in the first years of the plan, fell back steeply later. The two major disappointments of the plan were the failure to stimulate substantially private industrial investment and too low expenditure on developing rural infrastructure and on social needs.

The sixth plan covered the years 1983/84 - 1987/88. Key aims were: a continuation of rapid growth (GDP was targeted to grow by 6.5 percent a year on average in real terms); increased social expenditure; further development of rural infrastructure, especially electrification; increasing education opportunities; stimulating energy exploration and oil substitution; rapidly increasing exports; improving agricultural efficiency; increasing private sector investment; and raising the savings rate. The plan thus aimed to tackle some of the major

deficiencies in the Pakistan economy: low investment and savings ratios; low agricultural productivity; heavy reliance on imported energy, especially oil; and traditionally low spending on health and education.

The seventh plan, covering 1988/89 - 1992/93 provides for a total outlay in the public sector of PRs350bn, somewhat less than had been expected. The share of outlays to be devoted to energy was increased, while those for industry and housing were reduced. The seventh plan gives much greater emphasis than before to private investment in all sectors of the economy; total private investment is put at PRs292 bn. The private : public ratio of investment is expected to rise from 42:58 in 1987/88 to 48:52 in 1992/93. In 1990/91 the ratio was 47:53"[39].

Table No. 14

Development plan outlays in the public sector

	Sixth plan 1983/84-1987/88 (actual) PRs bn	%	Seventh plan 1988/89-1992/93 (target) PRs bn	%
Energy	78.9	31.7	131.8	37.7
Transport & communications	46.2	48.6	64.1	18.3
Water	23.2	9.4	30.2	8.6
Physical planning & housing	24.8	10.0	27.0	7.7
Education	14.5	5.8	24.1	6.9
Industry & minerals	15.5	6.2	17.0	4.9
Health	10.6	4.3	14.2	4.1
Agriculture	8.5	3.4	212.0	3.4
Rural roads & model villages	4.1	1.6	5.4	1.5
Other sectors	22.2	8.9	24.2	6.9
Total	**248.6**	**100.0**	**350.0**	**100.0**

Source: The Planning Commission, Draft Seventh Five Year Plan (1988/89-1992/93)

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[39] The Economist Intelligence Unit - Pakistan Country profile, 1991-1992

In accordance to an article in "The News" by Nadeem Hissain on April 19th 1992, the overall economic picture of the year 1991-92 emerging from different statistical sources shows conflicting figures. National savings and gross total investment ratios did not show any significant changes compared to the recent levels. This aspect is worrying the budget makers.

Sources in the Finance Ministry disclosed that the growth in total Government expenditure which was contained to 8.9 percent in 1990-91 has also shown an upward trend during the year 1991 - 92. The latest figures available indicate it to be around 10 percent. "Concern in this regard has been shown by the Prime Minister and all the ministries and departments have been directed to curtail their expenditures," the sources added.

The budgetary situation is of serious nature due to the shortfalls in revenues and foreign resources as compared to the budget estimates and upward pressure on expenditure. "Though the efforts are being made to contain the overall fiscal deficit, higher level of bank borrowing will be once again needed to finance reduction in foreign and domestic non-bank debt stock," the sources added. Estimated commitments of foreign economic assistance have further declined from 8.6 percent during 1990-1991 to 7.9 percent during the year 1991 - 92.

Aftab Ahmed Khan, a former Secretary of Finance, has said that if present budgetary trends continue, within a few years all foreign exchange earnings will be utilised to meet overseas debt serving and interest payments.[40] The former secretary said the deficit in the forthcoming budget is expected to be 2.9 billion dollars.

He stressed the need to drastically revamp the taxation system as only 14,000 people in the country have admitted to earning more than Rs 100,000 per month. Aftab Khan said that at present Pakistan owes approximately 20 billion dollars to foreign creditors in long and short term loans.

Speaking on the occasion, IBA Director Dr. Abdul Wahab Khan said that the savings rate in Pakistan was approximately 30% according to his research, which is higher than common belief.

He said the actual Pakistan economy is much larger than what statistics show, adding that it is the most prosperous economy in the sub continent which has already absorbed millions of immigrants from India, Iran, Sri Lanka, Bangladesh, Afghanistan and the Philippines. Commenting on the budget, Dr. Wahab sad "only a revolution will bring change. We sit and have seminars every year and no concrete changes

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[40] Prebudget seminar - Pakistan National Centre
- Institute of Business Administration, April 27th 1992

are incorporated."

Mumtaz A. Khan, a member of the IBA faculty, in his speech said that self reliance can be achieved through broadening of the tax base. "Barely 10% of the population pay taxes and only 14% of taxes collected are direct" he said.

According to a UNDP study from February 1992[41] "The economic performance of Pakistan has not been achieved without producing in the process some significant distortions, a growing inequality between people, and considerable damage to the environment. And these features of growth have been related at various points to limitations of human development for the majority of the people." Some major characteristics of growth basis in Pakistan reviewed from this perspective are:

- abundant natural resources
- dependence on cheap and unskilled labor
- dependence on an unregulated informal sector expanding to various illegal activities
- financial constraint.

The financial constraints raise doubts about the sustainability of the Pakistan economic growth.

Sustainable development means, first and foremost the elimination of absolute poverty that affects more than 1.1 billion people in the world today. Second, the aspirations of the middle 3 billion, who are neither rich, nor poor must be met. For this they need real growth in income per person. Third, both of these things must be done without jeopardizing the opportunities of future generations, without eating up the Earth's limited ability to provide resources and absorb wastes."[42]

In addition to various factors mentioned before, the following facts could underline the doubts concerning the economic growth sustainability:

- income from direct taxation is only a fraction of Government revenues and is regressing;

- heavy Government subsidies in the agricultural sector (fertilizers, seeds, energy etc.) representing about 25% of GNP, with income which is not taxed.

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[41] Balanced Development : an approach to social action in Pakistan (UNDP, 1992)

[42] Paul Harrison "Sustainability : a new dimension" ("The News", April 29th 1992)

- take savings amount to about only 19-20% of GDP in Pakistan

- difficulties in external financing and suspension of US aid[43]

- problems in the creation of new job opportunities and expansion of the venues of self-employment towards insuring a higher degree of financial self-reliance, etc.

In this respect, one should also add that the recommendations of the self-reliance commission, submitted in March 1991, are not yet implemented. Among them, it is worthwhile mentioning :

- programme of austerity curtailing conspicuous consumption and checking non-development expenditure.

- introducing a new tariff policy, establishing a public utilities commission to ensure that the interests of the consumers are safeguarded from the monopolistic power enjoyed by the large private sector concerns, establishing a self-reliance fund for financing the efforts towards self-reliance and introducing grassroots changes in the taxation system with a view to making it both equitable and prime source of resource mobilisation.

D. THE PHARMACEUTICAL SECTOR STUDY

1. OBJECTIVES :

1.1 To provide the Government of Pakistan with an in-depth analysis and evaluation of the present situation in the pharmaceutical sector of the country with pertinent and realistic data to that effect.

1.2 To present to the Government of Pakistan appropriate recommendations with policy options for possible changes in the sector, with the relevant impact of each option on the economical and social situation in this or other connected sectors.

2. EXPECTED RESULTS

2.1 The establishment of a nationally sustainable, affordable, equitable and accessible pharmaceutical products demand/supply situation, within the framework of the minimum requirements of the preventive and curative health services.

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[43] The Federal Minister of Finance said that the counting's total aid requirements is to the tune of US$ 2.36 billion, including US$ 1.95 billion project aid and US$ 410 million commodity and programme type aid (20 April 1992).

2.2 The building up of a strong base for conducting manufacture of fine chemicals i.e., of the pharmaceutical active ingredients with a view to create relative self-reliance and self-sufficiency in the country.

2.3 The possible identification of areas for future investments as under:

a) Development of human resources and specialised manpower:

- good manufacturing practice (GMP)
- good laboratory practice (GLP)
- management capabilities in the national pharmaceutical manufacturing units
- research and development of operational and applied nature
- establishment of hospital pharmacy services.

b) Rehabilitation and/or rationalisation of existing small and medium sized pharmaceutical manufacturing facilities.

c) Additional studies on specific topics, such as:

- traditional medicine
- self-medication
- exploitation of local resources
- long-term development plan for an integrated pharmaceutical industry
- other connected industrial development plans

3. POSSIBLE CORRECTIVE MEASURES

In order to achieve and ensure these results, adjustments and/or corrective measures may have to be undertaken for improving:

3.1 The import, manufacture, storage, marketing, selling (including pricing) and distribution of pharmaceutical products.

3.2 The balance between investments in physical and human assets.[44]

3.3 The consumption and prescription patterns of medicines, especially the rational drug use.

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[44] "since 1976 only 2.5 percent of total disbursed donor funds have gone to the social sector" - UNDP, Aid to Pakistan Meeting, Paris, April 1992

4. SCOPE OF STUDY

4.1 General considerations

4.1.1 The Government has initially identified the following major areas of the pharmaceutical Sector Study:

a) Consumption and utilization

b) Supply and production

c) Quality Control and Assurance

d) Operational and applied research

e) Government policy and legislation

After a detailed review of the present situation and discussions with authorities concerned from the Ministries of Health, Special Education and Social Welfare, of Planning and Development, of Industries, with members of the Pakistan Pharmaceutical Manufacturers' Association (including representatives both from the foreign and national pharmaceutical manufacturing units) and the University Grant Commission, it was understood that a "balanced approach should be undertaken in view of the complexity of the project and the long-term implications of any decision that may result".

It was however strongly recommended by all concerned that in accordance to the Government policy to encourage local manufacture, the main emphasis of the study should be directed towards the supply of pharmaceutical products and particularly centered on the development of national capabilities in the effective utilization of local human and natural resources for the manufacture of active ingredients, excipient and packaging materials.

> "The pharmaceutical industry should make headway in the field of Basic Manufacturing in order to achieve self-reliance"[45].

As far as the eventual fermentation of some antibiotics and the extraction of medicinal and aromatic plants is concerned, the availability of indigenous raw materials (from agricultural, animal or mineral origin) and energy sources are essential for achieving this goal.

For the gradual development of chemical synthesis capabilities (starting with a pilot scale manufacture of one or a small range of

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[45] The Minister for Health, Special Education and Social Welfare, January 18,1992 - Karachi University.

selected products at some stage of the chemical process), the existence of a strong petrochemical industry in the country and large capital outlays are not of utmost importance, as often claimed. A similar exigence for the necessity of a prior expertise and a long tradition in this field, seems also exaggerated. What is, however, indispensable, is the effective development of human resources and specialized manpower, as well as the acquisition and development of technologies; for obvious reasons, the latter will not be the best in the industry, but certainly adequate as a starting point and affordable. This is also valid for the development of biotechnology and genetic engineering.

The above mentioned facts could imply, that the sector study could recommend an additional study for a long term development plan for an integrated pharmaceutical industry in the country[46]. The first goal of such a study should be to achieve a maximum coverage in the field of formulation and packaging of pharmaceutical products, with a partial development of the capacities in the basic manufacture of pharmaceutical chemicals.

4.1.2 The next area of interest in the study on the Government priority list is the consumption and utilization of medicines, with detailed analysis and evaluation of the:

Existing drug consumption, or the actual pharmaceutical market size with determination of the real need and demand for pharmaceuticals.

a) The "Consumption Approach" is the simplest method of evaluation provided that precise statistical data of actual consumption of pharmaceuticals are available, and particularly the historical data illustrating consumption trends and stock requirements.

The problem to be faced in some developing countries is that although reasonably good statistical figures could exist, they do not necessarily reflect the actual demand and the pharmaceutical market size; often, due to a variety of reasons, but especially to the foreign currency limitations, some pharmaceuticals are not imported or domestically manufactured. In such cases, there are sudden shifts towards other similar products readily available at that time, which warps the entire picture, the frequent stock break-downs and the resulting abundance or shortage really determining the market size.

In addition to the above mentioned evaluation methods, the opinion of the trade, the academic circles, the Government officials, the managers of domestic and/or foreign pharmaceutical manufacturers, the medical and pharmaceutical profession should be taken into consideration. This should also be the case when projecting future demands and market growth.

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[46] UNIDO has prepared such studies for Algeria and the Philippines.

The figures obtained by one of the methods in pharmaceutical sales units or single dose units should be further decoded into active ingredients, excipient and, if possible, down to the packaging materials. This will show the national demand for active ingredients and excipient in kilograms or tons, which will be essential when determining the future size and progress path of the pharmaceutical manufacture development and integration.

The "Population" Approach

This method is based on the detailed analysis and assessment of the following parameters:

Demographic data

- total population
- population by age group and age pyramid
- structure of the population
- birth rate and fertility
- mortality by age and sex
- life expectancy at birth
- population growth projections

Sanitary state and epidemiology

- general situation, morbidity and mortality
- transmissible diseases including those controllable by environmental hygiene,[47] by vaccination[48] and other transmissible diseases[49]
- diseases of the cardio-vascular, gastro-intestinal, genito-urinary and nervous systems
- malignant tumors
- nutritional diseases
- accidents, including road and work accidents, and professional diseases
- family planning or "spacing" of births.

This approach consists of selecting a target area with as large a population as possible, determining its demographic composition and

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[47] such as dysentery, typhoid fever, viral hepatic, cholera, etc.

[48] such as tuberculosis, diphtheria, whooping cough, tetanus, poliomyelitis, cerebrospinal meningitis, etc.

[49] such as leishmaniosis, schistosomiasis, rabies, trachoma, hydatic cyst, etc.

structure, and applying the respective morbidity and mortality rates of prevailing diseases at each age group. This is followed by a calculation of the annual disease frequency in the target area, as well as the number and types of treatments for each disease. In utilizing previously fixed standard treatment schemes, or any other widely acceptable therapeutic schemes, one could determine the exact quantity of each pharmaceutical product necessary for each disease. One should add also the product necessary to fill in the distribution pipe-lines and the ones replacing eventual losses. Finally, the resulting amounts for the target area should be multiplied to cover the desired population. (If, for instance, the target area had a population of 500,000 and the country one of 115 millions, the figure to be used will be 230 etc.).

The "Services" Approach

This method of evaluation is based on the detailed analysis of the following parameters:

National health care system and Government health policy

Health legislation

Ministry's of Health and Welfare annual budget and its allocation for pharmaceutical products

Sanitary infrastructure (hospitals, clinics, health centers, consultation rooms, family planning centers, etc.) with the respective number of beds, hospital consultations and admissions, days of hospitalization, etc.

Human resources (physicians, surgeons, dentists, pharmacists, nurses, health agents, etc.)

The nomenclature of authorized pharmaceuticals (locally manufactured and imported)

The standard therapeutic schemes, etc.

The first step to be undertaken is a review of the number of services rendered by each type of unit in the sanitary infrastructure (hospitals, clinics, health centres, etc.), or each type of person dispensing drugs (physicians, pharmacists, nurses, health agents, etc.) in a given health programme. After a detailed scanning of the respective registers covering a one year period[50] a classification and list of the most widespread diagnoses and their frequency is

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[50] In case registers are incomplete or lacking, a minimum period of one year is necessary to accumulate all pertinent data.

established. Using the standard therapeutic schemes, the quantities of the annual requirements for pharmaceuticals are calculated for each installation, or each drug dispensing person, by multiplying the number of cases of a particular disease by the quantity of medicines used for its treatment and repeating the same procedure for all nosological units contained in the list. Finally, the total amount of necessary pharmaceutical products in all establishments or dispensing persons involved in the programme are calculated.

This method is more realistic and reflects the number and quantity of pharmaceuticals actually prescribed or dispensed to the population seeking consultation and treatment. The figures derived from this method are much lower than the ones resulting from the "population" approach.

Another approach in a similar direction could be the consideration of one or a group of rural and urban "Health Zones", with their established lists or pharmaceuticals, their quantities and their prices, covering a specific number of people and period of time. Taking these zones as representative samples and multiplying their respective drug consumptions with the total number of zones in the country, will produce a reasonably good estimate of the national consumption for a determined time span.

Finally, when determining the real demand and need for pharmaceuticals, due consideration should be also given to the "essential drug lists", the number of registered drugs in the country, the existing formularies, the "generic pharmaceuticals" and their acceptance, the prices and the price controls, etc.

b) self-medication

c) rational use of medicines

* choice of drug therapy
* drug combinations
* cost effectiveness
* dosage of the products
* particles compliance

d) prescription patterns

* over prescriptions
* wrong prescriptions

e) traditional medicine

* medicinal plants
* homeopathy

4.1.3 This is followed by:

a) human resources development in:

* pharmaceutical manufacturing management
* quality control and assurance
* research and development of operational and applied nature
* hospital pharmacy services
* other personnel in the pharmaceutical sector

The study should look into the availability of medicinal plants (spontaneous growth and/or cultivation) their crops, harvest, collection, drying, storage, packaging as such, or their extraction, with special emphasis on their marketing and selling, as well as the contents of allopathic drugs (corticosteroids, sex hormones to enhance their activity. By the same token, but under Government policies and legislation, the experts should analyse the ways and means to regulate the manufacture, storage and selling of medicinal herbs preparations.

The study should:

- identify the present and future needs of trained personnel in different areas of the pharmaceutical sector (manufacturing, distribution, research etc.)

- specify the curriculum for the different levels of pharmaceutical personnel, the educational degrees and the uniformity of studies in the different Universities.

- propose a programme for training of needed pharmaceutical personnel, the evaluate needs of other qualified staff required within the pharmaceutical sector, assess the financial resources required to meet the identified needs of training, and propose programmes for ongoing training of personnel working within the pharmaceutical sector.

b) quality controls assurance and Good Laboratory Practice (GLP)

c) research and development of operational and applied nature

d) hospital pharmacy services

4.1.4 Thus, by order of importance to the Pakistan authorities, the pharmaceutical sector study should cover the following areas:

a) supply of pharmaceutical products

* formulation and packaging
* manufacture of active ingredients and excipient

b) consumption and utilization of medicines

c) human resources development

d) quality control and assurance

e) research and development

f) hospital pharmacies services

g) Government policies and legislation

The study should incorporate, within the framework of the above mentioned points and in accordance with the Government family planning policies, the real needs and requirements of contraceptives (oral and injectable preparations, condoms, IUDs, foams, etc.) as well as their manufacture and distribution in the country.

5. STRATEGY

5.1 General considerations

The Government authorities have reacted very positively and are showing considerable interest in the pharmaceutical sector study, especially the Ministry of Health, the Ministry of Planning and Development and the University Grants Commission.

Steps and measures to be undertaken to ensure the success in the various phases of the study have been discussed. The Government authorities are prepared to make a firm commitment to identify and provide all necessary qualified human resources on a full time basis to assist in the:

5.1.1 conduct and execution of the study

5.1.2 implementation of the recommendations

5.1.3 follow up of their execution

5.1.4 regular updating of the study

5.2 Specific considerations

The Ministry of Health, is in a process of identifying the human resources and specialized manpower to assist in the execution of the study. As far as the implementation of the recommendations (which are accepted by the Government), the follow-up and the updating of the study data are concerned, the authorities could proceed to provide incentives, change the legal framework, institutional support and the identification of necessary personnel and take other required

measures when the recommendations of the study will be known.

The Government Implementing Agency is in a position to take appropriate measures to facilitate timely decisions on policies and to ensure the co-operation with other concerned public and private sector agencies by initiating the setting up of the following committees:

5.2.1 Steering Committee headed by the Minister for Health, or the Secretary for Health and comprising representatives of the Ministry of Industries, Planning an Development and others as may be considered necessary. The Committee may meet from time to time to provide an overall policy guidance for the execution of the study and to hear progress.

5.2.2 Technical Advisory Committee, headed by the Director General for Health and consisting of representatives of other Ministries, Departments and experts in the field, as deemed fit by the Ministry of Health, to advise on technical matters. The Committee will meet regularly once a month to advise the team of National and International experts in the conduct and execution of the study.

5.2.3 It is also recommended that a full-time National Project Director be appointed to work together with the Chief Technical Adviser in the daily coordination of the project team activities. The National Project Director should be remunerated from the project budget allocation, commensurate to his qualifications and skills, in accordance to levels practiced by the International Organizations.

5.2.4 The National Implementing Agency and the Ministries of Planning and Development, Industries and the Economic Affairs Division have expressed their desire that the United Nations Industrial Development Organization (UNIDO) serve as Executing Agency for this project in view of their experience in this field in the developing countries.

5.2.5 Finally, it is suggested that selected Pakistani students of pharmacy and/or medicine (one or two of each province) undertake assignments on specific topics within the scope of the study and present postgraduate theses to their University Authorities with respective analyses, evaluations and recommendations.

6. FIELDS OF EXPERTISE

6.1 General considerations.

The Government authorities have requested that the minimum duration of an expert's mission, to allow him a realistic analysis and evaluation in his area of expertise, as well as the formulation of justified and sustainable recommendations, should be of two and a half months. This is based on the importance and complexity of the study, on the wealth

of reference material, on the extensive coverage of the provinces and on previous Government experience in the field of studies and reports.

The duration of the mission of the National Project Director is estimated at 18 months, out of which 12 months together with the experts, 3 months for the preparation and dissemination of the study material and 3 months for the compilation and preparation of the final report and the executive summary, with the Chief Technical Adviser and the Industrial Economist.

The study should be finalized within a period of 18 months.

Twenty one area of expertise were identified, requiring a total of 60.5 man/months, excluding the National Project Director and the Chief Technical Adviser. Out of the total, six fields of expertise will be explored by Pakistani experts, the rest by International experts. The grand total of the required man/months will be 93.5 (see Table 15).

The experts (National and International) will be selected by the Pakistan Implementing Agency with UNIDO and approved by UNDP.

The National Project Director and the National Experts will be remunerated in accordance to the precedents established by the International Organizations when engaging the services of Pakistani Experts for similar type of studies. Whereas the USAID sponsored projects engage the services of high caliber Pakistani Experts at a rate of US $ 100 - 200 day 6 days a week, without allowances when based in Islamabad, the UN Agencies usually offer for special service agreements and contractual services a monthly remuneration of US $ 2000 and only on some occasions higher.

The Chief Technical adviser and the International Experts will be remunerated in accordance to the rules and regulations of UNDP and UNIDO.

All twenty two experts should have a home assignment of 0.5 month each to get acquainted with the reference material pertaining to their particular field of expertise and to the country. The National Project Director, together with locally hired junior personnel will select, prepare and send the material to the experts, prior to the beginning of their home assignment. This will permit the latter to proceed to the country familiar with the basic issues to be tackled within the framework of the existing political, economic and social environment of Pakistan, without waste of time, money and energy.

It is required that all International experts should have experience in developing countries and that they should have participated in studies and presented reports to that effect.

The detailed terms of reference for each expert should be elaborated by the Implementing and Executing Agencies, and approved by UNDP.

6.2 Specific Assignments

6.2.1 National Project Director

Qualifications: PhD in Pharmacy, with extensive experience in Drug Control and Management, in Quality Control and Assurance and in the formulation of policies and regulations on these subjects. He should have good contacts and relations with various Ministries and Departments in the country and be acquainted with the operations of International Agencies like WHO, UNIDO, etc. The candidate should possess good communication and leadership skills. Fluency in spoken and written English is essential[51].

6.2.2 Chief Technical Advisor

Qualifications: Industrial Pharmacist or Medical Doctor with extensive cross-cultural/international experience in Management of Industrial and Commercial Corporations, substantial operational experience in field sales, expertise in external aid administration, especially technical assistance, experience in programme and project management and in the elaboration and implementation of development plans. He should be well acquainted with the procedures and style of operations of International Agencies like UNIDO, UNICEF, etc. The candidate should possess excellent communication and leadership skills. Fluency in spoken and written English is essential. Working knowledge of other languages will be an advantage.

6.2.3 Industrial Economist

Qualifications: Industrial economist with extensive experience in the economic aspects of the pharmaceutical industry and markets, with special emphasis in the analysis and evaluation of the demand/ supply situation of pharmaceuticals, as well as the projections of future consumption and consumer trends.

6.2.4 Expert in Social Medicine and Health-Care.

Qualifications: Medical Doctor with extensive experience in primary, secondary and tertiary health care, and especially in initiating, studying and implementing health care programmes and projects.

6.2.5 Expert in Marketing and Distribution

Qualifications: Pharmacist, Medical Doctor or University graduate in

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[51] This is valid for all experts.

Marketing with extensive organizational and operational experience in marketing, sales and distribution of pharmaceutical products, including selection, training and motivation of field sales forces, advertising, promotional materials, sampling, prices, quantity and other discounts, etc.

6.2.6 Expert in Management of Pharmaceutical Manufacturing Units.

Qualifications: Industrial Pharmacist or University graduate in other fields with extensive experience in planning, organizing, staffing, leading and controlling of pharmaceutical manufacturing units.

6.2.7 Expert in Medicinal and Aromatic Plants

Qualifications: Botanist, Chemist, Phytochemist or Pharmacist with extensive experience in the cultivation, collection, storage and utilization of medicinal and aromatic plants, with particular emphasis on standardization and extraction.

6.2.8 Expert in Bio-active Substances

Qualifications: Biologist with extensive experience in bio-active substances from animal and human origin-collection, storage and utilization.

6.2.9 Expert on Formulation of Pharmaceutical Products.

Qualifications: Industrial pharmacist with extensive organizational and operational experience in the formulation and packaging of pharmaceutical products, with particular emphasis on manufacturing methods and process development including "product engineering".

6.2.10 Expert on Blood Derivation and Industrial Biotechnology:

Qualifications: Biologist with extensive experience in the collection, storage, packaging and utilization of blood derivatives.

6.2.11 Expert on Biotechnology and Genetic Engineering:

Qualifications: Biologist with extensive experience in the analysis and evaluation of existing human and other resources in the field of biotechnology and the development of operational and applied research within the framework of future development trends in biotechnology and genetic engineering.

6.2.12 **Expert in Fermentation of Antibiotics:**

Qualifications: Industrial Pharmacist, Chemist or Biologist with extensive experience in the design and exploitation of installations for the fermentation and extraction of antibiotics, with particular emphasis on existing obtainable technologies and their sources, as well as the utilization of locally available raw materials.

6.2.13 **Expert in Semi synthesis of Antibiotics**

Qualifications: Chemist or Industrial Pharmacist with extensive experience in the design and exploitation of manufacturing units for semi-synthetic Penicillin, with particular emphasis on existing accessible technologies and supply sources of raw materials and/or intermediates.

6.2.14 **Expert in Chemical Synthesis**

Qualifications: Chemist with extensive experience in the design and exploitation of pilot or small scale chemical synthesis plants, with particular emphasis on gradual up-stream integration of chemical processes and supply sources of intermediates.

6.2.15 **Expert in Packaging Materials (Glass).**

Qualifications: Engineer or Pharmacist with extensive experience in the manufacture of glass packaging materials for the pharmaceutical industry.

6.2.16 **Expert in Packaging Materials(Plastics)**

Qualifications: Engineer, Chemist or Pharmacist with extensive experience in the manufacture of plastic packaging materials for pharmaceutical products.

6.2.17 **Expert in the Manufacture of Disposable Syringes.**

Qualifications: Engineer with extensive experience in the design, installation and operation of disposable syringes manufacturing units (machinery and equipment, processes including sterilization, raw materials, packaging materials, printing, etc.).

6.2.18 **Expert in Gelatin Capsules**

Qualifications: Industrial pharmacist or Engineer with extensive

experience in the manufacture of gelatin capsules.

6.2.19 **Expert in Quality Control and Quality Assurance**

Qualifications: PhD in Pharmacy with extensive organizational and operational experience in the quality control (analytical methods, equipment and training of personnel) of pharmaceutical products (active ingredients, excipient, semi-finished and finished goods), as well as good laboratory practice (GLP) and quality assurance.

6.2.20 **Expert on National Drug Policies and Legislation**

Qualifications: PhD in Pharmacy with extensive experience and involvement in the formulation and implementation of the National Drug Policy and Legislation.

6.2.21 **Expert in Pharmaceutical Education and Training**

Qualification: PhD in Pharmacy with extensive pedagogic experience in human resources development with special emphasis on the education and training of pharmacists.

6.2.22 **Expert in R&D**

Qualifications: PhD in Pharmacy, Chemistry or Medical Sciences with extensive experience in the organization and management of operational and applied research.

6.2.23 **Expert in Traditional Medicine**

Qualifications: Medical Doctor with extensive experience in the field of traditional medicine (medicinal plants, homeopathy, etc.)

7. INPUTS

7.1 Government Inputs

The following Government inputs are expected to be provided:

7.1.1 Personnel

A team of qualified persons from the Government Implementing Agency (or other Agencies if necessary) will assist on a full-time basis the National Project Director, the CTA, the International and National Experts in the performance of their duties.

7.1.2 Office Facilities, equipment and supplies

Working facilities for the National and International staff such as office space, secretarial support, simultaneous translation when necessary, rooms for meetings and conferences will be provided by the Implementing Agency. Office equipment and materials required for the study will be supplied. In view of the existing facilities at the NIH, the latter could become a focal point for the execution of the study through its Drug Control and Traditional Medicine's Division if the Government so decides.

7.1.3 Miscellaneous

Expenses for photocopying, telephone calls and correspondence related to the project activities will be at the Implementing Agency's charge. Whenever possible, transportation for the National and International Experts will be provided.

7.2 UNDP INPUTS

The UNDP assistance will be as follows:

7.2.1 Project Personnel			US $
(a)	Chief Technical Adviser	15m/m	183,750
(b)	National Project Director	18 m/m	72,000
(c)	International Experts[52]	42.5 m/m	520,625
(d)	National Experts	18 m/m	36,000
(e)	Subcontract (students)		10,000
(f)	UNIDO backstopping monitoring missions to the field 2 x 0.25 m/m		15,000
(g)	Joint meetings UNDP/UNIDO/government and other interested agencies (progress of study, project recommendations, follow-up actions etc)		30,000
(h)	Air fare for International Experts[53]		62,500
(i)	Inland Travel for National and International Experts		20,000
(j)	City transportation		5,000

[52] The expert on Hepatitis B vaccine was eliminated, due to a bilateral cooperation in this field between the NIH and a foreign company.

[53] This amount might be already included in the total monthly remuneration of US$ 12,250.

7.2.2 Equipment

- Two IBM compatible computers, one laser printer and the necessary software along with accessories	15,000
- Two photocopiers along with accessories	10,000

7.2.3 Miscellaneous

Reproduction of individual studies and final reports, preparation of charts, graphs etc.	15,000

7.2.4 **TOTAL**	**994,875**

Table 15

EXPERTS (SUMMARY)

Experts	No.	MAN/MONTH	TOTAL COSTS US$
National Experts	7	36.00	108,000
International Experts	16	57.50	704,375
Total	23	93.50	812,375

Table 16

TOTAL SUMMARY

S. NO	Field of Expertise	Duration of assignment m/m	Costs per m/m US$	Total costs US $	Remarks
1.	National Project Director	18.0 (3+12+3)	4,000	72,000	National Expert
2.	CTA	15.0 (12+3)	12,250	183,750	
3.	Industrial Economist	6.5 (3.5+3)	12,250	79,625	
4.	Social Medicine and Health Care	3.5	2,000	7,000	National Expert
5.	Marketing and distribution	3.5	2,000	7,000	National Expert
6.	Management of pharm manuf. units	3.5	2,000	7,000	National Expert
7.	Medicinal and Aromatic Plants	2.5	12,250	30,625	
8.	Bio-active substances	2.5	12,250	30,625	
9.	Formulation of Pharmaceuticals	2.5	12,250	30,625	
10	Blood derivatives	2.5	12,250	30,625	
11	Biotechnology	2.5	12,250	30,625	
12	Fermentation of Antibiotics	2.5	12,250	30,625	
13	Semi-synthesis of Antibiotics	2.5	12,250	30,625	
14	Chemical synthesis	3.5	12,250	42,875	
15	Packaging materials (glass)	2.5	12,250	30,625	
16	Packaging materials (plastic)	2.5	12,250	30,625	
17	Manufacture of disposable syringes	2.5	12,250	30,625	
18	Gelatin capsules	2.5	12,250	30,625	
19	Quality Control and assurance	2.5	2,000	5,000	National Expert
20	Nat. Drug policies and legislation	2.5	2,000	5,000	National Expert
21	Pharmacists education and training	2.5	12,250	30,625	
22	Research and development	2.5	12,250	30,625	
23	Traditional Medicine	2.5	2,000	5,000	National Expert
	Total	93.5		812,375	

EXPLANATORY NOTES :

1. **The National Project Director will spend :**

   - three months to collect, prepare, reproduce and mail the reference material to the expert
   - twelve months with the CTA and the experts
   - three months with the CTA and the Industrial economist to compile and elaborate the final report.

2. **The CTA will spend in two split missions :**

   - twelve months with the NPD and the experts
   - three months with the NDP and the Industrial economist to compile and elaborate the final report.

3. **The Industrial economist will spend in two split missions :**

   - three months with the experts
   - three months with the CTA and NDP to compile and elaborate the final report.

8. **DATA TO PROVIDED TO THE NATIONAL AND INTERNATIONAL EXPERTS**

The following information necessary for the Expert's activities to reach the study objectives should be provided by the authorities :

I
1. Constitutional provisions and amendments, as well as principles and issues pertaining to health and pharmaceuticals.
2. Presidential, Prime Minister or Ministers speeches and addresses, or portions of them, concerning health and pharmaceuticals.
3. Bills originating from the House of Representatives and the Senate concerning health and pharmaceuticals.
4. Reports of Special Committees on the Pharmaceutical Sector, such as Interim Report of the Senate Special Committee on the Medicine Sector (March 18, 1991).
5. Patent laws concerning brand names, manufacturing processes, formulation, etc., of pharmaceuticals.
6. The pharmaceutical legislation concerning importation, storage, manufacture, quality control, distribution and utilization of drugs (Drugs Act 1976).
7. The Health legislation.[54]

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[54] The Federal and Provincial aspects in the Health and Pharmaceutical Sectors of the country should be duly considered.

II. 1. National Revenue Code (with particular emphasis on the pharmaceutical business and industry) :

1.1 Corporate and personal income taxes

1.2 Municipal taxes

1.3 Remittance taxes

1.4 Sales taxes

1.5 Value added taxes

1.6 Other taxes

2. Foreign exchange control regulations

2.1 Report of capital and capital goods

2.2 Repatriation of capital

2.3 Remittance of profits

2.4 Others

3. The Pakistan Investment Guide (Ministry of Industries 1991).

3.1 Pakistan Investment opportunities (Ministry of Industries 1991)

3.2 Promotional privileges and incentives (comparisons with other developing countries).

III. 1. Short and long-term National Drug Policies, their timing and degree of implementation in the areas of importation, storage, manufacture, quality control, distribution and utilization of drugs.

1.1 General Objectives

1.2 Specific goals

1.2.1 effective regulation of drug importation, production, marketing and utilization

1.2.2 efficient and cost effective Government procurement of drugs and medicines

1.2.3 rational use of drugs by health professionals and consumers

1.2.4 national relative self-reliance in selected areas of the pharmaceutical sector

1.3 Characteristics

1.4 Implementing mechanisms

Particular attention should be paid to price controls, regulations on advertising of pharmaceuticals, rules and regulations on labeling, the usage of generic names, the essential drug lists, national formulary import restrictions, registration of new products, regulations for

licensing of drug establishments, quality control requirements, measures in drug use and abuse.

2. The Government Development Plans, the incorporation of the pharmaceuticals and the pharmaceutical chemicals.

3. Reactions and recommendations of the House and Committees, the Pakistan Pharmaceutical Manufacturing Association, Pakistan Chemists and Druggists Association, Chambers of Commerce, the medical profession, the Academic Circles, the results of hearings etc.

IV. 1. The Government Health Policy and the National Health Care and Medicare Systems:

1.1 Total public expenditure on Health

1.2 The Ministry of Health annual budget and its allocation for pharmaceuticals

1.3 Health care financing

1.4 Criteria for accrediting suppliers

1.5 List of accredited suppliers

1.6 Government procurement mechanism, including procurement to the Armed Forces

1.7 Distribution of drugs

1.8 Reimbursement of drugs and services

1.9 Number of registered drugs (for the Ministry of Health use and on the market)

1.10 List of essential drugs and other reduced lists of pharmaceuticals[55]

2. Health infrastructure (hospitals, clinics, health centres, consultation rooms, family planning centres, etc.), with the respective number of beds, hospital consultations and admissions, days of hospitalization, etc.)

3. Human resources (physicians, surgeons, dentists, pharmacists, nurses, health agents, etc.)

4. The standard therapeutic schemes

5. Federal programmes and projects for health, nutrition and family planning and provincial rural support programmes.

5.1 Health

5.1.1 Primary health care

5.1.2 health infrastructure

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[55] See "Essential Drugs" for Pakistan (1988 and 1991)

5.1.3 manpower development

5.1.4 disease control[56] and eradication

5.1.5 education[57]

5.1.6 Medicare

5.1.7 employee compensation

5.1.8 R & D

5.2 Nutrition

5.2.1 nutrition intervention (growth monitoring, nutrition information and education, nutrition-related health services, food assistance, food production).

5.2.2 nutrition surveillance systems

5.2.3 Water supply and sanitation[58]

5.3 Responsible Parenthood

5.3.1 adolescent fertility

5.3.2 population education

5.3.3 family planning[59]

5.3.4 manpower development

5.3.5 population information management and dissemination.

6. Health state and Epidemiology

6.1 general situation, morbidity and mortality

6.2 infectious diseases

6.3 diseases of the cardio-vascular, gastro-intestinal, genito-urinary and nervous system

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[56] Communicable and non-communicable diseases.

[57] Changing consumption models (prescription patterns and auto-medication habits).

[58] See performance indicators (Social Action Programme - Planning Commission, April 1992).

[59] The Government has allocated Rs 1.156 billion (=US$ 46 million at Rs 25/1$) for the population programme of the VIIIth National Five Year Plan to reduce the present population growth rate from 3.2% to 2.5% per annum (Minister of State of Population Welfare April 21, 1992).

6.4 malignant tumors

6.5 nutritional diseases

6.6 accidents, including road and work accidents and professional diseases.

V. 1. The consumption of pharmaceutical products

1.1 Size and composition of the domestic market (ethicals, proprietary drugs, total at retail and/or wholesale price levels).

1.1.1 Sales through chemists and druggists

1.1.2 Sales through wholesalers

1.1.3 Sales through hospital pharmacies

1.1.4 Institutional sales (MOH, Armed Forces, etc.)

1.2 Breakdown of sales (in value and volume)

1.2.1 by region (geographic distribution)

1.2.2 by major therapeutic class

1.2.3 by second level therapeutic class

1.2.4 by dosage form (tablets, capsules, drops, syrups, injectables, creams and ointments, powders, suppositories and others[60]

1.3 Numbers of brands in major therapeutic classes subdivided in essential and non-essential drugs.

1.4 Number of brands in the top 10 or 20 Corporations.

1.5 Decoding of all dosage form volume sales in active ingredients, excipients and packaging materials presented in kgs, tons, litres, etc.

2. Importation of finished and semi-finished drugs (f.o.b. constant prices)

2.1 Historical data

2.2 Classification

2.2.1 by therapeutic class

2.2.2 by dosage form

2.2.3 by country of origin

2.2.4 by essential or non-essential drug

2.2.5 by finished or semi-finished category

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[60] pastilles, troches, emulsions, sprays, lotions

3. Importation of raw materials (active ingredients, excipients and packaging materials).

4. Drug Imports and Exports vs total imports and exports.

5. National Pharmaceutical Industry[61]

5.1 Estimated manufacturing capacity utilization ratios and incremental capacity of the industry by dosage form.

5.1.1 ampoules and vials

5.1.2 suspensions

5.1.3 tablets and capsules

5.1.4 creams and ointments

5.1.5 large volume of parenterals

5.1.6 suppositories

5.2 Pharmaceutical manufacturing[62]

5.2.1 Companies operating manufacturing units (including those producing generics for the MOH).

5.2.1.1 The formal and informal organization, the organization levels and span of management, line and staff authority relationship (functional and administrative authority), delegation of authority[63], etc.

5.2.1.2 The management and its managerial competence and skills in the technical commercial and financial fields, the managerial functions (planning, organizing, staffing, leading and controlling), the management tools with particular emphasis to the production and operation management, including all activities necessary to produce and deliver the product to the buyer, such as purchasing, warehousing, manufacturing and transportation. As far as the manufacturing function is concerned, particular care should be taken when analysing the type of products and the manufacturing mix, the available technology (license agreements, technical assistance agreements, manufacturing

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[61] General overview and its historical background, the actual stage of development and growth potential, degree of horizontal and vertical integration.

[62] It is realized that, due to the confidential nature of the data and to the fact that most of the pharmaceutical manufacturing units belong to the private sector, detailed information may not be available for point 5.2.

[63] Detailed audit encompassing all aspects of the organization, the management and the operations, as well as their performance.

contracts, etc.), the existing and incremental capacities and their utilization ratios, the manufacturing efficiency (flow charts, time and motion studies), the industrial costs, the allocation of expenses and the manufacturing margin, the production programme and budgets, the machinery and equipment and the capital investment plans for replacement, improvement or extension and their origin, etc.

5.2.1.3 The personnel and the personnel policies (number, recruitment, manpower development with career path planning, contract labour, wage scale systems, incentive programmes, pension funds, medical care and health insurance, canteen service, living accommodations, social and sporting activities, etc.)

5.2.1.4 Other functions such as internal control, financing, financial and cost accounting with complete performance analyses of balance sheets, income statement and pertinent rates (internal rate of return, return on equity, return on sales, etc.), marketing and sales, repair and maintenance (mechanical, electrical, electronic, etc.) and their respective degrees of efficiency and expense levels.

5.2.1.5 The quality control and quality assurance functions with their human, material and financial resources.

5.2.1.6 The site with eventual extension possibilities, the disposition and state of the buildings, the general services with the supply of water, steam, electricity, gas compressed and cooled air, the solvent yard and the recuperation of solvents, the purification system and installations, the safety and loss prevention measures, etc.

5.2.1.7 The existing R & D level, its facilities and resources.

5.2.1.8 The available technologies and their transfer, as well as the transfer of modern management concepts and techniques.

5.2.1.9 The presence and development state of some auxiliary industries such as paper, cardboard, glass, plastics, rubber, metal, solvents, sugar, food colorants, etc., as well as related industries manufacturing condoms, intrauterine devices, laboratory and dispensary equipment, diagnostics, syringes and needles, infusion sets and systems, nursing supplies, etc. (gloves, masks drapes, dressing bandages, plasters, etc.), formulation and packaging of veterinary drugs and animal feeds.

5.2.1.10 The existence of supporting functions such as repair, preventive maintenance, manufacture of spare parts, etc.

5.2.2 Manufacturers without plant[64]

5.3 Potential for upstream integration[65]

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[64] Manufacturing under temporary shelters, on trucks, caravans, etc.

[65] See also 5.2.1.7, 5.2.1.8, 5.2.1.9, 5.2.1.10 and 8.8

5.3.1 The availability of raw materials from agricultural origin[66] (including agrowaste).

5.3.2 The medical flora and its geographical distribution in a spontaneous and cultivated state.

5.3.3 The livestock, the slaughterhouses capacity, storage and freezing facilities and the availability and utilization of animal organs for the manufacture of bio-active substances[67].

5.3.4 The national transportation and communication system and their respective infrastructure.

5.3.5 The situation with consultancy organizations and their expertise in the design, the engineering and the project management.

5.3.6 The construction expertise and the existing enterprises, the availability of construction materials, the construction costs, etc.

5.3.7 The available foreign and domestic industrial financing options and the respective Government rules and regulations.

5.3.8 The multilateral and bilateral financial and technical assistance programmes and their socio-economic impact.

VI. Pricing of pharmaceuticals

1. Average annual growth rate (taking into account prices of imported raw materials, the foreign exchange rates and domestic inflation, tax rates, etc.)

2. Comparisons of consumer prices and drug prices and their trends.

3. Comparisons of the price movements of the pharmaceutical industry with other industries.

4. Comparisons of pharmaceutical prices with other countries.

5. The pharmaceutical industry cost structure.

5.1 Cost of goods manufactured and sold

5.2 Operating expenses (administrative and marketing)

5.3 Detailed marketing and sales promotion expenses (samples, medical visits, advertising, exhibitions, promotional material, personnel costs, operating margin per marketing employee).

6. Profitability of the pharmaceutical industry:

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[66] Such as corn used for the manufacture of cornsteep liquor, starch, syrup and oil, or molasses basic materials used in the fermentation of antibiotics.

[67] Such as the pancreas glands for the production of "Insulin".

6.1 return on sales

6.2 return on equity

6.3 return on assets

6.4 comparative profitability of the pharmaceutical industry to other industries

7. Supply and distribution :

7.1 distribution channels

7.2 distribution outlets

7.3 distribution chart

7.4 estimated distribution costs

8. Estimation of the potential consumption of pharmaceuticals, or the evolution of the demand.

8.1 The drug consumption at a given time and its historical development trends.

8.2 Demography

- 8.2.1 total population
- 8.2.2 population by age group and age pyramid
- 8.2.3 structure of the population
- 8.2.4 birth rate and fertility
- 8.2.5 mortality by age and sex
- 8.2.6 life expectancy at birth
- 8.2.7 population growth projections
- 8.2.8 aging of the population

8.3 Health state and epidemiology[68].

8.4 Health infrastructure[69]

8.5 The GNP per capita and the distribution of wealth.

8.6 Percentage distribution of total family expenditure by major expenditure group.

8.7 Factors conditioning the level of expenses :

- 8.7.1 size of the family

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[68] See also para IV 6.

[69] See also para IV 5.1.2.

8.7.2 income of the family

8.7.3 global household expenses

8.7.4 socio-professional category of the family head

8.7.5 housing and living conditions

8.7.6 place of settlement (rural or urban)

8.7.7 proximity to health facilities and distribution outlets.

8.8 The academic institutions abilities, capacities and budgets to educate and train medical, paramedical and pharmaceutical personnel, as well as highly specialized individuals on the technical, commercial and managerial fields, such as ;

- industrial pharmacists
- microbiologists
- chemists
- engineers (civil, structural, mechanical, electrical) etc.

8.9 The development of new drugs, new delivery systems and new therapeutic schemes.

G. EDUCATION

1. Adult Literacy[70]

2. Maximum years of schooling

3. Scientists/technicians (per 000)

4. Primary enrollment ratio

5. Secondary enrollment ratio

6. Tertiary enrollment ratio

6.1 Number of University Institutions forming medical doctors and pharmacists.

6.1.1 Education curriculum and uniformity of education

6.1.2 Years of study

6.1.3 Annual number of university graduates in these fields and type of degrees.

6.1.4 Training subsidies

6.1.5 Annual budget distribution

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[70] According to the statement of the Minister of State for Economic Affairs (April 20, 1992) the present adult literacy rate is of 16%. Every eight Pakistani is barely literate.

H. **NATIONAL ANNUAL BUDGET.**

1. Allocation to various Universities

2. Expenditure as a percentage of GNP

3. The VIIth (1988-1993) and VIIIth Five Year Plans (1993-1998)

9. SUMMARY

1. On the basis of a critical and objective analysis of the existing situation, the study should aim at a realistic assessment of the real demand for essential medicines, corresponding to the health needs of the country, and at ways and means to meet this demand.

2. In the light of the existing system for creating and stimulating the demand for medicines, the study should recommend options to encourage their rational use to activate the human resources development, as well as the conduct of operational and applied research studies.

3. The study should identify measures to enhance the formulation and packaging of pharmaceutical products to bring a high level of self-sufficiency in the country, coupled with a gradual up-stream integration in the manufacture of active ingredients through fermentation synthesis and semi-synthesis, the exploitation of local flora and fauna, and the application of modern methods of biotechnology and genetic engineering.

10. PEOPLE MET

Ministry of Health

* Mr. A.R. Siddiqi, Secretary, Ministry of Health
* Dr. Syed Mohsin Ali, Director General Health /Additional Secretar
* Dr. F.R. Yussuf Fazli, Chairman,Quality Control Authority
* Dr. Sarwar H. Rehman, Deputy Director General Health
* Dr. Kamran Masud, Assistant Director General Health
* Shelkh Ansar Ahmad, Federal Inspector of Drugs

Ministry of Planning and Development

* Dr. S. Inam Kazmi, Senior Chief Health Planning

Economic Affairs Division

* Sheikh M. Saleem, Joint Secretary

Pharmacy Council

* Mr. Naziruddin Ahsan, Secretary, Pharmacy Council of Pakistan

Ministry of Industries

* Mr. Riazul Hag, Deputy Secretary/Director
* Mr. Abit Bashir, Deputy Secretary

University Grant Commission

* Prof. G. J. Pareshan Khattak, Chairman
* Mr. Saeed Ullah Shah, Adviser (Finance & Planning).
* Dr. M. H. Qazi, Member
* Mr. Mohammed Afzal, Director General, (Academy of Sciences)

National Institute of Health

* Dr. Abdul Ghafoor, Executive Director, National Institute of Health, Islamabad
* Mr. Zafar Ali, Chief, Biological Production Division
* Dr. Younas Sheikh, Homeopathy
* Dr. Shahzad Qazi, Allergy
* Mr. Khalid Mansoor, Senior Accountant

Pakistan Institute of Medical Sciences

* Mr. A. Q. Javed Iqbal, Chief Pharmacist

Pakistan Pharmaceutical Manufactures Association

* Mr. Jawaid Tariq Khan, Chairman
* Mr. Amjad Ali Jawa, Member
* Mr. Mubashar M. Khan, Secretary
* Mr. Riaz A. Sheikh, Risma Labs., Karachi
* Mr. Mohammad Amin Khan, Managing Director, ZAFA Pharmaceutical Labs., Karachi
* Dr. Herbert Mauer, Managing Director, Merck, Karachi
* Mr. Kamran Y. Mirza, Chairman & MD of Abbott Labs., Karachi

Wilson's Pharmaceuticals

* Mr. Saad Aziz Siddiqui, General Manager
* Mr. Muddasar Habib Sheikh, Partner

Rhone-Poulenc Pakistan (Pvt) Ltd.

* Mr. S. H. Askari, Pharmaceutical Production Manager
* Mr. M. Shabbir, Quality Control Manager

Overseas Investors Chamber of Commerce and Trade

* Mr. Farooq Hadi, Executive Director

Distributors

* Mr. Mohammad Akram Peracha, Managing Director, the Healers (Pvt) Ltd.
* Mr. M. Ishaq Sagi, Chief Executive, Medicate International (Pvt) Ltd.

Daily Business Recorder

* Mr. Ikramul Haq, Bureau Chief

UNDP

* Mr. H. C. Graf Von Sponeck, Resident Representative
* Miss Fatima Shah, Programme Officer
* Mr. Hans Bjorn Olsen, Programme Officer

UNIDO

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A N N E X E S

ANNEX I

HEALTH INSURANCE IN PAKISTAN

Health Insurance is fundamentally a conservative & universally accepted way of raising money in which every one participates with no extra burden on the government exchequer. This is an approach available today to provide health coverage to majority of the population specially in a country which is otherwise economically poor and administratively weak.

CHAPTER - I

SITUATION IN OTHER COUNTRIES

INSURANCE CONTRIBUTION:

For health insurance, different systems prevail in different parts of the world. However, in most countries, insurance contribution is made both by employees and employers whereas the government also pays a subsidy e.g. to help unemployed and retired individual and for the treatment of long illnesses such as tuberculosis (e.g. in Australia).

In some countries, health contributions are borne jointly by Social insurance and by charity and industry (Norway). In others, every one is required to pay an earmarked hospital contribution or a percentage of their earnings is deducted from the pay which is matched with equal contribution from the government (Canada & Germany). In some countries monies derived from contribution of worker and employers are used to purchase special services from government hospitals & thus government, from this money, is able to expand and improve its facilities (India, Tunisia).

NEW HEALTH FACILITIES:

In certain countries, new polyclinics and hospitals are developed for insured people whereas special care system is developed for them in the existing hospitals (Chile, Peru). In other countries social security organizations are operating their own network of hospitals and polyclinics for different occupational classes of people.

PAYMENT OF BILLS:

For insured persons, under certain systems, the company pays the bills directly to the hospitals or to the doctors. While in others, the patient himself pays the bill which is reimbursed by the insurance company some times to a certain limit (e.g. 80% of the official rate) for cost sharing in-order to discourage excessive use of facility. (Australia, Norway).

In some countries Capitation system of renumeration is used where insured one chooses a general partitioner who is paid fixed monthly sum per capita on the panel (UK.).

RESTRICTED DRUG LISTS AND FEES:

In most countries, in order to maintain solvency, restricted drugs are allowed through a formulary under generic names with approved prices, only from which

doctors can prescribe or according to which money is reimbursed (UK., Germany, Holland). Extra money if any is paid by the patient himself. In some cases, a certain percentage (e.g. 20%) of drug cost is borne by the patient himself in order to avoid over-use of drug. Similarly as a normal practice a schedule of fee is also fixed for the doctors.

FREE ENTERPRIZE:

In contract to the welfare state system of National Health Services in most European countries there exists completely free enterprize through health insurance scheme as for example in USA, where some 1200 companies write many thousands of different policies each year in which benefits, options limitations and exclusions are "uniformly non-uniform" with bewildering complexities. In that country, more people go for group insurance which provides better facilities than individual policies.

CHAPTER - II

PAKISTAN SITUATION

IMBALANCES IN HEALTH SECTOR:

In Pakistan there are many imbalances in the Health Sector. In that, almost 50% of health money goes for the care of only 10% of the population whereas the remaining 50% have imbalance in the amplitude with which they effect 90% of population with low income. Some saving in thus possible by directing a part of money from rich to the poor.

Another important imbalance is in the use of drugs in Government Sector for which 30 - 50% of the total recurring health expenditure is spent as against about 7 - 15% in developed countries of the world. This highlights the over-use of drugs and the need for changing doctor - public attitude towards drug use with a view to bringing rationality and thus to lower this unnecessary high cost on health care facilities. This is also an area from which savings can be effected for contribution towards health insurance.

QUACKERY AND ILLITERACY:

Quackery is rampant in the entire health sector in many ways; in modern medical practice, drug distribution system as well as in the traditional systems of medicine which are virtually devoid of any scientific base.

The country is of primarily agricultural society but aiming at moving towards industrial based economy. Almost 80% percent of the population is illiterate and lives in rural area where there are meager health care facilities. Historically and politically they expect free health services although economically the government is not in a position to offer the same. People are also not aware of the benefits of Health Insurance thus there is a need for a vigorous health education campaign.

CHAPTER - III

PROPOSALS

COLLECTIVIZING RESOURCES:

Collectivization of economic support through health insurance scheme with gradually rising degree of social discipline in operation of health care system may be one of the successful approaches for Pakistan. Thus choice is available for a mixed system based on free enterprise as that of America and of Social Welfare state through existing network supported by the government revenues.

Economic Support is possible through individual and collective financing which includes governmental revenues, personal payments, social insurance, voluntary insurance, industry as well as charity. Culturally, being Muslims believe in compassion for the poor. This feature along with Zukat and Baital Nal can significantly contribute to the success of the scheme.

MEASURES FOR AFFECTING SAVING:

The Government Hospitals continue to offer free or almost free treatment to the public but may adopt the following measures for developing system efficiency and for affecting savings for contribution to the Health Insurance Scheme.

Autonomy of hospitals:

(a) Under the Federal Government the Pakistan Institute of Medical Sciences and Federal Government Services Hospital and in the provinces, all teaching and big hospitals including all district hospitals be made autonomous with annual allocation of budget. These institutions should develop their own management system through which while improving their services they develop supplementary sources of financing.

User Charges:

(b) For developing better resources and to discourage unnecessary patients visits, under changes be introduced in every hospital as already recommended by various committees and experts in the past. In that a fix charges be required for every consultation and a certain percentage of expunges on surgical operations as well as for laboratory diagnostic testing.

Essential Drug List:

(c) Essential Drug List should be introduced throughout the country's hospitals and for Medical Store Depots. The doctors should be made to strictly follow this list which prescription outside this list should be the purchase liability of the patients.

Payment for Drugs:

(d) Even for the Essential Drugs supplied on hospital account, either certain percentage of the cost of medicine or a fix amount on each

prescription say Rs. 20 be payable by the patient with a view to minimize the expenditure on drugs.

Hospital Pharmacy:

(e) Hospital Pharmacy Service on modern line as for example in Agha Khan Hospital be introduced according to which unnecessary and over dispensing of drugs be discouraged. They have a maximum 800 drugs on their list for entire services. These measures alone can lead to sizeable saving from expenditure on drugs. The hospital pharmacy could run on self-sustaining basis from putting some charges on drugs supplies and from savings in the procurement of drugs which could be effected at 30-40% below the trade price on the basis of effective negotiations with the industry.

CHAPTER - IV

HEALTH INSURANCE LEVELS:

The Health insurance scheme may be introduced at three levels:

AGENCY	BASES	BODIES
Capital Govt.	Purely service oriented	Govt. Institution
Semi Govt.	Self-sustaining non-profit	Trusts/Foundations
Private	Profit oriented	Private Hospital/ Group Practicing Doctors

Each of them may operate its own Health insurance scheme system. They may also work in conjunction with Health Insurance Companies whom they may sell their services on mutually agreed terms in accordance with their own policies. Existence of all three agencies would help create competition and improve the quality of services with competing terms.

GOVERNMENT HOSPITAL INSURANCE PRINCIPLES:

Government may conduct health insurance in accordance with the following general principles for different categories of people through hospitals for comprehensive coverage and through Satellite Clinics for Primary Health Care.

A. HOSPITALS:

(i) Compulsory insurance: All person receiving salary or payment of regular allowance form the government may be required to have compulsory Health Insurance with any government hospitals by paying a nominal percentage (say 1 - 2%) of their basic salary. This insurance shall be transferrable to any other government hospitals on the request or transfer of employee to another station with a view of having not only a choice of treatment but will also create competition amongst the hospitals in providing better

(a) People above 60 years except those with income above a certain limit e.g. Rs 5000 pm.

(b) Jobless with no source of income.

(c) Disabled.

(iii) Free treatment for destitute: Destitute and poor with long illnesses such as tuberculosis should be given full free treatment. To help such persons and to determine their genuineness each hospital should set up a social welfare unit to whom deserving individual should approach for help.

(iv) Voluntary Insurance for Others: Other category of people be required to pay insurance contribution to which the hospital may provide some subsidy. Different packages of offer be prepared offering various types of facilities. Expenditure above the insured amount according to the agreed package if any, may be made by the person concerned.

(v) Varied System be introduced to identify various type and categories of insured persons.

B. SATELLITE CLINICS:

Rural Health Centre (R.H.C.) and Basic Health Units (B.H.U.) may also introduce a system of insurance by which the insured individual is offered some facilities for primary health care in accordance to Basic Health Insurance Plan with the facility of referral to the government hospitals where the patient receive treatment according to the above for different categories of people.

Rural Health Centres & Basic Health Centres should provide out patient services in return for a nominal monthly "capitation" (per person). People living in the vicinity covering the Health Centre or Unit should be manned with a qualified doctor from these funds. It should provide physician services for consultation and referral to government hospitals where needed.

(i) emergency medical service.

(ii) prescription drugs.

(iii) Preventive Health Service.

(iv) Immunization, mother and child care.

(v) Voluntary family planning service.

(vi) medical examination of each contributor at least once quarterly.

(vii) Child Delivery in normal delivery cases.

In addition to basic premium, small charges be required for certain services like home visits.

Each Rural Health Centre/Basic Health Unit which should offer free medical services as above along with necessary prescription drugs.

Method of Administration, a Local Management Committee headed by Member, Chairman Union Council, Rural Health Centre may be formed for running this programme.

TRUST AND FOUNDATIONS:

Two types of self sustaining non-profit organization, etc. may be allowed to offer Health Insurance Plans:

(a) Trust and Foundation already established and offer health care in one way or the other.

(b) Eidee Trust, Ansar Burney Trust, Patmeed, Shifa, Fouji Foundation, Shaheen, etc.

(c) NGO's e.g. Bahbood and others and Medical doctors may be allowed to establish non-profit organizations to offer health insurance to care for the patients who require health insurance.

Every physician who is a member of P.M.D.C. may also voluntarily become a member of such foundation upon payment of certain fixed membership fee. The condition for such membership is that the Physician must agree to accept reimbursement for services in accordance with the schedule of fees established by the foundations carriers. He must also agree to guarantee the coverage agreed on and be monitored with a view to help control costs and to provide quality of care.

Subscribers pay monthly premium and can select physician from the list approved by the Trust.

TRUST PRACTICE:

Physicians who render medical care in cooperative fashion located in one facility under one roof. Such groups are composed of general practitioner, internists, pediatricians, surgeons and similar other specialists with paramedical staff and auxiliary services. The size and nature of the community and availability of other health resources.

- Insurance contribution to be paid on monthly basis.
- All medical staff should be salaried.
- All facilities should be integrated under one roof and consultative services readily available.
- It may have Satellite clinics for screening patients in the neighborhood.
- It should work 24 hours a day & 365 days a year by having doctors on call.
- It should offer only voluntary insurance coverage that should be comprehensive including both out patient and in patient home care health services and drug coverage. Health education and early diseases through the use of multiphasic health examination.
- Quality of Service should be under constant review.
- Unnecessary surgery and hospitalization are checked.
- No claim form to complete.
- Office visits and home care physician visitation fees should be nominal.
- A system of review be introduced to improve quality of service.

MONITORING OF INSURANCE ACTIVITIES:

While assessing insurance policies, it is important to evaluate the benefit cost ratio which would provide essential information about the performance of the companies in terms of the amount of funds collected which is returned to the insured. Such companies should not be allowed to operate whose benefit to the insured is less than 50%.

Continued efforts have to be made to encourage physicians, hospitals and others to hold down costs or to change their manner of operation to function more economically about retaining their quality of service.

Preventive Health Services such as routine Pap smear tests, immunization and periodic health examinations should also be one of the responsibilities of insurance companies.

In case of private insurance companies, it should be regulated in order to avoid any deceptive or misleading advertising.

Hospital benefits paid by the insurance companies should be tax free.

CHAPTER - V

HEALTH INSURANCE PLANS (H.I. PLANS)

Following Health insurance plans could be introduced.

A. PLAN : ADDITIONAL HEALTH INSURANCE PLANS

- Dental Service - Normal dental procedures such as examination, filing, extractions, clearing, provision of special dentures could also be included as extra payment for orthodontia, endo-dentin, bridge work, oral surgery and periodontia.
- Rehabilitation services
- Vision cares
- Hearing aids
- Cancer Treatment

B. PLAN : BASIC HEALTH INSURANCE PLAN

- Out patient Service
- Referral to Hospitals for complicated diseases
- Supply of prescription drugs

C. PLAN : COMPREHENSIVE HEALTH INSURANCE PLAN

- Out patient Service
- Hospital admissions

- Board facilities
- Routine nursing services
- Intensive care
- Laboratory and diagnostic facilities
- Operation room charges
- Surgical charges up to a certain limit or unlimited
- Extended Care - Post operative care after hospital discharge
- Maternity care - pre-natal, natal post natal care

D. PLAN : DISABILITY HEALTH INSURANCE PLAN

- For providing compensation due to disability
- Low income due to loss of work-hours

E. PLAN : ESPECIAL HEALTH INSURANCE PLAN

- Above benefits and with following supplementary benefits: Catastrophic coverage due to serious injury or cardiac care prolonged illness.
- Private Nursing care and special duty nurse
- physiotherapy
- Emergency ambulance service
- Convalescent home care
- Home calls
- Psychiatric care
- Blood, plasma, etc.

F. PLAN : FAMILY HEALTH INSURANCE PLAN

- Family Plan should cover the entire family in accordance with the contract of any of the above mentioned plans.

PACKAGE DEVELOPMENT

(a) Package Development: Different Packages may be developed defining extent and limitation of each package. It is understood that the higher the benefit, the higher the cost.

(b) Payment Policy: This may be considered if payment is to be made the patient following reimbursement by the insurance company or the company pays directly to the hospital/Physician/Surgeon.

ANNEX II

LIST OF REGISTERED PAKISTAN PHARMACEUTICAL UNITS

MINISTRY OF HEALTH, SPECIAL EDUCATION AND SOCIAL WELFARE

S. No.	Name of the Firm
Punjab	
1.	M/s A.W. Labs., Rawalpindi
2.	M/s Azad Cottage Indust., Lahore
3.	M/s Albro Manuf. Phar. Chemist, Lahore
4.	M/s Ali Indust., Lahore
5.	M/s Adil Pharma, Lahore
6.	M/s Alfajar Pharmatex Ltd., Sialkot
7.	M/s Antibiotics, Mianwali
8.	M/s B.I. Drug Co., Lahore
9.	M/s Barrington Pharma, Maultan
10.	M/s Biosynth Pharma, Rawalpindi
11.	M/s Biolabs, Rawalpindi
12.	M/s Consolidated, Lahore
13.	M/s Cyrus Pharma, Lahore
14.	M/s Cresent Cotton, Okara
15.	M/s cotton Craft Ltd., Lahore
16.	M/s Country Cotton Indust., Raiwind
17.	M/s Data Labs., Lahore
18.	M/s Dawn Labs., Lahore
19.	M/s Dosaco Labs., Lahore
20.	M/s Ethical Labs., Lahore
21.	M/s Everaids, Islamabab
22.	M/s Elixir Labs., Lahore
23.	M/s Elder Ghulam Masih, Gujranwala
24.	M/s Errowrute Labs., Rawalpindi
25.	M/s Ellies Labs., Rawalpindi
26.	M/s Fakma Pharma, Lahore
27.	M/s Folks Pharma, Lahore
28.	M/s Falcon Pharma, Gujranwala
29.	M/s Ferro Pharma, Islamabad
30.	M/s Farm Adi Group Pak, Islamabab
31.	M/s Fine Indust., Mian Channu
32	M/s Glaxo Labs., Lahore
33.	M/s Hussain Traders, Multan
34.	M/s Highnoon Labs., Lahore
35.	M/s Hassco Chemical Indust., Multan
36.	M/s Hydro Pharmaceutical, Lahore
37.	Harmann Pharmaceutical, Lahore
38.	M/s Hassco Chemical
39.	M/s Irza Pharma, Lahore
40.	M/s Ideal Pharmaceutical Indust., Lahore
41.	M/s IPHCO, Lahore
42.	M/s Irish Pharma, Sialkot
43.	M/s Jamson Pharmaceutical Labs., Multan
44.	M/s Kurram Chemical, Rawalpindi
45.	M/s Koninoor Cotton Indust., Sahiwal
46.	M/s Kalco Pharma, Lahore
47.	M/s Koninoor Cotton Indust., Sahiwal
48.	M/s Karim Indust., Raiwind
49.	M/s Kamtex Cotton Indust., Gujranwala
50.	M/s Lahore Chemical & Pharmaceutical Works, Lahore

51. M/s Lahore Pharma, Lahore
52. M/s Leonine Pharma, Lahore
53. M/s Life Pharmaceutical Co., Multan
54. M/s Maqi Chemical, Lahore
55. M/s Mian Brothes, Lahore
56. M/s Marshal Pharmaceutical, Lahore
57. M/s Micko Indust. Chem., Lahore
58. M/s Medipharm, Lahore
59. M/s Mohammad Ishaq & Co. Lahore
60. M/s Medipak Ltd., Lahore
61. M/s Meditex Int'l., Lahore
62. M/s Medivet Pvt Ltd., Lahore
63. M/s Multipharma, Lahore
64. M/s National Health Labs., Islamabad
65. M/s National Labs., Lahore
66. M/s Nawabsons Labs., Lahore
67. M/s N.H. Shahani, Faisalabad
68. M/s National Drug House, Faisalabad
69. M/s N.. Medicot, Multan
70. M/s National Textile Indust., Faisalabad
71. M/s Orient Labs., Lahore
72. M/s Olympia Labs., Sheikhupura
73. M/s Oval Pharmaceutical, Lahore
74. M/s Orta Labs., Lahore
75. M/s Punjab Drugs House, Lahore
76. M/s P.D.H., Lahore
77. M/s Popular Chemical Works, Lahore
78. M/s Pharmedic Labs., Lahore
79. M/s Pharmacare Labs., Lahore
80. M/s Pacific Pharm., Lahore
81. M/s Popular Chemical Works, Lahore
82. M/s Qamar Cotton Indust., Okara
83. M/s Reko Pharmaceutical, Lahore
84. M/s Rhone & Poulenc, Wah Cantt
85. M/s Reimngton Pharmaceutica, Lahore
86. M/s Redex Drug House Labs., Faisalabad
87. M/s Rehman Pharm, Attock City
88. M/s Rehman Phar, Attock City
89. M/s Rana Chemical & Pharm, Sialkot
90. M/s Shifa Labs., Lahore
91. M/s Schazoo Labs., Lahore
92. M/s Stand Pharm, Lahore
93. M/s Shah Brothers, Faisalabad
94. M/s Star Labs, Lahore
95. M/s Standard Chemical, Lahore
96. M/s Shamsi Pharmacy, Lahore
97. M/s Spectrum Pharmaceutical, Lahore
98. M/s Sharex Labs., Dist. Rahimyar Khan, Sadiqabad
99. M/s Sarco Chemical Indust., Multan
100. M/s Sapient Pharma, Lahore
101. M/s Standard Manuf. Co., Lahore
102. M/s Soma Labs., Lahore
103. M/s Shan Cotton Indust., Faisalabad
104. M/s Siza Inter., Lahore
105. M/s Surgical Textile, Multan Road, Patoki
106. M/s Sethi Indust., Chichawatni
107. M/s Syed & Sons, Gujranwala
108. M/s The Government Medical Store Depot, Lahore
109. M/s Unexo Labs., Lahore
110. M/s Umer Sons, Islamabad
111. M/s Unison Chemical Works, Lahore
112. M/s United Drugs Co., Lahore

113. M/s Unik Chem. Sheikhupura
114. M/s Venus Pharma(R), Lahore
115. M/s Veterinary Farms Adi, Sheikhupura
116. M/s Virgo Manufacture Chemists, Multan
117. M/s Wyeth Labs., Lahore
118. M/s Wallishnaria Pharma, Lahore
119. M/s Wilshire Labs., Lahore
120. M/s Wilson's Pharmaceuticals, Islamabad
121. M/s Zeb Labs., Lahore
122. M/s Zaco (Pak) Reg., Lahore

Sind

1. M/s Adamjee Pharm, Karachi
2. M/s Afan Pharma, Karachi
3. M/s Anglo French Drug, Karachi
4. M/s Abbott Labs., Karachi
5. M/s Ali Chemical, Karachi
6. M/s Ali Gohar, Karachi
7. M/s Afan Pharma, Karachi
8. M/s Ankaz Pharmex, Karachi
9. M/s Ahsons Drug Co., Tando Adam Sindh
10. M/s Anglo, Karachi
11. M/s Atco, Karachi
12. M/s Ardin, Karachi
13. M/s Bliss Indust., Karachi
14. M/s Brookes Pharm, Karachi
15. M/s Brookes Pharm, Karachi
16. M/s Bayer Pharma, Karachi
17. M/s Boots, Karachi
18. M/s Beecham, Karachi
19. M/s Catts, Karaci
20. M/s Cynamid, Karachi
21. M/s Ciba-Geigy, Karachi
22. M/s Coronet Enterprises, Karachi
23. M/s CKD Pharma, Karachi
24. M/s Chas-A-Mendoza, Karachi
25. M/s Elililly-Gohar, Karachi
26. M/s Eros, Karachi
27. M/s Eforze Chemical, Karachi
28. M/s Elko Org., Karachi
29. M/s Fabcon Intl, Karachi
30. M/s Glaxo, Karachi
31. M/s Geofman, Karachi
32 M/s Gabs Pharm, Karachi
33. M/s Grandiphar, Hyderabad
34. M/s Hospitex Intl, Dist, Dadu
35. M/s Hilton, Karachi
36. M/s Hoechst, Karachi
37. M/s Hakimsons Chem., Karachi
38. M/s H.P.L. Pharma, Karachi
39. M/s Indust. Pharma, Karachi
40. M/s Johnson & Johnson, Karachi
41. M/s Karachi Pharm, Karachi
42. M/s Karka, Karachi
43. M/s Karachi Chemical, Karachi
44. M/s Lisko, Karachi
45. M/s M.S.D., Karachi
46. M/s Medicure Labs., Karachi
47. M/s Meredoa, Karachi
48. M/s M/s Estern Pharm, Karachi
49. M/s Macter, Karachi

50. M/s Medicaids, Karachi
51. M/s Marvi, Karachi
52. M/s Nabviquasim Indust., Karachi
53. M/s Opal Labs., Karachi
54. M/s Organon, Karachi
55. M/s Progressive Cotton, Nooriabad
56. M/s Parke Davis, Karachi
57. M/s Pfizer Labs., Karachi
58. M/s Pioneer, Karachi
59. M/s Pakistan Pharm. & Chemical, Karachi
60. M/s Pakistan Pharm. Product, Karachi
61. M/s Progressive, Karachi
62. M/s Pharmakon, Karachi
63. M/s Prema Product, Karachi
64. M/s Reckitt & Colman, Karachi
65. M/s Regent Labs., Karachi
66. M/s Risma, Karachi
67. M/s Roche, Karachi
68. M/s Squibb, Karachi
69. M/s Sandoz, Sind
70. M/s SK & F, Karachi
71. M/s Sterling, Karachi
72. M/s Specific Research, Karachi
73. M/s SJ & G Fazul Ellahi, Karachi
74. M/s Sind Alkalis, Karachi
75. M/s Semi Pharm, Karachi
76. M/s Standard Drug Co., Hydreabad
77. M/s Smith & Nephew, Karachi
78. M/s Spencer Pharma, Karachi
79. M/s Shahbaz Labs., Hyderabad
80. M/s Tabros Pharma, Karachi
81. M/s The National Absorbent Cotton Mills, Karachi
82. M/s Wellcome, Karachi
83. M/s W. Woodward, Karachi
84. M/s Zafa, Karachi
85. M/s Zantock Pharma, Hyderabad

N.W.F.P.

1. M/s Atantic Pharma, Peshawar
2. M/s convell Labs., Faizabad, Saidu Sharif, Swat
3. M/s Fedro Pharma, Swat
4. M/s Ferozesons Labs., Nowshera
5. M/s Healer Labs., Peshawar
6. M/s I.P.P., Saidu Sharif, Swat
7. M/s Polyfine Cempharma, Peshawar
8. M/s Sibro Pharma, Nowsheera
9. M/s Swat Pharma, Swat
10. M/s S.D.H. Labs., Peshawar
11. M/s Hizat Pharmaceutical Indust., (Pvt) Ltd Peshawar

BALUCHISTAN

1. M/s A.D. Marker Alkaloids, Quetta
2. M/s Azad Manufacturing Indust., Lasbella
3. M/s Gelcaps Pak Ltd., Baluchistan
4. M/s Kaligon Agro Indust., Baluchistan
5. M/s Otsuka Pak Ltd., Baluchistan
6. M/s Pliva Pak Ltd., Baluchistan
7. M/s Qamar Indust., Quetta
8. M/s Swe-Pak Pharm, Baluchistan

ANNEX III

LIST OF ESSENTIAL DRUGS FOR PAKISTAN

Drugs	Route of Administration, dosage forms, and strengths
1. Anaesthetics	
1.1 General anaesthetics and oxygen	
ether, anaesthetic	inhalation
diazepam	injection, 5 mg/ml in 2 ml ampoule
halothane	inhalation
ketamine	injection, 50 mg/ml in 10 ml vial
nitrous oxide	inhalation
oxygen	inhalation (medicinal gas)
thiopental	powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule
1.2 Local anaesthetics	
bupivacaine	injection, 0.25%, 0.5% (hydrochloride) in vial
lidocaine	injection. 1% 2% (hydrochloride) in vial
	injection, 1%, 2% + epinephrine 1:100000 in vial
ethyl chloride	spray
2. Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs and Drugs Used to Treat Gout	
2.1 Non-opioids	
acetylsalicylic acid	tablet, 100-500 mg
allopurinol	tablet, 100 mg
ibuprofen	tablet, 200 mg
indomethacin	capsule or tablet, 25 mg
paracetamol	tablet, 500 mg
colchicine	tablet, 0.5 mg
probenecid	tablet, 500 mg
diclofenac	tablet, 25, 50 100 mg
lysine acetylsalicylate	injection
dipyrone	injection, 1000 mg in 2 ml
2.2 Opioid analgesics	
morphine	injection, 10 mg (sulfate or hydrochloride) in 1 ml ampoule
pethidine	injection, 100 mg (hydrochloride) in 2 ml ampoule
pentazocine	tablet, 25 mg
	injection, 30 mg in 1 ml ampoule
3. Antiallergic	
chlorpheniramine	tablet, 4 mg (maleate)
	injection, 10 mg in 1 ml ampoule

promethazine	syrup 2 mg in 5 ml injection 5 mg per 5 ml ampoule
dexamethasone	tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1 ml ampoule
epinephrine	injection, 1 mg (hydrochloride) in 1 ml ampoule tablet, 5 mg

4. Antidotes and other Substances Used in Poisonings

4.1 General

charcoal, activated	powder
ipecacuanha	syrup, containing 0.14%
ipecacuanhaalkaloids	calculated as emetine
magnesium sulfate	powder 10-30 g

4.2 Specific

atrophine	injection 1 mg (sulfate) in 1 ml ampoule
deferoxamine	injection, 500 mg (mesylate) in vial
dimercaprol	injection in oil, 50 mg/ml in 2 ml ampoule
naloxone	injection, 0.4 mg (hydrochloride) in 1 ml ampoule
sodium calcium edentate	injection, 200 mg/ml in 5 ml ampoule
sodium nitrite	injection 30 mg/ml in 10 ml ampoule
sodium thiosulfate	injection, 250 mg/ml in 50 ml ampoule
methylthioninium chloride	injection 10 mg/ml in 10 ml ampoule
penicillamine	capsule or tablet, 250 mg

5. Antiepileptics

diazepam	injection 5 mg/ml in 2 ml ampoule
ethosuximide	capsule or tablet, 250 mg
phenobarbital	tablet, 50 mg, 100 mg syrup, 15 mg/5 ml
phenytoin	capsule or tablet, 25 mg, 100 mg (sodium salt) injection, 50 mg (sodium salt)/ml in 5 ml
carbamazepine	tablet, 200 mg
valproic acid	tablet, 200 mg (sodium salt)

6. Anti-infective Drugs

6.1 Anthelminthic drugs

mebendazole	tablet, 100 mg
niclosamide	tablet, 500 mg
piperazine	tablet, 500 mg (citrate or adipate) elixir or syrup (citrate) equivalent to 500 mg hydrate/5 ml
praziquantel	tablet, 600 mg
pyrantel	chewable tablet, 250 mg (embonate) oral suspension, 50 mg (embonate)/ml
thiabendazole	chewable tablet, 500 mg

6.2 Antiamoebic drugs

diloxanide	tablet, 500 mg (furoate)
metronidazole	tablet, 200-500 mg
dehydroemetine	injection, 60 mg (hydrochloride) in 1 ml ampoule
di-iodohydroxyquinoline	tablet, 650 mg oral suspension 300 mg per 5 ml

6.3 Antibacterial drugs

6.3.1 Penicillin

ampicillin	capsule or tablet, 250 mg, 500 mg (anhydrous) powder for oral suspension, 125 mg (anhydrous)/5 ml powder for injection, 500 mg (sodium salt) in vial
benzathine benzylpenicillin	injection, 1.44 g benzylpenicillin (=2.4 million IU) 5 ml in vial
benzylpenicillin	powder for injection, 0.6 g (=1 million IU), 3.0 g (=5 million IU) (sodium or potassium salt) in vial
cloxacillin	capsule, 500 mg (sodium salt) powder for injection, 500 mg (sodium salt) in vial
phenoxymethylpenicillin	tablet, 250 mg (potassium salt) powder for oral suspension, 250 mg (potassium salt)/ 5 ml
procaine benzylpenicillin	powder for injection, 1 g (=1 million IU), 3 g (=3 million IU)
amoxycillin	tablet, 250 mg injection, 500 mg powder for injection syrup 125 mg per 5 ml

6.3.2 Other antibacterial drugs

chloramphenicol	capsule, 250 mg powder for injection, 1 g (sodium succinate) in vial oral suspension, 150 mg in 5 ml (palmitate salt)
erythromycin	capsule or tablet, 250 mg (stearate or ethyl succinate) oral suspension, 125 mg (stearate or ethyl succinate) in 5 ml powder for injection, 500 mg (lactobionate) in vial
gentamicin	injection, 10 mg, 40 mg (sulfate)/ml in 2 ml vial
metronidazole	tablet, 200-500 mg injection, 500 mg in 100 ml

salazosulfapyridine	tablet, 500 mg
spectinomycin	powder for injection, 2 g (hydrochloride) in vial
sulfadimidine	tablet, 500 mg
	oral suspension, 500 mg/5 ml
	injection, 1 g (sodium salt) in 3 ml ampoule
sulfamethoxazole+ trimethoprim	tablet, 100 mg + 20 mg, 400 mg + 80 mg
	oral suspension 100 mg + 20 mg per 5 ml
tetracycline	capsule or tablet, 250 mg (hydrochloride)
doxycycline	capsule or tablet, 100 mg (hydrochloride)
	injection, 100 mg (hydrochloride)/5 ml in ampoule
nitrofurantoin	tablet, 100 mg

6.3.3 Antileprosy drugs

clofazimine	capsule, 50 mg, 100 mg
dapsone	tablet, 50 mg, 100 mg
rifampicin	capsule or tablet, 150 mg, 300 mg
ethionamide	tablet, 125 mg, 250 mg
protionamide	tablet, 125 mg

6.3.4 Antituberculosis drugs

ethambutol	tablet, 100-500 mg (hydrochloride)
isoniazid	tablet, 100 mg, 300 mg
pyrazinamide	tablet, 500 mg
rifampicin	capsule or tablet 150 mg, 300 mg
streptomycin	powder for injection 1 g (sulfate) in vial
thiacetazone + isoniazid	tablet, 150 mg + 300 mg

6.4 Antifilarial drugs

diethylcarbamazine	tablet, 50 mg (citrate)
suramin sodium	powder for injection, 1 g in vial

6.5 Antifungal drugs

amphotericin B	powder for injection, 50 mg in vial
griseofulvin	tablet or capsule, 125 mg, 250 mg
nystatin	tablet, 500 000 IU
	pessary, 100 000 IU
	oral suspension, 100 000 IU per ml
flucytosine	capsule, 250 mg
	infusion, 2.5 g in 250 ml
ketoconazole	tablet, 200 mg

6.6 Antimalarial drugs

chloroquine	tablet, 150 mg (phosphate or sulfate)
	syrup, 50 mg (phosphate or sulfate)/5 ml
primaquine	tablet, 7.5 mg, 15 mg (phosphate)
quinine	tablet, 300 mg (bisulfate or sulfate)
	injection, 300 mg (dihydrochloride)/ml in

	2 ml ampoule
amodiaquine	suspension, 150 mg (hydrochloride)/5 ml
	tablet, 200 mg (dihydrochloride dihydrate)
sulfadoxine + pyrimethamine	tablet, 500 mg + 25 mg
mefloquine	tablet, 250 mg (base)

7. Antimigraine Drugs

ergotamine	tablet, 2 mg (tartrate)
ergotamine with caffeine	tablet 1 mg + 100 mg

8. Antineoplastic and Immunosuppressive Drugs

8.1 Immunosuppressive drugs

azathioprine	tablet, 50 mg
	powder for injection, 100 mg (sodium salt) in vial

8.2 Cytotoxic drugs

bleomycin	powder for injection, 15 mg (sulfate) in vial
calcium foliate	tablet, 15 mg
	injection, 3 mg/ml in 10 ml ampoule
cisplatin	powder for injection, 10 mg, 50 mg in vial
cyclophosphamide	tablet, 25 mg
	powder for injection, 500 mg in vial
cytarabine	powder for injection, 100 mg in vial
dactinomycin	powder for injection, 0.5 mg in vial
doxorubicin	powder for injection, 10 mg, 50 mg (hydrochloride) in vial
etoposide	capsule, 100 mg
	injection, 20 mg/ml in 5 ml ampoule
fluorouracil	injection, 50 mg/ml in 5 ml ampoule
mercaptopurine	tablet, 50 mg
methotrexate	tablet, 2.5 mg (sodium salt)
	injection, 50 mg (sodium salt) in vial
procarbazine	capsule, 50 mg (hydrochloride)
vinblastine	powder for injection, 10 mg in vial
vincristine	powder for injection, 1 mg, 5 mg (sulfate) in vial

8.3 Hormones and antihormones

dexamethasone	tablet, 0.5 mg, 4 mg
	injection, 4 mg (sodium phosphate) in ampoule
prednisolone	tablet, 5 mg
	injection, 20 mg, 25 mg (sodium phosphate or succinate) in vial
tamoxifen	tablet, 10 mg, 20 mg

9. Antiparkinsonism Drugs

biperiden	tablet, 2 mg (hydrochloride) injection, 5 mg (lactate) in 1 ml ampoule
levodopa + carbidopa	tablet, 100 mg + 10 mg, 250 mg + 25 mg
bromocriptine	tablet, 2.5 mg
amantadine	capsule, 100 mg

10. Blood, Drugs affecting the

10.1 Antianaemia drugs

ferrous salt (fumarate or gluconate)	tablet, equivalent to 60 mg iron oral solution, equivalent to 15 mg iron in 0.6 ml
ferrous salt - folic acid	tablet, 60 mg + 200 ug tablet, 1 mg injection, 1 mg (sodium salt) in 1 ml ampoule
hydroxocobalamin	injection, 1 mg in 1 ml ampoule
iron dextran	injection, equivalent to 50 mg iron/ml in 2 ml ampoule

10.2 Anticoagulants and antagonists

heparin	injection, 1000 IU/ml, 5000 IU/ml, 20,000 IU/ml in 1 ml ampoule
phytomendaione	injection, 10 mg/ml in 5 ml ampoule
protamine sulfate	injection, 10 mg/ml in 5 ml ampoule
warfarin	tablet, 5 mg (sodium salt)
dipyridamole	tablet, 25 mg

11. Blood Products and Blood Substitutes

11.1 Plasma substitutes

dextran 70	injectable solution, 6%
polygeline	constituted as haemaccel.

11.2 Plasma fractions for specific uses

albumin, human	injectable solution, 25%all plasma fractions factor VII concentrate (dried) should comply Processing
factor IX Complex	(coagulation and Quality Control of factors II, VII, IX) concentrate (dried) Human Blood and Blood Products

12. Cardiovascular Drugs

12.1 Antianginal drugs

glyceryl trinitrate	tablet, (sublingual) 0.5 mg
isosorbide dendrite	tablet. (sublingual) 5 mg
propranolol	tablet, 10 mg, 40 mg (hydrochloride)
	injection, 1 mg (hydrochloride) in 1 ml ampoule
verapamil	tablet, 40 mg, 80 mg (hydrochloride)
	injection, 2.5 mg/ml (hydrochloride) in 2 ml ampoule
nifedipine	capsule, 10 mg
	tablet (sustained release), 20 mg

12.2 Antidysrhythmic drugs

isoprenaline	tablet, 10 mg, 15 mg (hydrochloride or sulfate)
lidocaine	injection, 20 mg (hydrochloride_)/ml in 5 ml ampoule
propranolol	tablet, 10 mg, 40 mg (hydrochloride)
	injection, 1 mg (hydrochloride) in 1 ml ampoule
atenolol	tablet, 50 mg
metoprolol	tablet, 100 mg
quinidine	tablet, 200 mg (sulfate)
procainamide	tablet, 250 mg, 500 mg (hydrochloride)
	injection, 100 mg (hydrochloride)/ml in 10 ml ampoule
verapamil	tablet, 40 mg, 80 mg (hydrochloride)
	injection, 2.5 mg/ml (hydrochloride) in 2 ml ampoule
nifedipine	capsule, 10 mg
	tablet (sustained release), 20 mg

12.3 Antihypertensive drugs

hydralazine	tablet, 50 mg (hydrochloride)
hydrochlorothiazide	tablet, 50 mg
propranolol	tablet, 40 mg, 80 mg (hydrochloride)
sodium nitroprusside	powder for preparing infusion, 50 g in ampoule
reserpine	tablet, 0.1 mg, 0.25 mg
	injection, 1 mg in ml ampoule
methyldopa	tablet, 250 mg
captopril	tablet, 25 mg, 50 mg, 100 mg
labetalol	tablet, 100 mg
prazosin	tablet, 1 mg

12.4 Cardiac glycosides

digoxin	tablet, 0.0625 mg, 0.25 mg
	oral solution, 0.05 mg/ml
	injection, 0.25 mg/ml in 2 ml ampoule
digitoxin	tablet 0.05 mg, 0.1 mg
	oral solution, 1 mg/ml
	injection, 0.2 mg in 1 ml ampoule

12.5 Drugs used in shock or anaphylaxis

dopamine	injection, 40 mg (hydrochloride)/ml in 5 ml vial
epinephrine	injection, 1 mg (hydrochloride) in 1 ml ampoule
dobutamine	powder for preparing infusion, 250 mg vial

13. Dermatological Drugs

13.1 Antifungal drugs

benzoic acid +	ointment or cream 6% + 3% salicylic acid
miconazole	ointment or cream 2% (nitrate)
nystatin	ointment or cream, 100 000 IU/g
clotrimazole	cream, 1%

13.2 Anti-infective drugs

gentian violet	aqueous or alcoholic solution, 1%
neomycin + bacitracin	ointment, 5 mg neomycin sulfate + 500 IU bacitracin zinc/g
silver sulphadiazine	cream, 1%

13.3 Antiinflammatory and antipruritic drugs

betamethasone	ointment or cream, 0.1% (valerate)
calamine lotion	lotion
hydrocortisone	ointment or cream, 1% (acetate)

13.4 Astringent drugs

aluminum acetate	solution, 13% for dilution
aluminum chloride	solution, topical, 10-30% hexohydrate

13.5 Keratoplastic and keratolytic agents

coal tar	solution, topical 20%
podophyllin	solution, 10-25%
salicylic acid	solution, topical 5%
dithranol	ointment or cream, 0.25%, 0.5%
8-methoxypsoralen	solution, topical, 1%. tablet, 10mh.

13.6 Anti-acne agents

benzoyl peroxide	cream, 5% and 10%

13.7 Scabicides and pediculicides

benzyl benzoate	emulsion, 25%
lindane	cream or lotion, 1%

14. Diagnostic Agents

14.1 Ophthalmic drugs

fluorescein	eye drops, 1% (sodium salt)

14.2 Radiocontrast media

meglumine amidotrizoate	injection 60% in 20 ml ampoule
sodium amidotrizoate	injection, 50% in 20 ml ampoule
barium sulfate	powder
lopanoic acid	tablet, 500mg
propyliodone	injection, 600 g/l in 20 ml ampoule
lohexol	injection, 300 mg in 5 or 10 ml ampoule
lotroxate	solution, 8 g (iodine) in 100 to 250 ml
metrizamide	solution, 3.75 g or 6.75 g in 20 ml.

15. Disinfectants

chlorhexidine	solution, 5% (digluconate) for dilution
iodine	solution, 2.5%
gentian violet	topical solution, 1%
povidone iodine	solution, 10%

16. Diuretics

amiloride	tablet, 5 mg (hydrochloride)
furosemide	tablet, 40 mg
	injection, 10 mg/ml in 2 ml ampoule
hydrochlorothiazide	tablet, 50 mg
mannitol	injectable solution, 10%,, 20%
spironolactone	tablet, 25 mg
bendroflumethiazide	tablet, 2.5 mg

17. Gastrointestinal Drugs

17.1 Antacids and other antiulcer drugs

aluminum hydroxide	tablet, 500 mg
	oral suspension, 320 mg/5 ml
cimetidine	tablet, 200 mg
	injection, 200 mg in 2 ml ampoule
magnesium hydroxide	oral suspension, equivalent to 550 mg
magnesium oxide	10 ml
calcium carbonate	tablet, 600 mg
ranitidine	tablet, 150 mg
sucralfate	tablet, 1 g

17.2 Antiemetic drugs

promethazine	tablet, 10 mg, 25 mg (hydrochloride)
	elixir or syrup 5 mg (hydrochloride)/5 ml

	injection, 25 mg (hydrochloride)/ml in 2 ml ampoule
metoclopramide	tablet, 10 mg (hydrochloride) injection, 5 mg/ml in 2 ml ampoule

17.3 Antispasmodic drugs

atropine	tablet, 1 mg (sulfate) injection, 1 mg (sulfate) in 1 ml ampoule
hyoscine butylbromide	tablet, 10 mg injection, 20 mg per ml

17.4 Cathartic drugs

senna	tablet, 7.5 mg (sennosides) or traditional dosage forms
bisacodyl	tablet, 5 mg
glycerine	suppositories, 70%

17.5 Diarrhoea, Drugs used in

17.5.1 Antidiarrheal (symptomatic) drugs

furazolidone	tablet, 100 mg
kaolin + pectin	suspension: 5.832 g + 0.130 g per 30 ml

17.5.2 Replacement solution

oral rehydration salts	g/litre
sodium chloride	3.5
trisodium citrate dihydrate	2.9
potassium chloride	1.5
glucose	20.0

18. Hormones

18.1 Adrenal hormones and synthetic substitutes

dexamethasone	tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1 ml ampoule
hydrocortisone	powder for injection, 10 mg (sodium caseinate) in vial
prednisolone	tablet, 5 mg
fludrocortisone	tablet, 0.1 mg (acetate)

18.2 Androgens

testosterone	injection 200 mg (enantate) in 1 ml ampoule injection, 25 mg (propionate) in 1 ml ampoule

18.3 Contraceptives

ethinylestradiol + levonorgestrel	table, 0.03 mg + 0.15 mg, 0.05 mg + 0.25mg
ethinylestradiol + norethisterone	tablet, 0.05 mg + 1.0 mg
depot medroxyprogesterone acetate	injection, 150 mg in 3 ml vial
norethisterone	tablet, 0.35 mg injection, 200 mg in vial (enantate)

18.4 Estrogens

ethinylestradiol	tablet, 0.05 mg

18.5 Insulins and other antidiabetic agents

insulin injection (soluble)	injection, 100 IU ml in 10 ml vial
intermediate acting insulin	injection, 100 IU/ml in 10 ml vial (as compound insulin zinc suspension or isophane insulin)
NPH insulin	injection, 100 IU/ml in 10 ml vial
glibenclamide	tablet, 5 mg
chlorpropamide	tablet, 250 mg
metformin	tablet, 500 mg

18.6 Ovulation inducers

clomifene	tablet, 50 mg (citrate)

18.7 Progestogens

norethisterone	tablet, 5 mg

18.8 Thyroid hormones and antithyroid drugs

levothyroxine	tablet, 0.05 mg, 0.1 mg (sodium salt)
potassium iodide	tablet, 60 mg
propylthiouracil	tablet, 50 mg
carbimazole	tablet, 5 mg
Lugol's iodine	solution, 5%

18.9 Preparations of diabetes insipidus

desmopressin (DDAVP)	solution, 100 ug/ml injection, 4 ug in 1 ml ampoule

19. Immunologicals

19.1 Diagnostic agents

tuberculin, purified protein derivative (PPD)	injection

19.2 Sera and Immunoglobulins

anti-D immunoglobulin (human)	injection, 0.25 mg/ml
antirabies hyperimmune serum	injection, 1000 IU in 5 ml amp.
antivenom sera	injection
antiscorpion sera	injection
diphtheria antitoxin	injection, 10 000 IU, 20 00 IU in vial
immunoglobulin, human normal (2)	injection
tetanus antitoxin	injection, 50 000 IU in vial
tetanus antitoxin (human)	injection, 500 IU in vial

All plasma fractions should comply with the WHO requirements for the collection, processing and quality control of human blood and blood products.

19.3 Vaccines

19.3.1 For universal immunization

BCG vaccine (dried)	injection	All vaccines should comply with the WHO Requirements for Biological Substances.
diphtheria-pertussis tetanus vaccine	injection	
diphtheria-tetanus vaccine	injection	
measles vaccine	injection	
poliomyelitis vaccine (inactivated)	injection	
poliomyelitis vaccine (live attenuated)	oral solution	
tetanus vaccine	injection	

19.3.2 For specific groups of individuals

influenza vaccine	injection
meningococcal vaccine	injection
rabies vaccine	injection
typhoid vaccine	injection
yellow fever vaccine	injection
Hepatitis B vaccine	injection

20. Muscle Relaxants (Peripherally Acting and Cholinesterase Inhibitors

gallamine	injection, 40 mg (triethiodide)/ml in 2 ml ampoule
neostigmine	tablet, 15 mg (bromide)
	injection, 0.5 mg (methylsulfate) in 1 ml

	ampoule
suxamethonium	injection, 50 mg (chloride)/ml 2 ml ampoule
pyridostigmine	tablet, 60 mg (bromide)
	injection, 1 mg (bromide) in 1 ml ampoule
d-Tubocurarine chloride	injection, 15 mg/ml
pancuronium bromide	injection, 2 mg/ml

21. Ophthalmological preparations

21.1 Anti-infective agents

sulfacetamide	eye ointment, 10% (sodium salt)
	solution (eye drops), 10% (sodium salt)
tetracycline	eye ointment, 1% (hydrochloride)
chloramphenicol	eye ointment 1%
gentamicin	solution (eye drops) 0.3%

21.2 Antinflammatory agents

betanethasone	eye ointment, 0.1%
	solution (eye drops), 0.1%

21.3 Local anaesthetics

tetracaine	solution (eye drops) 0.5% (hydrochloride)

21.4 Miotics and antiglaucoma drugs

acetazolamide	tablet, 250 mg
pilocarpine	solution (eye drops), 2% 4% (hydrochloride or nitrate)
timolol	solution (eye drops), 0.25% 0.5% (maleate)
levobunolol	solution (eye drops), 0.5%

21.5 Mydriatics

homatropine	solution (eye drops), 2% (hydrobromide)
epinephrine	solution (eye drops), 2% (hydrochloride)

22. Oxytocics

ergometrine	tablet, 0.2 mg (maleate)
	injection, 0.2 mg (maleate) in 1 ml ampoule
oxytocin	injection, 10 IU in 1 ml ampoule

23. Peritoneal Dialysis Solution

intraperitoneal dialysis solution	parenteral solution (of appropriate composition)

24. Psychotherapeutic Drugs

24.1 Antidepressants

amitriptyline	tablet, 25 mg (hydrochloride)
maprotiline	tablet, 10 mg

24.2 Antipsychotic drugs

chlorpromazine	tablet, 100 mg (hydrochloride) syrup, 25 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2 ml ampoule
fluphenazine	injection, 25 mg (decanoate or enanthate) in 1 ml ampoule
haloperidol	tablet, 2 mg injection, 5 mg in 1 ml ampoule

24.3 Antimonic drugs

lithium carbonate	capsule or tablet, 300 mg

24.4 Hypnotics and sedatives

diazepam	tablet, 5 mg
lorazepam	tablet, 1 mg

25. Respiratory Tract, Drugs Acting on the

25.1 Anti-asthmatic drugs

aminophylline	tablet, 100 mg, 200 mg injection, 25 mg/ml in 10 ml ampoule
epinephrine	injection, 1 mg (hydrochloride) in 1 ml ampoule
salbutamol	tablet, 4 mg (sulfate) oral inhalation (aerosol), 0.1 mg (sulfate) per dose syrup, 2 mg (sulfate)/5 ml injection, 50 ug/ml in 5 ml ampoule
beclometasone	oral inhalation (aerosol), 0.05 mg (dipropionate)
cromoglicic acid	oral inhalation (cartridge), 20 mg (sodium salt) per dose
ephedrine	tablet, 30 mg (hydrochloride) elixir, 15 mg (hydrochloride)/5ml injection, 50 mg (sulfate) in 1 ml ampoule

25.2 Antitussives

pholcodine	tablet, 10 mg
dextromethodrophan hydrobromide	tablet, 10 mg

26. Solutions Correcting Water, Electrolyte and Acid-Base Disturbances

26.1 Oral

oral rehydration salts	For composition see 17.5.2 Replacement solution
potassium chloride	oral solution

26.2 Parenteral

Ringer	lactate
	1/6 molar lactate
Hartman	solution
potassium chloride	injection
7.5% sodium bicarbonate	injection normal saline, 1/2 normal saline
glucose 5%, 10% 25%, 50%	solution
10% fat emulsion I.V	injection
amino acid	infusion

dextrose 4.3% with 1/5 normal saline
5% dextrose with 1/2 normal saline

27. Vitamins and Minerals

ascorbic acid	tablet, 50 mg
ergocalciferol	capsule or tablet, 1.25 mg (50 000 IU)
	oral solution, 0.25 mg/ml (10 000 IU)
nicotinamide	tablet, 50 mg
pyridoxine	tablet, 25 mg (hydrochloride)
retinol	capsule or tablet, 7.5 mg (25 000 IU) 60 mg (200 000 IU)
riboflavin	tablet, 5 mg
sodium fluoride	tablet, 0.5 mg (fluoride)
thiamine	tablet, 50 mg (hydrochloride)
calcium gluconate	injection, 100 mg/ml in 10 ml ampoule

ANNEX IV

*DRUGS FOR TWENTY-TWO COMMON DISEASES

ALLERGIC DISORDERS	
Chlorphenamine Maleate	Tab. 4 mg
ANEMIA	
Ferrous Sulphate	Tab. 200 mg Syp. 200 mg/5 ml Drops 125 mg/5 ml
Folic Acid	Tab. 1 mg
Calcium Lactate	Tab. 300 mg
ASTHMA	
Ephedrine (1st line)	Tab. 30 mg
Theophylline (2nd line)	Tab. 200 mg
BOILS AND SKIN INFECTIONS	
Sulphadimidine	Tab. 500 mg
DIABETES	
Glibenclamide	Tab. 5 mg
DIARRHOEA	
Phthalylsulfathiazole	Tab. 500 mg
Metronidazole	Tab. 200mg
O.R.S.	
Daphenoxylate+Atropine 0.25 mg	Tab. 2.5 mg+
Promethazine	Tab. 25 mg
EAR INFECTIONS	
Sulphadimidine	Tab. 200 mg
Paracetamol	Tab. 500 mg
EPILEPSY (FITS)	
Phenobarbitone	Tab. 30 mg
EYE INFECTIONS	
Sulfacetamide	Eye Drops 20%
GENERAL PITTING OEDEMA	
Furosemide	Tab. 40 mg
Potassium Chloride	Tab. 500 mg
HYPERTENSION	
Bendroflumethazide	Tab. 2.5 mg

Sorbide Dinitrate	Tab. 5 mg Tab. 10 mg
Glyceryl trinitrate	Tab. 0.5 mg
JOINTS (INFLAMMATION)	
Aspirin	Tab. 300 mg
MALARIA	
Chloroquine	Tab. 150 mg Syp. 50 mg
Paracetamol	Tab. 500 mg
PELVIC INFECTIONS	
Tetracycline	Cap. 250 mg
Metronidazole	Tab. 200 mg
PSYCHIATRIC DISORDERS	
Amitriptyline	Tab. 25 mg Tab. 75 mg
Chlorpromazine Hydrochloride	Tab. 25 mg Tab. 50 mg
Diazepam	Tab. 2 mg Tab. 5 mg
RESPIRATORY TRACT INFECTIONS	
Sulphadimidine	Tab. 500 mg
Paracetamol	Tab. 500 mg
SCABIES	
Benzyl Benzoate	Emulsion 25%
SKIN IRRITATION	
Calamine Lotion	
TUBERCULOSIS	
Ethambutol	Tab. 400 mg
Isoniazid	Tab. 100 mg
Pyrazinamide	Tab. 500 mg
INH+Etham butyl+Pyrazinamide	
INH+Ethambutol	
TYPHOID	
Cotrimoxazole 80 mg	Tab. 400 mg+
Paracetamol	Tab. 500 mg

URINARY TRACT INFECTIONS

Nitrofurantoin (for pregnant women)	Tab. 100 mg
Sulphadimidine	Tab. 500 mg

WORMS

Nitlosamide (Tape Worm)	Tab. 500 mg
Pyrantal (Embonate)	Tab. 250 mg

* As per part VI para 42. Ref: controlled list

ANNEX V

LIST OF PHARMACEUTICAL RAW MATERIALS BEING MANUFACTURED IN PAKISTAN BY WAY OF BASIC/SEMI BASIC PROCESSES

1. Aluminum Hydroxide Gel
2. Ammonium Chloride
3. Broxyquinoline
4. Betamethasone 17-Valerate
5. Betamethasone Di-Sodium Phosphate
6. 18-Beta-Glycyrhitinic Acid
7. Betamethasone
8. Basoquin
9. Castor Oil
10. Clobetasol 17-propionate
11. Crude Glycyrrhizic Acid
12. Caffeine Citrate
13. 16-Dehydropregnolone Acetate
14. Ephedrine and its salts
15. Ferrous Fumarate
16. Ferric Ammonium Citrate
17. Griseofulvin
18. Gypsona Plaster of Paris Bandages
19. Potassium Citrate
20. Penicillin (Benzyl Penicillin & Phenoxymethyl Penicillin)
21. Paragon Zinc Oxide Plaster
22. Paragon Zinc Oxide Tape
23. Paragon Capsicum Adhesive Plaster
24. Ranitidine
25. Surgical Sutures and Ligatures (all types)
26. Sodium Citrate
27. Sodium Chloride
28. Santonin
29. Salbutamol
30. Stucca Plaster of Paris Bandages
31. Trichloro-ethyl Phosphate
32. Grude Diosgenin 90 to 95%
34. Calcium Stearate
35. Magnesium Stearate
36. Magnesium Trisilicate
37. DDT
38. B.H.C.
39. Sodium Bicarbonate

ANNEX VI

THE DRUGS ACT, 1976

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DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976

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RULES

RULES

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(Drugs for repacking)

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(Disease advertisement for treatment of which is prohibited)

ANNEX VII

ASIAN INVESTMENT INCENTIVES COMPARED

In September 1987, the SGV Group conducted a survey of current investments incentives in nine (9) Asian countries : China, Hongkong, Indonesia, Malaysia, the Philippines, Singapore, South Korea, Taiwan, and Thailand. The results of that survey are contained in a publication entitled "1988 Comparative Investment Incentives", portions of which are reproduced in this report with the kind permission of SGV.

The tally shows that the Philippines places itself at the base of the tail of the most generous givers of incentives to foreign investors, garnering a total of 20 incentives offered out of the 39 incentives and guarantees upon which the comparative ranking was based. The following ranking of the Asian countries surveyed, measured by the number of incentives made available out of the perfect score of 39, tells the story more graphically :

Rank	Name of Countries	No. of Incentives Given	% Out of 39
1	Malaysia	31	80
2	Taiwan	28	72
3	South Korea	27	70
	Singapore	27	70
4	Thailand	26	67
	China	26	67
5	Indonesia	22	57
6	Philippines	20	52
7	Hongkong	19	49

It is interesting to know that all of the above mentioned countries, except the Philippines and Indonesia, allow foreigners to own land in their respective territories.

A summary of the incentives offered by the countries surveyed is presented on the following pages.

A list of the nineteen (19) out of the thirty-nine (39) incentives that the Philippines does not offer but offered by other Asian countries to foreign investors include :

1. Guarantees against losses due to nationalization.
2. Guarantees against losses due to damage caused by war.
3. Guarantees against losses due to inconvertibility of currency.
4. Preference in the granting of government loans.
5. Protection against import competition. /ooo/

6. Protection against government competition. /ooo/

7. Real estate ownership by alien investors. /ooo/

8. Exemption from capital gains taxes.

9. Exemption from taxes on royalties.

10. Exemptions from withholding tax on interest on foreign loans (tax credits).

11. Accelerated depreciation allowance. /.../ooo/

12. Carry forward of capital allowance during the relief period. /ooo/

13. Carry forward of loss. /.../ooo/

14. Export allowance or deduction.

15. Deduction of organization expenses. /.../ooo/

16. Deduction of reinvestment of profits. /ooo/

17. Deduction of pre-operating expenses. /.../ooo/

18. Investment tax credits. /.../ooo/

19. Technical assistance to investors.

NOTA BENE :

a) The incentives immediately followed by triple asterisks (...) were included in the original Investments Incentives Act (RA 5186). For some unknown reasons, these incentives were deleted from the new Omnibus Investments Code (ED 226).

b) The incentives followed by triple bullets (ooo) are recommended by this report for inclusion in an improved package of incentives for the Philippines. This will upgrade the country's batting average to 30 out of 39, putting it right behind Malaysia in the comparative scale.

c) Two additional incentives, not included in the SGV Group Survey, are recommended for inclusion especially where they apply to the drug industry:

i. Exemption from custom duties and entry taxes for imported scientific equipment and parts for exclusive use in R&D to discover new product lines or improve existing ones; tax credits for locally manufactured scientific equipment.

ii. Drug procurement by the Government shall be sourced from local manufacturers, where available.

SUMMARY OF COMPARATIVE INVESTMENT INCENTIVES
(Based on a Survey of the SGV Group; with the Permission of SGV)

Countries Surveyed	MAL	TWN	KOR	SNG	THN	CHI	IND	PHI	HKG
Against 39 Considered, Number offered	31	28	27	27	26	26	22	20	19
Basic Rights and Guarantees									
Guarantee Against Expropriation Guarantee Against Losses due to:									
a) Nationalization	yes	yes	yes	yes	yes	yes	yes	yes	yes
b) Damage Cause by War	yes	no	no	yes	yes	yes	yes	no	no
c) Inconvertibility of Currency	yes	no	no	no	no	yes	yes	no	no
Remittance of foreign exchange earning and payments	yes	yes	yes	yes	yes	yes	yes	yes	yes
Repatriation of capital	yes	yes	yes	yes	yes	yes	yes	yes	yes
Protection Schemes and Priorities Given To Investors and Aliens									
Employment of Aliens	yes	yes	yes	yes	yes	yes	yes	yes	yes
Patent Protection	yes	yes	yes	yes	yes	yes	yes	yes	yes
Preference in the Granting of Government Loans	yes	yes	no	yes	yes	no	no	no	no
Protection Against Unjust Competition									
a) Import Competition	yes	yes	yes	no	yes	no	yes	no	no
b) Government Competition	no	no	no	no	yes	no	no	no	no
c) Local Competition	yes	no	no	no	yes	no	yes	yes	no
Real Estate Ownership by Alien Investors	yes	yes	yes	yes	yes	yes	no	no	yes
Exemption from Taxes and Tariff Duties									
Capital Gains Tax	yes	yes	yes	yes	yes	yes	yes	no	yes
Corporate Income Tax	yes	yes	yes	yes	yes	yes	no	yes	yes
Taxes on Imported Capital Goods	yes	yes	yes	yes	yes	yes	no	no	no
Taxes on Royalties	yes	yes	yes	yes	yes	yes	yes	yes	yes
Taxes on Imported Raw Materials	yes	yes	yes	yes	no	yes	yes	no	yes

Withholding Tax on Interest on Foreign Loans (Tax Credit)									
Other Taxes and Fee	no	yes	yes	yes	yes	yes	yes	yes	no
Deductions from Taxable Corporate Income									
Accelerated Depreciation Allowance	yes	yes	yes	yes	no	yes	no	no	yes
Carry forward of Capital Allowance during the Relief period	yes	no	no	yes	no	no	no	no	no
Carry forward of Loss	yes	yes	yes	yes	yes	yes	yes	no	yes
Export Allowance/Deductions	yes	yes	yes	yes	yes	no	no	no	no
Deduction of Organization and Pre-Operating Expenses									
a) Organization Expenses	yes	yes	yes	no	yes	yes	yes	no	no
b) Pre-operating Expenses	yes	yes	yes	no	yes	yes	yes	no	yes
Reinvested Profits	no	yes	no	no	yes	no	no	no	no
Investment Allowance	yes	yes	yes	no	yes	yes	yes	no	yes
Tax Credits (Direct Reduction from Corporate Income Taxes)									
Investment Tax Credits	yes	yes	yes	no	no	no	no	no	no
Tax Credit on Domestic Capital Equipment	no	yes	yes	no	no	no	no	yes	no
Other Tax Credits	yes	yes	yes	no	no	yes	yes	yes	no
Extension of Incentive Availment Period	yes	yes	yes	yes	no	yes	no	yes	no
Special Incentives									
To Multinational companies	nc	no	no	no	no	no	no	yes	no
To Exporters	yes	yes	yes	yes	yes	yes	yes	yes	yes
To Offshore Banking Units	yes	yes	no	yes	no	no	no	yes	no
Other Laws Granting Benefits to Foreign Investor	no	no	no	yes	yes	yes	no	yes	yes
Assistance to Investor									
Joint Venture Brokerage	yes	no	yes	yes	yes	yes	yes	yes	yes
Technical Assistance	yes	yes	yes	yes	yes	yes	no	no	yes

Processing of Application and Other Requirements	yes	yes	yes	yes	yes	yes	yes	yes	yes

LEGEND :

MAL - MALAYSIA	TWN - TAIWAN	KOR - SOUTH KOREA
SNG - SINGAPORE	THN - THAILAND	CHI - CHINA
IND - INDONESIA	PHI - PHILIPPINES	HKG - HONGKONG

Source : 1988 Comparative Investment Incentives Published by the SGV Group.

ANNEX VIII

REPORT OF THE COMMITTEE OF E.C.C.

ON PHARMACEUTICAL SECTOR

1. The E.C.C. in a meeting held on 24th April, 1991, while considering a Summary submitted by the Health Division regarding indexation of drug prices, decided to constitute a Committee under the Chairmanship of Dr. M. Tarig Siddigi, Director General, Civil Services Academy, Lahore and consisting of representatives of the Ministry of Health, Industries and Commerce with the following terms of reference:

   i. Examination of the existing controls and recommending the extent to which the Pharmaceutical Industry should be de-regulated.

   ii. Evolving of a retail pricing formula of drugs.

   iii. Suggesting measures to increase proportion of the domestic manufacture of drugs.

   iv. Review the system of registration of drugs.

   v. Examine the Report of the Senate Committee on Pharmaceuticals chaired by Senator Javed Jabbar.

2. The Committee held meetings with the representatives of concerned departments, pharmaceutical trade and industry and cross section of public to hear their views on the concerned issues. Mr. Akbar Ali Bhatti, M.N.A., was also invited in a meeting as per directive of the Standing Committee of National Assembly on Health.

3. The Committee found that the existing controls were related mainly to licensing of manufacture drugs, imports, drug registration, pricing and quality assurance which needed examination along with other issues, identified above. All these are therefore discussed as follows:

CHAPTER - I: EXISTING CONTROLS ETC.

1. **Licenses for Drug Manufacture:** Drug manufacturing Licenses are issued by a Central Licensing Board set up by the Ministry of Health, comprising of 18 members drawn from the Federal Ministries of Health, Industries, Commerce, C.B.R. and provincial Governments and technical experts from the fields of Medicine and Pharmacy. The Director General (Health) is the Ex-Officio Chairman and the Drug Controller is the Ex-Officio Secretary. Any person who fulfills the requirements for getting license as prescribed under the Drugs Act 1976 and the Drug (Licensing, Registering and Advertising) Rules 1976 is issued the necessary manufacturing license which is valid and renewable for a period of two years at a time. The Board, for the performance of its functions, meets every one to two months. Whereas, license continues to be valid if the application for renewal is received within validity but the actual renewal takes much longer time for want of inspection.

2. Four types of licenses are issued namely Formulation, Semi-Basic Manufacture, Basic Manufacture and Re-Packing. Presently some 226 Companies, including 29 multinationals, have been issued such licenses

in the country as per details in Annexure-I.

3. **Import of Raw Materials:** Any person holding a drug manufacturing license can import raw and packing materials for drug formulation from any source. Whereas import of such materials of "exclusive use" in drug manufacture is allowed duty free, those "not" of exclusive use, mostly inactive, are allowed to be released from Customs on 1 bank/insurance guarantee. This guarantee is released after certificate of the consumption of such materials in drug manufacture is issued by the Assistant Drug Controller who also issues another certificate at the time of import to the effect that the quantity of such raw material being imported is actually required for the manufacture of drugs. Both these certificates are in fact issued in routine on the basis of statement of the Company and not on actual verification on the spot which in any case is not humanly possible.

4. **Drugs Registration:** All drugs which are meant for manufacture, import, export or sale have to be registered with the Drug Registration Board which is the same and meets in the same manner as that of Central Licensing Board. The main purpose of registration is to evaluate the safety, efficacy, quality and economy of the drug. The procedure for registration is that application on a prescribed proforma is received by the Drug Control Section. The case for registration is placed before the Registration Board in its forthcoming meeting and the decision is communicated to the applicant. The whole process of disposal of the application usually takes about 2 to 3 months after the applicant has fulfilled all the formalities. However, some special or new drugs or formulations and some imported drugs require reference to experts and specialists or laboratories for evaluation and advice before registration, while in other cases, applicants' factory needs to be inspected. This necessitates more time and thus some delay may occur in disposal of such cases.

5. The certificate of registration, unless suspended or canceled, remains in force for a period of 5 years from the date of issue, renewable for a similar period each time.

6. At present, there are about 12,000 registered drugs out of which about 9000 are manufactured locally, while the remaining 3000 are imported in the finished form. The later are registered in view of the medical needs and to ensure adequate supply of drugs. Registrations are also withdrawn on grounds of toxicity.

7. **Drug Pricing:** Under the present policy, drugs which are manufactured by way of formulation in the country, as well as all imported finished drugs, are subject to price control. Price fixation is done by the Drug Registration Board as one of the conditions of drug registration on the recommendation of the Cost Accountant.

8. Price fixation of drug is based on the estimates of expenditure submitted by the manufacturing firms and on the basis of following formula:

IMPORTED DRUGS:	Cost and freight + Mark up of 40 percent = Maximum Retail Price.
LOCAL DRUGS:	Prime Cost (Cost of raw and packing materials + direct labor) + Mark up of 75 percent = Maximum Retail price.

9. **Transfer Pricing:** It is seen that there are large number of pharmaceutical raw materials imported by the multinationals in which transfer pricing is taking place (Annexure-II). Many companies try to justify this on the basis of superior quality and research expenses incurred by the parent company.

10. **Variation in Prices:** there is a great variation in the price of the same product originating from different sources under different brands. In that the multinationals always have the higher prices.

11. **Appellate Board:** Under the Drugs Act, an Appellate Board consisting of representatives from Federal and Provincial Government, law and medical experts have been set up by the Federal Government to hear appeals against any decision of Central Licensing and Registration Board in respect of Licensing, Registration or Pricing.

CHAPTER - II: SITUATION ANALYSIS

1. **Drug Market:** The drug market on trade price in 1991 was estimated to the tune of Rs 12 billion showing an increase of 400% since 1982. Out of 12000 registered drugs, only about 380 are with sale market above Rs 5 million and which comprise nearly 75% of the total drug market. Out of 226 companies manufacturing drugs, 15 companies constitute 50% of the total sale by value as well as by volume. A comparison of their turnover in 1991 with 1982 shows that most of these companies have increased in their turnover from 300 to 500% in the last 9 years. Thus despite availability of large number of competitors of the same product both from local manufacture and import under generic as well as under different brand names, the brand leaders continue to enjoy monopoly.

2. Unlike other commodities, pharmaceutical marketing is very specialized where general rules of competition are not applicable. For medicines, the demand is created for specific brands by the industry through sales promotion in which the multinationals dominate because of their vast experience in marketing. In drug use the choice is with the prescriber who is generally influenced by the aggressive sales promotion of the multinationals.

3. **Sales Promotion:** Of all the industries, pharmaceutical industry is the one which has highly organized system for sales promotion. This include services of highly trained men, giving off free samples, advertisement through medical journals, periodicals and beautifully presented literature and leaflets, besides holding Conferences, Symposiums and similar other activities. In order to boost up sales they also give bonuses and extra discounts sometimes as high as 50 to 60%.

4. **Drug Registrations:** The 12000 registered drugs are in fact the ramification of much lesser number of chemical entities or basic drugs since each dosage form and strength is granted as a separate registration with a view to identify such products to facilitate prescription by the doctors in accordance with the need of the patient. Out of these basic drugs, only about 400 can be termed as essential drugs which can meet the needs for prevention and treatment of prevalent diseases.

5. In order to grant registration, the drug should be effective and safe and the claims of indication are correct. It should also be checked that the manufacturers possesses necessary technical know how and

facilities to produce that particular drug and that the product does not counterfeit the design of another drug. However, due to inadequacy of staff, such a thorough scrutiny remains wanting.

6. Domestic Manufacturing of Drugs: In domestic production of drugs, the pharmaceutical industry has made phenomenal progress but only in drug formulation in which it is meeting about 80% of the country's requirements compared to nothing in 1947. There is however hardly any basic manufacture in the country. Although some 31 companies are licensed to conduct basic or semi-basic manufacture most of these are working only at an elementary level except for one major unit in private sector ie., Glaxo and two in the public sector, ie., M/s Antibiotics and M/s Kurrum,, the later has been sold to M/s Upjohn of U.S.A.

7. In fact, in 1960, a large number of units were set up which were closed down in early seventies after the policy of liberal import and consequently the investment became low. Besides following difficulties exist in conducting basic manufacture of drugs:-

   (a) Lack of petrochemical base for synthetic drugs;

   (b) Uneconomic size of production for fermentation based industry;

   (c) Non-availability of regular supply of medicinal herbs for production of plant based drugs;

   (d) Open Import of raw materials and of finished drugs from cheaper sources;

   (e) Lack of fiscal incentives; and

   (f) Duty on import of equipment and machinery for setting basic manufacturing plant.

8. In 1981-82 a new package of incentives was offered to encourage basic manufacture and thus M/s Glaxo expanded its basic manufacturing facilities in 1983 and now is producing six raw materials requiring high technology. This is resulting not only in foreign exchange savings of about Rs 150 million per year and earning through export of Rs 50 million/year. (total F.E. Saving Rs 200 million/year) but also bringing high technology and self-sufficiency in the field. Part of these incentives were however withdrawn later. This aspect along with complicated procedure of getting protection from C.B.R. discouraged further activity in the field.

DRUG PRICING

1. This has been one of the most controversial issues between the government and the industry and for that reason the relationship of the two have been rather somewhat tenuous. The Government believes that the public should receive the value for money it spends on the purchase of drugs while industry pleads that they do to earn adequate profit on investment and that higher prices are required to compensate for the rising trend in various elements of cost involved in drug production on which the government has no control. This matter has been discussed thoroughly with all concerned agencies including the Associations of drug industry and trade.

2. The Pakistan Pharmaceutical Manufacturers Association while strongly recommending total de-control have given commitment that they will not raise the prices unreasonably but have strongly opposed free import of

medicine as according to them it will ruin the local industry causing a serious blow to self reliance and rendering thousands of people jobless. Earlier, they had also recommended either fixing leader prices for all medicines with annual price indexation or to control prices of essential drugs only.

3. As regards transfer pricing, they have suggested that the authorities concerned may discuss this problem with the individual company as a consequence of which the prices of quite a number of finished drugs will automatically fall to a desirable level.

4. Earlier, in 1988, the Transnational subsidiaries, while requesting, from their formula total decontrol of drug prices and stoppage of imports of their competitive finished drugs, gave commitment to the following:

   (a) to reduce Transfer Prices of the materials to one of the lowest level of prices any where in the world;

   (b) to establish infirmaries, mainly in rural areas, to provide free medical treatment to one core people through 500 properly run clinics; and

   (c) to make life saving products available at a lower price by 25% under generic labels through company outlets.

5. The Pakistan Chemists and Druggists Association has recommended partial decontrol of prices and to control prices of drugs from five pharmacological groups feared to be monopolized by the pharmaceutical companies.

6. Price Control of drugs is indeed a very complex issue and difficult to conduct particularly when there are about twelve thousands drugs with a variety of packs each requiring price fixation. There is only one cost accountant and a Deputy Drugs Controller to handle this task. The Committee felt that the prime responsibility of the Health Ministry is to ensure quality control of drugs to which the Licensing and Registration Board and Quality Control Organization should give more time and emphasis. The drug prices should be left to the market forces to adjust which will provide impetus to the growth of the industry and to improve its manufacturing facilities.

7. **QUALITY ASSURANCE:** Various levels for quality assurance of drugs are as follows:

   (i) Licensing: At the time of Licensing and while granting license, it is ensured, after preliminary scrutiny of plans for establishing a unit and physical inspection of the premises by a panel of experts, that the company possesses adequate facilities to manufacture drugs applied for.

   (ii) Registration: At the time of registration the drug is to be evaluated for efficacy, safety and quality before granting registration.

   (iii) Post - Marketing Surveillance: Post marketing surveillance, a system of regular inspection of manufacturers and sellers and sampling through drug inspectors is already operating. The Federal Inspectors, eight in number at various provincial headquarters, check the manufacturing facilities while provincial inspectors appointed at the district level being 85, check primarily the sale of drugs, besides panel of inspector appointed from time to time for the pharmaceutical manufacturers.

8. **Testing Laboratories:** For drug testing, there are four laboratories one each in Punjab and NWFP, one at Federal level at Karachi and a most modern appellate laboratory at National Institute of Health. The Government of Sind is in the process of establishing its own. In these laboratories a total of about 11000 sample are tested per year. The results of testing in the drug testing laboratories however indicates that only 2-3 percent sample are found substandard per year which is quite normal in any country.

9. **Drug Administration:** The Drug Control Administration at the Federal and Provincial level are too small and ill-equipped to handle the problems of the industry.

10. **PATENT LAWS**

Patent laws provide for the process patent and with that the use of the product. However, the Ministry of Health is neither consulted before granting such a patent nor informed of its grant, extension or expiry. The length of the patent period for drugs is also too long. There is also a provision that the patentee within a certain period shall conduct local manufacture of the product. Similarly there is a provision for a compulsory licensing which is also being ignored. Consequently, no manufacture of the patent product by way of basic manufacture is taking place in the country.

11. The Senate Committee, in its report, has also recommended partial decontrol of drug prices by retaining control on essential drugs only. While in another occasion, it has recommended evolving a system of indexation for all drugs.

12. To encourage local industry, it recommends gradual reduction of imports of drugs and to remove import duty, sales tax and other surcharges on import of machinery for balancing and modernization which will certainly encourage expansion of the local industry. The committee also recommend 3 years tax holiday, an aspect which needs examination.

CHAPTER - III: RECOMMENDATIONS DEREGULATION MEASURES

1. **Licensing:**

Renewal of Licenses: The renewal of drug manufacturing licenses should be made automatic after the license has submitted inspection report for internal audit.

2. **PPMA Membership:** Membership of Pakistan Pharmaceutical Manufacture Association should be made compulsory for all manufacturers and for new licenses within a specified time say six months of receipt of drug manufacturing license. A PPMA member may also be included in the inspection panel appointed for the grant of license.

3. **Self Inspection by the Manufacturers:** The manufacturers are required to conduct regular self inspection for internal audit at least once a year and send a copy of the report to the Licensing Board. A PPMA member should be included in their internal audit team. The Licensing Board should also be informed of removal of defects found on self inspection. the Government inspector should need to conduct inspection for super check and to advise the industry in the areas of deficiencies.

4. **PC & DA Membership:** Similarly membership for Pakistan Chemists and Druggists Association should be made compulsory for all chemists. Their licenses should also be automatically renewed on receipt of license renewal fee and internal self inspection report by the PC & DA inspectors. The drug inspectors may take action for suspension or cancellation of license if they, at any stage, find serious violation of any of the conditions of license.

5. Working of Licensing Board: Present practice of consideration of all cases of quality control and GMP compliance by the Licensing Board may be modified to set up a smaller Committee of this Board to meet more frequently to consider such cases for quick disposal.

6. Raw Materials Imports: The practice of issuance of routine verification by Assistant Drug Controllers of quantitative assessment of requirement of raw and packing material of not exclusive use in the pharmaceutical industry and of issuance of rebate certificate may be dispensed with. Instead, the Customs authorities may obtain such statement and where necessary conduct verification regarding quantitative requirement of raw materials and their consumption after use. The Assistant Drug Controllers should be concerned only with the quality control inspections and sampling for which proper system be developed. On the other hand, in case of price decontrol in any form, the present facility of exemption from customs duty on raw material, which are not of exclusive use in the formulation of drugs, may be withdrawn if considered necessary. However, such facility should continue for materials used in the basic manufacture of drugs.

II PRICING

1. Total Price Decontrol:

(a) The Committee is of the considered opinion that there should be a total decontrol of drug prices which should be left to be adjusted to the market forces. It is believed that initially there shall be some increases in prices but after sometime they will find their own adjustment level.

(b) In order to provide competition in case of single ingredient branded drugs, it may be compulsory to use generic names along with brand name to be printed in equal prominence on the drug packaging. The Drugs Act, 1976 already requires registration of single ingredient drugs under generic names.

(c) The Government may also reach a gentleman's agreement with the manufacturers that they will not raise the prices unreasonably.

2. **Partial Decontrol:** If, for any reason, total decontrol is not considered feasible, then a partial decontrol be resorted to as under:

(a) All prices be decontrolled except the following two categories;

GROUP A: Medically critical drugs ie., drugs which are essential from medical point of view. Selection of these drugs be based in view of the medical need as for example already identified through publication of National Formulary of Pakistan for Hospital use, drugs required for chronic diseases eg. Tuberculosis, Asthama, intestinal, psychiatric, heart, etc., and new expensive research and patent products. Some 270 drugs as per Annexure-III have been identified. Price control may continue on these drugs.

GROUP B: (Economically critical drugs ie., leading products excluding those including those included in Group A).

Drugs included in this group will be those with high market share (eg. sale above Rs 5 millions) excluding drugs of 6 groups already exempted from price control with the approval of E.C.C. These 182 drugs have been identified in Annexure-IV. Price control may continue on these for the time being and later to be removed in view of the experience gained from decontrol of the remaining drugs.

(b) Prices fixed for drugs included under Group A & B be considered a leader prices ie., drugs with similar ingredients may sell within these leader prices.

(c) Any drug for Group A or B sold under generic name at any later stage should automatically be excluded from price control since it will have its own competition from other sources.

3. A system of monitoring should be developed to constantly evaluate market situation. In case of any abnormal price increase of a drug, it may be placed in the negative list for price control which may again be strikeout off until sufficient competition ensures price stability at a reasonable level.

III DOMESTIC PRODUCTION:

1. The incentives earlier granted to M/s Galxo for basic manufacture of drug be allowed to all intending basic manufacturers, which included certain price increases, duty free import of machinery and raw material and protection agent imports.

2. Liberal loans on soft terms be given for establishing plant for basic manufacture of drugs.

3. The facilities allowed to other industries being established in rural areas, of relief from income tax, customs duty, sales tax, import surcharge and import license fee be given to newly established units for basic manufacture of drugs in the urban areas. They should be exempted from setting up such units in rural areas which is not possible due to its peculiar nature of being of highly technical and secondly because any existing formulating company, which intends to take up this activity, will not find it feasible to set up a separate plant away from his existing facilities.

IV REGISTRATION OF DRUGS (SIMPLIFICATION OF PROCEDURE)

1. The Registration Board should consider registration of new drugs for thorough evaluation and review of existing formulations. But if a drug is already introduced in the country, a small sub-committee of Registration Board headed by the Director General (Health) should grant automatic registration if the applicant possesses adequate facilities for manufacture and quality control.

2. **IMPORTS:** Selective imports, where necessary, may continue as before from good sources to ensure satisfactory availability of cheaper drugs.

3. The Board should have permanent staff to conduct proper evaluation of data to ensure better quality, safety, and efficacy of the drugs.

V PATENTS:

1. The Patent Office should consult Ministry of Health before grant or renewal of patent for any drug. They should also provide information about the existing patents and their expiry.

2. The patent law should be strictly followed with regard to the obligation of the patentee on local production of patented materials and its compulsory licensing.

VI SENATE COMMITTEE REPORT

As recommended by the Senate Committee, recommendations of the Services Management Division of Cabinet Secretariat for strengthening the Drug and Quality Control Organizations and Laboratories may be approved. Similarly its recommendation for strengthening the Provincial Quality Control Organization and introduction of hospital pharmacy may also be approved for communicating to all concerned as a directive for implementation.

ANNEX IX

SENATE OF PAKISTAN

REPORT

OF THE

SPECIAL COMMITTEE ON MEDICINE SECTOR

MARCH, 18 1991

SENATE SECRETARIAT

1. Senator Javed Jabbar, Chairman of the Senate Special Committee on the Medicine Sector have the honor on behalf of the Committee, to present this Interim report of the committee on the following Adjournment Motion, namely:-

   "Adjournment Motion No. 19-11/87-QAP "I move that the House do now adjourn to discuss a matter of recent occurrence and of urgent public importance namely the administering of out-of-date medicines to patients suffering from heart ailments and hypertension for about 10 months at the Jinnah Postgraduate Medical Centre, Karachi. (as reported in Dawn, Karachi, dated 6th May, 1987)".
   (Moved by Senator Javed Jabbar).

2. On January 19th 1988 the Chairman of the Senate while dealing with the said adjournment motion constituted a Special Committee of the House to investigate the matter and present its report in the Senate. The Committee was constituted as follows:-

1.	Senator Muhammad Ali Khan	Member
2.	Senator Prof. Khurshid Ahmed	"
3.	Senator Akram Sultan	"
4.	Senator Abdul Majid Kazi	"
5.	Senator Hussain Bakhsh Bangalzai	"
6.	Senator Javed Jabbar	"
7.	Minister for Health	Ex-officio Member

3. The Committee held its first meeting on 28th January, 1988 and elected Senator Javed Jabbar as its Chairman and approved its terms of reference.

4. The Committee held its meetings at Islamabad, Lahore, Karachi, Peshawar, Quetta and Gawadar to facilitate its work. The details of the meetings and work done by the Committee are at Annexure 'B'.

5. On February 20, 1990 on an adjournment motion No. 13 - 25/90-QAP sought to be moved by Senator Prof. Khurshid Ahmed on the use of deficient Glucose (dextrose) drips at JPMC. In Karachi, the Chairman of the Senate, Mr. Wasim Sajjab referred the subject of the motion to the Senate Special Committee on Medicine Sector and requested the Committee to investigate aspects of this case as well as its study. A more detailed comment on this case is being presented in the final report of the Committee.

6. Based on its investigations and deliberations the Committee prepared a report which was discussed and finalized in meetings held on 16th and 17th March, 1991. The said meetings were attended by the

following members, namely:-

1.	Senator Javed Jabbar	Chairman
2.	Senator Muhammad Ali Khan	Member
3.	Senator Hussain Bakhsh Banglzai	Member
4.	Senator Prof. Khurshid Ahmed	Member
5.	Syed Tasneem Nawaz Gardezi Minister for Health	Ex-officio Member
6.	Mr. Shahid Iqbal	Ex-officio Secretary
7.	The Secretary and D.G. (Helath), Ministry of Health also attended the said meetings	
8.	The report, as approved by the Committee is Annexure 'A'	

signed
SHAHID IQBAL
SENATOR JAVED JABBAR
Secretary Committees Chairman
Special Committee on
Medicine Sector

ISLAMABAD
18th March, 1991

Annexure A

INTERIM REPORT OF THE SENATE SPECIAL COMMITTEE ON THE MEDICINE SECTOR

Introduction

On 30th July, 1987 after hearing arguments for admissibility of an adjournment motion sought to be moved by Senator Javed Jabbar in the House, the Chairman of the Senate Mr. Ghulam Ishaq Khan, admitted the adjournment motion concerning the administering of out-dated medicines in the Jinnah Post-Graduate Medical Centre, Karachi.

Under rule 77 of the Rules of the Senate two hours for a debate on this motion were fixed for 19th January, 1988.

At the conclusion of this discussion, with the concurrence of the Minister of Health and the House, a Special Committee of the Senate was constituted to investigate the specific case of JPMC, Karachi and look into related aspects of the pharmaceutical sector.

The House elected the following members of the Committee:

1. Mr. Mohammad Ali Khan
2. Professor Khurshid Ahmed
3. Mr. Akram Sultan
4. Mr. Abdul Majeed Kazi
5. Mr. Hussain Bukhsh Bangalzai
6. Mr. Javed Jabbar
7. The Minister for Health, Ex-officio Member

In its first meeting held on January 28, 1988 the Committee elected Senate Javed Jabbar as its Chairman.

On the cessation of his membership of the Senate on March 20m 1988, Mr. Akram Sultan ceased to be a member of the Committee as of that date. He participated in all meetings held up to that time.

In its first meeting in Islamabad on January 28, 1988 the Committee approved its basic Terms of Reference as follows:

1. To examine the causes of administering the out-of-date medicines to patients suffering from heart ailments and hypertension for about 10 months at JPMC, Karachi.

2. To examine the system of supply of drugs at JPMC with particular reference to purchase/supply of Trasicor.

3. To determine the present role of pharmacists in the drug management and health care systems and to identify specific ways - from education to professional regulation to adequate representation - in which pharmacists can make a rightful contribution to public health.

4. To recommended immediate, short-term and long-term measures for better drug and medicines management so as to help ensure public health.

During the initial phase of its work in view of a large number of related elements that merged as a result of deliberations and discussions, the Committee identified certain issues starting from relevant context of its studies which can summarized as follows:

1. The manufacture, marketing, import and sale of spurious and sub-standard drugs.

2. The education, employment and utilization of pharmacists in the health delivery system.

3. The need for hospital pharmacy services.

4. The operations of transnational pharmaceutical companies in Pakistan.

5. The issue of transfer pricing.

6. The control of prices of medicines by the Government of Pakistan.

7. The operations of Pakistani pharmaceutical companies.

8. The import of ready-to-use medicines and their pricing policy.

9. Medicine testing laboratories.

10. Medicine inspection system.

11. Amendments required in the Drugs Act.

12. Need for improved coordination between relevant Government Ministries, Departments, Federal and Provincial Governments.

13. The local basic manufacture of raw materials and chemicals.

14. The import of raw materials.

In this interim report notes and recommendations have been recorded separately for the first 7 principal issues. For the remaining 7 issue i.e. from items 8 to 14 some of the corrective measures required are already covered by recommendations specified for issues No. 1 to 7. To deal with some remaining recommendations of issues No. 8 to 14 will be presented in the final report.

The work of the Committee can be divided into 4 phases :

Phase-I
January 28, 1988 to May 31, 1988.

Phase-II
January 17, 1989 to February 21, 1990.

Phase-III
August 21, 1990 to September 28, 1990.

Phase-IV
(Review of Interim Report and presentation to the Senate) :
March 16-March 18, 1991.

The time frame of the Committee's work may be seen in the following parameters :

1. Initial investigations by the Committee indicated that the mal-administration of medicines at JMPC Karachi revealed a general malaise pervading the medicine sector which required further study. Each encounter with an aspect of the investigation opened up additional areas of inquiry.

2. On the dissolution of the National Assembly on May 29, 1988, the Senate became the sole surviving legislature of the country and an entirely new political situation developed claiming the time and attention of the members of the Committee, particularly the events before and after the elections held in November 1988. Similarly, in August 1990, once again on the dissolution of the National Assembly, the Senate assumed sole legislative duties, claiming due

time from members.

3. All members of the Senate Special Committee on the Medicine Sector were also nominated in August 1988 to serve on the Senate Special Committee on the Sind situation which, due to the grave crisis of the law and order situation prevailing in Sindh, required the Committee to immediately undertake visits and deliberations in Sindh, thus preventing members from also being able to revive and sustain work in the Committee on the Medicine Sector.

4. After the formation of a new Government in December, 1988, the Chairman of the Committee convened a meeting on January 17, 1989 to invite the attention of the members of the Committee to the fact that, on his having been asked to serve as Minister of State for Information and Broadcasting in the Federal Cabinet of that time, it may be appropriate for a new Chairman to be elected. The Chairman also informed the members of the Committee that the Prime Minister had desired that the Chairman continue in the same position with the consent of the members of the Committee. The members of the Committee reiterated their confidence with the Chairman of the Committee and proposed that he continue in this position.

5. The Committee subsequently revived its work for a brief period in January and February 1989. However, due to various unavoidable reasons, including the fact that the Minister for Health indicated that the Government was formulating a new national health policy and that the Committee might wish to delay its deliberations until the completion of that exercise, the work of the Committee remained in abeyance till August 1990.

However, the Committee did not allow the frequency of political changes in the country and the prior responsibilities of its members to delay or divert from the objectives for which the Committee was constituted.

By holding regularly and extensive meetings with a large number of official and private organizations including related Ministries and Departments of Federal and Provincial Governments, by inviting all relevant industry, professional and trade associations to present their viewpoints, by conducting field visits to important locations in all 4 provinces including unscheduled surprise visits, by identifying problems and subjects which require immediate intervention and action by Government Ministries, by securing such corrective action directly and indirectly and by maintaining a consistent interest in the subject, the Committee helped set in motion a process of critical self review within Government and has assisted in accelerating rationalization of Government policies with regard to the medicine sector.

In this sense, the Committee has de Facto also served as a Senate Standing Committee without, in any way, overlapping with the existing Senate Standing Committee on the Health Sector.

So vast and complex is the medicine sector that a specific committee to monitor its progress has been a useful step.

In view of the need for continuance and specific monitoring by Parliament of this vital sector it is recommended that the Senate may be requested to approve a proposal to allow the Senate Special Committee on the Medicine Sector to continue to remain in existence after the presentation of the interim report and the final report. Such a continuance will help supplement the work of the Senate Standing Committee on Health and enable the Senate to act as a catalytic factor on this subject with the public interest.

As the attached schedule of its meetings and work reveals, the Committee has conducted a wide range of field activities. The Committee has paid detailed visits to large hospitals and drug testing laboratories in the major cities and at the same time has travelled over dusty, unconcrete

roads to remote settlements and villages in the Gawadar District of Balochistan as well as to villages in the North West Frontier Province. The Committee has made incognito visits to crowded city markets to check the sale of spurious drugs and has also surveyed production facilities of overseas as well as local pharmaceutical companies.

The Committee has interviewed a large number of citizens, officers, doctors, pharmacists, drugs inspectors, businessmen, shopkeepers, compounders, paramedics and specialists in order to gain an insight as to how different professional groups perceive aspects of the medicine sector in the country.

In formulating this interim report the Committee has in addition to its own proposals studied and accepted either whole or in part certain constructive and positive proposals made by individuals as well as representative organization of the pharmaceutical industry and of pharmacy and the Committee is grateful for the large number of helpful suggestions brought to its attention. The range and depth of the material submitted to the Committee is an accurate indicator of the sincerely and national spirit with which each segment of the pharmaceutical sector perceives its respective responsibility in helping to bring about better conditions.

The Committee would like to record its thanks and appreciation to the Federal Government and the 4 Provincial Governments, the different respective Ministers of Health who have served during the past 3 years, the officials at all levels in the Ministry of Health in Islamabad and in the departments of health in the 4 provinces, the leaders and representatives of associations and organizations representing the pharmaceutical industry and professional groups, the proprietors and managers of various establishments including pharmaceutical industries, medicine stores etc. and all those who have extended cooperation, courtesy and hospitality to the Committee and have helped facilitate its work.

The Committee would also like to record its appreciation for the support provided by Mr. Aziz Ahmed Qureshi, the Secretary of the Senate, Mr. Shahid Iqbal, Secretary Committees and the staff to the Senate Secretariat in making possible the work of the Committee.

In particular the Committee lauds the role of the press in highlighting this issue and makes a special commendation of Dawn, Karachi which was the first newspaper to publish the report on the Trasicor case.

The structure of the report of the Committee is as follows:

PART-A

Record of investigative work conducted in Islamabad through meetings held in Parliament House with officials from the Federal Ministries and agencies and with representatives of non-governmental organizations.

Investigative work conducted in the field during visits to locations in the 4 provinces.

Material obtained during investigations and findings of the Committee.

PART-B Interim Report comprising:

(i) Introduction
(ii) Political commitment in the health field
(iii) Notes and observations
(iv) Recommendations for action
(v) Schedule of work

On March 18, 1991, the last day of the 30th Session of the Senate which coincides also with the last phase (ending March 20, 1991) of the current term of office of the Chairman of the Committee as a member of the Senate, the Interim Report, ie. Part-B is being presented to the House.

Part A will be presented shortly.

It is suggested that, along with a request to be made to the Senate to permit the Special Committee to continue its work, the 2 vacancies arising out of the cessation of the terms in the Senate of Messrs. Hussain Bukhsh Bangalzai, Abdul Majeed Kazi and Javed Jabbar on March 20, 1991, two or three new members be elected by the House to enable the Committee to have adequate membership.

This is, to the best of our knowledge, the first such report by a Parliamentary Committee on the pharmaceutical sector in Pakistan. We urge the Government and non-governmental institutions to take immediate actions for reforms on the lines defined in this Report.

The Committee Members placed on Record their Deep Appreciation of the work Rendered by the Chairman of the Committee.

SIGNED : 1. _____
SENATOR JAVED JABBAR
Chairman

Sd/-
2. _____
SENATOR MOHAMMAD ALI KHAN

Sd/-
3. _____
SENATOR Prof. KHURSHID AHMED

Sd/-
4. _____
SENATOR HUSSAIN BUKHSH BANGLZA

Sd/-
5. _____
SENATOR ABOUL MAJEED KAZI

Political Commitment to Health : the missing ingredient

The condition of the pharmaceutical sector in Pakistan has to be viewed within the context of the total health care system in the country. While there has been a 5-fold increased in rupee expenditure on health in the decade of the 1980's and the percentage share of health expenditure as part of GNP has doubled in the same period, the high rates of inflation, population growth in Pakistan diffuses the positive impact of increased expenditure. It is strongly recommended that allocation for health in the budget for 1991-92 be increased and not in any way reduced to ensure implementation of recommendations made in this report. In addition to the population growth rate the health care system reflects a lopsided imbalance in favor of an expensive curative approach to medicine instead of a direly needed investment in preventive medicine and in health education.

We observe the welcome sight of hospitals and health units opening in rural areas at Taluka level and we also note that the very same shiny new structure have equipment that does not work or medicine stores that do not have sufficient stocks of drugs.

There is also the spectacle of new medical complexes opening in the major cities even as older hospitals in the same cities remain starved of finances to meet perennially growing demand for space and for services.

In this panorama of pain and of paradoxes the crucial factor of authentic political commitment moves like a phantom fulfilling the formalities of image and lip-service but being unable to give solid evidence of genuine interest and concern. Though there can be no argument whatsoever on the fact that the health of the nation is often highest possible priority in reality in terms of receiving critical attention and understanding, the health sector comes low on the political agenda.

As an important part of the health sphere, the pharmaceutical sector offers a curious spectacle of excess as well as inadequacy, of excellence as well as mediocrity.

On one hand the pharmaceutical industry in collaboration with the system of curative medicine, pumps millions of pills and capsules and injects hundreds and thousands of needless into the body of the Pakistani nation. On the other, millions of Pakistanis remained desperately short of the money needed to buy ordinary medicines as well as expensive life-saving drugs.

At one extreme the Federal Government takes an almost oppressive interest in the pharmaceutical industry by imposing arbitrary price controls. On the other numerous subjects requiring urgent policy review remain neglected for long years due to apathy and disinterest.

In one and the same country and often in one and the same city pharmaceutical plants operate at the highest international standards of quality assurance and safety and a few kilometers away in backyards and in open sheds spurious medicines are produced and moved to the shelves of shops which sell them openly to an unsuspecting public.

While men are amongst those who suffer greatly from the omissions of our health system, women and children are certainly those who suffer the most. Already being the two disadvantaged segments of the population, women and children continue to be the worst victims of the adverse dimensions of our health system and the flaws in the pharmaceutical sector.

Recent advances made in spreading health service coverage such as immunization etc. only partially offset the degree off suffering.

In a developing country blighted by one of the highest rates of illiteracy in the world we observe outstanding instances of professional education and managerial ability in the pharmaceutical sector.

In a land where about 48,000 doctors strive to find an effective role, it is estimated that 100,000 quacks are free to meet the needs of the people.

Whether it is the education and proper recognition of the pharmacists or whether it is the upgradation requirements of the drug testing laboratories we note a generous number of sound proposals. The only ingredient that the pharmaceutical sector now requires is action at the highest political level to take note of the reformative steps already identified in this, and in earlier reports and simply, surely and

steadfastly proceed to implement these proposals immediately without fear or favor.

Towards seizing this illusive and yet obtainable ingredients of action by the political leadership to improve the health field, this report seeks to make a humble contribution.

PART-I DISPENSING OF OUT-OF-DATE MEDICINES AND THE MEDICINE MANAGEMENT SYSTEM AT JINNAH POST-GRADUATE MEDICAL ENTRE, KARACHI

Note :

The case regarding purchase of excessive amounts of Trasicor tablets by JMPC, Karachi and of the subsequent expiry of their date of suability followed by the dispensing of these tablets to patients suffering form heart ailments and hypertension at JMPC became the very basis for the establishment of the Senate Special Committee on the Medicine Sector.

The Committee was briefed on the background of this case by the senior officials of the Ministry of Health and of JMPC. Subsequently, the Committee visited JPMC and inspected the Central Medical Store and met relevant personnel.

The Trasicor tablets tale is a tragic story with a bitter-sweet ending. Some of the villains got some punishment - but there are neither heroes nor heroines. It is a small but symptomatic saga of the shameful system by which we manage the medicine system.

While it is fortuitous that no disability, distress or death was caused to any patient who was given out-of-date tablets, the general situation regarding the system by which medicines are purchased, received, managed and stored and dispensed is, in some respects appalling and in others barely able to meet minimal acceptable standards.

The well-established and deftly practiced tradition of declaring official inquiries about malpractices, irregularities, scandals, etc. then conducting inquires and promising strong action, followed by stages of steadily decreasing interest are actions made by those responsible resulting almost always in virtually no action being taken against those who are guilty seems to have also occurred in the case of the Trasicor tablet as also in the case of the supply of injurious Glucose (dextrose) drips which also occurred at JPMC and about which the final report of the Committee will give further details.

However, it is relevant to note that even though, in the case of Glucose (dextrose) drips, the drug inspection report had advised destruction of stocks, the stocks were returned undestroyed and thus units from these stocks eventually caused tragic suffering.

In this case of Trasicor tablets, the batch in question was actually manufactured in 1980. We are now, a full decade later in 1991, obliged to note with deep regret that appropriately punitive action was not taken against the various individuals in responsible positions at the relevant dates for placing an artificially inflated order.

While action was taken against the pharmaceutical company concerned (suspension of registration of Trasicor for 6 months, refund of amount), in real terms such action alone is not sufficient. The Committee notes that even the assurance given by the former Minister of Health in response to the adjournment motion moved by Senator Javed Jabbar regarding the Trasicor tablets in the Senate on January 19, 1988 an important action that was supposed to have been "already taken" has not actually been implemented so far. In this respect, reference is made to point 4 of the points contained in the draft of the reply by the former Minister of Health in which it was stated that "qualified pharmacists would be appointed in all hospitals up to Tehsil-Taluka level. Steps be taken for creation of posts of pharmacists and appointment thereto." This assurance given to a House of Parliament remains unfulfilled.

It is the abysmal failure to establish a hospital pharmacy service on recognized professional lines in JPMC which is the root cause of the

Trasicor tablets episode and of the continuing lack of satisfactory conditions in JPMC and in general in all other public and private hospitals - with one or two exceptions - in the field of medicine management and dispensation.

The unhygienic conditions in which the main dispensary of JPMC doles out medicines to out-patients every day is an apt sign-post to the overall malaise.

The Committee note with regret, after investigation, the following facts:

1. It is clear from an examination of the relevant informal inquiry report, etc. that an artificially inflated order for Trasicor tablets was made by JPMC in July and August, 1981. While the Assistant Director Medicine, the Medical Officer In-charge of the Central Medical Store and the Storekeeper at JPMC were interviewed by the Inquiry Committee which was given one week only the Director of JPMC at the time that the inflated order for Trasicor tablets was made, was not contacted simply on the ground that he had, by the time of the inquiry, retired from service. Retirement from service does not constitute a justifiable exemption from being interviewed to assess responsibility.

   Two of the three employees of JPMC who were found responsible by the Internal Inquiry Committee of placing the exaggerated order are still on duty at JPMC.

   Show cause notices were issued to the officers identified by the Inquiry Committee. Replies were given. However, there has been no response to these replies. Business carries on as usual! The third officer, the Medical Officer In-charge of the Central Medical Store, was not asked to give a statement to the Inquiry Committee simply because he happened to be abroad in Saudi Arabia at that time with the Hajj Medical Mission. It is not understandable why such a relevant officer was not interviewed at a later time. Soon after this episode, he was transferred to another medical institution in Karachi were he is presently working.

2. Possibly the single most important fact or responsible for the Trasicor case is that even though the Drugs Act was enacted in 1976 and contains a provision calling for the formulation and enforcement of Drugs labeling and Packing rules, it took as many as 8 long years after the enactment of the Drugs Act to finalize these rules.
   This sad story of neglect and delay did not end here. Whether it was due to pressure from certain, or all pharmaceutical manufacturers, local or overseas, for one unacceptable reason or another, the Drug Labeling and Packing Rules issued in 1986 were not enforced immediately, instead exemption was granted.

   It was only in December, 1989 as long as 13 years after the passing of the Drugs Act that the Drug Labeling and Packing Rules were actually enforced.

   The investigative work initiated by the Senate Special Committee is reported to have helped accelerate the process of enforcement of these rules because the Committee in its initial deliberations had raised this question and had expressed its displeasure at the delay in enforcing these rules.

   Thus, it will be seen that from the start to the end of the Trasicor tablet episode and the Glucose Dextrose drip episode there was no mandatory legal cover to ensure that the date of expiry be printed on the packs ad cartons.

The non-implementation of such a basic and essential provision to ensure safety and reliability in the use of medicines is in excusable.

All those associated with the Federal Government, at Senior Officers with authority to approve rules between 1976 and December, 1989 in the health sector share the responsibility for the failure to formulate and immediately enforce rules that are a minimum and simple deterrent against the purchase and usage of out-dated and potentially dangerous medicines.

Both the manufacturer and the distributor of Trasicor tablets took advantage of this loop-hole in explaining away the fact that the two crucial set of dates were not stamped on the consignment of Trasicor tablets.

3. It is never the less pertinent to briefly record the sequence of events by which the anomaly came to attention because it well-illustrates how neither the Federal health system nor the JPMC itself had, up to December 1989, an automatic internal 'early warning' system by which such lapses could be avoided.

The batch of Trasicor tablets in question was manufactured in November 1980 and had a utilization period of 5 years. Therefore, their ideal utilization date expired in November 1985. However, so unsatisfactory in the situation with JPMC that no question seems to have been raised about the possible decline in potency of these stocks for 5 whole years.

The issue arose only in May 1986, when JPMC requested Ciba Giegy to replace quantities of large unused stocks of Trasicor tablets.

In response to this request, the distributor of Trasicor tablets approached the Secretary, Ministry of Health in July 1986 complaining that if the request had been received six months before the expiry date of the tablets, then a replacement could have been made.

It was only then that the question of expiry date began to receive attention. Now it took a whole month ie. from July 30, 1986, the date on which the distributor raised the issue about expiry date in a letter addressed to the Ministry of Health to August 30, 1986, when Director JPMC received intimation from the Ministry about the expiry date with orders to discontinue usage.

On a matter as crucial as this, it is not possible to excuse a delay of 30 days in communicating from Islamabad to Karachi instructions to avoid usage of expired medicines.

Dispensing of limited quantities of these tablets did take place in this period but it is reassuring to note the statement by the Head of Cardiology at JPMC who said "I have to state that these tablets were administered to all our patients in Ward and OPD. No patient either complained, neither did I nor my staff notice any untoward side effects. As a matter of fact when the tablets were withdrawn, the patients continued to ask for them, even though they were told that the tablets have crossed their expiry date. We could not detect that the tablets had crossed their expiry date either by loss of its efficacy or any untoward side effects. This fact came to out knowledge only after the tablets were withdrawn by the administrator."

This was fortunate but by no means justifiable. Certain minimal, though not ideal, actions penalizing the manufacturer, issuance of show cause notices to the staff concerned, etc. have already been taken thereby removing the need for this Committee to make specific recommendations in this regard.

However, the need for corrective action on fundamental issues still remains requiring initiative by the Federal Ministry of Health and by JPMC.

RECOMMENDATIONS

1. Devolution of authority and decision making powers be so implemented that JPMC is made accountable for its administrative performance in place of the present arrangements where the distribution of responsibility is imprecisely defined.

2. Vigilance committees comprising of eminent citizens of Karachi be established in order to monitor the performance and operations of JPMC. Notices in Urdu, Sindhi and English be prominently displayed in JPMC and other major hospitals Informing visitors about the existence of such vigilance committees and giving details of how any citizen may contact the vigilance.

3. Based on a study of the hospital pharmacy service as being operated in the Agha Khan Hospital, Karachi a manual be compiled on the subject of hospital pharmacy service by the Ministry of Health for implementation and observance by JPMC, Karachi and for the benefit of all public and private hospitals.

4. JPMC should ensure that it obtains medicines from only those distributors and manufacturers who employ qualified pharmacists in order to avoid lapses that occur due to semi literacy on the part of the staff as in the case of supply of injurious glucose (dextrose) drips.

5. An explanation should be provided to the Committee as to why the replies to the show cause notices issued to the officers involved were not responded to promptly by JPMC and the Ministry of Health.

Part II - SERIOUS AND SUB-STANDARD DRUGS

Note :

There are 4 categories of spurious and sub-standard medicines:

(a) Deliberate, illegal counterfeit manufacture of medicines and/or medicines containing unapproved or dangerous substances.

(b) Substandard production of medicines due to deficiencies in the operations of licensed and legally established pharmaceutical companies.

(c) Medicines that deteriorate in efficacy due to poor storage conditions, particularly at distribution and retail marketing stages.

(d) Non-allopathic medicines which are packaged to appear similar to allopathic medicines and which are legally imported into the country or made locally and sold openly but which nevertheless are reported to have notably negative side effects, particularly products known as sex tonics etc.

While this phenomenon requires a basic and comprehensive approach at a national level, each of the above 4 categories often require action at a provincial and even at divisional and district level. Some of the corrective measures required are common to all 4 categories such as amendments to Federal and Provincial laws while others require individual and specific identification.

The problem of spurious and substandard drugs has been described to the Committee as constituting a major obstacle to the sale of authenticated quality medicines and therefore deserves appropriate and immediate attention at the political level and at all relevant administrative levels.

RECOMMENDATIONS

5. In order to detect and prevent deliberate manufacture of spurious drugs, the first and foremost action required is to significantly increase the personnel and facilities of transport etc. for the drugs inspectorate system at the Federal and at the Provincial levels.

   The present number of drug inspectors and their respective areas of responsibility are disproportionate. Transport means and funds for transport are grossly inadequate. A numerical increase for both personnel and facilities would be a minimal step necessary to initiate the process of reform.

6. While it is acknowledged that the resources of the police in every Province are also extremely inadequate to meet the requirements for law enforcement in a wide range of sectors, there is an urgent need to make the police both as an institution and at an individual level more informed and responsive to the needs of the drug inspectorate system in preventing the manufacture of spurious medicines that are harmful for human health. Therefore, at the Federal and Provincial level, the Ministers respectively of the Interior and of the Home Department should make a special effort to arrange, in co-operation with the Federal Ministry and the Provincial Departments of Health, special orientation courses and coordinate programmes of action so that the drug inspectors in the health system can work more cohesively with police officers in this respect.

7. In order to introduce an element of public accountability into the process of monitoring the manufacture of harmful medicines, each elected entity at its own respective level i.e. Metropolitan Corporation, Zonal Committee, a District Council, a Town Committee etc. should conduct an open public hearing once every three months in order to take note of reports on investigations made and actions taken by the drug inspector and police officer responsible for that area.

8. Appropriate amendments should be made in the Drugs Act to significantly increase the penalties to be imposed on an individual who indulges in the deliberate manufacture of spurious medicines.

9. In the category where licensed manufactures either deliberately or by failure to observe prescribed standards, produce substandard medicines a number of amendments to the Drugs Act of 1976 have been proposed by the Pakistan Pharmaceutical Manufactures Association which would help improve the monitoring of production by pharmaceutical companies.

   While most of these amendments have been proposed from the viewpoint of PPMA and may therefore reflect a degree of self-interest on the part of the pharmaceutical industry, in essence the intent of the proposed amendment appears to be based on the principles of fairness and reason. There being no justification for any further delay in marking required amendments to the Drugs Act 1976, the Federal Government should take note of the amendments proposed by PPMA and should submit the amendment Bill to Parliament at the very latest by June 30, 1991.

The reason for setting a target date that coincides with the end of the financial year is the fact that with the commencement of the next financial year ie. 1991-92 on July 1, 1991 the Federal Government can conceivably offer incentives to the pharmaceutical industry to enable it to implement good manufacturing practices and thus help eliminate scope of production of substandard medicines by licensed manufacturers. Such incentives are being referred to in recommendations under the relevant section ie. operation of Pakistani pharmaceutical companies.

10. In respect of medicines that deteriorate in their efficacy due to bad storage conditions particularly in medicine stores where products are exposed to sunlight and dust in inordinate degrees, necessary amendments should be made in the Provincial Drug Sale Rules so as to prescribe minimum physical standards for medicine stores.

In prescribing such minimum physical standards in a country where 60% of the population still does not have access to electricity, due consideration can be given to the need to have distinct categories of minimum standards.

However, lack of electricity in a location or lack of other amenities cannot be made as the basis for hazardous and inappropriate storage of medicines.

Even in relatively disadvantaged locations medicine stores can use simple but effective precautions to place medicines with necessary protection from light, heat and dust, 2 separate categories of chemist shops should be specified for registration.

11. There also appears to be undue variation in the Drug Sales Rules from one province to another. Such arbitrary and needless variation should be eliminated.

12. The mushroom growth of medicine stores may also be one contributory factor enabling the continuance of bad storage conditions and in preventing responsible drug inspectors from being able to properly inspect all such stores.

It is therefore recommended that licenses for retail chemist shops should be issued after a survey of the locality in which the new shop is proposed to be open with relevant reference to the population residing in that locality or using that locality as a shopping area, the projected rate of growth of demand, number of existing shops in the same locality, etc.

13. The renewal of the drug sale license every 2 years should be made only after a more collective participation by the representatives of each local community as in the present arrangements, the drug inspector enjoy too much power to renew the drug sale license. Such power is often misused and shops with bad storage conditions continue to flourish.

Therefore, the area mohallah committee or elected councilor along with at least 2 other respected citizens should have the authority to inspect and review the storage conditions at retail chemist shops before the drug sale license is renewed.

14. In addition to retail chemist shops, wholesalers of medicines also share responsibility for storing and handling medicines either with a deliberate intent to distribute spurious medicines or due to inadequate storage while the medicines are in their control

For example, it has been reported that some wholesalers take a batch of medicines from a licensed manufacturer which meet standard

specifications and mix this batch with batches of spurious medicines thus making it easier for harmful medicines to slip through stages of detection.

As one reason for this unethical practice by wholesalers may be the fact that no discount is officially prescribed by a proper notification under the Drugs Act 1976, it is recommended that the actual existence of about 0000's of wholesalers of medicines in the country be taken note of and necessary official acknowledgment be made.

Wholesalers are reported to handle about 70% of all stocks of medicines bought for imported into the country for distribution to various institutions and retail shops and it is therefore apt that the legitimate role and responsibilities of wholesalers be formally defined in order to make them accountable for the observance of prescribed rules for storage and distribution of medicines.

15. With regard to the easy import of non-allopathic medicines from overseas sources with packaging that misleadingly represent such medicines as allopathic medicines particularly in the case of sex tonic etc., the present discretionary powers vested with the Customs authorities to classify whether a product proposed to be imported is or is not a legitimate medicine and whether it is or is not an allopathic medicine or a non-allopathic medicine should be curtailed, if not eliminated.

Due to the present arrangement, a large number of such medicines are freely imported and openly sold and consumed without any hindrance causing suffering and hardship to citizens that has not yet been properly assessed.

15A. Campaigns should be conducted over the mass media to educate the public on aspects of how to ensure purchase of quality medicines what signs, seals, dates etc. to look for before buying medicines.

PART III - PHARMACISTS AND THE HEALTH DELIVERY SYSTEM

Note :

The pharmacist has a central and essential role to render in the health delivery system. Whether it is the definitive declarations on this matter made by the World Health Organization or promises made in the 5 year plan documents of our own country it is universally recognized that, along with the doctor and the paramedic, it is the pharmacist who constitutes the third part of the "triangle of medical care".

However, in Pakistan the entire system seems to be geared towards denying the validity of this rightful role.

Indeed there seems to be a concerted attempt to exclude the pharmacist from occupying positions of responsibility and influence that professionally belong to him so as to prevent the pharmacist from breaking a traditional monopoly of control over the health system.

In a subject as vital to the nation as the health and well-being of its people, the pharmacist is required to be associated with every facet of the medicine sector ie. the inspection and assessment of manufacturing facilities, formulation and quality control of pharmaceutical products, the assurance of product quality through the distribution chain, the monitoring of drug procurement agencies, participation in national and institutional formulary committees, representing in drug regulation and control and in the direction and administration of pharmaceutical services.

In practice in Pakistan the pharmacist is either completely absent from many of the above essential segments or is represented only in a token and ceremonial manner. By design as well as by inadvertence the pharmacist plays no decisive role whatsoever in the formulation of public policy with regard to any of the above segments.

There has been a glaring failure for about 20 years to implement numerous sections of the Pharmacy Act of 1973 by which the correct foundation for pharmacy education could have been established in the country. For example sections 17, 23, 25, 27, 29 and 30 of the Act which relate amongst other issues, to the establishment of pharmaceutical diploma colleges in all major cities of Pakistan in order to educate and train personnel who could replace less specialized compounders and dispensers have not been implemented with the result that not a single pharmacy diploma institution is functioning even in 1991.

On the other hand, at the higher education level in the universities, there is a wide disparity in the standards of education in pharmacy between the universities.

Universities do not comply with various provisions of the Pharmacy Act which was sponsored by the Ministry of Health because, amongst other reasons, universities are funded by the Universities Grants Commission which comes under the Ministry of Education, thus depriving the Ministry of Health from holding universities accountable for non-observance of the standards of pharmacy education.

In some cases the education of pharmacists is conducted by non pharmacists, symbolizing the irrational basis on which the country has been deprived of the due role of the pharmacists.

It is not surprising that this collective institutional barrier against pharmacists results in the curious anomaly that pharmacy graduates remain unemployed while there remains a need for many thousands of more pharmacists.

Where the pharmacist is actually able to circumvent numerous prejudices and obstacles and actually achieve some position of authority, he is often sidelined as appears to be happening in currently when the Drug Controller in the Federal Ministry of Health is not a specialist in pharmacy while positions of Deputy Drug Controllers remain vacant while their occupants pursue in-course training overseas even as qualified pharmacists remain posted on field duty rather than be promoted to occupy positions close to the policy process in Islamabad.

The institutional inhibition against the pharmacist is well evident in the fact that even in a specific organization such as the Federal Drug Control Administration which is so close to the specialized nature of the pharmacist's work, there are examples where are examples where the holders of Ph.D. degrees in pharmacy remain without a single promotion or career development for as many as 17 years whereas non-specialized officers receive regular promotions and recognition.

The non-governmental sector shares this characteristic of apathy and under-utilization of the pharmacist with the government sector. From manufacturing to retailing, from hospitals to dispensaries the pharmacies remains a professional who is discriminated against and who certainly deserves long overdue recognition and induction into all the segments of the pharmaceutical sector identified earlier in this note.

RECOMMENDATIONS

16. Implementation, commencing with the financial year 1991-92 at the Federal and in the Provincial levels, of provisions of the Pharmacy Act relating to the establishment of Pharmacy Graduate Colleges and Pharmacy Diploma Colleges, on a scale and with a programme so that it becomes possible to meet the needs of the country's institutions by the year 2000. To meet the target of producing a sufficient number of pharmacists to fulfill the requirement of over 25,000 retail chemists, government and private hospitals, pharmaceutical plants, clinics, health units, etc. it would be essential to encourage the establishment of pharmacy colleges in the public as well as the private sector under proper regulatory control.

17. A public announcement by the Federal and provincial governments that, with effect from, say 1st January 1992 or an appropriate date shortly thereafter, there would be no more certificates issued by government hospitals for compounders and dispensers as the educational levels required, for these 2 latter categories are not sufficient to meet the minimum qualifications for a pharmacist in either of 2 categories, ie. "A" category for pharmacy graduates and "B" category for pharmacy diploma holders.

    Henceforth, from the commencement date, only holders of pharmacy degrees or diplomas would be eligible for appointment to positions previously open to compounders and dispensers.

18. In order to absorb the existing compounders and dispensers with sufficient experience in handling pharmaceutical products in a manner to be determined by the Central Pharmacy Council, an announcement be made that all duly qualified and certified compounders and dispensers will be registered as pharmacists in Category B while Category A would be reserved for pharmacy graduates only. Such dispensers/compounders should be provided adequate minimal refresh training for registration in B category.

19. The Pharmacy Act 1976 be replaced by a more comprehensive "Pakistan Pharmacy Council Act, 1991" as is being presently considered.

20. Representation at a suitably senior level to be given to the Ministry of Health and the Central Pharmacy Council in the

Universities Grants Commission and Ministry of Equation in order bring about uniformity amongst all universities in standards of pharmacy education and in order to introduce linkage between the health sector and the pharmacy education sector.

21. While remaining conscious of the constraint on financial resources it is nevertheless essential to emphasize that the number of officers presently employed in the Federal Ministry of Health particularly in the drug administration sector and in the provincial governments is extremely inadequate to deal with the vast and multi-dimensional pharmaceutical sector. With only one officer in Grade 20 and only one officer in Grade 19 at the Federal level and with no officer of Grade 19 seniority in Sindh, N.W.F.P and Baluchistan the severe inadequacy of numbers is worsened by the fact that qualified pharmacists remain under represented even in these few numbers. Indeed the Committee has been informed that during the very tenure of the Committee itself the number of qualified pharmacist in the Federal Ministry of Health has actually declined.

In one province a dentist has served for a significant period of time as the Secretary of the Provincial Drug Quality Control Board and has also served as the Drug Controller.

The Committee is aware of the need to avoid expanding the bureaucracy but it is equally true that in the case of pharmacists there is an urgent need to give the pharmacist proper representation in order to secure the objective of ensuring public helath.

Therefore, the Committee recommends that even if positions in other sectors of Government activity have to be scaled down or rationalized it would be made possible for the creation of a Federal Directorate of Pharmacy and for Provincial Directorates of Pharmacy in each of the four provinces under the respective Directors General of Health.

These Directorates should respectively be staffed in the following manner and vital facilities such as vehicles for mobility for drug inspectors should be provided.

22. A Federal Directorate of Pharmacy be set up as under:

BPS	Designation	No.(s)
	Director Pharmacy	1
	* Dy. Director Pharmacy (Registration, Pricing and Legislation)	1
	* Dy. Director Pharmacy (Licensing, Inspection and Appeals)	1
	* Dy. Director Pharmacy (Procurement, distribution and storage)	1
	* Director Drug Testing Laboratories	2
	* Assistant Director Pharmacy	6
	* Dy. Assistant Director Pharmacy (Senior Field Officers)	10
	* Dy. Assistant Director Pharmacy (Senior Analyst)	6
	* Extra Dy. Assistant Director Pharmacy (Field Officers)	16

* Extra Dy. Assistant Director Pharmacy (Analyst)	12

N.B.- Drug Testing is proposed to be entrusted to BPS-17 rather than unqualified personnel at raw hand people of BPS-11.

23. A Provincial Directorate of Pharmacy be set up as under:

BPS	Designation No.(s)
Director Pharmacy Services	1
* Dy. Director Pharmacy (Organization and Planning of Hospital Pharmacy Services)	1
* Deputy Director Pharmacy (Planning, Quality Control, Market)	1
* Deputy Director Pharmacy (Planning of Quality Control for Government Stores)	1
* Chief Pharmacist Hospital Pharmacy	1
* Chief Pharmacist Drug Control	1
* Director Drug Testing Laboratory	1
* Divisional Drug Inspector	Division-wise
* District Drug Inspector	District-wise

- Promotion from one scale to the next higher scale be given after 5 years.
- Non-practicing allowance/technical allowance/special pay comparable to other professions be allowed to Pharmacists.
- Risks involved in detecting spurious drugs be recognized and inspection officers should be provided septile selfdefence means similar to her law enforcing agencies.
- Accelerated promotions be granted in cases where the drug inspectors display integrity and courage beyond the call of duty.
- At least 5 facilities for scholarships of 9-12 months from WHO and other donor agencies be awarded to Pharmacists as is given to doctors, statisticians, etc.
- All posts for which minimum qualifications is B.Pharmacy be placed in B-17.
- Technical officers and allocations be at least doubled for Central Drugs Laboratory, Karachi, Drug Testing laboratory, Lahore and the Drug Control Research Division, National Institute of Health, Islamabad besides establishing new laboratories like Federal Drug Laboratory.
- Vehicles be provided to the field officers so that they are able to effectively conduct inspections in the rural and in far-flung areas.

- Experts on drugs and medicines ie. Pharmacists, be taken on the Appellate Board, Drugs Courts and other Committees set up under the Drugs Act, 1976.

- Pharmacists be notified as professionals in all government documents including those of T&T Department which is reluctant to give priority to Pharmacists for installation telephones even though doctors, lawyers etc. are give priority.

- Drugs Inspectors who are in BPS-17 and 18 be redesignated as "Medicine Quality Survey Officers".

RECOMMENDATIONS FOR IMPROVING PLANNING ABOUT PHARMACY PROFESSION AND PHARMACEUTICALS

24. A cell for planning Pharmacy and pharmaceutical Services be established under a qualified and experienced pharmacist (BPS -19) in the Planning Division a s apart of Health Planning Section.

25. Pharmacy Council of Pakistan be strengthened to function within the same scope and regulatory authority as the Pakistan Medicine and Dental Council.

26. Pharmacists be notified as professionals in all government documents including T&T Department, KDA, LDA, FDA and CDA should give Pharmacists priority in Telephones as given doctors, lawyers etc.

27. Research at Quaid-e-Azam University:

The Quaid-e-Azam University, Islamabad should conduct studies for postgraduate diploma and degree courses leading Ph.D. in Pharmacy. The proposed Department of Pharmacy this University could be financed by allocating funds from the Central Research fund collected by the Ministry of Health from the pharmaceutical industry in the country. A special endowed fund should also be created for further resource mobilization.

28. A comprehensive plan for utilizing the services of 450-500 pharmacists being produced every year be developed. About 200 pharmacists who are already unemployed or under employed need immediate consideration.

29. The report on drug control administration prepared by the management services division and submitted in January, 1990 discussed with the relevant Standing Committees of the Federal Parliament in order to ensure implementation at the earliest.

30. As the pharmacist is required to play a credible role in the management and distribution of medicines in hospitals it is relevant to note that the policy objective outlined in the 6th Five year plan aiming for appointing one pharmacist for 100 beds in all Tehsil and Taluka level hospitals has not only been abandoned but no steps have been taken to establish hospital pharmacy services. In the Punjab for example, for 22,500 hospital beds, there are only 30 pharmacists.

Therefore, towards rectifying a serious historical omission in the hospital system it is recommended that the Federal Government formulate, separately as required, hospital pharmacy service rules for public and private hospitals to be enforced under the existing Drugs Act and the Pharmacy Act and, if legal opinion so recommends, under new legislation.

To fill the gap that has existed for over 40 years it is strongly recommended that legislation and executive orders to this effect be enforced during the Budget year Of 1991-92.

31. The Committee recommended that the hospital pharmacy services structure be based on the following system:

- A Chief Pharmacist (BPS 20) be appointed in the Centre and in each province and made responsible to plan and organize the Hospital Pharmacy Services.

- Director Hospital Pharmacy (BPS 19) be appointed and made responsible to organize and supervise pharmacy services for every 1000 beds.

- Deputy Director Hospital Pharmacy Services (BPS 18) be appointed and made responsible for every 500 beds.

- Assistant Director Hospital Pharmacy Services (BPS 17) be appointed for every 250 beds.

- Staff Pharmacists (BPS 17) be appointed for every hospital and for larger hospitals: one staff pharmacist be appointed for every 50 beds.

- A similar set up be organized for the hospitals under the Federal Government, Armed Forces, WAPDA, Railways and Autonomous bodies.

- Graduate Pharmacists be granted BPS 17 and the lower scales offered to them in Sheikh Zayed Hospital Lahore and some other hospitals of the Sindh Government and Armed Forces be upgraded and filled to rectify the anomalous situation if not done already' because the Ministry of Health and the Health Departments of Punjab, NWFP and Balochistan are already offering B-17 to fresh pharmacy graduates appointed as Pharmacist. Sindh Public Service Commissioned Finance have also agreed to upgradation. Upgradation is also justified as like engineers (who are appointed in B-17) Pharmacists also undergo 16 years education before the award of B.Pharmacy degree.

- Private hospitals and clinics be required to appoint full-time Pharmacists if they wish to maintain a Pharmacy.

- Effective action be taken against the person responsible for administration and dispensing of expired, spurious or substandard medicines to the patients or dispensing unlabelled drugs to patients.

- Ten Model Pharmacies as far (two each by the Federal Ministry of Health, Ministry of Defence and by each provincial Governments) be set up to prevent expired, substandard and ineffective medicines from being dispensed to the public.

- Complete phased Programme for implementation of the scheme be prepared as follows:

  Phase I: (to be completed in 1991-92) - Appointment of Chief Pharmacists, Dy. Director Hospital Pharmacy and Hospital Pharmacists up to 300 beds.

  Phase II: (For 1992-93) - Extension to District Headquarters level.

  Phase III: (For 1993-94) - Extension up to Tehsil Headquarters levels.

- Extensive Training Programme and Diploma Course on Hospital Pharmacy Services be organized in collaboration with Commonwealth Pharmaceutical Association and Pakistan Pharmacists Association.

32. The Agha Khan Hospital in Karachi which operates what is clearly the most well-organized hospital pharmacy service in Pakistan be requested to provide consultancy services in advising on the establishment of hospital pharmacy service throughout the country.

33. Awards proposed to be given to officers of the Federal Ministry of Health and in the Provincial Governments for notable performance of duties particularly with regard to monitoring malpractices, etc. as already initiated by implemented with immediate effect. It is revealing to quote here the not by the Director General Health in 1986 about the performance of certain drug inspectors and officers in 1985-86 who regrettably remain unrecognized even in 1991. "There is no denying that the risks taken by these officers were of extra-ordinary nature, over and above their routine duties and have been recognized as meritorious service in our preceding notes the Finance Division have also appreciated this fact by suggesting to recommend the case for the award of medals."

34. Pharmacists be given opportunities to avail themselves of scholarships, in service courses particularly at overseas locations in order to update themselves on new developments.

35. Private model pharmacies on the lines and pattern of the Agha Khan Hospital, Karachi, should be encouraged and they must employ qualified pharmacists to ensure quality and standard of drugs dispensed.

36. Monetary rewards should be given to drug inspectors other officers and staff who perform their duties with exemplary qualities and help protect public health, or saves public money.

36a. It is recommended that the Central Drug Research Fund presently controlled by the Ministry of finance be transferred to the Ministry of Health in order to enable prompt and effective utilization of the funds thus fir generate.

36b. It is recommended that all licensed pharmaceutical industries in the country be required to contribute 0.33% (one third of one per cent) of their annual turn over to the Central Drug Research Fund to be controlled by the Ministry of Health in a manner which gives adequate representation to all relevant segments.

36c. On the analogy of doctors, Soft term loans of 5 laces be offered to pharmacists for opening model whole sale/retail shops.

36d. Protection of pay and job security must be provided to pharmacists working in industry otherwise it will not be possible for them to give proper advice on rejection or reprocessing of faulty batches which involve monetary losses to manufacturers. Till rules are framed, instructions issued by Health Ministry in March, 1990 be strictly enforced.

36e. Distribution houses/whole sellers/retailers with annual turn over of 0.5 millions per annum be bound to employ pharmacists as pharmacy Managers to keep a check on expire, storage, recall and enforcement of Drugs Act and Rules Otherwise they may be discouraged in government supplies.

Part IV - TRANSNATIONAL PHARMACEUTICAL COMPANIES IN PAKISTAN

Note :

The situation of transnational or overseas pharmaceutical companies operating in Pakistan of which there are 30 major examples with production plants in the country today is a paradox of perceptions.

There is the vie that the TNC's make exorbitant profits on the sale of pharmaceutical products, use aggressive marketing and advertising techniques to promote their products and remit vast amounts to their overseas headquarters by means of transfer pricing as well as remittances of profit after taxes.

There is the other view which points out that about 90% of the allopathic medicines available in the market in Pakistan are the result of research and development conducted by the principals or associated companies of the TNC's operating in Pakistan today, that these companies have always observed high standards in good manufacturing practices, have fulfilled quality assurance criteria, have employed and trained thousands of Pakistanis, that they contribute about Rs. one billion in taxes, duties, workers, fund, share etc. and pay income tax of about Rs. 243 million each year and that they continue to make available to Pakistan the benefits of large investment in research made by their overseas principals.

However, the corporate style and profit motivation of TNC's are often in stark contrast to disparities and injustices that prevail in developing nations like Pakistan.

There is certainly sound justification for continual vigilance to ensure that the national interest and the public good are, in no way, threatened by the profit ethos of the TNC's. At the same time it is incumbent upon critics,

analysis, administrators and political leaders to take an objective and rational approach to the TNC's. There is a need to acknowledge the integrity and patriotism of the Pakistani personnel who work with professional skill in TNC's and who are bound to protect the national interest to the same degree that citizens working in any other sectors are committed.

While the subject of price controls which is a major concern for the TNC's is being dealt with in Part IV of these recommendations, at this stage recommendations in the context of TNC's are being made with reference to areas other than medicine prices.

RECOMMENDATIONS

37. It is recommended that the Pharma Bureau in the Overseas Investors' Chamber of Commerce and Industry should take the initiative in enabling Pakistani pharmaceutical companies and representative bodies of the Government of Pakistan to establish and institutional forum of exchange of information, research, ideas and opinions on the promotion of research and development in the pharmaceutical sector. The institutional responsibility in this regard has so far been borne exclusively by the Government of Pakistan. In furtherance of the spirit and action by which TNC's as well as Pakistani pharmaceutical companies contribute to a research fund, a new collaborative and co-operative forum supported by TNC's would partly help remove misconceptions about them and at the same time strengthen the development of an indigenous research capability which could include expanded clinical trial of products.

38. TNC's in Pakistan in collaboration with the Pakistan Pharmaceutical Manufacturers Association through coordination with the Federal Government should draft and prepare a manual on good manufacturing practices which can be reviewed each year and published for the benefit of all manufacturing units in the country.

39. It is recommended that TNC's demonstrate their commitment to preventive medicine in as credible a manner as is visible their commitment to, and capability i curative medicine. Towards this end, each TNC should sponsor a pilot health education programme in each district of the country to help meet the enormous challenge faced by Pakistan in the context of high illiteracy, high population growth rate and limited financial resources. Such a district level health education programme supported by TNC's could be conducted in collaboration with the official health delivery system, the educational system and voluntary non-governmental organizations. Such a contribution by TNC's would once again also help remove some of the misperceptions about their role and objectives in Pakistan.

Part V - THE ISSUE OF TRANSFER PRICING

Note :

It has been well described that the term "transfer price" is used to denote the price charged by the parent company or other associates to a subsidiary operating in another country for materials exported from the country in which the parent company is headquartered.

Such materials are stated to be ingredients for pharmaceutical products which are discovered or developed by the parent company's research and development operations.

There is a widely prevalent view that in this matter, parent companies of transnational corporations operating in Pakistan charge unproportionately high prices for the export of such materials whereas the same materials are reportedly available at significantly lower prices from other sources.

To evaluate the correct position in this matter, it is necessary to note that the transnational companies in the medicine sector claim to spend a large amount on the development of a new medicine and that the higher price of materials exported therefore reflects a legitimate return on such a high level of investment.

It is also stated that the parent offices of transnational companies strictly observe a large number of specific conditions to ensure meticulous standards of quality, purity and consistency in the materials exported to country such as Pakistan whereas Governments and countries offering the same materials at a lower price do not observe the same standards and procedures.

Such strict observance includes enforcement of internationally accepted standards of good manufacturing practices, details of clinical trails conducted of medicines produced from the raw material, proving data concerning the bio-availability, dissolution rate and serum level studies in respect of the products made from the exported materials and allowing inspection of production facilities by prospective buyers.

The most important element to consider before evaluating the issue of transfer pricing is that of the policy of Pakistan towards intellectual property rights and respect for international conventions and covenants regarding patents etc.

This is so because transfer pricing regarding materials for products under patent is entirely different form transfer pricing for materials for products where patents have expired.

Pakistan is a signatory to the Paris Convention on Intellectual Property Rights and it is therefor incumbent upon us to observe the terms prescribed by the convention.

Such respect for patents developed by overseas companies also ensures that Pakistan remains a respected members of the international community of nations and is able to ask for, and receive, the benefits of all research and development, science and technology that are relevant to our country's specific needs.

Our condition of development is such that we cannot afford to be blacklisted or boycotted by the international community of nations as a consequence of our disregard for international conventions on copyrights.

At the same time, as a developing nation, Pakistan has to remain alert to the problem of being charged inequitable and unfair high prices for the transfer of research and technology.

Therefore, a careful balancing act has to be conducted with a tilt in favor of respect for copyright and a bias against "pirate manufacturers" who may give us the short-term benefit of lower prices but may also help condemn us to increased difficulties in receiving a regular flow of research benefits.

It is pertinent to take note here of the case of a leading trans-national company in Pakistan which imported one particular material from its overseas principals up to 1989 for a total value of Rs. 35 million. However, in less than two years of commencing basic manufacture in Pakistan of the same material which was previously imported in the transfer pricing context, the same company has already exported products and materials of approximately Rs. 80 million in value, thus providing a credible rebuttal to the conventional and unfounded charge made that all transfer pricing transactions work against the interest of Pakistan.

Given the facts of the situation and careful analysis and monitoring by Government and the public, it is possible to take action on transfer pricing which is fair and practical to all concerned.

RECOMMENDATIONS

40. The Committee therefore recommends that where TNC's are able to establish that their parent overseas companies observe internationally recognized norms for the manufacture of materials and where prices quoted for import into Pakistan are approximately similar to the prices offered to a reasonably large number of other developing countries, we uphold the principles outlined in the Paris Convention on Intellectual Property Rights while maintaining close scrutiny of quoted prices, invoices, competitive prices, etc.

41. The Government must ensure that all institutions under its administrative authority as well as non-government institutions respect the law regarding patents so that the legitimate rights of the copyright owners, be that an overseas company or a Pakistani organization, are respected and enforced.

Part VI - CONTROL OF MEDICINE PRICES BY THE GOVERNMENT OF PAKISTAN

Note :

The control of prices of medicines by the Federal Government is possibly the single most contentious issue facing the pharmaceutical industry.

There is complete unanimity amongst the trans-national companies and the Pakistan pharmaceutical companies that the control of these prices by the Government is a gross injustice to the manufacturing segment of the pharmaceutical sector because similar price controls are to applied in the case of even essential food commodities such as cooking oil which registered an increase of 27% in six months in 1990, wheat (aata) which increased by about 40% in the same period, as well as other services such as electricity rates which increase by over 50% during the past 2 years.

The criticism leveled in the mass media in which it is alleged that prices of pharmaceutical products have been increasing rapidly and steeply is not substantiated by the actual data.

Whereas the Pakistan Rupee between 1982 and 1988 went through a massive devaluation against all major international currencies a devaluation ranging from 75% in the case of the US Dollar to 150% in the case of the Japanese Yen ad with other prices of raw materials, imports etc. also registering significant increase, the actual rise in medicines prices allowed by the Federal Ministry of Health has been only 4.5% on an annual average basis. During 1988-1991, there has been a lower rate of devaluation; frequent adjustments continue.

Whereas the price of imported medicines have also increased dramatically during the past 5 years, averaging and annual increase range from 10% to 20%, the annual increase for locally manufactured pharmaceuticals has remained at or below 5%.

An examination of the data for countries in this region as well as outside this region conclusively establishes that the prices of medicines in Pakistan except in certain instances are, as a rule, notably lower than prices in India, Sri Lanka and Bangladesh.

The Committee remains deeply conscious of the heavy burden placed on the citizens of Pakistan as a consequence of domestic inflation and recent events in the Gulf region leading to an increase in oil prices etc. At the same time, the Committee has a duty to acknowledge the principle of justice that is applicable to all institutions and groups working in the country. The pharmaceutical industry despite all its other shortcoming and need for reform is nevertheless fully deserving of a realistic and just response.

RECOMMENDATIONS

42. The most appropriate arrangement appears to be as follows:

42.1 Controlled List

(a) All products for the twenty two common diseases as listed in the Pakistan National Formulary (for Hospitals) should have their prices controlled vide Section 12 of Drugs Act 1976 (XXXI of 1976). (List attached).

(b) The pharmaceutical industry should endeavor to provide from the list of these products, new registered products at 20% below the highest price product currently available in the market within 180 days from the date of registration.

42.2 Exempted List

(a) All drugs under the following categories should be exempted from Section 12 of the Drugs Act 1976 (XXXI of 1976):

(i) All Bandages, Plasters and Dressing

(ii) All Multi-Vitamin Preparations

(iii) All Multi-Vitamin Mineral Preparations

(iv) All Vitamin B Complex Preparations

(v) All Digestive Enzymes

(vi) All Laxatives

(vii) All Rubefacients

(viii)All Cough and Cold Preparations.

(ix) All Antiacids and Anti-Flatulent Preparations.

(x) All Topical Antiseptics Except those containing corticosteroids and antibiotics.

42.3 Indexation

To allow for local inflation and the depreciation of the rupee, there should be a system of indexation of prices of all products, on an annual basis (1st July of each year), as follows:

- 40% of MRP (maximum retail price) shall be adjusted to the change in the rupee parity against the major currencies, viz., as published by the State Bank of Pakistan on the last working day of the fiscal year.

- 60% of MRP should be adjusted by the last published local inflationary rate of the State Bank.

Part VII - OPERATION OF PAKISTAN PHARMACEUTICAL COMPANIES

Note :

According to one estimate, in terms of value it is stated that 75% of the allopathic pharmaceutical market is controlled by 30 transnational companies operating in Pakistan while the remaining 25% of the market share is distributed amongst 150 operative Pakistani pharmaceutical companies. By another estimate, in terms of volume, Pakistani companies account for 60 percent of all allopathic medicines sold.

Working with the disadvantage of having to complete with the superior resources of the transnational companies and working in an environment where indigenous research capability is at a primitive level some of the Pakistani pharmaceutical companies have nevertheless shown a laudable capability to operate with high professional standards and produce a fairly wide range of quality products.

These companies also have to complete with trans-national companies in the manufacture of relatively ordinary medicines like vitamins, cough syrups, pain killers and other over the counter medicines whereas in many developing countries, transnational companies are not permitted to manufacture products that the local industry is capable of producing.

This feature, combined with the conventional preference for brand names of foreign origin make it difficult for the Pakistani pharmaceutical companies to break out of a restrictive pattern of growth. They validly complain that even Government organizations which purchase medicines in large volume prefer medicines made in Pakistan by transnational companies rather than by Pakistani pharmaceutical companies.

An extreme version of the predicament faced by Pakistani companies describes them as being on "the verge of collapse".

Visits to the manufacturing plants of Pakistani pharmaceutical companies particularly those operating with a corporate association with overseas companies and visits to the manufacturing plans of transnational companies operating in Pakistan bring out the contrast between the two. Whereas the local companies, with certain exceptions are barely able to observe, leave alone display, good manufacturing practices, the plants of transnational companies are well-organized and exhibit high standards of safety, hygiene and a rigidly controlled production environment.

Those few Pakistani pharmaceutical companies which have standards similar to transnational companies are examples worth propagating and emulating because they prove that, given good leadership, Pakistani pharmaceutical companies can also compete with international manufacturers.

While this may be a dramatic exaggeration of their plight it is quite clear that government needs to review its overall approach to Pakistani pharmaceutical companies and to take a number of measures to remove their difficulties.

RECOMMENDATIONS

43. It is recommended that in consultation with the Pakistani pharmaceutical companies and transnational companies a phased programme be formulated by the Government through which, over the next 10 years, relatively simple medicines such as vitamins, cough syrups, pain killers etc. are manufactured by Pakistani pharmaceutical companies wherever feasible and in the case of the transnational companies manufacture of such products is allowed only where parent companies of transnational companies have conducted the original research and/or where the same products are manufactured by these transnational companies have conducted the original research and/or where the same products are manufactured by these transnational companies in their home country. Where patents for products have expired, such products also should be allowed to be manufactured only by Pakistani pharmaceutical companies. Such a phased programme spread over the next 10 years would give a reasonable time scale to both TNC's and Pakistani companies to make necessary organizational plans. As the current capacity utilization is estimated to be not more than 70% the unutilized capacity of Pakistani pharmaceutical companies could help meet the increased production role.

44. As being recommended separately under the section on the import of medicines, if it is possible to place a progressive restriction over the next 3 to 5 years on the import of medicines that are being manufactured in Pakistan then this step should also be taken by the Government with a view of stimulating the qualitative growth of the Pakistani companies. In the case of products which cannot be manufactured in Pakistan due to absence of production technology or feasibility, imports should of course be permitted. A carefully defined 5-year time frame for a progressive restriction on imports of medicines would enable the Government and the public to monitor the performance of the Pakistani pharmaceutical companies in being able to achieve standards of quality and consistency which are fulfilled by the transnational companies. If the performance is

unsatisfactory, then this policy measure can be reviewed.

45. In view of the essential nature of the pharmaceutical industry, Government should remove import duty, sales tax and other surcharges on the import of machinery for improvement, balancing, and modernization by the pharmaceutical industry.

46. A 3 year tax holiday for the pharmaceutical industry is recommended to enable qualitative growth and to observe what positive use is made of this incentive.

47. The Pakistani pharmaceutical companies should sponsor, in each district of the country, a public health education campaign in coordination with the local health delivery system, the local educational system and a relevant non-governmental organization in order to contribute to the enormous national effort required in the face of high levels of illiteracy and population growth in Pakistan.

48. The Federal Government and the 4 provincial governments should adopt a progressive 3 year programme under which their purchases of medicines are made in favor of brands made by Pakistani pharmaceutical companies with a gradual reduction in the share of transnational companies, with product quality and consistency being regularly verified by an established drug testing laboratory.

49. In order to ensure that concessions given by Government are used to improve the industry and not to benefit a few investors, the PPMA should establish an effective self-regulatory mechanism to monitor occurrence of good manufacturing practices and ethical conduct by its members.

PART VIII - NOTES AND RECOMMENDATIONS FOR REMAINING SECTIONS

Note :

Detailed observations and recommendations concerning issues No. 9 to 14 will be presented in the final report.

Some recommendations about these issues already appear under recommendations for issues No. 1 to 8.

In this section certain additional recommendations pertaining to issues 9 to 14 are being made.

RECOMMENDATIONS

50. By the end of 1991 the Government should finalize amendments proposed to the Drugs Act 1976 and move a Bill in either house of Parliament to give effect to these amendments. Such amendments should be based on the very comprehensive studies and recommendations made by the Pakistan Pharmaceutical Manufacturers Association, the Overseas Investors' Chambers of Commerce and Industry, the Pakistan Chemists and Drugs Association, the Pakistan Pharmacists Association, the Pakistan Medical Association which have been with the Ministry of Health for several years.

The delay in making these amendments has now become unreasonable and the public interest demands that the Amendment Bill be considered and adopted in Parliament before the conclusion of the financial year i.e., 1991-92 in order that financial provisions arising from such amendments, e.g., creation of new posts, etc. can begin to be reflected in the budget to be adopted for 1991-1992 and thereafter.

51. An interministerial committee on the pharmaceutical sector should be constituted with immediate effect which would meet at least once every 60 days and which would include representation of all Federal Ministries and departments dealing with aspects of the pharmaceutical sector such as Health, Industries, Commerce, Central Board of Revenue, etc. thus serving as a single reference point for the pharmaceutical industry which otherwise at present has to go from organization to another in order to secure prompt action on a number of issues. An interministerial committee can be presided over by the Secretary of health or, in his absence, the Director-General, Health. Such a committee should also have representation of all 4 provincial Health Departments.

52. In order to stimulate higher standards of retail marketing, improved storage conditions, ethical practices etc. of retail medicine stores should be required to become members of the Pakistan Chemists and Druggists Association which is the sole representative body of retailers and is a member of the Federation of Pakistan Chambers of Commerce and Industry.

53. For the convenience of the public it should be ensured that at least one medicine store in each urban district and in each rural tehsil remains open during night hours to serve as an emergency pharmacy. A system of rotation to ensure equity can be enforced through consultations between the provincial health department and the Pakistan Chemists' and Druggists Association. Where necessary, police protection can be provided to ensure safety of life and property.

54. The discrepancy in the patent law by which the period of the patent is calculated from the date of application rather than from the date of registration should be removed as it often takes an unreasonable length of time, running into years, for the application to be processed before registration is awarded.

55. The long period taken in providing reports on medicine by the drug testing laboratories should be drastically reduced. There are many instances where the report on a substandard drugs takes as long as 60 days while the final and substantive report takes as long as 2 years. In the case of public health such delays are unacceptable as they posse a direct threat to the well-being of citizens who may use medicines that are substandard.

56. The convention by which pharmaceutical companies liberally supply doctors with free samples of new or existing medicines should be progressively curtailed and discontinued completely by December 31, 1991. Where entirely new medicines are introduced after having been cleared by relevant international and national efficacy testing institutions, free sampling only in limited quantities may be permitted in order to introduced the medicines to the medical profession.

57. There is a need for improved communication and cooperation between the representative bodies such as the Pakistan Medical Association, Overseas Investors' Chambers of Commerce and Industry, the Pakistan Pharmaceuticals Manufacturers Association, the Pakistan Pharmacists Association etc. particularly in order to bring about a better appreciation of the role of qualified pharmacists in the health system. The Government should take the initiative of sponsoring opportunities for improved communication and examination measures to institutionalize this process.

58. The committee in the Federal Ministry of health which examines and approves claims to be made in the advertising of pharmaceutical products in the mass media should meet at least once every 30 days in order to avoid delays in this respect and reduce waste of effort

by the pharmaceutical companies and by advertising agencies.

59. The Ministry of Health in ordering purchase of medicines should strictly observe the general rules of tender as cases have been reported to the Committee where such rules have been disregarded.

60. The Central Drug laboratory, Karachi housed in old barracks that are inadequate and inappropriate for such an important institution, should be shifted to premises that provide an environment suitable to its functions. An allocation or this purpose should be made in the budget for 1991-92 and the movement be completed at the earliest possible time.

61. Similarly, the staff resources of the Central Drugs Laboratory, Karachi need to be significantly increased and improved, by the immediate filling of existing vacancies, the upgradation of posts of testing responsibility from B-11 to at least B-17 and the creation of new posts to meet an increased workload.

62. The provision in the Drugs Act for the establishment of a Federal Drugs Laboratory to serve as a comprehensive superior institution in the drugs evaluation and testing field should begin to be implemented with effect from the financial year 1991-92 as even the existing drug laboratories do not have some of the most basic equipment.

For example, it has been observed that to test insulin medicine which is an essential drug for diabetic patients no facility exists anywhere in the country. The prolongation of such a situation is nothing less than an outrageous and special efforts should be made to end this serious omission.

63. Besides establishing a Federal Drugs Laboratory, the Government must immediately develop at least 2 full pledged Government testing laboratories, one for initial and one for appellate testing. Sectional heads must be in B-19 and posses 10 years experience of drug testing while the Director/In-charge should be in B-20 with 15 years experience and with postgraduate qualification in pharmacy.

64. Many posts of (B-18) sectional heads/Deputy Directors/Pharmaceutical Chemists/Senior Analysis lying vacant in drugs laboratories for period ranging from 5 to 10 years should be filled.

65. The Composition and work pattern of the Licensing and Registration Board, Appellate Board and Provincial Quality Control boards should be rationalized to become professional and objective to ensure justice and fair play in licensing, registration, pricing, evaluation of test reports of government analyst and approval for prosecutions where necessary.

66. The offer made by the World Health Organization in 1988 under the Essential Drug Programme to provide a mainframe computer for recording and retrieval of data on drug registration, pricing, training, surveillance studies, appointment of pharmacists etc. should be pursued and utilized, even though 2 years have gone by since the original offer was made. Similarly, coordination with international agencies such as WHO should be notably improved.

67. The federal Ministry of Health should institute a system by which examples of exceptional achievement in health delivery system and scientific pharmacy management such as those under the direction Provincial Governments particularly the ones located in rural areas be formally recognized and rewarded. The Committee noted, with interest and appreciation, the work rendered by the Department of Health of NWFP at Basic Health Unit in District near Peshawar and similarly the work being rendered in rural areas of Baluchistan in Mastung and in Gawadar Districts where personnel are rendering

commendable service with extremely limited resources.

CONCLUSION

The Committee would like to express its determination to ensure that the above recommendations do not simply add to the pile of existing proposals, and that the Federal Parliament and the Provincial legislatures ensure sustained scrutiny and pressure upon respective Governments and non-governmental institutions concerned to achieve prompt and effective implementation.

WORK DONE BY THE SPECIAL COMMITTEE OF MEDICINE SECTOR

Data of constitution of the Special Committee = 19-1-88

Date and Time	Venue	Nature of work done by the Committee
28-1-88 at 3.00 p.m.	Islamabad	The Committee approved its terms of reference and chalked out its future programme.
15-2-88 at 10.00 a.m. to 7.00 p.m.	- do -	Representatives of following associations met by Committee (i) Overseas Investors Chamber of Commerce and Industry (ii) Pakistan Pharmaceutical Manufacturers Association (iii) Pakistan Pharmacists Association (iv) Pakistan Chemists and Druggists Association
21-3-88 at 3.00 p.m.	--do--	Discussed work conducted by the Committee up to date and reviewed future schedule of the meetings.
4-4-88 at 9.30 a.m. to 8.30 p.m.	Karachi	Visited JPMC, Central Drug Laboratory, Agha Khan Hospital, Attended the bringing by Secretary Health, Government of Sindh at Qasre Naz. The Chairman along with D.G. Health and Secretary Health, Government of Sindh paid surprise visits to some Chemists shops in Karachi Gali, Met with the representatives of Pakistan Chemists and Druggists Association.
5-4-88 at 10.00 a.m. to 7.00 p.m.	Karachi	Surprise visit of Zafa Laboratories (PPMA) Visited Abbot Laboratories and met with the representatives of Overseas Investors Chamber of Commerce and Industry, visited EPIA Laboratories (PVT) and met with the representatives of PPMA.
29-5-88 at 9.30 a.m. to 6.00 p.m.	Lahore	Visited Shaikh Zaid Hospital and met with the drug Committee Headed by Lt. Gen. M.A.Z. Mohyuddin. visited Mayo Hospital.
30-5-88 at 9.00 a.m. to 6.00 p.m.	Lahore	Attended briefing by Secretary Health, Government of Punjab, Visited Madipak Limited. Paid Surprise visit to Fatima Memorial Hospital (Pvt.) Surprise visit of whole sale shops of Chemists/Druggists at Lahore and Opposite Mayo Hospital.

31-5-88 at 9.00 a.m. to 6.00 p.m.	Lahore	Visited Lahore Drug Testing Laboratories. Galaxo Laboratories. Met with the representatives of Pakistan Chemists and Druggists Association (Fuu). Met with the representatives of Pakistan Medical Association Lahore Branch.
19-8-88	Islamabad	Reviewed the progress made by committee so far and chalked out the schedule for its future meetings to be held from 15th August, 1988 to 22nd August, 1988 at Quetta.
17-1-89	Islamabad	Reviewed progress made so far.
23-1-89	--do--	Meeting with representatives from the Ministries Finance, Commerce and Industries and Central Board of Revenue.
1-2-89	Peshawar	(i) Briefing by Secretary Health NWFP at Provincial Secretariat (ii) Visited a Basic Health Unit at village near Reggi near Peshawar (iii) Visited chemists shops and a drug Factory
21-2-90	Islamabad	To chalk out a work plan.
20-8-90	Islamabad	Reviewed progress done by the Committee.
21-8-90	Islamabad	Briefing by Health Division
12-9-90 at 9-30 hrs.	Quetta	Briefing by Secretary Health, Baluchistan.
12-9-90 at 11.30 hrs.		Visited Basic Health Unit (BHU)
12-9-90 at 16-00 hrs.		Visited wholesale/retail shops of chemist/druggist.
13-9-90 at 10.00 hrs to 11-30 hrs	Quetta	Visited District Hospital, Quetta. Briefing by the Administrator of Marker Alkaloids.
15-9-90	Gawadar	Visited Health facilities with particular reference to availability of medicine at Gawadar.
23-9-90 at 10-00 hrs. to 1800 hrs	Islamabad	Representative of following associations met with the Committee: 1. Overseas Investors' chamber of Commerce and Industry, Karachi 2. Pakistan Pharmaceutical Manufactures Association, Karachi.

			3. Pakistan Pharmacists Association Karachi.
24-9-90	10-00 hrs. to 11-45 hrs		4. Pakistan Chemists and Druggist Association, Karachi.
			5. Pakistan Medical Association (Central) Karachi and Pakistan Medical Association Lahore.
16-3-91	15:00 hrs.	Islamabad	To review interim report.
17-3-91		--do--	To finalize the interim report.

ANNEX X

UNIDO comments on the preparatory mission report presented by experts Dr. K. Ivanov and H. Persson

The Government of the Islamic Republic of Pakistan has been taking actions towards improving the quality of the health services offered to the population. To achieve this objective, special attention has to be given to the development of the national pharmaceutical industry in order to increase the availability of essential medicines both preventive and curative.

The concluded preparatory mission enables assessment of the present status of development of the health and pharmaceutical services and evaluation of the country's requirements for implementing a detailed study for the development of the pharmaceutical sector including specific fields of activities.

The Islamic Republic of Pakistan had a population of 126,406,000 inhabitants in 1991, of which almost 85% is less than 45 years of age. It is estimated that the population will be approximately 162,409,000 by the year 2000 and 205,496,000 by 2010. The country will have a population equivalent to the population of all Western European countries combined. The infant mortality rate per 1000 live births equals 113.0. Among the most common causes of death are malaria, diseases of the digestive system, diseases of the respiratory system, infections of the intestinal tract and childhood diseases.

The above mentioned facts indicated the necessity to study on an urgent basis, the development of the pharmaceutical and medical sectors in order to satisfy the growing requirements of the population and to contribute to the amelioration of vital statistics of the country.

The experts strongly recommended proceeding with the performance of a detailed study for the development of the sector. Based on the findings and recommendations of the suggested study, it could be possible to decide the future activities to be undertaken for the development of the sector in order to satisfy the requirements of the population.

The recommendations of the study could represent a strong tool for programming the future development of the sector.

The study must emphasize the analysis of capabilities for the improvement of the quality control and quality assurance system for the pharmaceutical products and materials to be utilized for medical purposes. One important aspect that must be emphasized by the study is the development of an industrially oriented programme which could satisfy the requirements of the national programme against AIDS.

The experts also recommended analysis of the present demand for pharmaceuticals as well as the perspectives of future consumption and to study the domestic development possibilities for the production of basic pharmaceutical active principals.

The analysis of the above mentioned subject must also include the present status and future plans for development of the basic chemical industry sector and the capabilities of the industry to produce the intermediate products and fine chemicals required for the production of essential pharmaceutical active principals.

The availability of different contraceptives methods at accessible prices will contribute to reducing the population growth rate. The analysis of the existing capabilities and possibilities to introduce new modern products must also be supported.

The study must include the requirements for qualified personnel and indicate the activities which could be undertaken for the qualification and requalification of necessary personnel.

During the performance of the study, it is also recommended to study the mechanisms of linkage of the existing research institutes as well as the industrial producers in the country.

The above will enable identification of the problems and orientation of the research development activities towards the improvement of industrial production and modernization of the technological processes. Mechanisms for motivating the development of such types of linkages must be found and applied.

Upon the conclusion of the study, the government should have the necessary information for the decision required to execute the recommendations delivered by the study. For any specific recommendation, it is necessary to have indications about investment cost, schedule of activities, possible sources of technologies, possible conditions for cooperation in production, etc.

The concluded study represents a well organized guideline document that could be used for programming the future development of the sector.