



# STC

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SAARC Tuberculosis Centre's News Letter is published every six months, reports on the works, decisions of important meetings of the centre and recent information on Tuberculosis.

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(Scientific Session of the Seminar held on 1-4 July 1997)  
see page 4 for the report



(Scientific Session of the Workshop and Meeting held on 18-23 June 1997)  
see page 1 for the report

## Report on the SAARC Workshop on Formulation of Guidelines for Coordination in Government and Private Sector/NGOs Initiatives of TB Control and Meeting of the TB Experts for Compilation of TB Control Training Manuals for SAARC Member Countries, 18-23 June 1997, Kathmandu.

The delegates from India, Maldives, Nepal and Pakistan participated in the above mentioned workshop and meeting organised by SAARC TB Centre, in Kathmandu.

The specific objectives of the workshop and meeting were - to formulate clear-cut guidelines for coordination in government and private/NGO sectors initiatives of TB control and compilation of training manuals of TB control for SAARC member countries.

The following recommendations were made:

The group realising the fact that the SAARC countries account for 40% of the global Tuberculosis burden and taking into consideration the availability of manpower resources came to the conclusion that governmental efforts alone can not succeed in achieving the goal of Tuberculosis control in the Member Countries. Nearly half of the total Tuberculosis load of SAARC Countries at one point or the other is attended to by private for profit sector or by other NGOs. It was with this background, that the group unanimously appreciated the urgent need of involvement of the

private for profit sectors and to the NGOs which also enjoy the trust of the community. The group also felt that the private & governmental sectors should have working partnership built on mutual trust and respectability. The group debated on all relevant aspects including every aspect of the existing Tuberculosis control programme, formulation of technical and operational guidelines, coordination, defining initiatives of Tuberculosis control in the private sector, identification of their training areas and requirements leading to formulation of training modules and manuals required for the purpose.

The group decided to take a wholistic view of the existing scenario keeping in view the requirements of the SAARC countries made the following recommendations;

### **A. Guidelines for coordination between government/private sector:**

While discussing the ways and means of involvement of private for profit sector and other NGOs following guidelines have been recommended or the purpose.

1. Advocacy aimed at private for profit and other NGOs emphasising the importance of their role in complementing and supplementing governmental efforts in control of Tuberculosis.
2. Building up mutual trust and respect among the collaborators and jointly ensure promotion of the TB control programme without affecting the interest of either sector.
3. Publicising the endorsement of the governmental policies and programmes formulated to control Tuberculosis.

4. Identification and acceptance of the areas of collaboration amongst the partners.
5. National level organisations shall be involved in formulating broad policy guidelines and planning frameworks while the methodology for actual implementation shall be decided by implementation level of both sectors.
6. The private for profit and other NGOs shall have requisite infrastructure/system to undertake identified activities.
7. The private for profit and other NGOs shall extend full cooperation to the governmental agencies in evaluating and monitoring the activities being undertaken by them.
8. The governmental sector shall provide to the private sector a profile of Tuberculosis control programme activities in their respective areas.

**B. Incentives to involve private for profit and other NGOs.**

1. Representation to private sector at policy formulation, planning, programming and implementation levels.
2. Provision of training and exposure at national and international levels in all programme activities.
3. Provision of inputs to private sector for training of their members.
4. Technical assistance in the care of TB patients.
5. Provision of high quality diagnostic and curative services free of cost at designated centres.

**C. Initiatives of Private Sector in Tuberculosis Control Programme**

Private physicians and other NGOs can play an important role in control of Tuberculosis in the community by;

1. Advocating the use of sputum microscopy as the primary tool of diagnosis for pulmonary Tuberculosis and monitoring of its treatment.
2. Ensuring that each and every person with productive cough of three weeks or more has three sputum samples examined in a designated laboratory.
3. Referring patients to identified sites for diagnosis and/or treatment.
4. Referring contacts of sputum positive TB cases to the designated centres for screening.
5. Adopting the recommended regimens of treatment.
6. Propagating the message that DOTS is the standard of care and is the only means of ensuring "Cure"
7. Undertaking IEC activities on all aspects of Tuberculosis with special emphasis on completion of treatment.
8. Educating the community that TB patients are not rejected by their families and others.

**D. Identified Training Manuals & Modules;**

The group observed that the techniques of diagnosis and treatment of Tuberculosis have revolutionised in the SAARC countries during the last few years. Unfortunately new tools and techniques being adopted have not been adequately documented and made available to health care providers. Taking the realistic situation into consideration, the group felt the need for the effective and meaningful training. In addition to developing training manuals training modules with practical exercises also need to be developed for the various categories of health care providers. The group had a number of buzz and brain storming sessions on this critical aspect and recommended that formulation of following

manuals and modules of different categories of personnel engaged in TB control activities.

1. Technical guidelines for Tuberculosis control indicating the magnitude of problem, diagnosis, treatment, proper recording/reporting requirements and programme evaluation.
2. Operational guidelines depicting various operational aspects for each category of health care worker.
3. Peripheral level health worker manual indicating his/her job requirements as well as the methodology for its implementation.
4. Peripheral level health workers training module containing actual training requirements, methodology of the activity implementation and tools and techniques of imparting training.
5. A guide for community health volunteers highlighting important general aspects of TB as well as all activities related inputs.
6. A guide for private practitioners and other NGOs containing general aspects of Tuberculosis, their role in its control with emphasis on practice of adopted treatment regimens including the actions in case of possible side effects of drugs as well as diagnosis and management of HIV-TB co-infection.
7. Manual for laboratory technicians containing all aspects of his/her job responsibilities as well as guidelines for safe disposal of contaminated materials and maintenance of records.
8. Module for laboratory technicians containing actual training activities and methodology supplemented with practical exercises to evaluate the training imparted.

9. Comprehensive training manuals for the Medical Officers involved in Tuberculosis control programme covering all aspects of programme activities including supervision, monitoring and evaluation of services. It should also contain guidelines on education, coordination, motivation, facilitation and guidance required for subordinate workers.

10. Comprehensive training modules for the medical officer covering all aspects listed above with practical exercises including evaluation of training.

The group concluded its discussions with a recommendation that SAARC TB Centre should act as the nodal agency for exchange of training manuals/modules developed by member countries amongst them.

#### **Following Participants attended the Workshop & Meeting:**

Dr. G. R. Khatri,  
Director,  
National TB Control Programme,  
Dy. Director General  
Ministry of Health and Family Welfare,  
New Delhi, India.

Dr. S. P. Khanna  
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New Delhi, India.

Dr. Harish Grover  
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Chest Clinic, Male, Maldives

Dr. K. B. Shrestha  
Senior Chest Physician

Dr. Pushpa Malla  
Chest Physician  
National TB Centre,  
Thimi, Bhaktapur, Nepal

Dr. N. G. Amatya,  
Nepal Anti-TB Association  
Kalimati, Kathmandu, Nepal.

Mr. Abdul Qadir  
First Secretary  
Embassy of Pakistan, Kathmandu.

Dr. D. S. Bam,  
Director,  
Dr. P. Kumar,  
Dy. Director,  
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Nepal.

#### **Observers**

Ms. Bhubaeshwari Satyal  
President  
Nepal Anti-TB Association,  
Branch Office, Kathmandu, Nepal.

Mr. Mahendra Lal Kayastha  
Vice President  
Nepal Anti-TB Association,  
Branch Office, Bhaktapur, Nepal.

\*\*\*\*\*

## **Report on Seminar on Production Marketing/Distribution and Quality Control of Anti-TB Drugs in the Region, 1-4 July 1997, Kathmandu.**

The Seminar was organised by STC in Kathmandu. The delegates from India, Nepal, Pakistan and Sri Lanka attended in the seminar. The purpose of the seminar was to discuss the different aspects of the production, marketing/distribution and quality control of anti-TB drugs in the region and to recommend a suitable strategy.

### **The following Recommendations were made in the Seminar:**

#### **1. Interaction:**

There is a need for closer interaction between TB programme authorities and drug regulatory authorities of member countries in order to ensure rationality and uniformity of anti-TB drugs formulations as well as uninterrupted supply of quality medicines.

#### **2. Production:**

It was observed that variation in the functioning and infrastructure of drug

regulatory organisations in SAARC member countries leads to drug quality apprehensions for importing countries. Therefore, there is a need to adopt uniformity in Good Manufacturing Practice(GMP) requirements in the region for which the group recommended that WHO guidelines on GMP and certification scheme should be followed. For a uniform system of implementation, the WHO GMP certificates should however be issued by National/Federal drug regulatory authorities of the member countries.

### **3. Quality Assurance:**

#### ***Bio-availability:***

i) The group noted with concern the reports on bioavailability problem linked with Rifampicin in fixed dose combinations and felt that appropriate collaborative bioavailability studies should be undertaken by member countries where such facilities are available.

ii) The drug regulatory authorities of member countries may look into the possibility of directing manufacturers to provide bioavailability data of their fixed dose combinations of Rifampicin with other anti-TB drugs specifically at the time of registration or whenever required.

#### ***Monitoring:***

iii) In order to monitor the quality of anti-TB drugs supplied to the public and private sectors, the drug regulatory authorities of the member countries may also undertake regular

quality checks within their National quality survey programmes.

### **4. Distribution and Utilization:**

In the context of issues relating to distribution and utilisation of anti-TB drugs the group felt that there is a dire need to evolve a suitable mechanism of reporting and recording system of patients being treated in the private sector.

### **5. Storage:**

In view of the fact that improper storage conditions of anti-TB drugs may be one of the causes affecting their efficacy, it was recommended that the proper storage procedures should be adopted, under the supervision of a person qualified for the purpose to ensure that the quality of these drugs is not adversely affected during their shelf-life.

### **6. National TB Programme:**

Keeping in-view of the objective of the National TB Control Programme an effective mechanism should be evolved to ensure uninterrupted supply of quality medicines to all needy patients.

### **7. Availability of Anti-TB Drugs:**

Availability of quality anti-TB drugs at affordable prices has always been the prime concern of all member countries and it was felt that there was a need to further continue the efforts.

**The following participants attended the Seminar:**

Dr. P. Biswal  
CMO, DGHS,  
Mr. Ashwani Kumar, Jt. D.C. (1)  
Ministry of Health and Family Welfare,  
Nirman Bhawan, New Delhi,  
India.

Dr. D. S. Bam  
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National TB Centre/  
SAARC TB Centre  
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Dr. K. B. Singh Karki  
Director,  
Logistic Management Division,  
Dept. of Health Services, MOH  
Kathmandu, Nepal.

Dr. D. D. Bhattarai  
Act. Director  
Department of Drug Administration  
MOH, Kathmandu, Nepal.

Miss Farzana Choudhary  
MOH, Block C, Secretariat, Islamabad,  
Pakistan.

Mr. Abid Hayat  
Chief Pharmacist  
Govt. Lady Reading Hospital  
(NEFP), Peshawar, Pakistan.

Mrs. R.M.M. Nandini  
Pharmacist  
National Drug Quality Assurance Lab.  
Colombo 10, Sri Lanka.

Dr. P. Kumar,  
Dy. Director,  
SAARC TB Centre, Thimi, Bhaktapur,  
Nepal.

**Observers**

Mr. Rajendra Bahadur Tuladhar  
DGM  
Mr. Keshav Dhoj Joshi  
Manager  
Royal Drugs Limited, Babarmahal  
Kathmandu, Nepal. \*\*\*\*\*

## Commemoration of the World TB Day in Kathmandu

World TB day was commemorated on 24th March 1997 in a special function jointly organised by SAARC TB Centre, NTC, WHO, NATA at City Hall in Kathmandu. The special function was chaired by Minister of Health, Mr. R. K. Mainali and the Prime Minister, Mr. Lokendra Bahadur Chand graced the function as the chief guest. His Excellency, the Secretary General, Mr. Naeem U. Hasan along with Director, Ms. K. C. Namgyel represented SAARC Secretariat.

Mr. Lokendra Bahadur Chand the Right Honourable Prime Minister highlighted the importance of TB control. He further added that the establishment of the SAARC TB Centre in Nepal is right step in this direction. The centre has taken the leadership in coordinating the efforts of all SAARC member countries for regional cooperation in the field of Tuberculosis control. The special function was presided over by the Hon'ble Minister for Health, Mr. Radha Krishna Mainali. Mr. Mainali expressed his views on the

burden of Tuberculosis in the world and in the SAARC member countries. The National TB Centre which is a focal point of SAARC Tuberculosis Centre can play a vital role which can provide appropriate coordination, training and research to boost NTPs. Hon'ble Health Minister informed that Nepal has the advantage to have the SAARC TB Centre which is located in the same building as the National TB Centre. This centre is doing commendable work by coordinating efforts of National TB Control Programmes of member countries. This is a unique example of dealing with serious health problem through regional cooperation.

In the function. H. E. the Secretary General expressed the importance of Tuberculosis control in the Region and highlighted the role of SAARC TB Centre in the field of TB control.

In his address, H. E. called upon the policy makers and the public at large to support the Member Countries of SAARC in their efforts to prevent & control this dreaded disease. \*\*\*\*\*

### First South East Asian Regional Course on Tuberculosis Control 13th to 25th April 1997, in Kathmandu, Nepal

A twelve day training programme on Tuberculosis Control was organised by His Majesty's Government of Nepal, Ministry of Health, National TB Centre and World Health Organisation in collaboration with Research Institute of Tuberculosis (RIT), Japan, International Union Against Tuberculosis and Lung Diseases (IUATLD) and SAARC Tuberculosis Centre (STC), Nepal. The training was inaugurated by the Hon'ble Minister for

Health, Mr. Radha Krishna Mainali. The inaugural function was presided by the Hon'ble State Minister for Health, Dr. Bharat Kumar Pradhan. The participants from Bangladesh, Bhutan, India, Nepal, Sri Lanka, Indonesia and Myanmar attended the training.

### Study Tour

Dr. Prahlad Kumar, Deputy Director of SAARC TB Centre, visited the Tuberculosis Research Centre (TRC), Madras from 16th to 25th July 1997.

The objective of his visit was to follow-up the progress of multi-centric study of drug resistance to be undertaken by Tuberculosis Research Centre (TRC) of Madras.

The TRC has agreed to conduct this study in South India. The Ojha Institute for Chest Diseases, Karachi, NTC, Kathmandu and LRS Institute of Chest Disease, Delhi have agreed to conduct the study while as other centres have been requested to join the study.

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### Proposed Programmes of the Centre

1. Seventh Meeting of the Governing Board of STC.
2. Workshop Relating to Research on TB and HIV in SAARC Member Countries.
3. Seminar on Socio-anthropological Research Studies in the Field of Tuberculosis Conducted in the Member Countries.

# *Special Articles & Technical Information on Tuberculosis*

## **Production, Marketing/distribution and Quality Control of Anti-TB Drugs in Pakistan**

Miss Farzana Choudhari and Mr. Abid Hayat \*

### **Geography of Pakistan:**

Pakistan is a country which extends over an area of 796095 Sq.Km. of land comprising sea coast, plains, deserts and mountain ranges, lies between 23 and 37 degrees north latitude and 61 and 76 degrees east longitude in the northern hemisphere. It is flanked by India in the east end south-east, Afghanistan on the north and north-west and Iran on the west, whereas it shares a common border with China on the north-eastern end. Its sea coasts in the south face the Arabian Sea.

### **Climate:**

Pakistan enjoys a considerable measure of variety of climate. God has blessed it with all types of season varying from scorching summers to extremely cold winters. North and north-western high mountain ranges are extremely cold in winter while the summer months of April to September are pleasant. The vast plains of Indus valley are extremely hot in summer with a mild cold and dry weather in winter. The coastal strip in the south has a temperate climate. The annual average rainfall ranges from 16 centimeters in the southern parts of the lower Indus plains to 120 centimeters in the Himalayan Region. Rains are of a monsoon nature and fall late in summer.

### **Demographic Situation:**

#### **Population:**

#### **Size and Growth:**

Pakistan, the ninth most populous country of the World (estimated at 131.63 million), is categorised among those countries which have a high population growth rate (around 2.8%), high fertility (Crude Birth Rate around 39/1000), high mortality (Crude Death Rate of around 10/1000. infant Mortality Rate of around 102/1000 live Births), moderate expectation of life at birth (62 years).

#### **Distribution:**

The country's population is unevenly distributed among various provinces. Punjab, with about one-fourth of the country's total area is the most thickly populated being inhabited by more than half (56%) of the total population, whereas Sindh with 17.7% of the land area has 23 % of the total population, NWFP and FATA comprising 13 % of the total area are populated by 16% of the population. Balochistan which is the largest area-wise province (44%) has the lowest population concentration of 5 %.

## **Age and Sex Composition of the Population:**

The population figures are indicative of a greater male ratio as compared to the females. The sex ratio, in terms of males per hundred females is 103. High fertility is an indication of a high proportion of children in the population. The age distribution of the population of Pakistan is heavily inclined towards the younger productive ages.

## **Situation Analysis:**

### Global Scenario:

According to WHO report one third of world population is infected with TB bacillus. TB is considered the leading adult killer disease as compared to AIDS, malaria and the tropical diseases and by the next decade 300 million more people are estimated to become infected.

The disease is especially devastating in developing countries, where it accounts for more than a quarter of all preventable adult deaths. Asian countries, with their large cities, extremely high rates of TB bacillus infection and spread of HIV virus, currently account for two third of TB cases.

### National Situation of the Disease:

Tuberculosis is still a major health problem in Pakistan due to lack of infrastructure and financial constraints. WHO estimated an incidence of 361000 TB cases in 1995 (254 per 100,000 population). In the next 10 years (1995-2005) there will be 4.2 million cases of TB. The table

gives a picture of the estimated TB incidence from 1990 to 2005.

### **Estimated TB Incidence in Pakistan from 1990 to 2005**

Year	1995	2000	2005
Incidence Rate for 100,000	361000	425000	494000

75 % of cases occur in the age group 15-59 years the most economically productive sector of the society.

### **Tuberculosis Control Programme and Achievements:**

A 20 years National Tuberculosis Control Programme in Pakistan (1965-85) was launched in 1965. The magnitude of the problem was assessed on the basis of the results of the First Tuberculosis Survey conducted in 1950-52. The Directorate of Tuberculosis Control continued the implementation policies of this programme as under:-

- i) Manpower development of provincial governments.
- ii) Distribution of medicines to provinces received as assistance from UNICEF/WHO
- iii) Conduction of surveys to estimate the prevalence rate in the country.

To assess the prevalence of Tuberculosis three nationwide surveys have been carried out in the country from 1950 to 1988. The epidemiological picture according to the surveys conducted by the

National TB Control Programme of the disease in the country is as under:-

### Comparative Study of Prevalence and Infection According to Three Surveys

Year	X-ray (Active)	Infection Rate on Tuberculin Test	Sputum Smear +ve Rate
1951-52	4.5%	23%	-
1974-78	1.9%	13%	0.31%
1987-88	-	7.7%	0.17%

Source: 8th Five Year Plan, Planning Commission, Govt. of Pakistan, Islamabad, June, 1994

The above table indicates that;

- Infection rate which was 23% in 1951-52 survey (5-9 years age group) decreased to 13% in 1974-78 and further dropped to 7.7% in 1987-88 surveys thus showing a significant downward trend in the incidence of this disease.
- The sputum positivity rate, being an important indicator has shown a decline from 0.31 per cent in 1974-78 to 0.17 per cent in 1987-88. The annual infection rate of Tuberculosis still remains above 1 per cent.

Recognising the seriousness of the Tuberculosis epidemic the Government of Pakistan in collaboration with WHO prepared National Guidelines for Tuberculosis Control in Pakistan which is being implemented at 10 selected demonstration sites of the four provinces. Gradually it will be replicated all over the country in phases. The new programme will essentially be

integrated with Primary Health Care Programme and implemented right at grass root level for its successful implementation.

In addition to the 10 selected sites 4 more trial projects at four different cities are to be initiated in collaboration with two NGOs i.e. Marie Adelaide Leprosy Centre (MALC), and Association for Social Development (ASD).

### Physical Targets and Achievements of Preventive Programme During 1995-96

Programmes	Target (Nos) (Million)	Achievements	
		Estimated (No. in Mill.)	%
Immunisation of Children from six killer disease (Polio, Measles, Whooping cough, Tetanus, Diphtheria and Tuberculosis).	9.5	7.5	79

Source: Planning and Development, Division

Expanded programme of immunisation was launched in 1979 after the Alma Ata declaration of "Health for All by the Year 2000". The national coverage of immunisation against six preventive diseases was reported to be 80% by 1993-94. This programme was extended further for five years to gain sustainable achievements.

## Pharmaceutical Sector in Pakistan

### 1. General:

Pakistan Pharmaceutical industry has shown unprecedented progress since the creation of the country in 1947, when hardly any unit worth the name existed. To day over 300 pharmaceutical manufacturing units including 30 multinationals are producing drugs worth US\$ 1 billion and are meeting about 90% of the country's requirements. During recent years, the market for pharmaceuticals in Pakistan has been expanding at a very high rate i.e. 28-29 % per annum.

The pharmaceutical manufacture and trade in Pakistan is regulated through the Drugs Act, 1976, and the rules framed thereunder. This is a fairly comprehensive law. Pakistan was the first amongst the developing countries in the world to have introduced Good Manufacturing Practices as a mandatory requirement as far back as in 1976. The drug manufacturing licenses and drug registrations are granted by the Central Licensing and Registration Boards, constituted under this Act. These Boards include experts on medical and pharmaceutical professions. The Quality Control system at the Federal and Provincial levels is supported by the professionally competent drug inspect orates and laboratory services.

Presently the industry is producing some 10,500 formulations in various pharmaceutical dosage forms including injectables, tablets, syrups, suspensions, ointments and creams etc.

Whereas Pakistan has attained almost complete self sufficiency in drug formulation, it has also made a good progress in the past few years in the basic manufacture of pharmaceutical raw materials. Presently some 35 units are engaged in

basic manufacture. In the coming years, Pakistan is also expected to have well developed industry for the manufacturing of basic pharmaceutical raw materials.

### Manufacturing Licenses

Years	Licenses
1977	129
1980	198
1985	245
1990	281
1995	316
1996	326
1997	329

### Pharmaceutical Units in Pakistan

Years	Pharmaceutical Units
1994	250
1995	276
1996	306
1997	304

### Pakistan Pharmaceutical Market

Year	Retail Sales Rs. Billion	Value Growth	Instituti onal Sales Rs. Billion	Value Growth	Total Sales Rs. Billion	Value Growth
1992	13.08	22%	1.96	22%	15.04	22%
1993	14.34	10%	2.15	10%	16.49	10%
1994	18.77	28%	2.82	28%	21.59	28%
1995	24.29	29%	3.64	29%	27.93	29%

## **Production of Anti-TB Drugs**

Over 31 pharmaceutical units are actively involved in production of various formulations and dosage forms used in the therapy of tuberculosis.

### **Chemotherapy of Tuberculosis and Use of Fixed-Dose Combinations as Recommended by WHO**

The WHO recommended chemotherapy of tuberculosis consists of:

1. **Initial Phase:** Four drugs Rifampicin, Isoniazid, Pyrazinamide and Ethambutol are given for 2 months which greatly reduce the number of viable tubercle bacilli and prevent emergence of drug resistance.
2. **Continuation Phase:** Two drugs are given for another 4-6 months to eliminate the remaining tubercle bacilli and the risk of relapse. The recommended two drugs during this phase are Isoniazid and Rifampicin. Isoniazid may also be used with Thiacetazone for economic reasons in some situations.
  - 2.1. Fixed dose combinations for Rifampicin 300mg + Isoniazid 150mg,  
  
OR
  - 2.2. Rifampicin 150mg + Isoniazid 100mg, in each tablet/capsule respectively, should be used.

Manufacturers of fixed-dose combinations in Pakistan have been asked to switch over to these formulations.

### **3. Advantages:**

The use of these combination dosage forms achieves;

- 3.1. **Better patient compliance even with reduced supervision,**
- 3.2. **Simplifies drug handling by patients and health workers/suppliers,**
- 3.3. **It also guards against shortage of individual drugs, and**
- 3.4. **Minimise the chances of development of drug resistance, particularly if fixed-dose combination of the four recommended drugs in a single tablet/capsule can be used during the initial two months of therapy.**

### **Marketing and Distribution of Anti-TB Drugs**

The sale of drugs within the country is regulated by the provincial Governments through District Health Officer/Drug Inspectors who grant licenses for sale of drugs and conduct regular inspections of the sale channels. Provincial Quality Control Boards have also been set up for overall checks on the quality control situation in the provinces. An estimated 30, 825 retail sale outlets exist within the country, which stock and sell human pharmaceutical products.

Generally most of the pharmaceutical units deal in the distribution of medicines; (i) Market - through their respective "regional distributors"/ "whole salers" who in turn make supplies to the retail sale outlets. (ii) Institutions - through their various authorized "institutional suppliers" appointed for deferent institutions.

### Estimated Requirement of Anti-TB drugs in Pakistan

S.No	Drug	No. of Tablets
1.	Ethambutol	168,177,438
2.	Rifampicin	164,839,444
3.	INH	177,401,916
4.	Pyrazinamide	111,943,780

### Quality Control

1. The modern day concept of "Quality Control" does not limit this term to laboratory operations and testing alone. In its entirety is involves all decisions concerning the quality of medicinal products and from the part of Good Manufacturing practices concerned with sampling, specifications, and testing as well as the organization, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use nor finished products released for sale of supply, until their quality has been judged satisfactory.
2. In Pakistan the quality of drugs is regulated both at the federal and provincial Governments' level in accordance with the provisions of the drugs Act, 1976 and various rules framed thereunder.

3. For ensuring quality control at the level of the manufactures/importers, the licenses to manufacture and import of drugs are granted by the central Licensing and Registration Boards setup under the Drugs Act 1976 and comprising of members including representatives of Federal and Provincial Governments and experts in the medical and pharmaceutical fields.

4. Assurance of quality of drugs is primarily the responsibility of the manufactures/sellers while the Government agencies only exercise supervisory controls.

### Federal Quality Control Organization

5. In the Federal Government the prime responsibility of quality control of drugs is that of the Central Licensing and Registration Boards. A Quality Control Unit also functions within the Ministry of Health Islamabad.

### Inspection Services

6. The drug inspectors appointed by the Federal and Provincial Governments' conduct inspections of pharmaceutical units, to ensure that the manufactures comply with the Good Manufacturing practices. To Cheek the quality of drugs they pick the samples on random basis from the market as well as from the pharmaceutical units for testing purposes in the concerned Drug Testing Laboratories.

## Provincial Inspection Services

7. The Provincial Governments have appointed Drug Inspectors at district and the divisional levels and a chief inspectors.

## Laboratory Services:

8 The following five drug testing laboratories have been set up by the provincial and federal Governments to regularly check the quality of drugs.

## Federal Laboratories:

- (i) Central Drugs Laboratory, Karachi for Federal Government and Government of Balochistan.
- (ii) An appellate laboratory, set up at the National Institute of health, Islamabad for retesting of drug samples when appeals are preferred by the persons who do not agree with the initial report of the other four drug testing laboratories. The right of appeal is provided under the Drugs Act. 1976.

## Provincial Laboratories:

- (i) Drugs Testing Laboratory, Lahore for Government of Punjab.
- (ii) Drugs Testing Laboratory, Karachi for Government of Sindh.
- (iii) Drugs Testing Laboratory, Peshawar for Government of Peshawar.

## DEMOGRAPHIC SITUATION

### Population:

◇ Total Population	131.63 million
Urban	43.52 million (34%)
Rural	84.48 million (66%)
Refugees	1.452 million
◇ Crude Birth Rate	39.30/1000
◇ Infants (Under 1 year)	4.779 million
◇ Pre-school Children (1-5 yrs.)	15.8 million
◇ Children (Under 16 yrs.)	58.8 million
◇ Sex Ratio at Birth (M/100F)	103
◇ Annual Population Growth	2.8%
◇ Total Fertility Rate	6.1
◇ Average Life Expectancy at Birth (in years)	61.4

(Main Source: 1. Economic Survey 1995-96,  
Government of Pakistan  
2. The State of the World's  
Children, 1995, UNICEF)

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Mr. Abid Hayat, Chief Pharmacist,  
Government Lady Reading Hospital,  
Peshawar, Pakistan.

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## *Wel Come News:*

### *STC Visit:*

*His Excellency Mr. Naeem U. Hasan,  
Secretary General, Visits SAARC TB Centre*

His Excellency, Mr. Naeem U Hasan, Secretary General, Directors Ms. K. C. Namgyel and Mr. Tahir Iqbal Butt visited SAARC TB Centre on Friday, February 7, 1997. During the visit, H. E. encouraged the STC staff for the smooth and creative work of the centre.

The Director, STC introduced all staff of the centre and explained on the activities/programmes of the centre briefly. H.E. made on the spot observation of the functions of the centre.

### *Visit of Rt. Hon'ble Prime Minister of Nepal to STC*

The Right Honourable Prime Minister of Nepal, Mr. S. B. Deuba visited the STC during the inaugural ceremony of

VIIIth National Seminar & Workshop on TB Control Programme, held on 24-26 Feb. 1997 at NTC/STC premises.

*A very Warm Welcome to Princess AKISHINO, Her Imperial Highness of Japan.*

Princess Akishino, Her Imperial Highness of Japan, visited SAARC TB Centre on 28th Feb. 1997. All staff of the centre heartily welcomed Her

Imperial Highness in a reception ceremony organised in the premises of STC and NTC, at Thimi, Bhaktapur.

### *Visit of SAARC Delegates*

Director, and other staff of the centre received the delegates of the SAARC Workshop on Formulation of Guidelines for coordination in Government and Private Sector/NGOs Initiatives of TB Control and Meeting of the Tuberculosis Experts for Compilation of TB Control Training Manuals for Member Countries, visited SAARC TB Centre on 18th June 1997.

Similarly, the delegates of SAARC Seminar on Production, Marketing/distribution and Quality Control of Anti-TB Drugs in the Region visited the centre on 1 July 1997.

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### *Notice to our STC Newsletter readers*

*SJC Newsletter welcomes letters to the editor. Responses and comments, regarding the information, reports etc. included in this issue are most desirable. Letters may be edited for reasons of clarity or space.*

*Thank you very much.*

*- Editor*

# Letters to the Editor

## The Editor:

✉ I got this opportunity to suggest on the reader's views on *STC Newsletter*. It will be very much beneficial if you include occupational risk in relation to TB infection, for instance construction workers or workers in the cement factory as well as quarries.

Dr. K. P. Ghimire, MO,  
NHTC, Dept. of Health,  
Kathmandu, Nepal.

✉ I was really impressed by the work done about which I read in your *STC Newsletter*. I would like to be a member of your *STC Newsletter*, so as to increase my knowledge about this growing problem in our countries.

Dr. Bharat Gopal  
D-72, Naraina Vihar  
New Delhi - 110 028  
Ph 91-11-5797330.

✉ .....you have an opportunity of being absolutely factual in your *Newsletter* and write about the problems on the ground without fear or favour.....

Prof. C.N.Deivanayagam  
Govt.Hospital of Thoracic, Medicine,  
Madras 600 047, India.

✉ I am happy to have been receiving the *STC Newsletters*. There are very useful, informative and illustrative. It is really a commendable job by your team.

Dr. Sudhakar Patnaik,  
Medical Superintendent,  
RBTB Hospital, Delhi -9,  
India.

✉ Health Education Material on Tuberculosis:

We learn that you have some latest materials about Tuberculosis which would greatly help us in carrying out our programme on public

awareness about TB. I shall be grateful if you would kindly send us whatever materials you can so that we can carry out our programme effectively.

Dr. S.T.Jeyadaran  
DTCO, Chest Clinic, Vavunia,  
Sri Lanka.

✉ It is a pleasure to go through the newsletter which is compiled very nicely. I have suggested a logo be adopted for *STC's* separate identity.

Dr. B. Vidyasagar,  
Prof. & Head, Dept. of Chest Diseases,  
JJM Medical College,  
Darangere 577 004, India.

✉ Thank you very much for sending me the latest copy of the *STC Newsletter*. I must congratulate you and your all staff for making the *Newsletter* more and more informative.

Dr. N. K. Jain  
New Delhi TB Centre  
Jawahar Lal Nehru Marg, New Delhi  
110 002, India.

✉ I received your *STC Newsletter*. I am glad to thank you and your team.

Dr. Sk Lutfur Rahaman,  
Chest Specialist and Consultant,  
TB Clinic, Dinajpur, Bangladesh.

✉ I would like to take this opportunity to congratulate you and the members of your organization on active involvement and dedicated team work for the control of Tuberculosis in SAARC region. *STC Newsletter* is useful source of professional and technical information. Articles, reports and professional news included in the issue are of great value.

Dr. Nadeem Razvi  
Consultant Physician & Chest  
Specialist,  
Jinnah Post Graduate Medical Centre,  
Karachi, Pakistan.


✉ ....the *STC Newsletter* display in our college central library journal

section. Our college and hospital staff appreciate the valuable information.

Officer I/C of Library  
Perundurair Medical College  
Perundurair 638053  
India.

has submitted my suggestions on the "Readers Views on STC Newsletter".

Dr. Nisar Khan,  
Village & Post Office, Kheski,  
Payan,  
Tehsil & District, Nowshera,  
NWFP, Pakistan.

 We appreciate your keen interest to develop this publication. I



*Dear Readers*

Thank you very much for sending acknowledgments of STC Newsletter Vol. VII.

We have received some suggestions, comments, and lot of appreciations from our readers regarding the improvement of the STC Newsletter. We request our readers to send their valuable technical articles on TB control, research papers, etc. to include in STC Newsletter under the special articles and technical information on TB control. We wish to extend our special thanks to the readers who had sent the Readers' Views on STC Newsletter form. The suggestions mentioned in this form are very useful. We try our best to improve the STC Newsletter as per your suggestions. We request you once again to guide us to further improvement the publication.

This time we have got more letters. We are sorry to say that due to the constraints of the space, we could not publish all letters.

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## *Free Publications of SAARC Tuberculosis Centre*

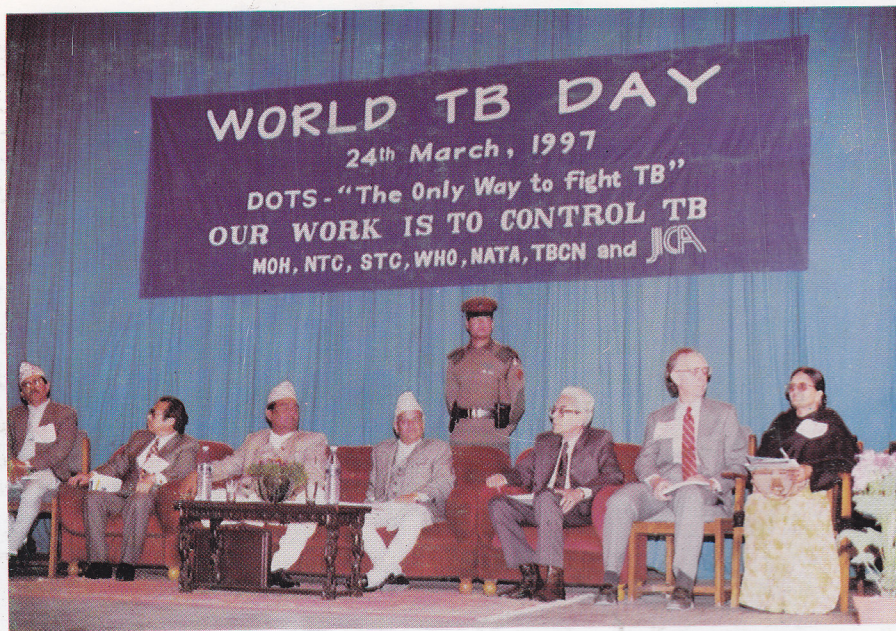
- |    |                                                                                           |                                                                            |
|----|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 1. | STC Newsletter                                                                            | Vol I to VII.                                                              |
| 2. | Proceeding Reports                                                                        | 1st. Trainers' Training<br>TB Programme Managers<br>TB Control Through PHC |
| 3. | Directory of Tuberculosis Institutions & Specialists in SAARC Member Countries, Jan 1996. |                                                                            |
| 4. | Role of SAARC Tuberculosis Centre in TB Control - A pamphlet                              |                                                                            |
| 5. | NTPs in the SAARC Member Countries                                                        |                                                                            |



(Discussions during the visit of H.E. Secretary General to STC)  
see page 15 for the news



(Participants of the Seminar, held on 1-4 July 1997)  
see page 4 for the report



(Commemoration of World TB Day in Kathmandu)  
see page 6 for the report



(Building of the SAARC TB Centre and National TB Centre)