RESURGENCE OF TUBERCULOSIS: THE CHALLENGE

(Working Paper for the Technical Discussions)
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>2. TUBERCULOSIS SITUATION IN THE REGION</td>
<td>1</td>
</tr>
<tr>
<td>2.1 Current and Future Magnitude of the TB Problem</td>
<td>1</td>
</tr>
<tr>
<td>2.2 Potential Impact of AIDS</td>
<td>3</td>
</tr>
<tr>
<td>3. NATIONAL CONTROL PROGRAMMES – SITUATION ANALYSIS</td>
<td>4</td>
</tr>
<tr>
<td>4. WHO TUBERCULOSIS CONTROL STRATEGY</td>
<td>5</td>
</tr>
<tr>
<td>4.1 Objective and Targets</td>
<td>5</td>
</tr>
<tr>
<td>4.2 Strategies</td>
<td>5</td>
</tr>
<tr>
<td>4.3 Policy Package</td>
<td>6</td>
</tr>
<tr>
<td>5. WHO SUPPORT TO NATIONAL PROGRAMMES</td>
<td>6</td>
</tr>
<tr>
<td>6. ISSUES FOR CONSIDERATION</td>
<td>8</td>
</tr>
<tr>
<td>7. PRIORITY AREAS</td>
<td>9</td>
</tr>
<tr>
<td>8. CONCLUSIONS</td>
<td>11</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

Tuberculosis (TB) is an ancient disease which continues to be a challenge as well as a major public health problem. During the last 40 years, TB has declined — rather has been wiped out in the industrialized countries — but in developing countries, in the absence of effective programmes, there is virtually no decline. In the SEA Region, the concept and practice of management and treatment of TB were changed from institutional (sanatorium type) to domiciliary treatment. Encouraged by the success in the initial phase of the malaria eradication programme and the technology available for domiciliary treatment, many countries started vertical programmes for the control of TB. Realizing the difficulties of the vertical programme, the countries subsequently initiated control of TB through integrated basic health services. However, the programme suffered due to various reasons, most importantly, the policy/emphasis on TB was not adequate, leading to deterioration in programme implementation. Incorrectly conceptualised TB control programmes have not only increased the burden of the disease but have also led to the emergence of drug-resistant TB. Rapid industrialization and urbanization giving rise to distinct peri-urban areas with overcrowding and poor environmental sanitation have increased the transmission of TB. It is unfortunate that the Region which revolutionised the management and treatment of TB from institutional to domiciliary has itself not been able to control TB.

Globally, 8 million people develop TB and 3 million people die of the disease each year. The South-East Asia Region contributed nearly 50% of all cases reported worldwide during 1993. India alone contributes one-fourth of the global TB cases. The World Development Report, 1993, states that TB kills more adults each year than any other infectious disease such as AIDS, diarrhoea, malaria and other tropical diseases combined. Of the total global deaths, nearly 95% are in the developing world. Eighty per cent of those deaths are in the most productive age-group (15-59 years) causing a serious impact on socioeconomic development. The region having large numbers of TB cases also has the largest share of adverse socioeconomic impact.

A new dimension has been added to the problem of tuberculosis with the emergence of HIV/AIDS. The impact of HIV/AIDS on TB will be less perceptible in western countries which have a low prevalence of TB, whereas, this region, where 40% of the population have latent/dormant tubercular infection, will have a major TB problem associated with HIV/AIDS.

With the emergence of HIV/AIDS and realizing that without effective control, the problem of TB will be unmanageable, countries in this region have shown renewed interest in TB control with the available effective drugs in order to cure TB with or without association with HIV infection.

2. TUBERCULOSIS SITUATION IN THE REGION

2.1 Current and Future Magnitude of the TB Problem

As stated earlier, due to the declining interest in effective TB control in the countries of the Region, reporting is not adequate either for clinical cases, or microscopic or bacteriologically confirmed cases. During 1991, more than 2.1 million TB cases have been notified from the SEA Region (see Table). The major contributors are India – 1.5 million cases, and Indonesia with 0.5 million cases. Nearly one-fourth of the global TB cases are estimated to have occurred in India alone. TB cases have shown a steady increase in the Region since 1980 (Figure 1). Much of this has been contributed by India with
**Table. Estimated tuberculosis cases and rate in SEAR countries, 1992**
(per 100,000 population)

<table>
<thead>
<tr>
<th>Country</th>
<th>All forms</th>
<th></th>
<th>Smear-positive</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Rate</td>
<td>Percentage</td>
<td>Rate</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>56,052</td>
<td>47.2</td>
<td>35</td>
<td>16.5</td>
</tr>
<tr>
<td>Bhutan</td>
<td>996</td>
<td>169.6</td>
<td>30</td>
<td>50.9</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>India</td>
<td>1,555,353</td>
<td>182.5</td>
<td>22</td>
<td>40.6</td>
</tr>
<tr>
<td>Indonesia</td>
<td>469,832</td>
<td>245.4</td>
<td>16</td>
<td>39.6</td>
</tr>
<tr>
<td>Maldives</td>
<td>380</td>
<td>172.4</td>
<td>31</td>
<td>53.4</td>
</tr>
<tr>
<td>Mongolia</td>
<td>1,611</td>
<td>71.6</td>
<td>7</td>
<td>5.0</td>
</tr>
<tr>
<td>Myanmar</td>
<td>16,440</td>
<td>38.3</td>
<td>72</td>
<td>27.9</td>
</tr>
<tr>
<td>Nepal</td>
<td>8,983</td>
<td>45.8</td>
<td>47</td>
<td>21.5</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>6,174</td>
<td>35.4</td>
<td>54</td>
<td>19.1</td>
</tr>
<tr>
<td>Thailand</td>
<td>50,185</td>
<td>88.7</td>
<td>75</td>
<td>66.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,116,006</td>
<td>163.5</td>
<td>23</td>
<td>37.6</td>
</tr>
</tbody>
</table>

... = Information not available.
Source: WHO/SEARO

**Figure 1. Number of reported tuberculosis cases – South-East Asia Region**
(1974-1991)

Source: WHO/SEARO
increased reporting of smear-negative, X-ray positive TB cases. Except India, the infection is fairly stable in the other countries of the Region. Based on the annual infection rate (ranging from 1 to 2%), it is estimated that 2.5 million TB cases per year would occur in SEAR countries. Though there is no uniform information on the prevalence of TB, Thailand has reported a decline in the prevalence of TB for all ages, from 40% in 1977 to 30% in 1991. Indonesia has also reported a decline in the age-group of 7 to 10 years between 1984 and 1988.

### 2.2 Potential Impact of AIDS

In the present situation of TB control and rapid increase of HIV infection in the Region, the potential impact of HIV/AIDS will be immense unless effective control measures are taken against TB. It is estimated that globally over 5 million TB cases are also infected with HIV. Nearly half a million HIV positives are currently ill with TB. HIV associated TB has a high risk of resistance to two main drugs, i.e., rifampicin and isoniazid, as observed in New York city in 1992. Nearly one-fifth of the cases detected were multidrug resistant. It is estimated that in the USA nearly 80 per cent of cases infected with multidrug resistance have died.

HIV pandemic has recently unfolded in Asia. Its impact is yet to be realized. TB is one of the most important life-threatening opportunistic infection associated with HIV in Asia. Between 60 and 80% of AIDS cases in Thailand, India, Nepal and Myanmar developed TB. Figure 2 depicts HIV seroprevalence among TB patients in some cities of this region. This indicates increasing HIV prevalence amongst TB patients from 1989 to 1992.

**Figure 2. HIV seroprevalence among patients with tuberculosis (1989–1992)**

![HIV Seroprevalence (%)](image)

Source: GPA/WHO/SEARO
3. NATIONAL CONTROL PROGRAMMES – SITUATION ANALYSIS

The strategy of National Tuberculosis Control Programmes (NTPs) in the Region is based on early detection and appropriate treatment of cases with priority to those with positive sputum smears. BCG vaccination is part of the tuberculosis control strategy and it is implemented by the Expanded Programme on Immunization (EPI). Programme integration into primary health care (PHC) is considered a priority objective of all NTPs of the Region. It is integrated based on the national network of general health services, especially for case detection. It is supported in almost all programmes by specialized tuberculosis services such as chest clinics and tuberculosis hospital at national, regional or district level. These institutions play a pivotal role in diagnosis and treatment and often form an essential part of tuberculosis services. Two countries (Bangladesh and Maldives) have joint tuberculosis/leprosy programmes.

In most countries, recording and reporting is inadequate for programme management and decision making. Information feedback, if any, is slow and reports are often outdated. In most programmes, supervision and monitoring in general warrants improvement.

In all countries, the government is responsible for buying anti-tuberculosis drugs and some are supported with external assistance. All NTPs provide tuberculosis treatment free of charge to the patients.

In most countries, the private sector is active in tuberculosis control. In general, there is little collaboration between private practitioners and NTP. In countries with a dynamic and aggressive private sector, a large proportion of cases are under the care of private physicians. In India, for example, it is estimated that 50% of patients have been attended to by private physicians prior to their reporting to NTP. In Sri Lanka, private practitioners do not treat tuberculosis patients but only refer suspects to the nearest chest clinic. Most countries have National Anti-Tuberculosis Associations while in some (India, Bangladesh, Nepal, Bhutan) nongovernmental organizations (NGOs) are involved in anti-tuberculosis activities. External support to anti-tuberculosis activities is also provided by international NGOs.

Case finding is passive in all countries of the Region and based on self referral. In most instances, there is no distinction between new, relapse and failure cases although it has been suggested that in some countries up to 50% of cases had been previously treated.

All the countries of the Region have reference laboratories. The vast majority do culture and drug sensitivity testing. Chest clinic or district tuberculosis centres play a dominant role in diagnosing tuberculosis. In peripheral areas (health posts/primary health centres) facilities exist for microscopic examination of sputum. In many instances, diagnostics suffer due to poor equipment and inadequate or lack of reagents, lack of support, supervision, quality control from the reference laboratory, poor training of microscopists, excessive decentralization of diagnostic services and work load.

Of the ten countries which responded to the WHO survey, Bhutan, Maldives, Mongolia, Sri Lanka and Thailand reported that they now administer short course chemotherapy (SCC) to 85% or more of the sputum smear-positive cases treated. The use of SCC is still limited to 37% of sputum smear-positive cases treated in India, and only 5% of such cases in Bangladesh.

Although most countries in this region use some form of cohort analysis to assess treatment results in selected groups, none conducts this analysis with all sputum smear-positive patients. The reported cure rates varied from 37% to 76%. Nepal, Sri Lanka and Thailand all reported cure rates of over 70%.
Four countries in the Region provided information on recent drug expenditures, with a range of US $27 to US $67 per case. A majority of the countries, reporting on their drug supply situation, noted that they did not have sufficient funds to meet drug needs.

Bhutan, Thailand and Maldives have NTPs that are achieving good results with well-managed treatment programmes focusing on the provision of SCC. Major focus will need to be given to the revitalization of TB control activities, and standardization of practices. Special attention will need to be given to developing programme management strategies in the face of the rising HIV epidemic in the Region.

4. WHO TUBERCULOSIS CONTROL STRATEGY

4.1 Objective and Targets

Considering the seriousness of the TB situation, particularly the potential impact of HIV/AIDS, the Forty-fourth World Health Assembly (1991) urged the Member countries to strengthen/augment TB control activities to achieve a target:

- To cure 85% of the detected smear-positive TB cases, and
- To detect 70% of existing cases by the year 2000.

Recognizing the already serious situation, which is rapidly worsening in both developing and developed countries due to insufficient priority being given to TB control programmes and noting the lack of adequate political will and resources for operating effective programmes, the Forty-sixth World Health Assembly (1993) requested Member Countries to improve the detection of smear-positive cases through reliable microscopic examination, introduction of standardized short course chemotherapy, with particular emphasis on properly supervised therapy during the initial two months, introduction of standardized case registers and provision of regular and uninterrupted supplies of anti-TB drugs and promotion of public awareness on prevention on TB.

4.2 Strategies

The World Health Assembly endorsed a global TB control strategy, which is to provide adequate and efficient treatment, i.e. short course chemotherapy to at least all smear-positive TB cases identified. Accordingly, the revised strategies adopted by WHO are as follows:

1. All countries with TB problem must provide standardized short course chemotherapy to all TB cases. If resources are scarce, priority must be given to sputum smear-positive cases and seriously-ill smear-negative cases (e.g. cases of TB meningitis or miliary TB) because this will have the greatest impact on reducing mortality, morbidity and transmission of TB. It has been estimated from the data from developing and industrialized countries that an untreated smear-positive case would infect annually 10 to 14 healthy persons. A smear-positive case usually excretes bacilli for about two years. Thus before a patient dies or becomes smear negative, he would have infected 10-28 new persons. Therefore priority attention should be given to smear-positive cases. However, ideally, all TB cases should receive SCC, which is one of the most cost-effective intervention so far identified.
(2) WHO recommends BCG vaccination in early childhood for TB high prevalence countries.

4.3 Policy Package

The success of this strategy depends on the implementation of a TB control policy package\(^1\) which includes the following five elements:

1. **Government commitment** to a TB control programme aiming at nationwide coverage, should have an integrated activity within the health system infrastructure with technical leadership from a central technical unit. Also, effective leadership, which requires a permanent team qualified in the management of TB control.

2. **Case detection** through predominantly passive case finding. Active case finding is not cost-effective with the present load of TB cases in the Region. Those persons presenting themselves to a health worker with symptoms indicative of TB should be referred to appropriate health facilities for confirmation of diagnosis, primarily by microscopy examination.

3. **Administration of standardized short course chemotherapy to at least all confirmed sputum smear positive cases of TB under proper case management conditions.** Proper case management ensures patient compliance by supervised administration of the recommended short course chemotherapy with at least four drugs in the initial phase (two to three months) in order to avoid the emergence of resistant strains and, further, to ensure that the patient undergoes a full course of treatment (6-8 months) to avoid relapse.

4. **Establishment of a system of regular supply of all essential TB drugs (isoniazid, rifampicin, pyrazinamide, streptomycin, ethambutol and, in some areas, thiacetazone).** Advance planning for drug procurement and timely delivery should be based on the number of cases registered during the last complete six-month period and stock levels.

5. **Establishment and maintenance of a monitoring system** to be used both for programme supervision and evaluation. This system is based on recording individual patient information in registers at the district or the county level and on regularly reporting, preferably on a quarterly basis, from the same level. Information must be obtained, firstly, on new cases and relapses and, secondly, on treatment outcome.

The adoption of this framework is particularly urgent in countries confronted with an HIV epidemic, which will result in an increasing number of TB cases and specific operational problems.

5. WHO SUPPORT TO NATIONAL PROGRAMMES

Recently, Regional Tuberculosis Programme activities were intensified through review and discussions with national programme managers. Emphasis was placed on the formulation of national tuberculosis

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\(^1\)This policy package remains unaltered even in the presence of HIV infection.
programmes in accordance with the WHO global strategies and technical policies as described above. The following is a summary of main activities performed during the 1992-1993 biennium:

- The Regional Office was strengthened with an additional post of Medical Officer (TB) to assist countries in the formulation of national tuberculosis control programmes in accordance with the global strategies and technical policies, as recommended by WHO and adapted to national conditions; to assess training needs and to organize and conduct training courses accordingly; and to monitor the research projects carried out in the Region.

- At the country level, the Regional Office gave priority to, and focused on, countries with serious tuberculosis problems contributing significantly to the global problem. This resulted in a joint programme review (GOI/WHO/SIDA) in India in September 1992, which led to the development of a revised national plan with higher national priority and increased resources and external cooperation for the financing of tuberculosis control from the World Bank. WHO is assisting in project formulation with support to operational research and project implementation in pilot districts.

- WHO also assisted in the launching of a major World Bank Project in Bangladesh where WHO has been identified as the implementing agency for the US$ 29 million Tuberculosis and Leprosy Control project.

- During the biennium, several countries (Bangladesh, Bhutan; India, Indonesia, Maldives, Sri Lanka and Thailand) were provided technical assistance and support mainly in the areas of preparing internal evaluations; developing revised plans of action; facilitating training activities; and providing financial support for their control efforts.

- An Intercountry Workshop on Managing TB at District Level was organized in the Regional Office in July 1993 using the newly-developed WHO training modules. Ten of the eleven countries of the Region attended with a total of 28 participants. This training was repeated at the country level in India, Bangladesh and Bhutan.

- Trends in the WHO country budget for country allocation for tuberculosis from 1982 to 1995 show a major increase in the 1992-1993 biennium in both regular and extrabudgetary resources for tuberculosis from US$ 1.5 million to US$ 7.8 million. However, the proposed regular budget for tuberculosis activities in 1994-1995 is US$ 811 100, representing a sizeable decrease of US$ 280 100 (28%) in budgetary terms as compared to 1992-1993. It is likely that extrabudgetary resources in the next biennium will exceed that of 1992-1993.

Tuberculosis control activities supported with WHO country budget include:

- Training in all countries except Maldives
- Workshops in Indonesia and Nepal
- Programme review, evaluation and project preparation for external funding India, in India, Indonesia, Bangladesh
Operational research in Nepal and India

Supply for diagnosis, such as X-ray equipment and films, to Myanmar and India, and microscope/reagents to Mongolia and Sri Lanka

Supply of drugs to India, Maldives and Myanmar

In the area of research, WHO is technically supporting some of the ongoing studies in India, including on the role of the private sector in tuberculosis treatment and the role of NGOs in providing tuberculosis management. In Thailand, operational research on a retrospective cohort analysis of self-administered short course treatment has started in six districts of three provinces. Thailand is among only a few countries in the world that provide this form of treatment. Several other studies related to tuberculosis in Member Countries are also funded through the WHO country budget.

6. ISSUES FOR CONSIDERATION

Although the challenge of tuberculosis may seem overwhelming, experience shows that the disease can be controlled more effectively with available technology and within the existing health care infrastructure and control programmes. However, NTP needs to address a wide range of issues. These considerations do not apply equally to all programmes but they provide a framework which have some relevance to most.

- Tuberculosis control in South-East Asia, as in many other parts of the world, has an "image problem" it is too expensive; governments and people cannot afford the drugs; tuberculosis is a chronic disease, not an emergency; programmes do not have any impact; improving the general living conditions is sufficient; technical information on tuberculosis does not seem to reach those who need it most, and there is often no consensus within a country on the technical policy. Political leaders and the general public alike do not perceive the magnitude of the problem and the negative impact of tuberculosis on development. They are not aware of the enormous potential of good treatment programmes. It is a challenge to look beyond the technical aspect of disease control to address tuberculosis with a new and wider perspective in order to modify the way this disease is perceived. It is indispensable to generate the resources needed for the challenge ahead.

- For many years, tuberculosis control strategy has emphasized the identification of cases. Case finding targets, often unrealistic, have been set and field workers have struggled to reach them. What happened to patients, once identified, was a secondary concern reinforced by the frequent lack of drugs. Despite this emphasis on case finding, diagnosis services are weak. Peripheral laboratories are often poorly equipped, training of laboratory technicians is inadequate, there is no supervision and no quality control system. The consequences are that a large number of patients receive inappropriate treatment and those who need it most are missed. X-ray equipment, if available, is of poor quality. In fact, it is often the sole diagnostic tool.
Treatment is still too often based on standard chemotherapy. When introduced, SCC is too frequently considered a panacea which will solve all problems. SCC is too often unsupervised and treatment follow-up inappropriate in the countries of the Region. The introduction of SCC should be carefully planned to ensure supervision of drug intake and individual monitoring of patients with smear examination. Otherwise, drug resistance will increase and there will be no substantial gain in the cure rate. Most NTPs do not differentiate between new cases and those who require a re-treatment regimen. Re-treatment regimen, wherever they exist, are generally not standardized.

Tools for programme monitoring and evaluation are inappropriate. The cohort analysis method to measure treatment results is not widely used in any country. Registers and reporting forms are consistently too complex, time consuming and do not provide the type of information needed to assess programme operations and performance. Programme monitoring and evaluation is often based on the measurement of process indicators with quantifiable targets of limited relevance to programme management and performance.

Supervision of health workers and of laboratories is poor in the absence of transportation, supervisory checklist, incentive and lack of supervisory skills.

Drug supply is inadequate in many countries not only because of lack of resources but also due to poor logistics and management. Financial needs for drugs, which have to be paid for in foreign currency, have increased whereas resources have decreased. Because diagnostic services and treatment management are inadequate, significant wastage of drugs occurs in many countries. Patients are misdiagnosed and they are not cured.

Regional training centres are few, neglected, out of the mainstream and training content is out of date. Training content and impact on programmes have not been evaluated. Academic and research institutions have similar problems with respect to tuberculosis. Only limited operational research occurs in a region which contained some of the leading research institutions in the past and there is no evidence that this research is being used to solved programme needs.

7. PRIORITY AREAS

While considering the WHO Global TB Strategy and Policy Package and examining the worsening epidemiological situation with respect to TB, national tuberculosis programmes need to concentrate their efforts on the following priority areas:

(1) Advocacy

The low priority given to tuberculosis in a majority of the countries has resulted in inadequate funding and, consequently, lack of drugs. Advocacy efforts must be devised to improve the visibility of the problem and of the national tuberculosis programme in each country. Understanding of the burden of disease, the resulting impact on economic and social development, and the cost-effectiveness of the TB control strategy must be increased. The likely outcomes of these efforts include greater political commitment; financial and human resources; endorsement of technical policies by the medical community; and the trust of patients and of the community in the programme.
(2) Resource mobilization

The principal objective is to mobilize resources, both internally and externally, for national tuberculosis programmes.

(a) Internal resources

While considering the higher allocation from internal resources, it is admitted that the countries have many priorities for the prevalent communicable diseases. As regards the demand for higher allocation for TB control, certain activities within the health infrastructure can be coordinated with mutual benefit for TB control and other communicable diseases. Examples are the integrated package of health information, education and communication (IEC) and development/augmentation of peripheral laboratory services.

Many NGOs have funds for TB control activities in some areas if proper collaboration and coordination with the NGO activities would supplement and complement government activities for TB control.

(b) External resources

In addition to the reallocation of existing internal resources, it is necessary to raise funds from external sources for initial upgrading of revised programme activities.

Possibilities of bilateral governmental assistance, international assistance (e.g., World Bank, Asian Development Bank), and cooperation with nongovernmental organizations should be investigated.

(3) Technical cooperation

To develop plans for implementation of the policy package as stated above, WHO has extended technical cooperation to the Member Countries. These include programme reviews, development of a plan of action, manual preparation, programme monitoring and evaluation.

(4) Programme manual

National Tuberculosis programme manuals must be developed or revised based on the WHO TB control policy package.

(5) Demonstration areas

In the present context, where the TB control programme in many countries are not well designed, it is essential that each country starts TB control programme in a demonstration area. Based on the experience gained in the demonstration areas, the programme could be extended gradually to other parts of the countries with the ultimate objective of covering the entire country. The purpose of the demonstration area is to know the pitfalls in implementation which could be suitably rectified before it is extended to larger areas. The demonstration areas would serve as a training centre for the staff involved in the training control areas.
(6) Training

Implementation of the policy package will require the training of a large number of professionals. The WHO modules on "Managing Tuberculosis at the District Level" have been found to be a useful instrument for training and should be used in all countries, if necessary, after adaptation. Staff in demonstration areas must be given the first priority for training. Training for laboratory and other peripheral staff must also be strengthened.

(7) Research

Many attempts at tuberculosis control have failed for operational reasons. Operational research needs to be continued on problems in TB control in order to devise solutions and measure their effectiveness, including research on the magnitude of the problem; the scientific rationale for improvements in control; the cost-effectiveness of control strategies; measures to strengthen local research capacity; and ways to combat major new threats to TB control such as HIV infection and drug-resistance. The aim is to improve the performance of tuberculosis programmes. In the past, India, the largest country in the Region, has played a leading role in developing new approaches in testing new drug regimens and training.

8. CONCLUSIONS

The burden of tuberculosis in the Region is staggering by any measure. More than 2 million cases were notified in 1991, about half of the adult population is infected, and there may be as many as one million tuberculosis deaths annually, half of them among young productive adults. Many children die of miliary TB and TB meningitis. Social and economic consequences of tuberculosis for individuals and for the society are enormous in terms of human suffering, economic loss, decreased productivity and, as a direct result, perpetuates poverty. Recent trends do not appear to indicate any overall improvement in the situation in the Region. The existing diagnostic tools and chemotherapy can deliver excellent results if administered through a well-designed TB control programme. Short course chemotherapy and BCG immunization in countries having a high risk of infection is the most cost-effective method of control. HIV/AIDS has just unfolded in this Region, which is likely to produce severe adverse effect on the TB situation. Considering the financial situation in the countries of the Region, extra resources are needed till such time as the load of TB goes down, which will enable the Member Countries to continue their programmes with their own resources.