Regional Strategy for Sustaining Leprosy Services and Further Reducing the Burden of Leprosy - 2006-2010

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1. **INTRODUCTION AND BACKGROUND**

The 44th World Health Assembly in May 1991, adopted a resolution calling on Member States to intensify efforts to eliminate leprosy as a public health problem by the year 2000, through effective implementation of multi-drug therapy (MDT). The elimination of leprosy as a public health problem was defined as a prevalence rate (PR) of less than one case per 10 000 population.

In the mid 1980s, when MDT was introduced in phases, there were 122 leprosy-endemic countries, with a national prevalence exceeding one case per 10 000 population. This included 10 of the 11 Member States of the WHO South-East Asia (SEA) Region, the only exception being DPR Korea. By the end of 2000, the goal of elimination of leprosy as a public health problem was achieved in 108 of the 122 countries at the national level, leaving only 14 countries still to attain the goal. This list did not include small island countries with <one million population. MDT had cured >10 million cases globally, with extremely low relapse rates and no reports of multiple drug resistance.

Among the 14 countries that missed the goal in 2000, three were from the SEA Region – India, Myanmar and Nepal. In order to achieve the goal in these 14 countries, and to sustain leprosy elimination in countries which had achieved national-level elimination, WHO developed the “Strategic Plan for the Final Push towards Elimination of Leprosy, 2000-2005” aimed at elimination of leprosy as a public health problem in all countries by the year 2005, using wide coverage and effective implementation of MDT as the primary tool.

At the beginning of 2005, only nine countries, including two in the SEA Region, namely India and Nepal, were yet to achieve the elimination goal (Timor-Leste is not included in this list, as it has a population of < one million). However, as a result of the steep decline in the prevalence and new case detections in India, the country with the highest disease burden, the SEA Region as a whole is expected to achieve leprosy elimination by the end of 2005.

Since elimination of leprosy as a public health problem is aimed at reducing the disease burden, new cases of leprosy would continue to occur, albeit in smaller numbers, for some more years. Though most countries have
attained the leprosy elimination goal at the national level, a few countries are at risk of not achieving the goal by 2005 and there are pockets of high endemicity at sub-national levels in most countries.

The low endemic situation and the overall reduction of cases can pose the following problems:

- Reduced political commitment, policy support and priority, as well as reduced resources allocated to leprosy;
- Decline in the capacity of health systems to diagnose and treat leprosy, and
- Marginalization of the remaining old deformed cases who continue to need care and support.

In view of the above, it was considered necessary to review the leprosy situation in the SEA Region, identify the remaining challenges and develop appropriate goals, objectives and approaches for the future.

A draft framework of the future goal and strategy: 2006-2010 was presented by the Regional Office at the Second Meeting of the Regional Technical Advisory Group (RTAG) for Elimination of Leprosy, held in New Delhi, 12-13 May 2005. The RTAG reviewed the draft framework, made appropriate modifications and advised the Regional Office to elaborate on the framework and finalize the document.

This document presents the future strategy, with scope for flexibility for adaptation by Member States. It complements the WHO "Global Strategy for Further Reducing the Leprosy Burden and Sustaining Leprosy Control Activities: 2006-2010", and the Bi-regional (SEARO-WPRO) strategy to "Sustain Leprosy Services in Asia and the Pacific".

2. **Evolvimg Situation of Leprosy in the SEA Region**

The regional leprosy prevalence declined from 4.6/10000 population in 1996 to 1.05/10000 population as of June 2005. The regional new case detection declined from a peak of 47.8/100000 population in 1998 to 17.9/100000 population in 2004. Thus, the SEA Region is on the verge of achieving the leprosy elimination goal i.e. prevalence of less than one case per 10 000 population, at the regional level and in countries, by the end of 2005.
Among the 11 countries of the Region, India, Nepal and Timor-Leste are yet to achieve elimination, with PR of 1.2, 1.8 and 3.9/10000 population respectively, as of June 2005. The remaining eight countries have achieved and sustained the elimination goal at the national level.

The prevalence and new case detection rates declined in all countries in 2004 compared to 2003, except in Indonesia, where the annual new case detection rate has remained static around 15000 cases over the last four years. The decline was most significant in India with 44% reduction in prevalence and 29% decline in new case detections, due to vigorous efforts in minimizing ‘operational factors’ which were influencing the indicators previously.

Of the nearly 14.2 million cases cured globally with MDT, about 12 million were from the SEA Region, more than 10.8 million of them being from India.

Bangladesh, Bhutan, DPR Korea, Indonesia, Maldives, Myanmar, Sri Lanka and Thailand have sustained the elimination at the national level and are targeting sub-national-level elimination. Bangladesh and Myanmar have achieved sub-national elimination at the second administrative unit i.e. all six divisions in Bangladesh and all 17 states/divisions in Myanmar. Thailand has achieved elimination in 75 of the 76 districts, Sri Lanka in 21 of the 25 districts and Indonesia in 18 of the 30 provinces. Maldives reported only eight cases in 2004, while Bhutan has been annually reporting less than 20 cases for the last five years, most of them being multi-bacillary (MB) cases.

The Region, including the three remaining countries - India, Nepal and Timor-Leste - is very much on target to achieve the goal by December 2005. From current trends, India is likely to achieve the goal, and Nepal may be able to achieve the goal or come very close to achieving it. However, Timor-Leste with a prevalence of 3.9/10000 population as of June 2005, is in danger of not achieving the goal.

The political commitment continues to be sustained in all countries and leprosy elimination efforts have been integrated into the general health services.
The Regional Office will continue to provide technical support to Member States in achieving national and sub-national elimination and assist the countries in advocacy at policy levels, mobilizing the required resources and in strengthening partnerships, in order to further reduce the burden of leprosy in the Region.

3. FUTURE OF LEPROSY ELIMINATION, AND REGIONAL ISSUES AND CHALLENGES

3.1 Future of Leprosy Elimination

- In the early part of the period 2006-2010, even with sustained elimination at national levels, about 100 – 200 000 new cases are expected to be detected annually in the Region; nearer 2010, the figure is expected to be below 100000;
- In addition, a substantial number of cured persons with disabilities will continue to need care and rehabilitative services, and
- In view of the low endemic situation in most countries, there is a risk of declined political commitment, decreased resources and insufficient capacity for timely detection and treatment of cases.

3.2 Regional Issues and Challenges

- Sustaining political commitment and ensuring adequate resources in order to sustain elimination at national level, and progress towards sub-national elimination and further reduction in the burden of leprosy;
- Strengthening integration of leprosy services into the general health system through capacity building and skill development, in order to ensure quality leprosy services, including timely diagnosis and treatment;
- Ensuring wider coverage of leprosy services, especially in the currently under-served population groups, such as in remote rural areas and urban slums, and migrant labour;
Increasing community awareness through sustained advocacy and information, education and communication (IEC) activities to promote voluntary case detection and decrease the stigma;

- Preventing discrimination, displacement, and human rights abuses of those affected by leprosy, and ensuring community-based rehabilitation and integration of cured/disabled leprosy persons into the community, and

- Streamlining the MDT supply and stock management at all levels, considering the low endemic situation.

4. GOAL AND OBJECTIVES FOR 2010

4.1 Goal

All countries of the Region to sustain leprosy services, and to further reduce the burden of leprosy with the annual new case detection rate of less than 10/100000 population for the Region as well as for each country, by 2010.

4.2 Objectives

- Sustain elimination at national level and achieve sub-national-level elimination at the administrative level within the timeframes to be determined by each country;

- Progressively reduce annual new case detections through timely case detection, prompt treatment and achievement of high cure rates, and

- Ensure and sustain quality leprosy services.

5. KEY ELEMENTS OF THE STRATEGY

The following are the key elements:

(1) Strengthening integration of leprosy services into the general health system through capacity building of programme managers and general health staff at various levels, to enable them to provide quality leprosy services;
(2) Sustaining quality leprosy services by ensuring timely case detection, quality of diagnosis and treatment, prevention and efficient management of disabilities and achieving high cure rates;

(3) Supporting intensified activities in countries or areas within countries which are high endemic or areas or population groups which are underserved;

(4) Providing free supply of MDT to all countries of the Region and assist the countries in MDT stock and supply management;

(5) Ensuring effective supervision, monitoring and evaluation;

(6) Supporting IEC/advocacy activities in order to further increase awareness on leprosy, and reduce the stigma associated with it;

(7) Strengthening and promoting partnerships, and

(8) Promoting research aimed at improved tools, better approaches and cost-effective implementation.

The strategy would allow sufficient flexibility for adoption of innovative approaches, adaptation to local conditions, and improved implementation process.

6. DESCRIPTION OF KEY ELEMENTS

6.1 Integration of Leprosy Services into General Health Services

All countries of the SEA Region have integrated leprosy services into general health services, while retaining some “specialized” staff to provide technical support. However, the levels and quality of integration vary from country to country. Thus there is need to strengthen the integration to ensure that the general health services assume full responsibility for all activities related to leprosy – diagnosis, treatment, management of complications, community awareness, advocacy, records and reporting, and supervision and monitoring. This will require capacity building of general health staff on technical, operational and management aspects of leprosy, and linkage of general health system to public and private health facilities and referral centres like medical colleges and research institutes.
6.2 Sustaining Quality Leprosy Services

The achievements and gains that have been made in reducing the burden of leprosy in the Region and in Member States need to be maintained, and progress made to reduce it further. Therefore, sustaining quality leprosy services is crucial to ensuring timely reporting of new cases to the nearest health facility; accurate diagnosis, and proper and prompt attention to meeting their needs. Towards these objectives, the following activities are important:

- Creating community awareness;
- High level of accuracy in diagnosis;
- Efficient referral system from the community to the health facility and from the health facility to the referral centre;
- Availability of MDT drugs at the health facility;
- Patient-friendly approach and counselling of the patient/family;
- Recognition and efficient management of complications, including prevention/care of disabilities and advice or referral for rehabilitation services, and
- Close follow-up in order to ensure high cure rates.

Creating community awareness

The focus of this activity will be the village community, where the reach of the print and electronic media is either non-existing or limited. The activities that could be useful are: orientation of the local community leaders; and inter-personal communication using general health workers, community volunteers or cured cases of leprosy. Development and dissemination of simple messages in local languages would be useful.

In addition, the mass media will be used to disseminate information on leprosy, availability of free treatment and the need for integration of the cured leprosy persons into the community.
Ensuring quality of diagnosis

In view of low endemic situations and the declining trends in leprosy prevalence, it would be important to build the capacity of medical/non-medical officers to correctly and accurately diagnose leprosy. The case validation studies in India and Nepal and in some other countries have provided evidence of the high level of over-detection in leprosy through “wrong diagnosis” and “re-registration” of cases. This demands that medical officers (MOs) and other staff have to be oriented not only on the signs and symptoms of leprosy and its treatment, but also on the need to exert great caution in diagnosis of leprosy. Leprosy should be diagnosed only if the signs are “definite” because a wrong diagnosis unjustly exposes the patient and his/her family to the stigma and social consequences of leprosy. Furthermore, “re-registration” leads to wastage of very expensive and valuable drugs. Wrong diagnosis and re-registration can be prevented or minimized if the WHO/National Guidelines on “Case Definitions” are strictly adhered to.

Efficient referral system

The success in providing sustainable leprosy services is dependent on a well-functioning referral mechanism for referring cases from the village or community level to the nearest health facility, and from the nearest health facility to the nearest referral hospital or referral centre. This requires identification and orientation of a focal point at the village level that will refer suspects to the health facility, and capacity building of the medical/non-medical officer at the health facility with regard to diagnosis and initiation of treatment, and the criteria to be used for referring cases to a referral hospital. A mechanism to periodically review the referral system also needs to be established.

Availability of MDT and patient-friendly approach

The referral system will fail if the health facility is not patient-friendly. This would include availability of: the MO or other staff for diagnosing leprosy; adequate stocks of MDT; the pharmacist or other staff responsible for dispensing drugs, and staff who can advise and counsel patients/their family members and show empathy and concern. The timings of the health facility should also be convenient to patients.
Recognition and management of complications and rehabilitation

A small number of leprosy cases can develop complications related to peripheral nerve involvement and damage, or to the phenomena of lepra reactions. The early recognition, and prompt and correct management or referral of these cases is crucial to prevent permanent nerve damage and its sequelae like trophic ulcers, and paralysis of muscles.

Though the number of new cases with disability has reduced, a fairly large number of old cases with disabilities/deformities are still existent in the community. They would continue to need care in terms of ulcer management, physiotherapy, reconstructive surgery, protective footwear, and in a minority of cases-rehabilitation services - physical, social, economic or psychological. Rehabilitative services available to persons with disabilities due to other diseases should also be made available to the leprosy-affected.

Stigma, discrimination and human rights

Many of those affected by leprosy have been victims of stigma, discrimination and human rights abuses. The stigma and its consequences have been more predominant in those disabled by leprosy. It was only in 2004 that the issue of human rights abuses in leprosy cases was brought to the attention of the United Nations Human Rights Commission, thanks to the efforts of Mr Yohei Sasakawa, WHO Goodwill Ambassador for Leprosy Elimination. WHO will support Member States in effectively dealing with human rights abuses through necessary legal and administrative instruments, and also advocate for repeal of outmoded laws, acts and regulations discriminating against the leprosy-affected, so that they can live with dignity and honour as equal members of society. WHO will also advocate for social welfare benefits for the leprosy-affected not only on the basis of physical or functional losses but also on the basis of possible health damage on account of loss of sensation.

Achieving high treatment completion/cure rates

The correct diagnosis, registration and initiation of MDT is only the first step. This needs to be followed up regularly in order to ensure that the patient completes the treatment within the prescribed duration of six months for PB
leprosy and 12 months for MB leprosy. Persons who cannot come regularly to collect their monthly-supervised doses of MDT should have the benefit of “Accompanied MDT” i.e. MDT for a longer duration or even the full course of treatment. This is a lesser risk compared to the patient turning out to be irregular or a defaulter.

Some of the actions required to achieve high cure rates are:

- Strict adherence to WHO/national guidelines on treatment duration;
- Timely deletion of cases (who have completed MDT) from the under-treatment list;
- Regular updating of registers;
- Promoting ‘accompanied’ MDT;
- Regular counselling, and
- Effective follow-up and defaulter-retrieval mechanism.

6.3 Intensified Activities in High Endemic Areas/Pockets or Under-served Populations

Though most countries of the Region would have achieved elimination at the national level by 2005, it is expected that some high endemic pockets will still remain at the sub-national level in many countries. These high endemic pockets will need special focus through a situation analysis, followed by appropriate corrective actions.

Though MDT coverage is reported as 100% by all countries, there still are some under-served populations, such as those living in hard-to-reach or intercountry or intra-country border areas, or in urban slums or as migrant labour. Innovative approaches are needed to ensure that such under-served groups have access to MDT and other services. “Accompanied MDT” is one of the options for such groups.

In many countries, public health services in urban areas and metropolitan cities are weak, with the NGOs, private sector and private practitioners involved in bridging the gap. However, the poor people affected by leprosy cannot afford private services generally based on user fees. Therefore, a coordination mechanism is needed to ensure that leprosy
services in urban areas are strengthened. Such a mechanism would involve ministries of health, municipal health system, NGOs, and the private sector and general practitioners, particularly dermatologists.

6.4 Drugs Supply Management

Leprosy elimination programmes in all endemic countries of the Region, except Thailand have had the benefit of free supply of MDT - from 1995-2000, through grants from the Nippon Foundation, and from 2000 onwards, from the Novartis Foundation. Novartis has pledged free supply through WHO until 2010. In view of low endemic situation in most countries, the management of the required MDT and other drugs/materials for the leprosy programme assumes importance in order to ensure adequate supply on one side and prevention of wastage on the other. WHO will need to play a major role in building national capacity towards ensuring efficient drugs supply management.

6.5 Supervision, Monitoring and Evaluation

An important component of capacity building of the general health system will be supervision, monitoring and evaluation of the leprosy programme, as part of overall responsibilities. A simple check-list may be developed for supervision. It is obvious that the general health system will be able to generate only limited reports and data on individual diseases like leprosy. Therefore, a simplified information system that is acceptable to the general health system needs to be evolved with not more than two leprosy indicators for monthly reports generated at the peripheral level. However, since leprosy is targeted for elimination by WHO, it would be useful to conduct a more detailed review of the progress through the leprosy elimination monitoring (LEM) exercise. The RTAG has recommended LEM in all countries where the annual new case detection is considered high. In countries where there is indication that operational factors could be influencing indicators, it would be worthwhile to conduct case validation studies along with LEM or as a separate exercise.

Geographical Information System (GIS) and Simplified Reporting/Information systems have developed into useful tools in reviewing and monitoring the progress of leprosy elimination and in analysis of endemicity
and its trends. Most countries have developed GIS and Simplified Reporting and Information systems. These systems need to be further strengthened, simplified and made user-friendly, while the capacity of programme managers needs to be enhanced in analysis and interpretation of data. Support should also be provided to programme managers to initiate corrective measures.

6.6 Advocacy and IEC

The focus on IEC activities and on advocacy will continue. Apart from community awareness, IEC will be specially targeted at key groups, such as the media, religious leaders, teachers, professional associations, local community leaders, youth and women. Advocacy will be targeted at policymakers, NGOs, private sector and donor agencies. Endemic countries need to be assisted in the development and implementation of advocacy/IEC and resource mobilization plans.

6.7 Partnerships

One of the important factors for the success and achievements of the leprosy elimination programme, globally, regionally and in Member States has been the strong partnerships among ministries of health, WHO, national/international NGOs and national and international development partners. These partnerships need to be sustained and strengthened, and new partners co-opted in order to consolidate the achievements and gains made so far, sustain quality leprosy services and support efforts in further reducing the burden of leprosy. The partnerships should be based on mutual trust, constant sharing of information and joint reviews/discussions on a regular basis.

6.8 Basic and Operational Research

Though the burden of leprosy has reduced dramatically in most countries of the Region, the search for improved tools and interventions, and for more cost-effective approaches will continue. There is scope for research to study new drugs, better combination of drugs, shorter duration of treatment, better tools to prevent or manage disabilities in leprosy, and for development of immunotherapy or primary prevention. Scope also exists for operational
research aimed at better implementation and management of the programme, and better understanding of patient dynamics, such as reasons for irregularity/defaulting, effects of stigma, discrimination and human rights abuses, and impact of IEC/advocacy, etc. Thus, there is continued scope and need to support Member States and research centres in basic as well as operational research.

7. INDICATORS FOR MONITORING PROGRESS

The primary indicator for monitoring progress of leprosy elimination so far has been the prevalence rate per 10000 population. This prevalence indicator was enshrined in the definition of elimination of leprosy as a public health problem and included in a World Health Assembly resolution in May 1991. The indicator was endorsed by the WHO Seventh Expert Committee on Leprosy, WHO Technical Advisory Group (TAG) and ministries of health of all endemic countries.

It needs to be emphasized that the prevalence indicator and the target date to achieve it - originally 31 December 2000, later extended to 31 December 2005 - served to enthuse and motivate national programmes to intensify efforts towards leprosy elimination. The fact that 113 of the 122 countries which had a national-level prevalence of >1 case per 10000 population in 1985 have attained the goal is proof that the WHO recommendation to use the prevalence indicator was sound.

All indicators have certain disadvantages and this holds true for the prevalence indicator. Now that the prevalence indicator has served its purpose, and there has been a dramatic decline in prevalence globally, regionally and nationally, many experts have proposed that in low endemic situations, annual new case detections would be a more sensitive and useful indicator. However, the usefulness of new case detection as an indicator is directly related to the quality of diagnosis, which in many field situation seems to be poor, as reflected in case validation studies conducted in India in 2003 and 2004.

The RTAG after considering the above facts have recommended the following indicators for use in Member States of the SEA Region:
7.1 Main Indicators

(1) Annual New Case Detections per 100000 population – for all countries, with the proviso that the quality of new case detections should be closely monitored;

(2) Registered Prevalence rate per 10000 population – for countries which are yet to achieve elimination and large countries which have already decided on prevalence as an indicator for achieving sub-national-level elimination. Once the pre-determined sub-national-level elimination is achieved, the primary indicator should be the annual new case detections, and

(3) Treatment completion/cure rates – A satisfactory treatment completion rate is an indication of good counselling, acceptability of treatment, good follow-up and client satisfaction. All attempts should be made to ensure that MDT is completed within the prescribed duration of six months for PB and 12 months for MB.

7.2 Additional Indicators

(1) Proportion of new cases with deformity grade-2;

(2) Proportion of child cases among new cases, and

(3) PB/MB proportion among new cases.

7.3 Indicators for Monitoring the Quality of Leprosy Services

It would be useful to evaluate the quality of leprosy services periodically at least on a sample basis. The following indicators could be used for the purpose:

(1) Proportion of new cases diagnosed correctly;

(2) Proportion of treatment defaulters;

(3) Number of relapses, and

(4) Number of suspects referred by field workers or community volunteers.
8. EXPECTED OUTCOMES BY 2010

- Annual new case detections will be less than 10/100000 population regionally and in all endemic countries; many countries will record a figure of less than 5/100000 population.
- National-level elimination sustained and sub-national-level elimination up to pre-determined administrative units achieved in all countries with prevalence less than one per 10000 population as an indicator;
- Quality leprosy services within the general health system available and sustained in all countries. This would include improved quality of diagnosis and greater attention to prevention and care of disabilities.

9. ROLE OF WHO

The success of the strategy and its implementation will depend on global and regional partnerships between and among all stakeholders, with national governments assuming a leadership role and with all partners assuming shared ownership. WHO will function as a facilitator for the smooth functioning of partnerships and provide the necessary technical inputs. It is expected that such partnerships will sustain the commitment for leprosy elimination at all levels; ensure allocation of the required additional resources; ensure free supply of MDT drugs and materials; facilitate effective implementation of activities, and establish an effective monitoring, supervision and evaluation mechanism.

The specific WHO inputs would include:

1. Human resources to provide technical assistance to endemic countries in the planning, development, implementation and monitoring of country-specific plans of action, and in meeting the specific needs of countries; the priority for placement of technical staff will be countries which are currently detecting substantial
number of new cases annually - Bangladesh, India, Indonesia, Nepal, and Myanmar;

(2) Supporting intensified efforts in Timor-Leste which is at risk of not achieving the leprosy elimination goal by 2005;

(3) Management training and capacity building of general health staff in all countries;

(4) Assistance in conducting LEM and case validation exercises in specific countries to monitor the progress of leprosy elimination and ensure quality of diagnosis;

(5) Providing free MDT supply and supporting capacity building in drugs supply management;

(6) Promoting advocacy with policy-makers and senior functionaries in ministries of health, and in other ministries like Education, Social Welfare, Rehabilitation, and with bilateral/multilateral development partners, NGOs and the private sector;

(7) Supporting development of advocacy, IEC and resource mobilization plans and their implementation;

(8) Assisting national programmes, research centres and interested NGOs in developing operational research protocols and in conducting research;

(9) Supporting intercountry, national and sub-national periodic review meetings;

(10) Maintaining regional surveillance and geographic information systems and conducting trend analysis;

(11) Promoting computerization of information/data at national and sub-national levels, and

(12) Advocacy for repealing outmoded legislation which discriminates against people affected by leprosy in relation to their employment, marriage and travel, etc.
10. BIBLIOGRAPHY