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Report of the Tenth Meeting of the WHO Technical Advisory Group on Leprosy Control

New Delhi, India, 23 April 2009

Regional Office for South-East Asia

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1. Introduction

The Tenth Meeting of the WHO Technical Advisory Group (TAG) on Leprosy Control was held in New Delhi, India, on 23 April 2009, immediately after the Global Programme Managers' Meeting at the same venue held on 20–22 April. The meeting was attended by members of the TAG; experts invited from the areas of chemotherapy research, drug resistance surveillance and social science; representatives from the International Federation of Anti-Leprosy Associations (ILEP) and the International Leprosy Association (ILA) and Regional Advisers from the WHO Regions. The meeting was chaired by Professor WCS Smith. The terms of reference of the WHO Technical Advisory Group on Leprosy Control, programme of the meeting and the list of participants are given in Annex 1, 2 and 3 respectively.

2. Report of the Ninth TAG Meeting

The report of the Ninth TAG Meeting held in Cairo, Egypt, on 6–7 March 2008 was approved by all the members.

3. Endorsement of the Enhanced Global Strategy 2011–2015 and the Operational Guidelines

The Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy 2011–2015 and the accompanying “Operational Guidelines” were endorsed unanimously by the TAG members. These were earlier endorsed by the national programme managers from around the world and partners at the Global Programme Managers' Meeting.

The General Secretary of ILEP indicated the endorsement of the Strategy by its members and Technical Commission. He thanked WHO for providing the opportunity to various stakeholders to give their inputs in developing the Strategy and broadening its ownership. In addition, on behalf of the International Leprosy Association, its president informed that the Board

members of the Association have endorsed the Enhanced Global Strategy 2011–2015.

The TAG members agreed to assist with future discussions about how best to implement the enhanced items in the Strategy at the country level. Professor WCS Smith thanked the Global Leprosy Programme and the working group which had prepared the background documents for the Global Programme Managers' meeting which was held during the previous three days.

The Strategy will come into force at the beginning of 2011. Over the next few months, the text will be revised in the light of discussions held during the Programme Managers' Meeting, with the final version to be distributed to all partners by October 2009. It will be translated into major languages and a series of regional and national meetings will be organized to explain the contents as widely as possible. A series of training workshops will be held simultaneously, based on a country-by-country assessment of need.

4. Mechanisms for monitoring progress using the global target

Dr HJS Kawuma introduced the topic of mechanisms for monitoring progress in using the global target of at least 35% reduction in the rate of new cases with grade-2 disabilities per 100 000 population at the end of 2015, compared to the baseline at the end of 2010. The importance of collecting grade-2 disabilities regularly and from all new cases was highlighted. Professor Smith presented detailed data about grade-2 disabilities from a number of countries. Although all countries report data on new cases with grade-2 disabilities, it is not clear how complete or reliable they are.

- It was suggested to arrange meeting of a working group experts under the Technical Advisory Group to review current data in terms of collection, reporting and analysis; and to ensure that maximum benefit is gained from its use in monitoring progress towards the new global target.

5. Guidelines for the global surveillance for drug resistance in leprosy: Next steps

The global surveillance for drug resistance in leprosy was introduced by Dr M. Matsuoka. Three new countries have agreed to participate (China, Philippines and Columbia) in the network. Additional endemic countries will join the near future. WHO will provide assistance to national laboratories conducting molecular tests to promote transfer of technology and to ensure quality control. The field component which involves correct diagnosis of a case of relapse and proper collection of samples along with a shipment of these samples to the laboratories for testing is vital for the effective running of the surveillance system.

- The TAG reiterated its support for this initiative, expressing the desire that other partners, including ILEP members, would help to expand the work in selective countries in collaboration with WHO.

6. Report on the progress of multi-centric Uniform-MDT (U-MDT) study

Dr B. Nagaraju reported on the progress of the multi-centric study on Uniform-MDT

(U-MDT) study for paucibacillary (PB) and multibacillary (MB) patients. This study is being supported by the Special Programme for Research and Training in Tropical Diseases (TDR) in collaboration with the Global Leprosy Programme (GLP). The study design originally aimed at recruiting 2 500 PB and MB cases in each arm but only 2 094 PB and 1 302 MB cases were recruited.

At the steering committee meeting in December 2008, the principal investigator and co-investigators agreed to the recommendation to extend the intake to five additional areas in order to obtain the required sample size. The follow-up period has been extended to eight years in order to have a longer follow-up period to identify relapse cases. The additional recruitment

of cases will extend the study period for another five to eight years and the full results will not be available until after 2015.

Special events are being closely monitored during the follow-up period. A total of 70 type-1 reactions, 23 type-2 reactions and 23 adverse drug reactions were reported. A total of 230 cases were lost to follow-up.

As on end 2008, there have been six cases of relapse. Four among them are MB cases.

7. Progress with the prospective ongoing study comparing 24-month MB-MDT versus 12-month MB-MDT in Brazil

Dr M.G. Cunha reported on the study comparing 24-month MB-MDT with 12-month MB-MDT in Brazil. In the 12 months MB MDT group, one relapse was found among 128 cases followed-up for six years. In the 24-month MB-MDT group, three relapse cases were found among 85 cases followed up for eight years. Essentially, there were no statistical differences in the relapse rates among the two groups.

Dr Cunha also shared the results of the trials using ofloxacin in Brazil, indicating that 28 days of daily treatment with rifampicin and ofloxacin had a high failure rate after a follow-up period of seven years. The addition of ofloxacin 400 mg daily for 28 days in the WHO regimen for MB for 12 months also did not show any statistical difference in the relapse rates. The TAG encouraged Dr Cunha to publish the results as soon as possible.

8. Opportunities and challenges in developing more effective anti-leprosy drugs and combinations

Professor Baohong Ji presented the next steps in developing more effective anti-leprosy drugs and combinations. Although some new drugs such as rifapentine and R 207910 displayed promising bactericidal activities against *M. leprae* in mice, they are still required to be tested in human trials for confirmation of their bactericidal activity and tolerance. In addition, several

possible combinations of currently available drugs—such as moxifloxacin, clarithromycin and minocycline were suggested for treatment of a MB who cannot tolerate rifampicin or is resistant to it. These regimens will have to be tested among proven rifampicin-resistant leprosy patients for their efficacy and safety in carefully conducted clinical trials before they can be recommended for use in routine programmes.

For the next steps, it was suggested that (1) seeking consensus on the needs of new anti-leprosy drugs and drug-combinations among major partners; and (2) conducting a research capability survey related to drug screening; experimental chemotherapy and clinical trials to identify the institutes and the programmes which still have the capacity or potentiality to carry out these research activities. The importance of broad coalitions and collaborations was emphasized as the only way to sustain the capacity for leprosy research in future".

9. Infectivity of leprosy

Dr P. Saunderson introduced the topic of infectivity of leprosy highlighting the bactericidal effects of a single dose of rifampicin on *M. leprae* and its growth in mice. The members unanimously agreed to the following statement on the infectivity of leprosy:

"A leprosy patient's infectiousness is related to the size of the bacillary population in the body. It has been shown that a single dose of rifampicin decreases the load of viable bacilli to such low levels that it is no longer possible to cultivate the organism in an animal model. In public health terms, it is reasonable to conclude that infectiousness becomes unlikely after starting multidrug therapy (MDT)".

It was suggested that the Secretariat should seek legal counsel on the interpretation and legal consequences concerning the above statement.

10. Other issues

- It was recognized that maintaining expertise in leprosy at the country level is a major challenge in all regions, but perhaps

especially so in Africa. This is closely linked with the task of establishing and maintaining well-functioning referral facilities and the centres that are capable of providing advanced level training in leprosy.

- It was felt that the topic of chemoprophylaxis, which was discussed at some length in the Programme Managers' meeting, and the feasibility of its use in routine programmes, needs further discussion in order to make specific recommendations about contact examination and the circumstances under which chemoprophylaxis could be used. The Global Leprosy Programme will, therefore, set up a working group under the auspices of the TAG later in 2009 to review these issues.

11. Conclusions and recommendations

The following conclusions arrived at and recommendations made:

- (1) The TAG members unanimously endorsed the "*Enhanced Global Strategy for Further Reducing the Disease Burden due to Leprosy 2011–2015*" and the accompanying "*Operational Guidelines*".
- (2) The TAG recommends that a working group be formed under the auspices of the TAG to review current information on data collection, reporting and analysis of the new global target indicator, that is, new cases with grade-2 disabilities rate per 100 000 population, and to advise on ways to improve data collection and validation of this indicator for monitoring progress.
- (3) The TAG recommends that a working group be formed under the auspices of the TAG to review the present data on chemoprophylaxis and to advise on areas of research with the aim to develop appropriate guidelines for its application in future leprosy control strategies.
- (4) The TAG strongly supports the global drug resistance surveillance initiative and recommends that more sentinel sites be included from various Regions.

- (5) The TAG agreed with the statement that “in public health terms, it is reasonable to conclude that a leprosy patient’s infectiousness becomes unlikely after starting multidrug therapy (MDT)”.

Annex 1

Terms of Reference of the WHO Technical Advisory Group on Leprosy Control

General Background

In 1995 the Leprosy Elimination Advisory Group (LEAG) was established by the Director-General to advise the former WHO Action Programme on Elimination of Leprosy (LEP) on implementation and management of the strategy to eliminate leprosy as a public health problem by the year 2000. This was defined as reducing the prevalence of the disease to less than one case per 10 000 population. It was disestablished in 1999 following WHO restructuring.

In order to advise WHO on effective implementation of the intensified strategy and monitoring its progress, particularly in the areas of capacity building, MDT supply, communications and information, as well as monitoring and surveillance, the Director-General decided to establish a *Technical Advisory Group on Leprosy Control (TAG)* consisting of independent experts. There are currently nine members representing all WHO Regions and having different expertise and vast experience in various fields. The first meeting of TAG was held in Geneva in 2000.

Terms of Reference

The WHO Technical Advisory Group on Leprosy Control is composed of experts who are independent of WHO. Members are chosen for their expertise in leprosy and programme management with particular reference to public health, epidemiology, community mobilization and advocacy, operational research, and disability prevention. They form a strong team with a good technical balance and geographical representation.

The members of this advisory body are selected and appointed by WHO and meet at least once a year. The period of membership is three years, with the possibility of extension.

The Technical Advisory Group's deliberations are open to representatives of national and international partners as observers to encourage open debate.

In addition, the Group may invite, as necessary, representatives from selected leprosy endemic countries and other experts to its meetings.

- To review and monitor the implementation of the Global Strategy to further reduce the leprosy burden and sustain leprosy control activities.
- To advise WHO on new strategies and approaches if necessary.
- To monitor progress in further reducing the leprosy burden.
- To give technical advice and guidance on sustaining leprosy control activities.
- To identify and facilitate implementation of a research agenda in order to improve the quality of leprosy control activities, including prevention of disabilities and rehabilitation.
- To support efforts related to reducing stigma and discrimination against individuals and families affected by leprosy.

Annex 2

Programme

23 April 2009 (Thursday)

- 09:00–09:15 Welcome by Chairperson Professor WCS Smith
Introducing of participants
Rapporteur: Dr Paul Saunderson
- 09:15–09:30 Approval of report of the Ninth TAG meeting, 6–7 March 2008, Cairo, Egypt
- Endorsement of the *Enhanced Global Strategy* for Reducing the Disease Burden Due to Leprosy 2010–2015 (*Prof WCS Smith*)
- 09:30–10:00 Discussion on mechanisms on monitoring progress in terms of the global target of reduction in the rate of new cases with grade-2 disabilities per 100 000 population (*Introduction by Dr HJS Kawuma*)
- 10:00–10:30 Guidelines for global surveillance for drug resistance in leprosy and next steps (*Introduction by Dr Masanori Matsuoka*)
- 11:00–11:20 Report on the progress of multicentric Uniform-MDT Therapy (U-MDT) study (*Dr B. Nagaraju*)
- 11:20–11:40 Progress with 12-month MB-MDT study in Brazil (*Dr M.G. Cunha*)
- 11:40–12:00 Next steps in developing new anti-leprosy drugs and combinations
(*Introduction by Professor Baohong Ji*)
- 12:00–12:30 Discussion on technical issues:

- Infectivity of leprosy (*Dr Paul Saunderson*)

12:30-13:30 Conclusions and recommendations

Annex 3

List of participants

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