Chapter 5
The role of international agencies and nongovernmental organizations

5.1 The Nippon Foundation (formerly Japan Shipbuilding Industry Foundation) and the Sasakawa Memorial Health Foundation
Y. Yuasa

WHO’s regular budget for leprosy was only about US$ 300 000 in 1975 and has remained at more or less the same level since then. However, the contribution of the Japan Shipbuilding Industry Foundation (JSIF) increased to US$ 2 million in 1976, of which two-thirds went to leprosy. By 1980, the total contribution of JSIF, now called The Nippon Foundation (TNF), had reached almost US$ 4 million. TNF also announced an additional contribution of US$ 50 million for the purchase of MDT drugs, for free global distribution through WHO, to meet the needs of leprosy-endemic countries from 1995 to 1999. The announcement was made in July 1994, on the occasion of the First International Conference on Leprosy Elimination, held in Hanoi, Viet Nam, under the joint sponsorship of WHO and TNF/SMHF. The main focus of that meeting, prompted by the forty-fourth World Health Assembly in May 1991, was “how to accelerate the global elimination of leprosy”, and the announcement by Mr Yohei Sasakawa, son and successor of Mr Ryoichi Sasakawa, of the additional US$ 50 million contribution from TNF was intended to support the intended acceleration. At the inauguration of the Global Alliance for the Elimination of Leprosy (GAEL) in Abidjan, Côte d’Ivoire, in November 1999, again under the joint sponsorship of WHO and TNF/SMHF, Mr Y. Sasakawa announced that TNF would make a further contribution of US$ 24 million over the period up to 2005, taking the total contribution of TNF to WHO nearly US$ 150 million – a testimony to remarkable collaboration.

Collaboration between WHO/LEP and SMHF intensified in 1982 with publication of Chemotherapy of leprosy for control programmes (WHO Technical Report Series, No. 675), the report of the 1981 WHO Study Group on MDT. At this time, the financial support from SMHF to leprosy-endemic countries became concentrated on implementation of MDT in these countries.

A few years earlier, when WHO had established THELEP under TDR, the involvement of some key members of the THELEP group in a chemotherapy trial co-sponsored by SMHF was most beneficial. These trials were on a quite modest scale, and a limited number of drug combinations were used. However, an important contribution made by the trial was the annual standardization workshop, held at the Leonard Wood Memorial (LWM) laboratory in Cebu, Philippines, for doctors and laboratory technicians from the three countries directly involved in the trials but also with participants from other countries, including Indonesia, Myanmar, Nepal, and Viet Nam, with which SMHF had working relationships. When the WHO recommendation on MDT was published in 1982, these countries already had some knowledge of MDT, and some field workers had first-hand experience of MDT implementation, although the actual regimens recommended were
different. The involvement of these countries in the chemotherapy trial was one of the principal reasons that they were able to implement MDT with relative ease compared with many leprosy-endemic countries in other parts of the world. Equally significant for these countries was the undertaking by SMHF to supply MDT drugs rather than dapsone.

From the outset, the policy of SMHF was to supply MDT for MB patients for 2 years only; any extension of treatment beyond 2 years, mostly until smear negativity, would have to rely on drugs from other sources. Interestingly, however, the Minister of Health of Indonesia, Dr Adhyatma (the former head of a leprosy service), requested permission from SMHF to use MB MDT for one year only; his reasoning was that the quantity of drugs being supplied would mean many MB cases having to go without MDT altogether. This permission was not given but, with hindsight, agreement to this suggestion would have seen Indonesia become – by some years – the first country with a national policy to use a 12-month MB regimen, which is now standard throughout the world.

This supply of MDT drugs, to as many as 20 countries at times, continued until 1995, when the extra contribution of US$ 50 million from TNF was able to provide the required amount of MDT globally.

An important contribution to the implementation of MDT was the use of blister calendar packs. In 1984, a pilot study of MDT involving 2500 patients was undertaken in the provinces of Ilocos Norte and Cebu in the Philippines, with support from SMHF, WHO and others. In order to facilitate the delivery of MDT drugs and to avoid rifampicin being diverted to purposes other than leprosy treatment, the Government of the Philippines and WHO requested Ciba-Geigy to develop a presentation of MDT drugs in blister calendar packs. Following the success of the trial, albeit with a limited number of patients, the Government of the Philippines decided to use these packs for the entire national leprosy programme – and for the national tuberculosis programme as well.

SMHF/TNF and WHO/LEP, initially under Dr H. Sansarricq and later under Dr S.K. Noordeen, were able to work very closely towards common objectives. Formal annual visits by the Medical Director of SMHF – for consultation on TNF’s annual contribution – continued but, since there were many other opportunities during a year to discuss issues of mutual concern, including the use of TNF funds, the period of formal consultation was eventually cut to just one day.

Dr H. Nakajima, first as Regional Director of the WHO Regional Office for the Western Pacific (WPRO) and later as Director-General of WHO, gave wholehearted support to the MDT programme; his understanding and cooperation were valuable in the collaboration between TNF/SMHF and WHO/LEP. The two bodies jointly organized the first International Conference on the Elimination of Leprosy (Hanoi, Viet Nam, 1994), and had similar involvement in the second and third International Conferences (in New Delhi, India, 1996, and Abidjan, Côte d’Ivoire, 1999). Coordination of their activities was particularly apparent in certain countries, including the Federated States of Micronesia and Papua New Guinea.

Without the TNF contribution, which covered a major portion of WHO’s leprosy budget for 25 years from 1975, it is likely that global leprosy situation would be quite different from what it is now. It is particularly doubtful that WHO/LEP would have been able,
in 1991, to make the bold proposal of globally eliminating leprosy as a public health problem; even if it had done so, fewer of the world’s leprosy-endemic countries would have reached the elimination target by the end of 2000 without the additional US$ 50 million for the free supply of MDT.

After 1982, SMHF channelled the major portion of its financial support to leprosy-endemic countries for purposes such as training, monitoring, transport facilities, equipment, etc. to support the implementation of MDT. It may be worth pointing out that SMHF, despite being an NGO and a member of ILEP, decided from the outset to support the leprosy control programmes of the national health authorities, rather than conduct its own projects or support projects by other NGOs. This approach was based on the belief that the national health authority is ultimately responsible for the health of a country’s citizens, and that support from outside, whatever its extent and however long-lasting, could never meet the needs of the entire population permanently. Thus, SMHF tried always to strengthen national capacity so that, on withdrawal of that support, the national programme was better off than it had been. In the 1980s, a provisional time-limit was set for this support – usually 3 or 5 years. After 1991, SMHF’s support was extended, lasting until the elimination target was achieved by the national health authorities; this meant that many of the countries of east and south-east Asia, such as China, Indonesia, Philippines, Republic of Korea, and Thailand, where leprosy control efforts have been successful, have gradually ceased to need that support. Now, the greatest proportion of SMHF support goes to three Asian countries – India, Myanmar, and Nepal – that have yet to achieve their national leprosy elimination goal. Elsewhere, some support is extended to three other countries (Brazil, Madagascar, and Mozambique) that also have yet to achieve the goal, as well as to a handful of others that have only recently achieved it. A limited amount of SMHF support also goes to non-elimination activities, such as the prevention of disabilities or empowerment of people affected by leprosy and education of communities about leprosy, in the belief that the ultimate goal, a world without leprosy, can be achieved only with the full participation of ordinary citizens and not by the efforts of health and medical professionals alone.

### 5.2 The International Federation of Anti-Leprosy Associations

*H. Sansarricq*

Most of the information given in this section regarding ILEP support for MDT implementation is based on statements of ILEP representatives at various meetings organized by WHO; figures on MDT thus include WHO MDT and a number of other combined drug regimens.

1981–1990: continuing good ILEP/WHO cooperation, with a few clouds

As mentioned in Chapter 2, the late 1970s saw a widespread demand – from voluntary organizations as well as from other quarters – for recommendations from WHO on MDT for leprosy. Chapter 2 also recalls that, in mid-1981, ILEP agreed not to issue recommendations before WHO had done so.

As early as 10 December 1981 (the WHO Study Group having met in mid-October), the ILEP Medical Commission endorsed the WHO MDT regimens and recommended that ILEP members follow the WHO recommendations in the projects that met the required standard. At its General Assembly in June 1982, the Federation approved a resolution to ensure the widest possible application of WHO MDT in the field (1, 2). However, at the coordinating meeting of February 1984 (1), it was made clear that “the adoption by ILEP of
the new drug therapy as proposed by WHO does not mean that each member association is obliged to apply that regimen alone in its leprosy work”. As a consequence, ILEP reports to WHO sponsored meetings never made a distinction between WHO MDT and other combined drug regimens, notably the rifampicin/Isoprodian® combination, use of which was supported in several projects by the German Leprosy Relief Association.

By the end of 1983, the ILEP reporting system was updated, in collaboration with WHO, in order to include relevant information on MDT regimens and patient statistics (i.e. numbers of registered patients, numbers of patients receiving or having completed MDT or under post-MDT surveillance, etc.). In 1983, ILEP published a booklet on the introduction of WHO MDT (4), prepared by its Medical Commission, which gave priority to assisting with implementation of MDT; a revised edition was published the following year.

In the early 1980s ILEP-supported control projects covered some 1.2 million patients (5). In 1983, the Damien Foundation from Belgium, an ILEP member, created a Drug Fund for MDT, with an initial endowment of US$ 400 000; a number of other ILEP members provided additional grants. Also in 1983, most of the ILEP-supported projects with sufficient infrastructure (more than 150 projects out of 700) started “implementing MDT, in one way or another, covering an average of 10% of their patients” (2).

There was a steady increase in the use of MDT (WHO MDT and other combinations) in ILEP-supported leprosy control projects in the latter half of the 1980s; numbers of patients on MDT as reported by ILEP at the third coordinating meeting on implementation of multidrug therapy, September 1988 (6), were:

1984: 100 000
1985: 145 000
1986: 188 000
1987: 250 000

By the end of December 1988 a total of 768 706 patients were on chemotherapy in ILEP-supported projects, of whom 270 616 (35.20%) were receiving MDT (WHO-recommended MDT in most cases). Regionally, the proportion of patients on chemotherapy who were receiving MDT was nearly 42% in Asia, 32% in the Americas, and 27% in Africa. In 1988, ILEP members were supporting 814 field projects in some 92 countries, in addition to 136 other projects, with a total annual expenditure of about US$ 60 million (7).

1991–2000: growing difficulties in ILEP/WHO cooperation

In May 1991, the World Health Assembly adopted resolution WHA44.9, Elimination of Leprosy as a Public Health Problem. The objective of MDT for all leprosy patients by the year 2000 had already been adopted by ILEP in June 1990 (8). This objective had apparently the same practical meaning as the elimination target of WHO – with one important difference. ILEP did not accept the WHO definition of a case of leprosy as recommended by the WHO Expert Committee on Leprosy at its sixth meeting in 1987 (9), according to which all leprosy patients who had completed MDT were considered to be cured and were excluded from the prevalence. For ILEP, patients who had been treated with MDT but who presented deformities or permanent nerve damage continued to be cases of leprosy and therefore contributed to prevalence. This position had implications for the use of prevalence to monitor the elimination of leprosy as a public health problem and for fundraising activities.
At the second meeting of the WHO Working Group on Leprosy Control in July 1992, ILEP expressed concern over the slowing down of MDT coverage in recent years in their projects, which seemed to be facing some difficult areas (10). Concern was also voiced about “the limited progress made in developing a true collaboration between ILEP and WHO” and “the attitude of some ILEP member associations, which are reluctant to make national partners in the projects carried out in the country”.

At the third meeting of the Working Group in July 1993 (11), ILEP made the following statement: “At the end of 1991, a total of 1.34 million patients were under treatment, surveillance or care by ILEP-supported projects; 636 000 people were registered for chemotherapy, 60% of whom were receiving MDT” (of unspecified nature). Expenditure by member associations in 1992 amounted to US$ 77 million, spent in 103 countries with 63% going to support of control work, 7% to research, 10% to training and 7% to rehabilitation. Further, “ILEP members were concerned about the potential negative impact on donors of loose use of the term ‘elimination’. They considered that publicity should put the targets clearly in context and stress the continuing tasks set by the unchanged level of newly detected cases, areas where it would be difficult to implement MDT, and patients with disability”.

At the first meeting of the Leprosy Elimination Advisory Group (LEAG) in July 1995 (12), ILEP reported that, at 31 December 1993, a total of 589 934 leprosy patients (35% of the global total of registered patients) were under chemotherapy in ILEP-supported projects. ILEP’s interim target and first priority was to provide MDT by the end of 1995 for all patients in all ILEP-supported projects (other than those adopted during that current year). Other priorities included prevention of disabilities and rehabilitation. In 1996 (13), within ILEP-funded projects:

- A total of 402 072 patients were on MDT registers (46.8% of the world total).
- The total number of new cases was 246 829 (44.1% of the total worldwide).
- Support for socioeconomic rehabilitation was strengthening (217 projects in 34 countries).
- Support to combined leprosy/tuberculosis programmes was growing: 180 976 tuberculosis patients were being treated in 62 ILEP projects.
- Research expenditure totalled 5.62% of expenditure by all ILEP member associations, with efforts being made to increase this proportion.

At the third LEAG meeting in July 1997 (14), ILEP reported that the budget of the Federation in 1997 was about US$ 65 million, that support to leprosy and tuberculosis programmes amounted to US$ 6.8 million, and that support for socioeconomic rehabilitation accounted for 28% of projects. ILEP initiatives then included:

- joint ILEP/WHO efforts to reach undetected cases;
- guidelines on the sustainability of elimination activities;
- advice on socioeconomic rehabilitation;
- provision of essential learning materials to a wide range of health staff;
- integration of non-leprosy NGOs in leprosy control activities;
- advice on research priorities.

Meeting participants reported that some ILEP members were diverting their attention to diseases other than leprosy, but ILEP’s president considered that combining leprosy and tuberculosis work was cost-effective.
Immediately after the third LEAG meeting, there was a joint ILEP/WHO workshop on reaching unknown patients (hidden prevalence) (15) – a non-controversial issue but a problem of central importance. In the course of this workshop, ILEP reported that the Federation and its partners were currently financing more than 40 special initiatives aimed at discovering undetected patients in 15 countries, using a variety of approaches. Among the recommendations to emerge from the workshop were the strengthening of the primary health care system and use of leprosy elimination campaigns (LECs) and special action projects for the elimination of leprosy (SAPELs). As indicated in section 3.1, 1997 – the year when this workshop was held – was the first year in which 100% geographical coverage with MDT was achieved worldwide.

At the fourth LEAG meeting in June 1998 (13), ILEP pointed out that the overall forecast annual budget of the Federation for 1998 stood at around US$ 65 million (for the third year running) and that, during the decade 1986–1996, the total expenditure of ILEP member associations in support of leprosy elimination was just under US$ 700 million. A second ILEP/WHO workshop followed immediately after the LEAG meeting. The topic was special initiatives for reaching undetected cases, and the workshop made a number of recommendations, essentially on means of improving coordination between partners (15).

The following box and Figure 5.1 summarize recent information on ILEP-supported projects.

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<tr>
<th>ILEP global indicators end 2001&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td>Reports have been received from 637 projects in 75 countries – 631 projects that submitted ILEP B questionnaires, 5 WHO national or state programmes, and for 1 project for which data came from previous years.</td>
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<tr>
<td>➢ Total combined population of ILEP-supported projects*</td>
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<td>➢ Total number of patients registered for treatment at year end</td>
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<td>➢ Total number of newly detected cases during 2001</td>
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<td>% MB among all new cases</td>
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<td>➢ Total number of children among the newly detected cases</td>
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<td>% children among all new cases</td>
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<td>➢ New cases with disability assessment at detection</td>
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<td>➢ New cases with disability 2 among all those assessed</td>
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<sup>a</sup> Total ILEP coverage is obtained by adding together the coverage of the individual projects.
Clearly, collaboration between ILEP and WHO during the early part of the elimination strategy (1991–2000) was affected by differences of opinion, especially in relation to various aspects of the same strategy. Nevertheless, ILEP member associations have continued to support leprosy in endemic countries and to attend GAEL meetings.

References


5.3 Novartis

S.J. Yawalkar, P. Grewal

Drug development

In the past 15 years, more than 12 million patients with leprosy have been successfully treated with MDT in accordance with WHO’s 1982 recommendations. Three drugs make up the recommended MDT – clofazimine (Lamprene®), rifampicin (Rimactane®), and dapsone. Two of these three drugs originated in the research laboratories of Novartis (created by the merger of Ciba-Geigy and Sandoz).

Lamprene

The active ingredient in Lamprene – clofazimine (B 663, G 30320) – is a substituted iminophenazine bright red dye. It was synthesized in 1954 by Vincent Barry et al. (1) at Trinity College in Dublin, Ireland, within the framework of a research agreement between Geigy and the Irish Medical Research Council. Clofazimine was originally developed for tuberculosis, against which it proved effective in the test-tube and in mice but ineffective in patients. Further development of the compound was almost abandoned. However, at the end of 1959, Chang (2) reported that clofazimine inhibited \textit{M. leprae} in a murine leprosy model.

In August 1960 at a meeting between Vincent Barry, Robert Cochrane and Wolfgang Vischer (Geigy) in London, Cochrane suggested asking Stanley Browne – who was in Uzuakoli, Nigeria, at the time – whether he would be willing to carry out a clinical trial. Browne agreed immediately, collected the drug in November 1960 and, working with Hogerzeil, started the clinical trials. Feedback from the trials was positive, and the scientists at Geigy increased their efforts to produce an acceptable formulation that would solve the problem of poor absorption.

Browne and Hogerzeil in Nigeria provided the first confirmation of the efficacy of clofazimine in lepromatous leprosy patients in 1962 (3), and Browne visited Geigy the same year for a discussion of their results. Clofazimine was judged very favourably from a therapeutic point of view, as patients seemed to feel much better after taking the drug and the morphological index decreased. However, Browne was of the opinion that its action was no quicker than that of dapsone. Clofazimine would be more expensive than dapsone and, since the reappearance of normally stained \textit{M. leprae} had suggested the emergence of clofazimine-resistant bacilli, it was concluded that further development of the drug was not worthwhile. Since both handling and production were also proving problematic (the compound stained everything intensely red), a decision was taken to discontinue the development of clofazimine.

Nevertheless, Browne continued to treat more patients with clofazimine, using formulated material that remained in stock. In 1965 he reported that he had observed an anti-inflammatory action of clofazimine in erythema nodosum leprosum (ENL) reactions (4) and urged the scientists at Geigy to conduct further clinical trials. This observation, together with the first reports of dapsone resistance, highlighted the need for further development and bulk production of clofazimine, as well as for intensive testing of the product. Trials were organized in a number of countries and the results were presented at the Ninth International Leprosy Congress in London in 1968. In 1969, Geigy launched clofazimine under the trade name Lamprene®.
Clofazimine is the only antileprosy drug that displays anti-inflammatory action and is effective in the prevention and treatment of ENL reactions in leprosy patients. Its overall antileprosy effect is about the same as that of dapsone; it is principally bacteriostatic and only weakly bactericidal. Unlike rifampicin, clofazimine has no effect on dapsone excretion by leprosy patients (5).

To date there has been no confirmed case of clofazimine resistance.

**Rimactane**

While the development work on clofazimine continued at Geigy, scientists from the pharmaceutical company Ciba in Basel were also engaged in the search for new products against infectious diseases such as tuberculosis. They were collaborating closely with researchers from Lepetit in Milan who had isolated rifamycin from the bacterium *Streptomyces mediterranei* and found it to have an antibiotic effect.

As is often the case, chance played an important role in this discovery. The fermentation product rifamycin B has only a slight inhibitory effect and would therefore probably never have been picked up in a screening process. Fortunately, however, rifamycin B is relatively unstable and degrades very rapidly to rifamycin S, which is highly biologically active and produced striking results in the studies carried out at that time. On the basis of these studies, rifampicin – a semi-synthetic derivative of rifamycin S – was developed and introduced by Ciba in 1968, under the trade name Rimactane®, for the treatment of various bacterial infections.

Rifampicin acts by inhibiting bacterial RNA synthesis. It is the most potent bactericidal antileprosy drug available today: a single dose as low as 600 mg will kill most leprosy bacilli within a few days.

The first results of treatment of leprosy patients with rifampicin were published in 1970 by Rees (6). The commonly recommended dosage of rifampicin was 450-600mg daily. As regimens with daily rifampicin are very expensive, only a small percentage of patients could benefit from this treatment. Moreover, daily rifampicin without supervision led to patients taking the drug irregularly and the first reports of rifampicin-resistant leprosy emerged.

Clinical trials to establish the efficacy of once-monthly usage of rifampicin

Although dapsone, clofazimine and rifampicin were available to combat leprosy, none of them was ideal when used alone: resistance developed against dapsone, clofazimine caused skin discoloration at high doses, and rifampicin was too expensive to be accessible to most of patients in developing countries. For Shantaram Yawalkar, an Indian dermatologist and leprologist working in the medical department of Ciba-Geigy in 1974, the solution lay in administering the readily available dapsone once a day, together with rifampicin – the most highly bactericidal but much more expensive antileprosy drug – once a month. Since treatment of leprosy, even with a highly potent drug like rifampicin, can be futile if patient compliance cannot be assured, Yawalkar decided to administer it once a month only, under paramedical or medical supervision, to ensure regular treatment and follow-up.
An international, multi-centre, single-blind, controlled trial was therefore planned by Yawalkar to compare the therapeutic effects of dapsone in combination with rifampicin – 450 mg daily or 1200 mg once monthly under supervision – in patients with lepromatous leprosy. Languillon agreed to carry out the trial in Dakar, Senegal. The results revealed the high efficacy, good tolerability, and practicability of the once-monthly 1200-mg rifampicin schedule (7). The results were presented by Yawalkar at the International Leprosy Congress in Mexico City in 1978. Later, Opromolla and Ghosh repeated the trial in Bauru, Brazil, and at the Institute of Tropical Medicine in Calcutta, India, respectively (8, 9).

The bacteriological and histopathological investigations were carried out by A.C. McDougall in Oxford, and the data for all three centres presented by Yawalkar at the World Dermatology Congress in Tokyo in 1982. Interestingly, when Yawalkar submitted his paper to The Lancet for publication, it was returned with a request for an explanation as to why that journal should publish it. Yawalkar explained that publication of the findings in The Lancet would enhance acceptance of once-monthly rifampicin by the scientific community and would have significant public health impact if the regimens were to be adopted. The Lancet subsequently accepted the article without change and published it as the leading article in May 1982 (10).

WHO-recommended MDT regimens, also published in 1982, were the first to include once-monthly supervised administration of 600 mg rifampicin and 300 mg clofazimine in addition to 100 mg dapsone and 50 mg clofazimine once daily for at least 2 years for patients with multibacillary leprosy (BB, BL, LL) (11).

**Contribution to implementation of WHO MDT**

*Involvement of the Novartis Foundation for Sustainable Development*

Involvement of the Novartis Foundation for Sustainable development in leprosy field programmes was a natural extension of the Novartis tradition in leprosy drug development. Although MDT had been recommended as the standard treatment for leprosy by WHO in 1982, four years later fewer than 10% of registered patients were on treatment with MDT. This situation prompted the decision, in 1986, to directly support field programmes, to help improve understanding and overcome the obstacles to improving access to MDT treatment.

The Foundation set up an independent Scientific Advisory Committee of five members who selected and guided the programmes, which have always been developed and implemented in close collaboration with the local health authorities – from the outset, the Foundation has operated independently of the business interests of the company.

*Key areas of the Foundation's work*

*Introducing MDT*

The early programmes, such as those in the Democratic Republic of the Congo, Indonesia, and Sierra Leone, concentrated on meeting the prerequisites for the successful introduction of MDT. Introducing MDT necessitated a major change in the way leprosy control programmes were run, as the once monthly antibiotic dose had to be provided under supervision. A complete reorganization of leprosy control services was needed, including the establishment of laboratory facilities to diagnose and classify leprosy.
Social marketing – tackling the hidden disease burden

In 1988, like other countries, Sri Lanka had a large pool of “hidden cases” – people suffering from leprosy but not on treatment. It was clear that detecting and treating these hidden cases required an entirely new approach, which relied on people coming forward for treatment on their own initiative. In close collaboration with the Ministry of Health, the Novartis Foundation developed a social marketing approach to generate and meet “demand” for leprosy services. This involved large-scale advertising campaigns, developed by a leading local advertising agency, to improve the awareness of leprosy and dispel the fear surrounding the disease. To complement the campaign in the mass media, a wide cross-section of local leaders spread the message of the freely available treatment and the importance of seeking early cure (14). This initiative, together with the extension of the network of leprosy clinics, led to a sharp increase in the total number of patients, in particular those self-reporting. As a result, the disease had reached the elimination prevalence target at the national level within just eight years, by 1996.

After this success, a scaled-down version of the campaign was adopted by the Mexican authorities. Initially, the Foundation supported extensive public information campaigns, as well as training programmes to improve the diagnostic and treatment skills of health care workers in the 10 endemic states. Once leprosy had reached the elimination prevalence target at the national level, efforts focused on the four remaining endemic states.

Changing the image of leprosy

Public information campaigns designed to change traditionally negative perceptions of leprosy remain an important part of the Foundation’s work. At the global level, the Foundation collaborates with WHO in the production of information and communication material. At the country level, it has been supporting Brazilian efforts to project a “positive” image for leprosy, aided in this by the advocacy of various celebrities, including the popular singers Ney Matogrosso and Targino. The Foundation also helped to extend the free telephone hot-line service, Telehansens, to the national level, thereby providing easy access to information about leprosy.

The Foundation is assisting the Ministry of Health in Madagascar in a campaign to conquer people’s fear of leprosy and encourage patients to come forward for treatment. This campaign was developed in partnership with WHO and Tam Tam, a leading local advertising agency. The Foundation takes great pains to ensure that such campaigns are not launched before the local health services are in a position to deal with new cases seeking treatment.

Bringing treatment closer to patients

Extending the network of leprosy services to bring them closer to communities is the most crucial element in the elimination effort. Integrating leprosy services into the general health services offers the most effective way of doing this, and the Foundation has worked with local health ministries on the often difficult detail of achieving this.
In 2000, the Novartis Foundation helped the Sri Lankan Ministry of Health to develop the blueprint for integration and support its implementation. Leprosy is now part of the job description of every medical officer in the country and is treated within the general health services at all health facilities. In Brazil, together with the Ministry of Health, CONASEMS (Association of Municipal Health Secretaries) and WHO, the Foundation supported efforts to decentralize leprosy services. The initiative was started in the north-east, and the programme has gained momentum among health authorities throughout the country.

These efforts are a natural complement to the Foundation’s work to change the image of the disease and encourage people to come forward for diagnosis and treatment. The Foundation's first involvement in this sphere dates back to 1988, with its support to the International Nepal Fellowship in assisting the Nepalese Ministry of Health with integration. Mobile clinics were set up to help local health centres in the transitional phase of integration and provide on-the-job training to their staff. Subsequently, it helped to establish the Butwal referral clinic, which addressed the pressing needs, especially for disability care, in the south-west of the country.

From 1990 to 1996 in Turkey, mobile teams travelled by air and road to bring MDT treatment closer to patients; until that time, treatment facilities had been confined to the outpatient departments of the leprosy hospitals. The programme succeeded in reaching and treating 94% of all registered cases in the country, many of whom had previously been given only dapsone. In addition, the mobile teams were able to screen people in high-risk communities for signs of leprosy.

Comprehensive care

In 1989, the Foundation set up the Comprehensive Leprosy Care Programme (CLCP) in India, the aim of which is to provide comprehensive care services (MDT treatment and disability care) to patients. Emphasis is placed on simplifying disability care and bringing these services closer to patients through the network of government health care staff. Empowerment of patients is the guiding philosophy of the programme. Patients are helped in techniques of self-care, particularly in protecting insensitive hands and feet and caring for ulcers, using the self-care kit plus attractive microcellular rubber, or MCR, footwear designed and provided by CLCP. CLCP also pioneered the use in field programmes of simple, prefabricated hand and foot splints that help to correct disabilities and/or prevent their progression. Specialized services, such as reconstructive surgery, are provided where necessary. Patients with advanced, inoperable hand deformities are given made-to-measure grip aids. Those who need it also receive income-generation assistance. CLCP has a record of successful collaboration with state health ministries (Gujarat, Goa, and Maharashtra) and has pioneered the provision of disability care services at the village level. It has standardized data collection (including computer software) in order to assess the scale of the disability load in a community for purposes of planning and implementation. It has provided a model for integrated disability care in other countries, such as Sri Lanka.

The Global Alliance for the Elimination of Leprosy

Novartis and the Novartis Foundation joined GAEL at its creation in November 1999 in the final push to eliminate leprosy. The specific contribution of Novartis to GAEL is MDT donation and country-level support.
The MDT donation – providing free treatment to all patients worldwide through WHO

From 1995 to 1999, WHO provided high-quality MDT free of charge to patients around the world, financed through the drug fund provided by The Nippon Foundation. There were two sources for the MDT drugs, one of which was Novartis. In 1998 WHO dropped the other supplier on the grounds of inadequate drug quality and procured the MDT drugs exclusively from Novartis. Novartis therefore restarted manufacture of Lamprene® in India since existing stocks were being rapidly depleted.

As the drug fund was due to expire in 2000, concerns about maintaining the quality of MDT beyond that date loomed large, as WHO would have had to relinquish its role of quality control. In view of the long-standing involvement of Novartis in leprosy, informal discussions took place between WHO and Novartis/Novartis Foundation, culminating in the signing of a Memorandum of Understanding (MoU) on 12 August 1999. According to this agreement, Novartis is committed to:

− providing sufficient quantities of high-quality MDT, in blister packs, free of charge to WHO for six years (2000–2005) to treat and cure all leprosy patients worldwide;
− maintaining buffer stocks to respond to fluctuations in demand for MDT and to emergency requests from endemic countries;
− providing WHO with the necessary funds for the shipment of MDT and independent quality control; these funds are calculated at 9% of the value of the MDT to be shipped (based on 1999 MDT prices).

Novartis will also consider extending the donation beyond the expiry of the MoU. WHO and Novartis meet annually to discuss issues related to the donation, including logistics and orders for the following year.

MDT supplied

Close to 100% of the global supply of MDT is provided by WHO/Novartis. Working through the network provided by the United Nations system has proved to be an effective method of ensuring wide distribution of drugs to communities in need, together with the necessary technical support and monitoring at the country level. In the first 3 years of the donation, more than 24 million blister packs were distributed in line with official requests to WHO from more than 85 national governments. Buffer stocks of MDT are held in Denmark and by WHO in Geneva as an emergency supply.

The value of MDT provided in 2000–2003 amounts to about US$ 26 million. An additional sum of US$ 2.3 million was provided in cash to WHO Geneva to cover the costs of shipment and independent quality control.

Packaging: blister packs, patients packs, and field packs

The use of MDT blister packs was first proposed in 1983 by McDougall (12). A first model of the blister pack was manufactured in collaboration between Ciba-Geigy Manila and Ciba-Geigy Basel following a request from the Government of the Philippines (13). In 1987, Novartis introduced the first commercially available MDT blister pack, containing a 4 weeks treatment with each day’s treatment clearly marked. These packs are now standard and they make a vital contribution in helping patients to comply with treatment regimens. They protect the drugs from moisture and insects, have greatly simplified dispensing, and have also eliminated the chances of shortages or expiry of an individual drug.
In 2002, WHO and Novartis developed and launched a new line of packaging – patient packs. Made of heavy-duty cardboard, these packs serve as further protection for the drugs, particularly in transit or when stored in health centres and homes. As standard units, they also simplify logistics and inventory control. The smaller patient pack makes it easier to manage the smaller quantities of drugs needed by some health centres, especially with the integration of leprosy into general health services. The packs are colour-coded for the four patient categories: MB child and adult, PB child and adult.

References

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