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# Report of the Second Meeting of the Nongovernmental Organizations Coordination Group for Ivermectin Distribution

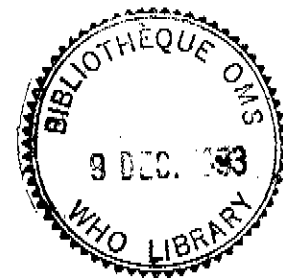
Geneva

1 - 3 June 1993

## ABSTRACT

The NGO Coordination Group for Ivermectin Distribution has, in its first half-year of formation, assisted Nigeria and Cameroon in the development of their national plans for onchocerciasis control, which are nearing finalization. It has carried out large-scale ivermectin distribution in Cameroon, Central African Republic, Chad, Malawi, Nigeria, Tanzania, Uganda and Zaire. It has also supported ivermectin distribution in four countries in the area of the Onchocerciasis Control Programme in West Africa.

With regard to mobilization of the needed resources for global control of onchocerciasis, the Group has prepared a procedural manual on ivermectin distribution, for the attention of Member States and collaborating agencies, in particular the World Bank, presently considering the setting-up of an extra-OCP Trust Fund. The Group also has extended invitations to other NGOs, particularly those with projects in endemic countries to join in the activity of ivermectin distribution. Finally, the Group is in the process of developing a common information system to allow uniform annual reporting of the activities of its members.



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The second meeting of the NGO Coordination Group for Ivermectin Distribution was held at the headquarters of the World Health Organization (WHO) in Geneva from 1 to 3 June 1993. It was opened by Dr B. Thylefors, Programme Manager, Programme for the Prevention of Blindness, who welcomed the participants and expressed his pleasure at the fact that all members of the Group were attending the meeting. Apologies were received from Dr J. Rochon, Director of WHO's Division of Health Protection and Promotion.

Dr P. de Raadt, Director of WHO's Division of Control of Tropical Diseases, gave the opening address. He welcomed the representatives of the nongovernmental organizations (NGOs) as well as the representatives from Merck & Co. Inc. and The Mectizan Donation Program. He expressed his satisfaction at the solidarity being demonstrated by the Group and compared their work with that of the NGO groups working against the elimination of guinea-worm and leprosy. He added that he was looking forward to the report on the technical issues which should serve as an input to the forthcoming Expert Committee on Onchocerciasis Control in late 1993. He advised that special attention should be paid to the potential danger posed by the existence of *Loa loa* in certain countries where ivermectin is being distributed against onchocerciasis, but this possibility should by no means discredit ivermectin.

Dr B.O.L. Duke, continuing his term of office as Chairman, moved for the adoption of the agenda (Annex 1), which was modified to include an item dealing with the proposal for the World Bank to set up an extra-OCP Trust Fund for the control of onchocerciasis in endemic countries outside the Onchocerciasis Control Programme (OCP) area. Agenda items, "Sustainability of ivermectin distribution programmes" and "Manpower development" were postponed to the next meeting because of time constraints. The list of participants is shown as Annex 2.

#### 1. Overview of WHO activities for 1993

During the first half of 1993, the activities of the Coordinator, which were broadly defined at the first meeting of the Group, consisted of (a) assistance to the endemic countries of Nigeria and the Cameroon, (b) follow-up on the recommendations from the first meeting in connection with operational research to ensure their implementation, and (c) efforts for resource mobilization.

(a) Assistance to endemic countries. This concentrated on the formulation of national plans. Nigeria is in the process of finalizing a five-year plan which foresees the expansion of already existing state distribution programmes to include all endemic local government areas (LGAs) and the starting of state programmes in endemic states which do not yet have any programmes. The plan envisages that the programme expansion and setting-up, which require considerable resources in the form of external aid, would be completed in the first five years. Thereafter, a maintenance phase, which should be sustainable and rely on a minimum of external aid should be attained. A similar plan is presently being drafted by the Ministry of Health in Cameroon. Visits were conducted to some of the distribution programmes in both countries.

(b) Assistance for research development. Assistance was given to Cameroon for the elaboration of a study proposal to develop and test out a methodology for rapid epidemiological mapping for onchocerciasis which was submitted to, and accepted by, the Special Programme for Research and Training in Tropical Diseases (TDR) for funding (see 5.3.1).

(c) Resource mobilization. A display was put up at the Forty-sixth World Health Assembly in May 1993 depicting the activities of the NGO Coordination Group for Ivermectin Distribution. Handouts were given to members of NGOs collaborating with WHO in the field of primary health care (PHC). The handouts consisted of (a) an address appealing to the NGOs to partake in the distribution effort, (b) a pamphlet, which has been developed in English and French, on ivermectin distribution to control onchocerciasis, (c) the report of the Group's first meeting, and (d) the PBL booklet on "Strategies for Ivermectin Distribution through Primary Health Care". Contact had been made with Interaction, as requested by the first NGO Coordination Group meeting, through Africare and the International Eye Foundation (IEF) with the view to recruiting more NGOs to join the Group, in an attempt to mobilize resources. It is expected that this preliminary contact will pave the way for interested NGOs of Interaction to attend the third meeting of the Group, which is planned for 14-16 December 1993 in Washington, D.C. It is planned that the display will be exhibited at the third meeting of the Group in the USA.

(d) Others:

(i) The Coordinator has had briefing in the WHO Regional Office for Africa (AFRO) and has pledged the Group's cooperation in the control of onchocerciasis in the Region. Discussions on the Group's activities have been carried out with the PBL counterparts in the WHO Regional Office for the Eastern Mediterranean (EMRO) and the WHO Regional Office for the Americas (AMRO) in Geneva.

(ii) The Coordinator rendered assistance, with financial support from the University of Stuttgart, Germany, in the training of a Cameroonian ophthalmologist in the evaluation procedure of ocular onchocerciasis after ivermectin treatment. It is expected that this will contribute to the strengthening of research and national programme monitoring in Cameroon.

(iii) The Coordinator had participated in the meetings of the WHO In-House Ivermectin Committee and the preparatory work for the WHO Expert Committee on Onchocerciasis Control to be held in late 1993.

## 2. Overview of NGO activities for 1993

2.1 Africare. Africare is carrying out ivermectin distribution in five states in Nigeria and in Chad. Preliminary discussions and planning are under way for undertaking ivermectin distribution in Ethiopia.

Since the first NGO Group meeting, Africare had carried out the evaluation of the first phase of its Ivermectin Distribution Programme (IDP) in Kwara State in Nigeria and had embarked on the second phase with funds from USAID; this has enabled the expansion of the Programme to cover nine out of 11 LGAs. In Adamawa/Taraba States, the Adamawa/Taraba States Onchocerciasis Control Programme (ATOP) project with funding by USAID and the River Blindness Foundation (RBF) has expanded from the original three to six LGAs and another 90 000 persons will be treated by the end of the first half of 1993, on top of over 85 000 treated by the beginning of the year. The Borno State project, funded by RBF, will have close collaboration with ATOP and will start distribution to some 50 000 persons during the first half of the year after completing the necessary preparations. The Kogi State project will benefit from technical assistance from Africare/Kwara State, and will start distribution to some 30 000 persons in two LGAs this year. Africare is exploring the

possibility of obtaining aid from Sight Savers. Africare receives considerable support in funds from local governments, which is a sign of sustainability.

Funded by RBF, the Chad project will treat, by mid-year, 80 000 persons in affected communities in Logone Oriental, Logone Occidental, Mayo Kebi and Tandjile with mobile teams.

2.2 Christoffel Blindenmission (CBM). CBM has large-scale ivermectin distribution programmes in Sierra Leone, in Zaire and in the Central African Republic and smaller ones in Ecuador. In Sierra Leone, where the distribution is hospital-based, two teams using 4WD vehicles cover the Rokel river basin and areas to the north and the central part of Sierra Leone.

Programmes in Zaire are experiencing difficulties due to domestic turmoil and it is planned to send a medical officer this year to assess the situation. The Lusambo programme, in cooperation with the Ministry of Health, treated only 28 000 of the 100 000 target population in 1992, compared to 74 000 treated in 1991. In Dimbelenge, approximately 10 000 people from 50 villages have been treated during the second round in 1993. Along the Uele river, the target for 1993 is 10 000.

A new national programme in Central African Republic has started this year with partial funding from RBF and it aims to treat an estimated 600 000 in meso- and hyper-endemic communities. Seven teams of two persons each, using mobylettes, have been trained in the north-west. They have conducted epidemiological mapping of onchocerciasis in the area and treated over 10 000 persons.

In Ecuador, treatment continues in the main focus around Zapallo Grande, whilst an extension into other foci is being established. CBM makes ivermectin from the Mectizan Humanitarian Program available to its network of partner projects in onchocerciasis-endemic areas. In 1992, an estimated 200 000 tablets were used.

2.3 Helen Keller International (HKI). HKI is supporting Burkina Faso and Niger in their devolution activities and its role has been defined in Detailed Implementation Plans prepared recently in collaboration with the respective Ministries of Health and OCP. HKI will provide technical and financial support for training, health education and operational research.

In Cameroon, HKI has trained clinic staff and community health workers and developed an intensive health education strategy for ivermectin distribution from clinics to people living in endemic communities near the Sanaga river. The programme was awaiting the delivery of ivermectin which had been held up at the port in Douala.

In Mexico, HKI continues to work with health officials in Oaxaca and Chiapas States to modernize the Management Information System of their onchocerciasis control programmes.

2.4 International Eye Foundation (IEF). IEF implements IDPs in Cameroon, Malawi and Guatemala. Furthermore, in March 1993, it concluded its three-year involvement in the IDP in Kwara State, Nigeria, which is now exclusively backstopped by Africare.

In the Division of Dja and Lobo, South Province, Cameroon, approximately 25 000 people have received ivermectin since the beginning of distribution activities in August 1992. More than 90% of these were treated in health centres. After prevalence of nodules and/or leopard skin had been established to be the most appropriate rapid assessment method in this rainforest area, project personnel completed the mapping of the entire project area.

In the Thyolo Highlands of southern Malawi, more than 80 000 people had received a dose of ivermectin since November 1991. Distribution methods consisted of the use of mobile teams, community volunteers, tea estate distribution sites as well as public and private health centres. The mobile team method emerged as the most efficient and effective method in this area.

The existence of an onchocerciasis focus was confirmed in the District of Mwanza, southern Malawi, an area that had been suspected to be endemic for onchocerciasis. Over 30% of the 62 villages surveyed showed a prevalence of 40% and above and only 19% of the villages had no onchocerciasis at all. Mwanza District will be included in the ongoing IDP in the Thyolo Highlands. The target population is 34 000 people living in 67 villages.

In Guatemala, IEF supported two programmes in the Provinces of Chimaltenango and Suchitepequez with target populations of 15 000 (Chimaltenango) and 90 000 (Suchitepequez). In June 1993 both programmes became part of the "National Plan to Eliminate Onchocerciasis in Guatemala". This National Plan is part of the "Onchocerciasis Elimination Program in the Americas (OEPA)" and is backstopped by IEF.

2.5 The Mectizan Donation Program (MDP). MDP was set up to stimulate and promote the use of ivermectin to control onchocerciasis. It works closely with WHO, including PAHO, and with RBF and it is also involved in the Latin American initiative to eliminate onchocerciasis by ivermectin distribution. MDP approved 1.4 million tablets of ivermectin for treatment in 1990, 2.8 million in 1991, 5.3 million in 1992 and, as at May 1993, it had already approved 4.1 million tablets. Merck also continues with the Humanitarian Donation Program. In 1992, 760 000 tablets were given out and it is expected that a similar amount will be provided this year, as the Humanitarian Donation Program appears to have reached its plateau.

MDP is experiencing problems with regard to sending out tablets into some countries which insist on levying customs duty or into others where political unrest presents an obstacle. Further, in some countries, ivermectin tablets find their way into unauthorized hands for sale.

MDP has recommended to Merck & Co. Inc. to allow the substitution of height for weight in estimating the dose for ivermectin treatment and to produce ivermectin tablets in the formulation of 3 mg.

The Group noted that though ivermectin donation and distribution were increasing there was still a lot to be done towards the control of onchocerciasis by ivermectin distribution. It also learned, with appreciation, of the interest of President Carter in ivermectin distribution to control onchocerciasis. The Group considered according maximum visibility to ivermectin distribution as this will have the effect of getting the commitment of endemic countries to the control of onchocerciasis as well as their cooperation in ivermectin distribution. The Group therefore decided to approach endemic countries with the view to suggesting that they submit a resolution on ivermectin distribution to the next World Health Assembly.

2.6 Organisation pour la Prévention de la Cécité (OPC). OPC supports distribution activities in Senegal, Guinea and Mali. In Senegal, active treatment of 4342 persons continued in the area of Faleme (Saissentou) and Kedougou in January and February 1993. In these areas, it is planned to change the method of treatment to community-based and increase the target population from 25 000 to 45 000 by the end of 1993. Similarly, the area of Bissirah-Kedougou with a population of 15 000 will start community-based treatment in 1993. Negotiations are being conducted with the Ministry of Health for a study utilizing an outreach programme combining ivermectin, EPI and leprosy treatment on a population of 17 000 in the Department of Kolda in Haute Casamance in 1994.

In Guinea a plan for community-based treatment of 25 000 persons residing in the basins of Fie, Sankarani, Baoulé and Milo had been received recently. The representative of OPC in West Africa will negotiate for the first treatment to be conducted in 1993.

In Mali, where active treatment has been going on for three years running in the areas of Koudian, 11 800, and Damoou, 11 000 persons, the method is to change to community-based treatment. Further, 75 000 persons in 146 villages in the Bafoulabé and 80 000 persons in 133 villages in Lontou-Segala-Samé will start community-based treatment between June and December 1993.

2.7 River Blindness Foundation (RBF). RBF is supporting ivermectin distribution in West, Central and East Africa and Latin America.

West Africa: In Nigeria, RBF has distribution programmes in five states and funds partially five others out of 15 states where ivermectin distribution programmes are ongoing. In the Plateau State, distribution has been expanded to cover 750 000 people and plans are on the way to delegate progressively administrative and operational responsibility to the state. The state programmes in Edo, Delta, Imo and Abia States are being organized and should, at the end of three years, distribute three million annual treatments altogether. RBF is contributing to the effort of the National Onchocerciasis Control Programme (NOCP) to facilitate and coordinate the work of the NGO community and UNICEF and is assisting the NOCP to put together a national action plan which addresses the long-term control of the disease. The Group was informed that UNICEF supports ivermectin distribution in five states in Nigeria and had offered to support three further states. It therefore appears evident that there is a need for forging cooperation with UNICEF in the distribution of ivermectin in Nigeria.

Central Africa: In Cameroon, a distribution programme which has been integrated into the newly formed primary health care system has started in the "Province du Nord". One hundred and twenty thousand persons are projected to be treated under a cost-recovery system exacting CFA 75 per treatment by the end of the dry season. In the Congo, 30 000

persons have been treated around Brazzaville. In Chad, RBF funds the National IDP which is being executed by Africare. In Central African Republic, RBF is providing funds for IDP carried out by CBM.

East Africa: In Uganda, 50 000 people have been treated in the south-west and treatment is moving further north of the country. In Tanzania, a government ophthalmologist is in charge of the treatment of 65 000 people in the south-west of the country. An entomologist will be included in the project next year.

Latin America: RBF works in close collaboration with PAHO and the Mectizan Donation Program in supporting the Latin American Onchocerciasis Elimination Program. RBF's new initiative includes the setting-up of an external affairs programme which oversees broader international engagements and fund-raising activities.

2.8 Sight Savers. Sight Savers is active in six countries - Mali, Sierra Leone, Guinea, Ghana, Nigeria and Uganda. Sight Savers works with, or through, the ministry of health and national teams; approximately 300 000 people have been treated as at May 1993.

In Mali, Sight Savers is active in four districts where 140 000 people have been treated. Negotiations are going on to include a fifth district and it is expected that 400 000 people would have been treated by the end of 1993.

In Sierra Leone, 71 000 people have been treated and an expansion is foreseen.

No treatment has, as yet, occurred in Guinea because of continued administrative problems. Sight Savers is, however, involved with the devolution process in the area under OCP.

In Ghana, Sight Savers has provided materials for the treatment of the Western Region.

In Nigeria, Sight Savers has treated 45 000 people in Kaduna State and is involved in the treatment of the Federal Capital Territory.

In Uganda, Sight Savers has treated 55 000 people in the Masindi-Hoima districts and is negotiating to add a third district, Kimbale.

Currently, Sight Savers is working on a 10-year plan for ivermectin distribution.

### 3. Common information system for NGO-supported ivermectin distribution

The Group reviewed the Health Information and Management Information Systems which have been developed by one of its members. The section on community database provides record information for each community on (a) skin-snip, (b) nodule palpation and (c) ivermectin distribution on which information on a maximum of 10 different treatments in a community can be stored. There is a programme listing by name and identification number of communities.

The annual report form allows statements on the population covered in relation to endemicity as well as on cost-effectiveness. There was no provision for reference population, thus making it difficult to express the impact of treatment on endemicity. Discussions centred on the merits of having this parameter and the difficulty involved in its estimation, particularly in the case of clinic-based distribution. The Group appointed a subgroup to study and make recommendations for changes on the forms. The result of the subgroup's deliberation is contained in Annex 3. The Group recommended to its members to have the forms field-tested and to report the outcome to the next meeting for final decision. The Group further requested each NGO to comment on the part of the annual report dealing with cost-effectiveness and send its reactions to WHO/PBL. The Group also urged the members to read longitudinal and latitudinal coordinates of communities from the map to enable the production of geographical information system maps.

#### 4. Mobilization of resources

4.1 This subject was dealt with extensively by the Group. A presentation was given by Mr R. Anderson, Acting Manager, WHO Programme for Resource Mobilization. The Group learned that WHO is experiencing zero budget growth since the last 12 years and has been relying on extrabudgetary funding from some 20 donor countries. The donor countries give two forms of assistance - bilateral and multilateral - which are generally administered by their offices of development agencies normally located in their ministries of foreign affairs. WHO receives the second largest extrabudgetary funding after FAO and some of its main programmes for technical cooperation with countries rely almost solely on extrabudgetary funds.

4.2 The meeting was also briefed on the effort by the WHO Office of Governing Bodies and Protocol which, since the beginning of May and following WHO/PBL's request, tries to obtain information on NGOs working in the field of health that may be interested in the NGO Coordination Group and its work in ivermectin distribution. Several organizations and countries such as the European Community, the United Nations Nongovernmental Liaison Service (UN NGLS), Organisation for Economic Cooperation and Development (OECD) and the UK Overseas Development Administration (ODA) were contacted and responded. A long list of NGOs working in the field of health and/or in the endemic countries had been received. The Group might consider writing to some of the NGOs to inform them of the Group's activities and ask them to join in the ivermectin distribution.

4.3 Extra-OCP Trust Fund proposal to the World Bank. The Group was briefed on the approach to the World Bank to raise an extra-OCP Trust Fund to serve 15 countries in Africa and Yemen in ivermectin distribution to control onchocerciasis. The submitted plan is to be cost-effective and sustainable; it should enhance the PHC systems of the countries involved, and it should have a clear final result and impact. An amount of US\$ 130 million dollars to be disbursed over 10 years is being envisaged to be raised to support the 16 countries outside OCP. The Bank's contribution is expected to be one million dollars per year with an administrative cost of US\$ 300 000 in connection with managing the Trust Fund, chairing the Committee of Sponsoring Agencies (CSA) and mobilizing funds from other donors.

The administrative structure of the extra-OCP programme will be made up of CSA and the Programme Review Committee (PRC). The 16 national plans would be reviewed by the PRC. Once approved, they would be forwarded to CSA for final review and authorization of funds. Several questions, general, technical and administrative, in connection with the plan have been raised by the Bank. The Bank intends to engage an independent consultant to assess the interest of the extra-OCP countries, and to put together a working group to address some of the issues needing clarification. The Group spent a lot of time discussing answers to the series of questions raised by the World Bank concerning the possibility of establishing an extra-OCP Fund. A copy of the text answering the Bank's questions is contained in Annex 4.

The Group further appointed some of its members to write up topics which were to be compiled as a procedural manual on ivermectin distribution programmes which could be used either by ministries of health, the World Bank or NGOs for fund-raising purposes. The compilation of the manual should be completed by the end of August.

5. Operational research:

5.1 Previous proposals: The meeting reviewed the progress that had been made on operational research proposals made at its first meeting. It noted progress in the following proposals.

5.1.1 The use of height instead of weight for estimating the dose of ivermectin: The Group noted that the Mectizan Expert Committee had proposed to Merck & Co. Inc. to accept the substitution of height for weight of patients in the estimation of the dose of ivermectin.

5.1.2 Macrofilaricidal potential of ivermectin: The meeting was informed that the research group in the "Institut Pasteur" in Yaoundé, Cameroon, is prepared to conduct the study, and half the requisite funds for the study had been found. A proposal is being sent to WHO/Macrofil, whilst an approval had been received for using ivermectin at a dose of 400 mcg/kg body weight for the study. The meeting was also informed of another planned study to be conducted at the Onchocerciasis Chemotherapy Research Centre in Hohoe, Ghana. This study is backed by WHO/Macrofil and will test the safety of the use of high dose of ivermectin to be followed by the study to determine the macrofilaricidal action of ivermectin on *Onchocerca volvulus*. The study has met the approval of WHO/SCRIHS and is awaiting comments from Merck & Co. Inc.

5.1.3 Long-term beneficial effect of annual treatment with ivermectin: The Group was informed that funds have been found for reviewing ophthalmological studies in Kaduna, Nigeria. Funds have also been found for annual distribution of ivermectin in the study area of "Institut français de Recherche scientifique pour le Développement en Coopération" (ORSTOM) in Cameroon until 1995. Thereafter, funds from TDR will be sought for ophthalmological evaluation.

## 5.2 Other proposed operational studies

- 5.2.1 The effect of routine ivermectin treatment on transmission of *O. volvulus*: Ivermectin is known to have considerable impact on transmission which can be measured by entomological means based on the measurements of annual transmission potential and/or the numbers of infective *O. volvulus* larvae per 1000 flies. It has also been shown that skin-snipping 5-year-olds admitted to ivermectin treatment each year shows diminishing prevalence rates; this reflects a decreased incidence of new infections as a result of reduction in transmission. It is therefore recommended to skin-snip 5-year-olds presenting for ivermectin treatment for the first time in as many places as possible each year, to determine the changes in the prevalence of infection in this age group and therefore indirectly also changes in the incidence of new infection in the population as a result of the impact of ivermectin treatment on transmission. The meeting recommended that skin-snipping 5-year-olds might be considered in the distribution programmes going on in Malawi and in Chad.

The meeting was informed that data from Ghana in OCP, Asubende, suggest that, after five years of ivermectin distribution, there is more reduction in microfilarial loads than would be expected on the basis of the usual impact of ivermectin treatment on transmission as demonstrated in the first years of ivermectin distribution. OCP is conducting transmission studies in three areas: (a) in the Coruba river basin in Guinea-Bissau, where ivermectin distribution is carried out three times in the year in an area of hypo- to meso-endemicity, (b) in the Mako focus in Senegal, where ivermectin distribution is carried out twice in the year, and lately (c) also in another area in the Bakoye river basin in Mali, where annual ivermectin treatment is being carried out. The evaluation of the impact of ivermectin on transmission will be based on both epidemiological (incidence of new infection) and entomological (changes in infection in the vector) studies.

- 5.2.2 The efficacy of clinic-based treatment programmes for the distribution of ivermectin: The need for a study to determine the factors which mitigate for and against the voluntary attendance of infected persons at clinics, to collect ivermectin free, was stressed. It was suggested that the HKI distribution programme on the Sanaga river in Cameroon has an ideal design to test for the factors in question.
- 5.3 Cooperation with TDR. The Group received briefing from TDR in connection with onchocerciasis operational research which it is carrying out.
- 5.3.1 Rapid epidemiological mapping: TDR has carried out a small workshop in Cameroon to design a protocol which enables broad recognition of areas where onchocerciasis can occur to allow the decision on priority areas to treat. Based on topographic, hydrological and demographic criteria, Cameroon was first divided into 19 strata. Six of the strata were selected for testing out the criteria. The method consists of a biased selection, independently by three experts on a panel, of six to eight villages with the worst state of onchocerciasis in the defined stratum for rapid assessment of onchocerciasis. In the event that the results are positive, six more villages, located 10 km away from the first set of villages, are then selected for examination. The second step of the procedure is dropped if insignificant onchocerciasis is found in the examination of the first set of villages when the area is considered not to be onchocerciasis-endemic. The method has proven the existence of onchocerciasis

where it was predicted and also the contrary. Further testing of the method may be necessary in areas where the ecology may be significantly different from that of Cameroon, for example East Africa. A workshop is planned in Geneva in early July to review the results and to write-up guidelines for epidemiological mapping of onchocerciasis based on the results of the study.

- 5.3.2 Onchocerciasis operational research in Nigeria: The meeting was informed of the impending second-round studies involving small grant proposals in Nigeria, which were to determine the public health importance of onchocercal skin disease. A workshop of four multidisciplinary research groups from Nigeria and four others from elsewhere is going to be held in Calabar from 14 to 19 June. The workshop will develop a protocol on which the studies are to be based and will deal with socioeconomic effects of onchocercal skin disease and the effect of repeated treatment on onchocercal skin disease and pruritus. The third and final round of the onchocerciasis operational research in Nigeria was being advertized and will deal with simple and rapid methods of evaluation, effectiveness of community mobilization and monitoring by RAS.

## CONCLUSIONS AND RECOMMENDATIONS

The Group, reviewing the recommendations of its first meeting and appreciating the progress made in implementing those, again strongly reiterated its commitment to encourage financial and programme participation by additional NGOs including those already working in onchocerciasis endemic countries. The following new recommendations were made in the course of the present meeting :

### 1) National plans for other endemic countries

The Group recognized the need to encourage the formulation and initiation of national plans in all African countries where onchocerciasis is endemic. The Group agreed to offer its assistance and collaboration within the context of national committees or working groups for the planning of such programmes.

### 2) National plans - Nigeria and Cameroon

The Group noted the considerable progress that has been made in the formulation of a Nigerian Five Year Plan of Action for onchocerciasis control. It also noted that the National Plan of Cameroon is currently being drafted. The Group requested the Secretary, in consultation with Group members, to take appropriate steps to support efforts in both countries to expedite this process of development and implementation of viable national plans. The inclusion of administrative mechanisms in each plan for quality control and fiscal accountability will facilitate efforts to raise the substantial funds required from external donors.

### 3) World Bank extra-OCP fund

Given the positive outcome of the OCP Programme in West Africa, and the critical role played by the World Bank in the mobilization of needed resources for that Programme, the Group strongly **recommends** that the Bank be encouraged to establish an extra-OCP fund, for onchocerciasis control through ivermectin distribution in countries in the African and Eastern Mediterranean Regions outside the OCP area. Dr. M. Heisler, Director of the Mectizan Donation Program, will serve as the liaison member between the NGO Coordination Group and the World Bank on this matter.

### 4) Procedural manual

The Group recognized the utility of documenting current approaches to planning and execution of ivermectin distribution programmes. Accordingly, the Group decided to compile a manual of guidelines that would be of use as a background document to ministers of health, NGOs involved in Mectizan distribution, the World Bank, other funders and fund-raisers. The document could be printed by WHO, pending availability of funding.

5) World Health Assembly Resolution

There is a need to give more visibility to the opportunity and priority for onchocerciasis control through ivermectin distribution. The Group therefore strongly **recommends** that interested countries be approached with a view to the possible submission of a resolution on ivermectin distribution to the World Health Assembly in 1994.

6) Cooperation with UNICEF

Noting the US UNICEF Committee's initiative and UNICEF's current increasing interest in supporting programmes to control river blindness, the Group **recommends** that the WHO Secretariat should include the issue of ivermectin distribution programmes in their forthcoming programme consultations with UNICEF. In addition, the Group will hold discussions with UNICEF/New York, UNICEF/Lagos and, if appropriate, UNICEF/Yaoundé in order to encourage greater sharing and coordination of onchocerciasis control information and activities.

7) Data base

Further to the recommendation made at the first meeting of the Group, it was noted with appreciation that a working draft for an annual reporting form for ivermectin distribution programmes, including cost estimates, had been developed. It was **recommended** and agreed that the draft form, as finalized during the present meeting (Annex 3), will be circulated to ivermectin programme managers in the field for comments. The feed-back from this "field testing" should allow for a final version to be approved by the Group at its third meeting.

8) Operational Research

The Group noted that a start has been made in the execution of operational research recommendations made at its first meeting. It noted in particular, with appreciation, the response of the TDR to its requests for developing a manual on epidemiological mapping, among other initiatives on operational research, and it accordingly **recommended** continued collaboration with TDR including the OCP Macrofil Chemotherapy Project in the pursuance of further operational research to optimize ivermectin distribution to control onchocerciasis.

ANNEX 1

AGENDA

Opening of the meeting

Adoption of Agenda

Administrative Announcements

1. Overview of activities in 1993 :
  - (a) WHO
  - (b) NGOs
2. Review of common information systems for NGO-supported ivermectin distribution
3. Assessment of cost-effectiveness of ivermectin distribution
4. Mobilization of resources
5. Proposal to set-up World Bank extra-OCP Trust Fund
6. Operational research; ongoing and planned projects

Conclusions and recommendations

Date and place of next meeting

Closure of the meeting

ANNEX 2

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IDP ANNUAL REPORT

1. Project name:
2. Implementing agencies:
3. Donors:
4. Funding period (the period for which external funding has been secured):
5. Cost recovery (is a fee charged to ivermectin recipients?):
6. Target area (name the administrative region or regions in which the project will distribute ivermectin to all eligible communities):
7. Date that field activities started:
8. Date that project first distributed ivermectin:
9. This report provides information about the 12-month period from:
10. Estimated total population of the target area:
11. What criteria are used to determine whether a community is eligible for community-wide ivermectin therapy?
12. Estimated number of eligible communities in the target area:
13. Estimated population of eligible communities in the target area:
14. Total number of people treated during this reporting period:
15. Total number of communities treated during this reporting period:
16. Total population of communities treated:
17. Average % of total population treated in these communities:
18. Distribution strategy  
During reporting period how many people were treated by:
  - (a) Fixed centres (i.e. distribution from existing health centres, clinics, hospitals, etc.):

Annex 3

- (b) Mobile teams (i.e. distribution by health professionals travelling to the eligible communities):
- (c) Community-Based Distributors (CBDs) (i.e. distribution by a lay person who is resident in the eligible community or in a nearby community):
- (d) Other distribution strategy (describe):

19. Endemicities of communities treated:

For the purposes of this report the level of endemicity of a community or a group of communities is defined as follows:

- Hyperendemic: skin-snip prevalence among adults  $\geq 80\%$   
or nodule prevalence among adults  $\geq 40\%$
- Mesoendemic: skin-snip prevalence among adults 40% to 79%  
or nodule prevalence among adults 20% to 39%
- Hypoendemic: skin-snip prevalence among adults  $\leq 40\%$   
or nodule prevalence among adults  $\leq 20\%$
- Unknown: epidemiological assessment not performed in this community nor in any community within 10 km.

	HYPHER	MESO	HYPO	UNKNOWN	TOTAL
NO. COMMUNITIES TREATED					
TOTAL POPULATION OF COMMUNITIES TREATED					
NO. PEOPLE TREATED					

Note: (a) If skin-snip or nodule data have not been collected in the community itself, classify the community according to the average skin-snip or nodule prevalence of those communities within 10 km for which data have been collected.

(b) If data are not available on individual communities, please provide data on groups of communities.

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20. Method used to estimate the population of each community.
21. Estimating the recurrent cost of ivermectin distribution.

Estimate how much it has cost to distribute ivermectin during this reporting period. Include the cost of publicity, training and supervision, as well as the cost of distribution.

(a) Do not include the following costs:

- (i) Expenditure for skin-snipping or rapid assessment.
- (ii) Other start-up expenditure that will not recur.

(b) Do include expenditure during the reporting period on the following items<sup>1</sup>:

(i) Recurrent field expenditure paid for by donor:

	U.S.\$
FIELD/TRAINING INCENTIVES	
SALARIES/BENEFITS OF FIELD WORKERS EMPLOYED BY PROGRAMME	
FUEL	
RENTAL OF VEHICLES AND MOTORCYCLES FOR FIELD USE	
RENTAL AND UTILITIES FOR FIELD OFFICE	
PRINTING/PHOTOCOPYING OF CARDS, FIELD RECORDS AND TRAINING MANUALS (incl. stationery)	
DRUGS FOR TREATMENT OF SIDE-EFFECTS	
OTHER (please specify)	
TOTAL	

<sup>1</sup>Some expenditure may not be 100% attributable to the cost of publicizing or distributing ivermectin. If this is the case, please estimate the percentage of the expenditure which is attributable.

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- (ii) Costs of short-lived equipment (based on a total of 1 000 days of use and including maintenance/repairs estimated to cost 50% of the original purchase price).

Vehicle No. 1:  
purchase price x .0015 x days of use = U.S.\$

Motorcycle No. 1:  
purchase price x .0015 x days of use = U.S.\$

Photocopying machine:  
purchase price x .0015 x days of use = U.S.\$

FAX machine:  
purchase price x .0015 x days of use = U.S.\$

Computer + printer:  
purchase price x .0015 x days of use = U.S.\$

Other (please specify)

- (iii) Items paid for by government or other local agency:

	U.S.\$
STAFF SALARIES/BENEFITS <sup>2</sup>	
FIELD INCENTIVES	
OTHER <sup>3</sup>	
TOTAL	

<sup>2</sup>For government staff who work only part-time on the programme, please determine what fraction of their time and thus what fraction of their salary and benefits to attribute to the IDP.

<sup>3</sup>Include any other in-kind contributions for which the government or other local agencies must spend extra in order to provide to the IDP.

## ANNEX 4

**ISSUES REQUIRING RESOLUTION PRIOR TO COMPLETING  
THE FINAL DRAFT OF THE WORLD BANK EXTRA-OCP PROPOSAL  
1 JULY 1993**

1. **The administrative structure of the extra-OCP programme includes the Committee of Sponsoring Agencies (CSA) and the Programme Review Committee (PRC). The sixteen national plans would be reviewed by the PRC. Once approved, they would be forwarded to the CSA for final review and authorization of funds.**

- i. **What organizations will be represented on the Committee of Sponsoring Agencies (CSA)?**

The exact configuration of the Committee of Sponsoring Agencies remains to be determined. In principle, those agencies that have made a major contribution to the funding support of the extra-OCP programme will be represented. The World Bank/WHO, as with OCP, will certainly have a seat. Agencies like UNDP, UNICEF and others, should they agree at some point in the future to support this initiative as donors, would also have a seat. The Mectizan® Donation Program, from The Carter Center in Atlanta, has also been suggested as a possible member of the Committee of Sponsoring Agencies, although not formally serving in the role of donor. Ideally, the representatives of the respective agencies will have the appropriate level of seniority and authority to directly represent their organization.

- ii. **Who/what organizations should have seats on the PRC?**

Organizations should not have seats on the PRC. They will be represented, as discussed later, in the Joint Programme Committee (JPC). Seven individuals should be appointed to the PRC with selection based upon their recognized, international expertise in either technical or operational areas related to onchocerciasis, ivermectin delivery programmes, or in African field operations that are similar to the Mectizan® donation initiatives, for example, guinea-worm control.

- iii. **How should appointments to the PRC actually be made?**

By the Committee of Sponsoring Agencies.

- iv. **How should PRC membership be rotated?**

Appointments should be made for two-year terms initially on a staggered basis so that there will be continuity in the membership. Appointees can be asked to serve for an additional two-year term at the discretion of the CSA.

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v. **How often should the PRC meet?**

Twice a year and additionally as needed.

2. **The Onchocerciasis Control Programme (OCP) has an annual Joint Programme Committee (JPC) meeting. Should there be a "JPC" for the extra-OCP?**

Yes. There should be a Joint Programme Committee. Representation should include ministries of health from the 16 endemic countries served by extra-OCP, the nongovernmental organizations involved in ivermectin delivery activities, all of the donors, including the CSA, and invited guests. The JPC should meet once a year. Funds for the Joint Programme Committee meeting should include monies to cover one representative from each ministry of health. All the other members of the JPC will be asked to provide their own support. The executing agency and the administrative staff at the World Bank will take responsibility for coordinating and staffing the Joint Programme Committee meeting.

3. **There are a number of administrative issues concerning the programme application and approval process that must be resolved:**

i. **Who is responsible for drafting the national plans? The Federal Ministry of Health? A consortium of NGOs with approval of the MOH? Other?**

National plans, by definition, must come from the national ministry of health. However, the requests for proposals from the Bank to the ministries will indicate clearly that national plans should provide evidence for integration and support of the primary health care system, for coordinated activities at national boundaries when endemic onchocerciasis exists across borders, and for clear evidence that nongovernmental organizations currently at work in the country or NGOs interested in participating in an expanded national plan have a well-defined and guaranteed role, both in the drafting of the national plan and the implementation of the programme.

ii. **Who should actually be responsible for administering and accounting for national programme funds?**

When indicated, budgets will be drafted to identify specific amounts of funds designated for specific regions of the country and for the use by particular nongovernmental organizations in partnership with local ministries and/or local commissioners of health. The actual funds designated for NGOs and local governments will be released as part of the funding approved by the Bank for this specific national plan, through WHO on the basis of contractual service agreements.

Annex 4**iii. How frequently should internal/external programme reviews take place? By whom?**

Funding cycles for the initial phase of the extra-OCP programme will be three years. The second cycle will be four years and the final cycle will be three years. During the first cycle, a separate internal review of each national programme should take place at 18 months and an external review of each programme should take place between the 30th and 32nd month to allow the external programme review to be completed in time for consideration of additional second cycle funding at 36 months. Of course, individual ministries and nongovernmental organizations may conduct their own programme reviews more frequently than this as indicated.

**4. Who else should be included in the review and final drafting of the extra-OCP proposal?**

In addition to the WHO/NGO Coordination Group, the ministries of health of the 16 countries will be asked to review, in general terms, the next draft of the extra-OCP proposal. The World Bank is in the process of identifying a consultant who will visit a number of the countries to explore potential interest in an extra-OCP programme. It would be appropriate if the general presentation, review and discussion of the extra-OCP proposal take place at that time.

**5. There are a number of operational and technical issues that must be clarified before a final proposal can be submitted to the Bank Special Program Review Committee:****i. What criteria must be established to assure that programmes actually are incorporated into and enhance primary health care?**

If the World Health Organization is identified as the executing agency, the general guidelines available as a result of WHO's commitment to enhance primary health care should be followed. More specifically where primary health care systems are functional, the ivermectin delivery programme should be incorporated into the primary health care system administratively and operationally. Inclusion in the essential drug list, participation as part of the Bamako initiative where applicable and specific relationships between ivermectin delivery and other programmes should be identified. The core issue is sustainability. Where primary health care systems are not functional, the ivermectin programme should be used as an entry point for primary health care. Health workers assigned to the ivermectin programme should also be trained in the delivery of basic health services. These services may well include health education, well-baby evaluation, basic pharmaceutical distribution, oral rehydration, basic maternal child evaluation, etc. The ongoing effort within OCP to develop effective, comprehensive, integrated, horizontal devolution plans, may also provide a model for the development of ivermectin linked primary health care initiatives.

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ii. **Should there be a uniform budget and budget review process?**

Yes. There should be a uniform budget form included in all of the 16 proposals to allow more streamlined financial administration. The budget review process will be the responsibility of the PRC with final authority vested in the Committee of Sponsoring Agencies. There should be a series of criteria established by the PRC to assist in the process of evaluating the budget submitted as part of the national proposals.

iii. **Should "cost-recovery" be included in national plans?**

In general, cost-recovery as a concept is one that should be supported by the extra-OCP Trust Fund. Although Merck & Co., Inc. does not permit the sale of ivermectin donated as Mectizan® under any circumstances, it is possible to recover costs by charging an appropriate fee for the distribution of the commodity. Cameroon is currently attempting to develop and test a cost-recovery method based on this concept. In general, cost-recovery should be encouraged, although not required and certainly not prohibited.

iv. **Are there basic epidemiological and entomological components that must be incorporated into every national plan? What are they?**

Yes. Certain basic epidemiological components should be incorporated in every national plan. These components should be defined and stated in the request for proposal so that national ministries are aware of the expectations of the Programme Review Committee. The components should include:

- (a) Distribution of infection and its severity. There must be a plan to conduct rapid epidemiological mapping based on nodule palpation. (In areas where studies have not been done to demonstrate the relation between the prevalence of skin microfilaria and nodules, this relation will need to be confirmed in a small study.)
- (b) Baseline census and prevalence surveys prior to beginning the first treatment round.
- (c) Accurate mapping of endemic areas based on appropriate geographic, hydrologic and surveillance data.
- (d) Monitoring programme effects by collecting data on the microfilarial reservoir in adults from sentinel and/or randomly selected indicator communities.
- (e) Assessment of the reduction of transmission based on changes in the prevalence and intensity of infection in each year's new intake of five-year olds to the Mectizan® distribution programme.
- (f) Entomological, ophthalmological and dermatological components may be included in the assessment where they can be carried out in a reliable manner.

Annex 4**v. How should programme impact be measured, monitored and evaluated?**

Assuming the availability of accurate baseline survey data defining population and prevalence, programme effects can be monitored and evaluated by a percent of the population at risk covered effectively by ivermectin treatment programmes. The effect of health education programmes in creating a tradition and demand for treatment; the effectiveness of integration with the primary health care system and the establishment of acceptable cost-recovery strategies; the effects of alleviating ocular, dermatological and general clinical manifestations and of reducing transmission; the evaluation of the impact on morbidity and disability, where applicable; the evaluation of impact on socioeconomic development; and the degree of general "recipient-satisfaction", should all be components of the monitor and evaluation process.

**6. What are the epidemiological, entomological and operational factors that justify the creation of a "regional" (i.e. coordinated, simultaneous national strategies) extra-OCP programme?**

There are a number of factors that justify the creation of a "regional" programme. They include:

- i. The control of onchocerciasis with ivermectin has proven to be a well-defined approach at disease intervention with clear benefit to the population at risk; this is distinct from interventions against other diseases currently found in the developing world, despite their higher public health importance rating. This fact and the expected, highly successful outcomes (OCP experience) and the unprecedented provision of the drug, free of charge, for the control of the disease mitigate taking advantage of the opportunity to establish a special programme to provide funds to stimulate coordinated, comprehensive and simultaneous national plans.
- ii. In order to eliminate the phenomenon of introducing a new source of infection through reinvading flies from a non-controlled area to an area under control, it is necessary to conduct simultaneous activities of onchocerciasis control in the region. Such a regional programme will also eliminate, as a source of infection, the migration of highly-infected human populations from highly-endemic areas to already controlled areas as all populations in the region would have been treated. A regional programme so created will not only protect the southeastern flank of the OCP, but will also ensure the maintenance of the control effort in countries, for example, in Central Africa, where onchocerciasis stretches across country borders.

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- iii. Mectizan® delivery programmes provide an entry point for the strengthening and enhancement of primary health care systems. A regional programme is, therefore, necessary to effectively coordinate training, health education and operational research activities, which are the essentials of disease control in general, as well as primary health care.
- iv. The nongovernmental organization community, both blindness-related and others, have already displayed a serious commitment to the establishment of ivermectin distribution programmes. An extra-OCP special programme provides an opportunity for the Bank to strengthen and enhance both international and indigenous NGOs.
- v. There is an opportunity for broad-based operational and basic science research programmes, stimulated by TDR, that will address issues that are not only pertinent to ivermectin delivery but are applicable to other programmes as well. These include cost-recovery strategies, linkage to primary health care systems, rapid assessment methodologies and others. Simultaneous activities in the region will provide an opportunity to design operational research initiatives that include a large enough cohort to have important, practical impact.

**7. Are there operational research issues that should be incorporated into every national plan? For example - cost-analysis, delivery strategies, other?**

Yes. There are a number of operational research issues that ought to be addressed as part of a regional extra-OCP programme. The programme should have a research component built into it from the beginning, as was done and subsequently found to be vitally useful in OCP. None of the individual operational research protocols should be required to be incorporated into "every" national plan. However, when possible, the following issues should be addressed in partnership with the executing agency. There may be others in addition to these listed below:

- i. Studies to determine the macrofilaricidal potential of ivermectin.
- ii. The impact of long-term annual treatment with ivermectin on the transmission of *Onchocerca volvulus*.
- iii. Studies to confirm (a) the relationship between the prevalence of nodules and skin microfilariae in areas where this relationship has not been demonstrated previously; (b) the applicability of the method of rapid epidemiological mapping in areas with an ecology which is significantly different from the ecology of West Africa.

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- iv. The long-term benefits and effects of ivermectin treatment at the current annual dosage level.
- v. The efficacy of clinic based (or "passive") treatment programmes for the distribution of ivermectin.
- vi. The integration of ivermectin distribution with the primary health care system or with other health delivery programmes thus improving the potential for ultimate national sustainment.
- vii. Methods of implementing the cost-recovery programme covering ivermectin distribution in accordance with the Bamako initiative.
- viii. Development assessment of parameters to be used in the evaluation of ivermectin distribution programmes.
- ix. Assessment of risks of using ivermectin in areas where infections with *Loa loa* are present.
- x. Health education methods in relationship to ivermectin distribution.

Other topics may include the use of ivermectin in the under age five population, the comparison of the cost-effectiveness of different forms of ivermectin delivery (community self treatment, mobile team distribution, outreach distribution, health centre base, etc.), the optimal frequency of ivermectin dosage for the control of onchocercal skin disease and pruritus and social impact studies on usage patterns, impact of annual dosing on skin lesions and/or on pruritus, the relationship between onchocerciasis and ivermectin treatment in populations with epilepsy, goitre, or dwarfism and social impact studies on usage patterns.

**8. Should there be a basic uniform reporting and/or a computer-based MIS included in each national plan?**

There should be a basic uniform reporting system included in each of the national plans. This uniform reporting system should be defined and incorporated in the request for proposals released by the Bank prior to the development of national plans. There is no reason, however, to require that national plans have a computer-based information system.

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