

DNDi

Drugs for Neglected Diseases *initiative*

An initiative founded by the Indian Council of Medical Research, Institut Pasteur, Kenya Medical Research Institute, Ministry of Health, Malaysia, Médecins Sans Frontières, Oswaldo Cruz Foundation, WHO/TDR

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"DNDi is different because it identifies the needs of neglected diseases, works for the development of the proper tools to fill the needs, and then takes these to those who are in need. "

Dr Shyam Sundar, Professor of Medicine,
Banaras Hindu University, India

Overview

DNDi's meeting in Malaysia to identify regional R&D capacity and strengthen the Asia network was well attended. Dr Simon Croft, currently head of the Parasitology Department at the London School of Hygiene and Tropical Medicine, will be joining DNDi as R&D Director in June 2004. In addition, DNDi is progressing on the portfolio front - contract negotiations with principal investigators are almost complete and we have received more than 90 proposals in response to the second call for letters.

A visit to Japan

Yves Champey was in Tokyo for 5 days in January on a visit organized by Chris Bruenger, a DNDi volunteer with considerable pharmaceutical experience in Japan, and MSF Japan. Yves visited

- **Japanese Pharmaceutical Manufacturer's Association (JPMA):** Director General Ichikawa, Managing Director Yamabe, and the Director for International Affairs Matsuki
- **Kitasato Institute:** Dr Yamada, Dr Otoguro and Dr Omura
- **Tokyo University School of Pharmaceutical Sciences:** Prof Tsutani; School of Medicine: Prof Kita (biochemist working on trypanosomiasis)
- **MSF-Japan:** where he presented DNDi at the Board of Directors meeting
- **Ministry of Health, Labour and Welfare:** Dr. Kasai, Deputy Director, International Cooperation
- **Ministry of Foreign Affairs**

DNDi will provide continuous updates to the JPMA and the Ministry of Health, Labour and Welfare on DNDi activities globally and in Japan, and explore possibilities of collaborative research with Tokyo University.

DNDi was informed of the JPMW project (a collaboration between Japanese Pharmaceutical Manufacturers Association, Ministry of Health, Labour and Welfare, Japan, and WHO/TDR that addresses the need for developing new antimalarial drugs) and will explore ways of applying the mechanism used by JPMW to conduct research for most neglected diseases.

Asking for Action in Delhi

Bernard Pecoul was in Delhi in February at a DNDi meeting hosted and chaired by Prof. Ganguly of the **Indian Council for Medical Research (ICMR)**. In his introductory speech, Prof Ganguly expressed strong support for DNDi's work and aspirations.

The objective of the meeting was to define areas of collaboration with DNDi's Indian partners. The meeting

brought together representatives from ICMR, CDRI, MSF, NGOs, the Indian pharmaceutical industry and several independent physicians working in the field. Bernard provided an update on DNDi. Several presentations followed on:

- Perspectives of Government agencies (CSIR and S&T)
- R&D and Biotechnology
- Drug Research Agencies in the Public Sector
- Snippets of Recent Clinical Trials
- Regulatory Provisions
- Infrastructure and Ethical Issues
- Perspectives of the Private Sector

Dr Shyam Sundar gave a presentation on the epidemiology and control of kala azar. This was followed by a discussion on the specific areas of collaboration.

ICMR is currently helping to identify a liaison person for DNDi who will be based in Delhi.

A participant list and report of the meeting will soon be available at jbanerji@dndi.org

Bernard also visited the Ranbaxy Laboratories in Delhi, and CIPLA in Mumbai.

Building R&D bridges in Malaysia

With enormous assistance from DNDi's Founding Partner the **Malaysian Ministry of Health, and the Malaysian Institute for Medical Research**, DNDi held an extremely productive Workshop in Kuala Lumpur. (A report is being produced and will soon be available on www.dndi.org)

The objectives of the workshop were to identify drug R&D capacities in the region, identify key regional concerns and ongoing R&D efforts, and strengthen DNDi's growing network in Asia. To a large extent, these objectives were achieved. Seventy three participants attended the workshop from the Asian region (India, Nepal, Bangladesh, Sri Lanka, Vietnam, Philippines, Thailand, Malaysia, Singapore, Japan, China, and Australia) as well as other regions of the world. Several large regional medical research institutions were represented.

The meeting was reported by the Malaysian National News Agency and the new Straits Times-Management Times. (Articles available at jbanerji@dndi.org)

DNDi also attended MSF's Neglected Diseases Group Meeting in Penang. (Report available at mai.do@paris.msf.org)

Strengthening ties with Institut Pasteur

DNDi members visited the **Institut Pasteur** to discuss the institute's contribution to DNDi. Bernard Pecoul made a short presentation on DNDi and together with Yves Champey, Els Torreele, and Jean-Rene Kiechel, met researchers from Institut Pasteur, France, as well as the heads of Pasteur institutes from all over the world.

An excellent article on neglected diseases "L'éthique du Nord sacrifie les malades du Sud" written by Prof Philippe Kourilsky, Director General, Institut Pasteur, has been published in *Le Monde* and is available in French at jbanerji@dndi.org

Portfolio Progress

Project portfolio update: In its portfolio DNDi currently has nine projects. Four of these are discovery projects to identify novel lead-compounds against trypanosomiasis and/or leishmaniasis. One project focuses on protein farnesyltransferase inhibitors. Two others use high throughput screening on either whole cell trypanosomes or the enzyme target trypanothione reductase (TR) to identify inhibitory compounds. And the fourth is a target validation project on dihydrofolate reductase (DHFR) at three universities. Contract negotiations with the principal investigators of these projects are underway.

More downstream in the drug development pipeline, DNDi is looking at drug interactions between existing anti-leishmanial drugs, including miltefosine, paromomycin, and amphotericin B, to support a clinical strategy for combination treatment aiming to reduce treatment duration and toxicity, and protect against resistance.

DNDi continues to work on nifurtimox for HAT with TDR and Bayer; and paromomycin for visceral leishmaniasis with TDR and IOWH.

The FACT of the matter: We are making headway in the two projects on Artemisinin fixed-dose

combinations for chloroquine resistant malaria. Despite some minor delays in accessing drug substance data, all activities for the preparation of clinical supplies of Artesunate-Amodiaquine and Artesunate-Mefloquine will be pursued and these supplies will be delivered to the trial sites by June/July 2004. Finalization of the clinical protocols is underway and agreement on quantity of supplies has almost been reached; consequently, supply manufacturing should be able to take place in April 2004.

Project identification

- **Call for letters:** The deadline for proposal submissions for the second call for letters of interest was 15 March. The response has been significant - more than 90 proposals have been received.
- **Proactive exploration:** Other projects are actively being explored, for example, modified meglumine for HAT, topical treatment for cutaneous leishmaniasis, macrolides for their potential as anti-parasitic agents, sitamaquine for visceral leishmaniasis .

A giant LEAP for mankind

Monique Wasunna and Catherine Royce are working together to organize a Leishmania East Africa Platform (LEAP) meeting in Addis Ababa in May with scientists from Kenya, Ethiopia and Sudan.

Created in Khartoum last year, LEAP's mandate is to explore the different promising treatment options for kala-azar, estimate needs in terms of capacity strengthening for clinical studies, plan and design training programmes to improve capacities, develop protocols, and talk with the health and drug registration bodies in each country. The ultimate goal is to set up clinical studies for improved treatments for leishmaniasis starting with paromomycin.

Recruitment update

R&D Director: Dr Simon Croft, Professor of Parasitology at the London School of Tropical Medicine and Hygiene will be DNDi's R&D Director. A research scientist with a broad background in chemotherapy of tropical diseases, Simon's experience spans both academic and private sectors. He has a strong network of international collaborators in drug

discovery and research - chemists, structural biologists, biochemists, and pharmacists. The DNDi team is looking forward to his joining us full time in June 2004.

Fundraising and Advocacy Director: Numerous applications have been received for the post of DNDi's Fundraising and Advocacy Director. The screening process is underway.

Consultants:

- **Catherine Royce**, a medical doctor with experience in clinical drug development, has joined the project management team and is working actively with Monique Wasunna on paromomycin, as well as following up on sitamaquine.
- **Antonella Caminiti**, a post-doc in Biochemistry, is working from Bordeaux to help coordinate the FACT project with Jean Rene Kiechel.
- **Eloan dos Santos Pinheiro**, well known to DNDi as the former head of Far Manguinhos, is working in Brazil for DNDi, proactively exploring projects such as modified meglumine and a leishmaniasis vaccine.
- **Jana Armstrong**, previously with MSF Switzerland, will join DNDi as a fundraising consultant from the end of March for a period of 3 months.

Intellectual Property Policy

DNDi's IP Policy document is being drafted in consultation with a small group of lawyers: Christopher Garrison, Sisule Musungu, Frederick Abbott and Warren Kaplan. The draft policy will be presented to the Board of Directors at their meeting in June 2004.

Communications & Advocacy

Website: Kathleen Victoir, a part-time consultant will develop the website into a more interactive, dynamic site, trying to make it a one-stop resource for anyone interested in neglected diseases. She has been exploring ways to start a scientific discussion forum, which she will moderate.

Publications: A new set of fact sheets and DNDi's strategy document on trypanosomiasis and leishmaniasis is in the making. A revised version of *An Innovative Solution* will be going into print.

Identity Building Workshop: Held in Kuala Lumpur, the Workshop revealed that people working with DNDi had similar views about DNDi's identity. A report is available at jbanerji@dndi.org

Contact us

If you wish to contribute to the newsletter or would like to comment on any of the above topics, please write to feedback@dndi.org.

Or write to us at:

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We look forward to your suggestions and contributions.

DNDi's Calendar March-June 2004

DNDi meetings

Geneva	SAC meeting	6-7 May
Geneva	3 rd Board meeting	24-25 June
Addis Ababa, Ethiopia	LEAP/Africa DNDi	11-12 May

Meetings where DNDi will be present

Bangalore, India	5 th Sir Dorabji Tata Symposium on Leishmaniasis	11 March
Prague	Drug Information Association Euro-meeting	12 March
London	European Agency for Evaluation of Medicinal Products (EMA)	15 March
Kuala Lumpur, Malaysia	First ASEAN Conference on Parasitology & Tropical Medicine	23-25 March
London	"Combating Drugs Associated with Poverty" (IPPPH)	15-16 April
Brussels	European Parliament Conference on lack of R&D for neglected diseases	26-27 April
Maputo, Mozambique	MMV Annual Meeting	1 June
Barcelona, Spain	Forum Barcelona 2004	8 June
San Francisco	BIO 2000	6-9 June
Paris	Institut D'etudes des Politiques de Sante	10-11 June
Sao Paolo, Brazil	LatinPharma	10-11 June
Turin, Italy	6th Centenary of Turin University	11 June