Advocacy for enhanced political leadership and more resources to carry out R&D for neglected diseases, and for the need of innovative sustainable funding mechanisms is at the core of DNDi’s mission.
An enabling Global Framework for R&D

The fight to bring new health tools to end the suffering of millions of neglected patients is more than just about developing medicines. Since its inception, DNDi has actively advocated for a new and more favourable environment for neglected diseases R&D. In 2010, three policy research projects developed or commissioned by DNDi – on regulatory environment, IP management, and sustainable funding – came to completion or were presented at international meetings.

NEW INCENTIVES FOR INNOVATION

Despite positive signs from donors, funding for scientific and medical innovation for neglected diseases remains inadequate. Global neglected disease R&D funding in 2009 totalled USD 3.2 billion (including malaria, tuberculosis, and HIV/AIDS)[1] which is still insufficient to support development efforts. Of this amount, only USD 162 million – slightly over 5% – was spent on the kinetoplastid diseases (sleeping sickness, leishmaniasis, and Chagas disease).

To contribute to discussions on R&D financing and coordination at WHO and in other fora, and to support its own long-term funding strategy, DNDi conducted in 2010 an evaluation of existing and proposed R&D incentives and funding mechanisms. This analysis, ‘Financing Neglected Diseases R&D: Principles and Options’, was published on DNDi’s website and discussed with various stakeholders including WHO, UNITAID, the EU, other PDPs, and NGOs. Although DNDi’s analysis and recommendations naturally focused on innovative options to support the development of new treatments for the ‘most neglected’ diseases, many are applicable to other diseases and product types.

Substantial rewards for attaining specified milestones could act as useful supplements to grants and other ‘push’ funding to boost innovation for diseases for which market incentives are deficient, and to attract new R&D players. As with other ‘pull’ mechanisms [see chart], prizes are advantageous in that sponsors only pay for success. In addition, milestone prizes promise far earlier pay-outs than advance market commitments, Priority Review Vouchers, or prizes for licensed products, and are thus more likely to attract new actors such as biotechs, which cannot make major investments in pursuit of rewards that may be more than a decade away.

PDPs have now advanced several compounds to clinical development, but financing is not ensured for large efficacy trials, manufacturing scale-up, registration, and other activities required to ensure adoption and equitable access in disease-endemic countries. The urgency of providing the necessary health tools to address the global neglected disease burden requires an expeditious and efficient response from the international community. In considering innovative and sustainable financing mechanisms for health R&D, we should build upon the successes of existing international organizations and mechanisms that are already addressing market and public policy failures, such as UNITAID.

‘PUSH’ MECHANISMS TO FINANCE R&D AND ‘PULL’ INCENTIVES TO SPUR PRIVATE SECTOR INVESTMENT[2]

PUSH MECHANISMS
- Innovation funding/grants
- Subsidies for research
- Tax credits on R&D
- PDPs
- Expedited regulatory review
- Facilitation mechanisms
- Liability protection

PULL MECHANISMS
- Market guarantees
- Purchase funds
- Prizes for successful research
- Improved market information
- Tax credits on sales
- Intellectual property incentives
- Patent buyouts

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STRENGTHENING OF REGULATORY CAPACITY IN ENDEMIC REGIONS

What would be the best registration strategy for the approval of a new drug to treat sleeping sickness, which primarily affects neglected patients in Central and West Africa? What would be the best way to support African regulatory authorities in their evaluation of new drugs developed to treat their own populations? How should essential standards for the conduct of clinical trials be defined? These are some of the issues addressed in the report, Registering New Drugs: The African Context, sponsored by DNDi and commissioned to the George Institute for International Health. The report was launched in Pretoria, South Africa, at the COHRED (Council on Health Research for Development) & NEPAD (New Partnership for Africa’s Development) meeting on pharmaceutical innovation in Africa, in February 2010.

While new tools have been developed and others are soon to be made available, the registration of new drugs in endemic countries, particularly in Africa, remains problematic. Most African regulatory authorities are experienced in registering generic treatments, but lack resources to evaluate the safety, efficacy, and quality of new medicines, generally relying on registration by regulatory authorities in developed countries, notably the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The latter, however, do not have the necessary field-knowledge and political responsibility to make appropriate risk-benefit assessments for the populations most affected. The experts involved in this study expressed that African regulators have a crucial role to play in assessing health tools being used to respond to specific patient needs in their countries. The report issued key recommendations to strengthen regulatory authorization processes in Africa:

- ensure closer collaboration between developing and developed countries by involving regulators of endemic countries in all regulatory assessment of new drugs for neglected diseases;
- extend WHO’s role in the prequalification process of new tools against neglected tropical diseases, in addition to HIV/AIDS, malaria, and tuberculosis;
- strengthen regulatory capacity in Africa through the creation of Regional Centres of Excellence in each of Africa’s main sub-regions.

ACCESS-ORIENTED MANAGEMENT OF IP AND OPEN INNOVATION

The lack of funding and incentives for R&D in neglected diseases calls for a open model of sharing knowledge and research data to create a more enabling environment for neglected disease R&D.

DNDi has partnered with the Program on Global Health and Technology Access of Duke University to draw lessons from its experience, notably in access to compound libraries and licensing agreements. The aim was to gain insight into what an open innovation platform for neglected disease R&D might look like. Preliminary conclusions of this research project were presented at a DNDi workshop, organized in New Delhi.

From the GSK pool launched in 2009 to the Medicines Patent Pool Foundation for HIV/AIDS, launched by UNITAID, initiatives for open innovation are flourishing, a clear indication of a more open environment to boost innovation within the private sector. DNDi’s experience in licensing agreements and management of intellectual property (IP) is driven by its IP policy, based on two fundamental principles: (1) the need to ensure that treatments are ultimately affordable to patients and that access is equitable; (2) the desire to develop drugs as public goods when possible, disseminating results of DNDi’s research work as widely as possible to encourage the research community to engage in additional or follow-on research in the field of neglected diseases.

Hence, none of the new treatments developed by DNDi, e.g. ASAQ and ASMQ, are protected by patents. DNDi negotiates access to and licensing of IP on a routine basis for all products under development to ensure access to all neglected patients. Operating on a virtual basis, DNDi needs to negotiate sub-licensable licensing rights to have access to compounds, knowledge, and data, as well as to coordinate R&D activities on a worldwide basis. As the IP generated may be individually or jointly owned by DNDi and/or its partners, DNDi secures a non-exclusive, sub-licensable royalty-free license on the IP generated from the research partnership to keep control of the outcome of the joint research in the field of neglected diseases. To ensure affordable and equitable access to the final products, DNDi negotiates to secure sustainable manufacture and distribution of the product at the lowest possible price in endemic countries. For neglected diseases, a field in which competition between manufacturers hardly exists, affordability can be reached through agreements with industrial partners committing to produce at the lowest possible cost and include a reasonable margin in the price to ensure long-term production, thereby delinking the costs of R&D from the final price of the product.
NEW GRANTS RECEIVED IN 2010

EUR 14 Million
Dutch Ministry of Foreign Affairs (DGIS)
The Ministry of Foreign Affairs of The Netherlands (DGIS) granted EUR 14 million to DNDi to fight neglected tropical diseases. The grant will be disbursed over four years (2011-2014) and will provide critical funding for DNDi’s core disease programmes for human African trypanosomiasis, Chagas disease, and leishmaniasis. While this is the second time that the Dutch Government has awarded funding to DNDi, it is first that is targeted at the most neglected diseases. Mrs Reina Buijs, Head of the Health and Aids Division of the Dutch Government, said that one of ‘the strongest points of DNDi is that it works very actively to share information and to build capacity between partners in industrialized and developing countries’. In 2006, the first grant (EUR 3M) from The Netherlands to DNDi helped develop and give access to two new WHO-recommended artemisinin-based combination therapies (ACTs) for malaria.

CHF 4 Million
Swiss Agency for Development and Cooperation (SDC)
The Swiss Agency for Development and Cooperation (SDC) granted CHF 4 million to DNDi. The grant will be disbursed over three years (2010-2012) and will contribute to DNDi’s core disease programmes. This grant reaffirms SDC’s increasing role as a major supporter of development and implementation of new treatments to fight neglected diseases.

CHF 600,000
Republic and Canton of Geneva, Switzerland
The Republic and Canton of Geneva granted CHF 600,000 to DNDi to be disbursed over three years (2010-2012) to support clinical studies in Burkina Faso, Kenya, and Tanzania to assess the fixed-dose combination of artesunate and mefloquine (ASMQ) developed by DNDi and its partners, as an alternative antimalarial treatment for children in Africa.

EUR 1.3 Million & 0.5 Million
French government (AFD & MAEE)
The French Development Agency (AFD) and Ministry of Foreign and European Affairs (MAEE) granted EUR 1.3 million and 0.5 million respectively for the period 2009-2011/12. These grants support specific discovery and pre-clinical projects (IPK screening, HAT lead optimization, Oxaborole for HAT) and a DNDi malaria project (FACT). The French Government has supported DNDi since 2006 through four grants reaching a total amount of EUR 9.3 million.

EUR 380,000
European and Developing Countries Clinical Trials Partnership (EDCTP)
EDCTP granted EUR 380,000 to DNDi. The grant will be disbursed over three years (2010-2012) to support clinical studies in Burkina Faso, Kenya, and Tanzania to assess the fixed-dose combination of artesunate and mefloquine (ASMQ) developed by DNDi and its partners, as an alternative antimalarial treatment for children in Africa.

EUR 221,900
The Global Fund to Fight AIDS, Tuberculosis, and Malaria
The Global Fund to Fight AIDS, Tuberculosis, and Malaria granted EUR 221,900 to DNDi. The grant was for the year 2010-2011 and supports a study that aims to evaluate the availability, affordability, use, and market share of artemisinin-based combination therapies (ACTs) in Ghana, in collaboration with Komfo Anokye Teaching Hospital, Kumasi (KATH).
FRIENDS OF DNDi

The ‘Friends of DNDi’, comprised of select, internationally-renowned individuals, share in DNDi’s mission and vision by engaging global influencers, policy-makers, and supporters to help DNDi in vital ways. Their role is key to the achievement of DNDi’s objectives.

Yves Champey, former Chair of DNDi Board of Directors. Served as Medical and Scientific Director, and then as Senior Vice President, International Drug Development, at Rhone Poulenc, France

John Bowis, former Member of the European Parliament (MEP) for London and the spokesman on the Environment, Health, and Food Safety in the European Parliament, UK

Nirmal K. Ganguly, former Director General of the Indian Council of Medical Research (ICMR), India

Stephen Lewis, Chair of the Board of the Stephen Lewis Foundation, former Minister of Foreign Affairs of Canada, former United Nations Special Envoy for HIV/AIDS in Africa, Canada

Morten Rostrup, former international President of Médecins Sans Frontières, Norway

Dyann Wirth, Chair of the Department of Immunology and Infectious Diseases, Harvard School of Public Health, USA

Yongyuth Yuthavong, former Minister of Science and Technology, Thailand

Sheba K. Meymandi, Director of the Center of Excellence for Chagas Disease at Olive View-UCLA Medical Center, in Sylmar, California, USA

Darin Portnoy, former President of the MSF USA Board of Directors, USA

Rafael Vila San Juan, Director Laboratorio de Ideas, Institute for Global Health of Barcelona (ISGlobal), Spain

Rowan Gillies, former President of MSF International Council, Australia

Samih T. Darwazah, Founder and Chairman of Hikma Pharmaceuticals, Jordan

Paulo Buss, Professor of Health Planning, National School of Public Health, Oswaldo Cruz Foundation (Fiocruz), Brazil

Awareness-

« Nous créons des médicaments innovants pour les plus pauvres »

Premières causes de mortalité au monde, le paludisme, la tuberculose et la maladie du sommeil portent bien leur nom de maladies « négligées ». En trente ans, seuls 1 % des médicaments développés leur ont été destinés. À travers la fondation qu’il dirige, Bernard Pécoul cherche à combler ce fossé. Avec succès.

«1$ for 1 life» documentary on ARTE

The French and German TV channel ARTE broadcast this documentary on malaria, neglected diseases, and DNDi. The documentary has been realized by the French filmmaker Frédéric Laffont, who followed several projects worldwide to give a voice to the most neglected.
raising for neglected patients

DNDi has enjoyed worldwide media coverage in 2010. In addition to television and radio coverage, DNDi was featured in the following press articles.

**DNDi IN INTERNATIONAL PRINT MEDIA**


**SCIENTIFIC PUBLICATIONS BY DNDi TEAM AND PARTNERS**

An increase in the number of scientific publications occurred in 2010 in comparison to previous years, an important marker of DNDi’s activities and advancement of its projects.


DNDi SYMPOSIA AND MAIN CONFERENCES

DNDi 3rd Partners’ Meeting
in collaboration with Indian Council of Medical Research (ICMR)
New Delhi, India, 3-4 December 2010
- DNDi and ICMR brought together more than 150 Indian and international health researchers, policy makers, and experts from 22 countries to stimulate greater regional research partnership to fight the most neglected diseases.
- In collaboration with partners from the Program on Global health and Technology Access of Duke University, DNDi organized a workshop on intellectual property and open innovation that gathered around 50 participants including DNDi partners, representatives of Indian civil society, and DNDi staff.

American Society of Tropical Medicine and Hygiene (ASTMH)
Washington DC, USA, 3-7 November 2010
- Joint symposium, DNDi and Central Drug Research Institute (CDRI): ‘Current Challenges and Opportunities in Managing Visceral Leishmaniasis in the Indian Subcontinent’
- Joint symposium, DNDi and Leishmania East Africa Platform (LEAP): ‘VL in East Africa- Current Needs and Latest Clinical Developments’
- Satellite symposium, ‘Challenges and Successes of the FACT Project through Innovative Partnerships for the Development of Artesunate Combination Therapies for Malaria’

XIIth International Congress of Parasitology (ICOPA)
Melbourne, Australia, 15-20 August 2010
- DNDi symposium, ‘Artesunate-based Combination Treatments for Malaria’
- DNDi symposium, ‘The DNDi Model for Drug Discovery Programmes of Neglected Diseases’

Partnering for Global Health Forum 2010
Chicago, USA, 4 May 2010

MEDTROP 2010: XLVI Congresso da Sociedade Brasileira de Medicina Tropical
Foz do Iguaçu, Brazil, 14-18 March 2010
- ‘Azoles Compounds in Chagas Disease: The Current Situation’
- ‘Evaluation of Extemporaneous Formulations of Benznidazole for the Paediatric Treatment of Chagas Disease’

Congressional Malaria & NTD Caucus Briefing
Washington DC, USA, 22 February 2010
- ‘Controlling Deadly Neglected Tropical Diseases: Opportunities to Expand the US Impact’
- DNDi session: ‘Game Changing New Treatments in Less than 5 Years’

COHRED & NEPAD Meeting:
Strengthening Pharmaceutical Innovation in Africa
Pretoria, South Africa, 18-20 February 2010
- DNDi presented the background need for strengthened regulatory capacity in Africa
- DNDi held a regulatory workshop