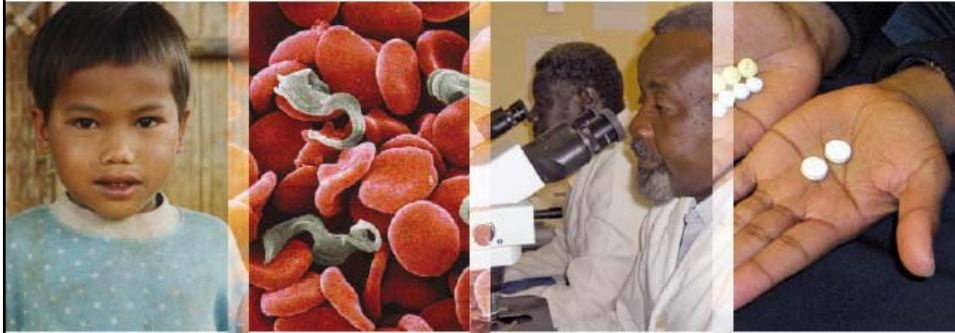


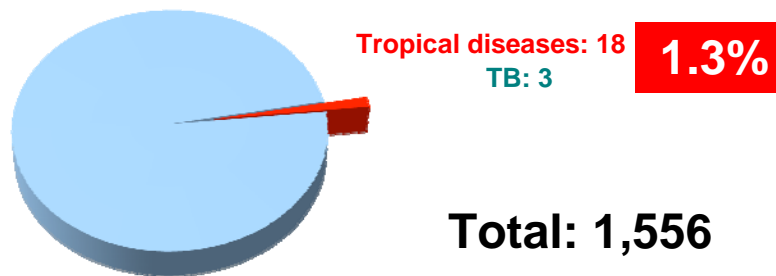
IP management in R&D for Neglected Tropical Diseases

Jean-Pierre Paccaud, PhD, **DNDi**, Director Business Development



IP management in the Life Science Symposium, Dec 15th, 2008, **WIPO**

Only 21 New Drugs Developed for Neglected Diseases (1975-2004)



Tropical diseases and tuberculosis account for **12%** of the global disease burden but only **1.3%** of new drugs developed.

Source: Chirac P, Torreele E. *Lancet*. 2006 May 12; 1560-1561.

The Patients & The Neglected Diseases: DNDi's Focus



Malaria



Visceral Leishmaniasis (VL)



Sleeping Sickness (HAT)



Chagas Disease

DNDi
Drugs for Neglected Diseases Initiative

Product Development Partnerships (PDPs): Addressing unmet medical needs



DNDi
Drugs for Neglected Diseases Initiative

A Solid and Global Foundation

7 Founding Partners

Indian Council for
Medical Research (ICMR)

Kenya Medical Research
Institute (KEMRI)

Malaysian MOH

Oswaldo Cruz Foundation
Brazil

Medecins Sans Frontieres
(MSF)

Institut Pasteur France

WHO/TDR (permanent
observer)

5 Regional Support Liaison Offices

Coordination team
Geneva + consultants

USA

India

Brazil

Kenya

Malaysia

2 Project Support Offices

DNDi
Drug Neglected Diseases Initiative

DNDi Objectives

Primary:

Deliver 6 - 8 new treatments by 2014 for leishmaniasis, sleeping sickness, Chagas disease, & malaria

Establish a robust portfolio for new generation of treatments

Secondary:

Use and **strengthen existing capacity** in Disease Endemic countries

Raise **awareness** and **advocate** for increased public responsibility

DNDi
Drug Neglected Diseases Initiative

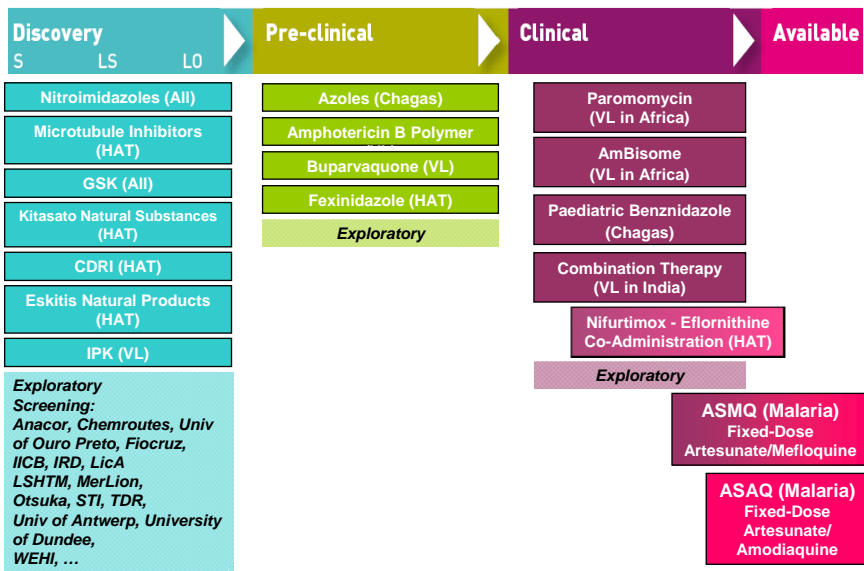
Scope of Activities for DNDi

Major focus on kinetoplastid diseases
(HAT / VL / Chagas)



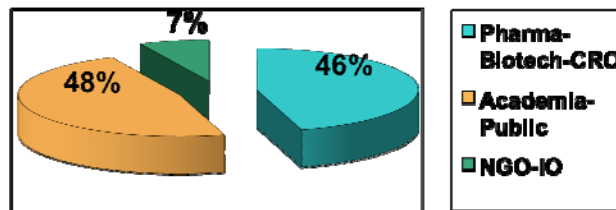
DNDi
Drug Development
Dissemination / Distribution / Delivery

A Robust and Dynamic Portfolio 2004-2008



DNDi
Drug Development
Dissemination / Distribution / Delivery

Virtual structure:
>400 Agreements, 214 People, 5 continents



DNDi's IP policy

- Affordable treatment and equitable access
- Develop drugs as public goods
- Decisions regarding ownership of patents and of licensing terms are made on a **case-by-case basis**
- Reflecting characteristics of DNDi's products:
 - Little commercial value
 - Distributed through the public sector
 - Developed in partnerships

DNDi's IP policy

Contracts typology:

- MTAs:
 - To test compounds
 - Mainly with academic institutions
 - IP rights generally not negotiated (faster to access compounds) => rights to be negotiated if follow-up...
- R&D contracts (CROs and academia)
 - Involve testing and improving (med. chemistry)
 - Ownership of IP sorted out => generally owned or co-owned by DNDi
- R&D + License contracts (mainly private sector)
 - Results of R&D mostly remain with partner
 - License rights fully negotiated => ensure access up to fully developed product

DNDi's IP policy

IP/know-how generated through DNDi's sponsored R&D

a) DNDi owns IP:

- CRO, sponsored public or private institutions
- ⇒ Publication(s), evaluation of interest to do protective patenting

b) DNDi shares IP with partner:

- Public or private institutions, private companies
- ⇒ If DNDi does not want to file, party grant license to DNDi

c) Partner owns rights derived:

- Private companies
- ⇒ License to ensure freedom to operate within the field/territory

DNDi's IP policy

Essential license rights **to be negotiated**:

- *FIELD* : NTD, malaria+kinetoplastids, kinetoplastids
- *TERRITORY*: endemic countries, production countries
- *DISTRIBUTION SECTOR* : public vs private
- *LOWEST POSSIBLE COSTS* : no royalties, "at cost" production
- *SUB-LICENSING* : essential to work with third parties
- *DISSEMINATION OF INFORMATION* : publications (and patents)

DNDi's IP policy

Conclusions:

- Results of the work carried out by DNDi are considered public goods
⇒ Publications, communications,
- DNDi does not seek to finance its work through IP revenues
⇒ Development for Neglected Diseases is considered to be a public duty
- DNDi may on a case by case enforce its IP rights through patenting
⇒ Patenting only as protective measure to ensure access to medicine
- Whenever IP rights are negotiated, ensure access
⇒ License rights without impediments for follow-on research, development and distribution of new treatments in endemic countries

Thank you!