

IP Management/Tech Transfer Strategies for Improved Global Health: Selected Illustrative Deals with the Private Sector



Jean-Pierre Paccaud, PhD
Director Business Development

Neglected Diseases: Current Treatment Limitations

Best Science for the Most Neglected



Melarsoprol



Eflornithine

- Ineffective (resistance)
- Toxic
- Expensive
- Painful when delivered
- Difficult to use
- Not adapted to the field
- Not registered in endemic regions
- Restricted by patents

We Need Safe, Effective, Easy-to-Use Drugs

DNDi

Drugs for Neglected Diseases initiative

A New Model for Drug Development: DNDi

- **Non-profit drug research & development (R&D) organization founded in 2003**
- **Addressing the needs of the most neglected patients**
- **Harnessing resources from public institutions, private industry and philanthropic entities**

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)

7 support offices

Coordination team
Geneva + consultants

USA

Brazil

DRC

Kenya

India

Malaysia

Japan

Scope of Activities for DNDi

Major focus on kinetoplastid diseases:

Sleeping Sickness
Chagas Disease
Visceral and cutaneous Leishmaniasis
Malaria



3 New Treatments Developed So Far

Best Science for the Most Neglected

DNDi

Drugs for Neglected Diseases initiative

2007

ASAQ (Malaria)
Fixed-Dose
Artesunate/
Amodiaquine



2008

ASMQ (Malaria)
Fixed-Dose
Artesunate/
Mefloquine



2009

NECT
Nifurtimox -
Eflornithine
Co-Administration
(HAT)



Partners

sanofi-aventis
(France)

Farmanguinhos
(Brazil)

Cipla
(India)

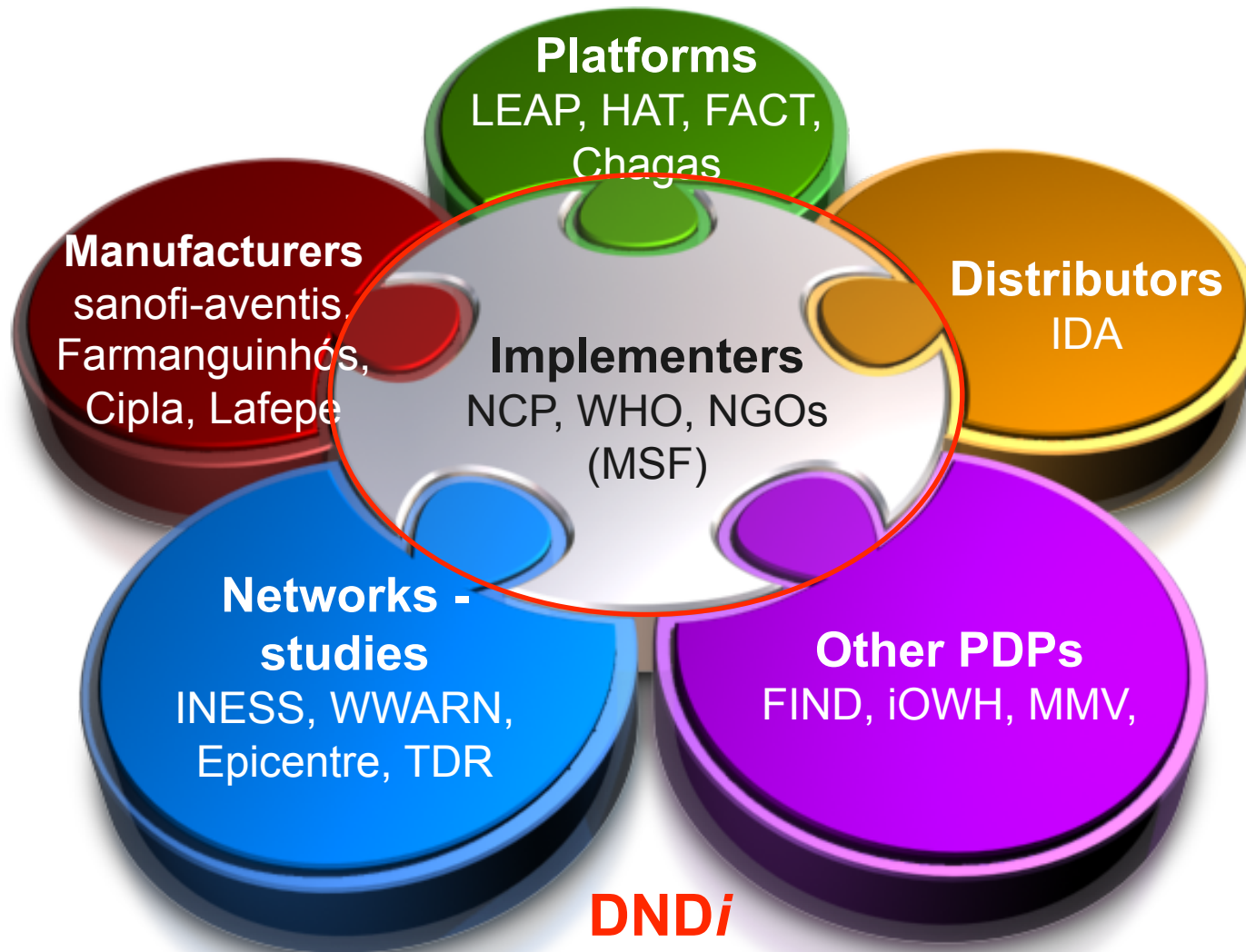
**National Control
Programs**

MSF

WHO

- **Easy to Use**
- **Affordable**
- **Field-Adapted**
- **Non-Patented**

Partnership is Key



DNDi 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:
 - No commercial value
 - Distributed mainly through the public sector
 - Outsourcing

DNDi IP Policy

Major issues to negotiate:

- *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)

Case 1: DNDi-sanofi-aventis Agreement

AS-AQ: a product *out-licensed* to pharma

Deal characteristics:

- Developed by DNDi: formulation & clinical studies
- Out-licensed to sanofi-aventis:
 - further development, scale-up, registration, distribution,
 - collaboration through post-registration
- **Not patented**
- Registered in 2007: now in 26 countries
- Public price: “**at cost**”:
 - < US\$1 for adult, US\$0.50 for children



Simplified dosing with ASAQ
(artesunate-amodiaquine)

Case 2: DNDi-Merck Agreement

Accessing the **R&D resources** of pharma

Deal characteristics:

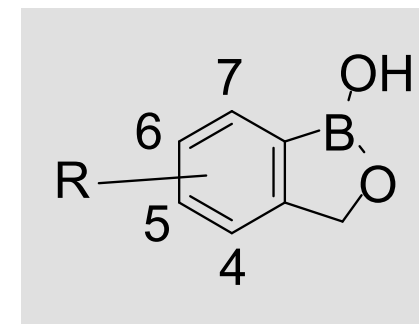
- Access to selected Merck's *compounds libraries*
- Access to Merck's *know-how*
- **Joint IP** generated through early development
- Non-exclusive, royalty-free, and sub-licensable license granted to DNDi for NTDs
- Opt-in option for Merck to undertake late clinical development and registration:
 - at its own expenses
 - commitment to provide the final product at the least possible cost to the public sector

Case 3: DNDi-Anacor Agreement

Harnessing biotech creativity

Deal characteristics:

- Access to proprietary class of compounds:
 - **no upfronts or milestones**
 - collaboration with Anacor's scientists
- **IP generated gets back** to Anacor:
 - rights for NTDs in endemic countries
 - no royalties on sale in public markets



Some Keys to Success

- Buy-in top management...
- Insure understanding of PDPs goals and business model
- Build trust
- Demonstrate successful examples and achievements
- Favour “out-of-box” thinking

By working together in a creative way,
PDPs, large and small pharma, and the
public sector can bring innovation to
neglected patients!



Thank you!