DNDi
Drugs for Neglected Diseases *initiative*

Research & Development for Diseases of the Poor:
A 10-Year Analysis of Impact of the DND*i* Model

Report provides real and estimated costs of repurposing drugs and new chemical entities, evoking the lessons learned based on alternative pathways and partnerships

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FACTS & FIGURES

In a nutshell:

The report *"An innovative approach to R&D for neglected patients, Ten years of experience & lessons learned by DNDi"* provides facts & figures about the model of DNDi, after 10 years of R&D.

- **Partnerships** in 43 countries, over 350 collaborations, namely with 20 pharmaceutical and biotechnology companies and with over 50 universities and research institutes.
- DNDi **expenses** from 2003-2013: EUR 182.5 million => to deliver 6 improved treatments and develop 12 new chemical entities (NCEs) in DNDi's pipeline
- Out of the expenses, EUR 138 million dedicated to **Research and Development**:
    - EUR 51 million for Research stage (screening, hit-to-lead, lead optimisation)
    - EUR 33 million for Translation stage (pre-clinical, clinical Phase I and Phase II/proof-of-concept)
    - EUR 31 million for Development stage (clinical Phase IIb/III, registration)
    - EUR 23 million for Implementation stage (access)

5 case studies of treatments developed by DNDi and partners:

The new report offers case studies of three treatments delivered and two new chemical entities in development by DNDi, including total monetary costs but excluding in-kind contributions from many partners and attrition rates for drugs still in development:

1. **ASAQ: artesunate-amodiaquine fixed-dose combination for deadly malaria**
    - **Cost of DNDi's R&D: a total of EUR 12 million**
    - Objective: develop and monitor implementation of a fixed-dose combination therapy for malaria
    - Timeline: began development in 2003 and was delivered in 2007
    - Impact: over 250 million treatments distributed by Sanofi throughout Africa (31 countries) since its launch in 2007.

2. **NECT: nifurtimox-eflornithine combination therapy for sleeping sickness**
    - **Cost of DNDi's R&D: a total of EUR 6.8 million**
    - Objective: develop an improvement over previous therapies, some of them being highly toxic (arsenic-based)
    - Timeline: began development in 2003 and was delivered in 2009

- Impact: the first new treatment option in 25 years for sleeping sickness (human African trypanosomiasis). Today, 96% of all late-stage patients are treated with NECT, replacing melarsoprol, a toxic, arsenic-based drug that killed 1 in 20 patients. Over 13,000 treatments distributed.

3. **SSG&PM: sodium stibogluconate and paromomycin new combination therapy for visceral leishmaniasis in Africa**
    - **Cost of DNDi's R&D: a total of EUR 11.5 million**
    - Objective: develop an improved, short-course therapy (monotherapy length being 30 days of infusions)
    - Timeline: began development in 2004 and was delivered in 2010
    - Impact: Since 2010, 23,000 patients in East Africa have been treated with SSG&PM.

4. **Fexinidazole, a new drug candidate (new chemical entity) for sleeping sickness**
    - **Cost of DNDi's R&D: an estimated cost of EUR 26.5 million for development and registration**
    - Objective: develop an oral treatment to replace the current combination therapy (NECT), that include infusions twice a day/7 days
    - Timeline: began development in 2005 and currently in Phase II/III clinical trials. Estimated to be delivered by 2016
    - Impact: potential impact is to treat all the patients, even in the most remote areas, with pills, in their village.

5. **Oxaborole SCYX-7158, the first new chemical entity developed specifically for sleeping sickness**,
    - **Cost of DNDi's R&D: an estimated cost of EUR 38.3 million for development and registration**
    - Objective: develop an oral treatment with a single pill to replace the current combination therapy (NECT), that include infusions twice a day/7 days
    - Timeline: began development in 2003 and currently in a Phase I clinical trial. Estimated to be delivered by 2018
    - Impact: potential impact is to treat all the patients, even in the most remote areas, with a single pill, in their village

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